Monoclonal Antibodies in Clinical Practice: Promise, Precision, and Persistent Challenges – an editorial

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The therapeutic landscape of modern medicine has been transformed by the advent of Monoclonal antibody therapies. Since the approval of muromonab-CD3 in 1986, monoclonal antibodies (mAbs) have evolved from experimental immunological tools into central pillars of treatment across oncology, autoimmune disease, infectious diseases, and beyond. Their clinical success reflects a broader shift towards targeted and precision medicine. Yet, alongside their undeniable benefits, important limitations persist.

The principal advantage of monoclonal antibodies lies in their specificity. Engineered to recognise defined antigens, they permit selective modulation of disease pathways. In oncology, agents such as Trastuzumab have revolutionised the treatment of HER2-positive breast cancer by targeting tumour-specific receptors, substantially improving survival[1]. Similarly, immune checkpoint inhibitors, including Nivolumab, have reshaped the management of advanced malignancies by restoring anti-tumour immune responses[2]. In autoimmune conditions such as rheumatoid arthritis and inflammatory bowel disease, tumour necrosis factor (TNF) inhibitors have mitigated inflammation and prevented structural damage[3].

Beyond efficacy, monoclonal antibodies often offer improved tolerability compared with traditional cytotoxic agents. Their mechanism-driven design reduces off-target toxicity, and in many cases enables durable disease control. During the COVID-19 pandemic, neutralising monoclonal antibodies provided early therapeutic options against SARS-CoV-2, highlighting their adaptability in emerging infectious threats[4].

However, the expansion of mAb therapy has exposed substantial challenges. Foremost among these is cost. The development and manufacturing of biologics are complex and resource-intensive, rendering monoclonal antibodies among the most expensive therapeutics worldwide. Limited access in low- and middle-income countries exacerbates global health inequities[5]. Although biosimilars offer promise for cost reduction, regulatory and market barriers remain.

Immunogenicity is another concern. Despite humanisation strategies, anti-drug antibodies can develop, reducing efficacy and occasionally provoking hypersensitivity reactions[6]. Furthermore, immune checkpoint inhibitors, while transformative, may precipitate immune-related adverse events affecting the skin, gut, endocrine organs, and myocardium—complications that can be severe and require long-term immunosuppression[7].

Resistance mechanisms also undermine sustained benefit. Tumour heterogeneity, antigen loss, and pathway redundancy may diminish response over time. In infectious diseases, viral mutations can render neutralising antibodies less effective, as observed with emerging SARS-CoV-2 variants[8]. Thus, biological precision does not equate to permanence.

Logistical limitations further complicate widespread use. Most monoclonal antibodies require parenteral administration and cold-chain storage, constraining their deployment in resource-limited settings. Additionally, long half-lives may complicate management of adverse effects.

Ethical considerations accompany scientific progress. As therapeutic options proliferate, clinicians must balance marginal survival benefits against financial toxicity and quality-of-life implications. The sustainability of healthcare systems is increasingly questioned as biologic expenditures rise.

Nonetheless, innovation continues. Advances in antibody–drug conjugates, bispecific antibodies, and Fc engineering are expanding therapeutic horizons while attempting to optimise efficacy and safety. The development of biosimilars signals a step towards improved accessibility, though vigilance in pharmacovigilance and regulatory oversight remains essential.

Monoclonal antibodies exemplify the triumph of translational immunology. They offer unprecedented specificity and have altered the natural history of diseases once deemed intractable. Yet, their integration into routine clinical practice demands careful consideration of cost, equity, adverse effects, and long-term sustainability. As medicine advances deeper into the era of biological therapeutics, the challenge will not merely be to develop more antibodies, but to deploy them judiciously, equitably, and responsibly.

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Serum Iron Profile in Children with Congenital Heart Disease Attending a Tertiary Care Hospital

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ABSTRACT

Background: Congenital heart disease is the most common congenital anomaly and has been associated frequently with malnutrition and hematologic complications, particularly iron deficiency and IDA. This study was done to assess the serum iron profile in children with CHD attending a tertiary care hospital. **Methods & Materials**: This cross-sectional study was conducted from July 2023 to June 2024 among 91 children aged 1 month to 12 years with echocardiographically confirmed CHD at the Institute of Child and Mother Health, Dhaka. Serum iron, ferritin, and total iron-binding capacity were measured, and iron deficiency and IDA were defined using the standard age-specific ferritin and haemoglobin criteria. Data analysis was done by using SPSS version 26, and a p-value less than 0.05 was considered statistically significant. **Results:** The mean age of participants was 12.7 months; 51% were male. Acyanotic CHD accounted for 78% of cases, with ventricular septal defect being the most common lesion (39.56%). Malnutrition was highly prevalent, with 51.6% of children wasted and 39.6% stunted. The mean serum iron, ferritin, and TIBC were 57.59 ± 34.49 µg/dl, 125.25 ± 141.34 ng/ml, and 322.15 ± 71.85 µg/dl, respectively. Iron deficiency was present in 53.5% of acyanotic and 65% of cyanotic CHD cases. Ferritin deficiency was also higher in cyanotic CHD (70%) compared to acyanotic CHD (56.3%). **Conclusion:** This study demonstrates a high prevalence of iron deficiency in children with congenital heart disease, as evidenced by low serum iron and ferritin levels in the majority of children and increased TIBC in many. While there was a trend towards a higher rate of deficiency in the cyanotic as compared with the acyanotic patients, this did not reach statistical significance.

Keywords: *Congenital Heart Disease (CHD), Iron Deficiency Anaemia, Serum Iron Profile.*

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INTRODUCTION

Congenital heart disease is the most common congenital anomaly in children and continues to be a major cause of morbidity and mortality among children in many parts of the world. Despite advances in diagnosis and treatment, it still remains a major global health concern and requires more emphasis on early detection and management strategies. It has been estimated that CHD accounts for a considerable proportion of deaths in children and so calls for timely intervention and improved supportive care [1,2]. CHD encompasses a wide range of structural cardiac malformations that are conventionally classified as either cyanotic or acyanotic. The most common acyanotic lesions include Ventricular Septal Defect (VSD), Atrial Septal Defect (ASD), and Patent Ductus Arteriosus (PDA), while Tetralogy of Fallot (TOF) is the most common cyanotic lesion [3,4]. Because of the chronic hypoxia, abnormal haemodynamics, and increased metabolic stress due to these conditions, the patients are at a significantly increased risk of nutritional deficiencies, with an especial predisposition to iron deficiency anaemia. Iron deficiency anaemia is one of the most common and yet under-recognized comorbidities among children suffering from CHD. Iron is an important mineral involved in oxygen transport, cellular respiration, and energy metabolism. Its deficiency can further aggravate tissue hypoxia, diminish exercise tolerance, and adversely impact overall cardiac performance. Both cyanotic and acyanotic CHD children are prone to diminished iron stores due to poor dietary intake, chronic illness, and increased erythropoietic demands [5,7]. The compensatory erythropoietin response to persistent hypoxia seen in cyanotic CHD promotes increased production of red blood cells and thus gradually depletes the iron reserves over time, often before the onset of clinically evident anaemia [6]. Many children may have a polycythaemic appearance, which masks the underlying iron deficiency and delays its diagnosis [8]. Assessment of iron status in CHD requires evaluation of serum iron profile, which consists of serum iron, serum ferritin, total iron-binding capacity (TIBC), and transferrin saturation. These biochemical parameters provide a more accurate reflection of iron stores and utilisation compared to red cell counts alone [9]. Red cell indices, including Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), and Red Cell Distribution Width (RDW), are also useful early indicators of iron depletion and may help in diagnosing subclinical deficiency [8,10]. Iron deficiency in children with CHD has significant clinical implications. Low iron levels have been associated with increased hospitalisation, fatigue, and poor clinical outcomes in paediatric cardiac patients.[11] Frequent cyanotic spells and delayed recovery are more likely in children with cyanotic CHD and iron deficiency [12]. Similarly, preoperative anaemia is related to

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higher perioperative risk with a prolonged postoperative recovery [5]. Accordingly, identification and correction of iron deficiency are important for improving growth, neurodevelopmental status, and overall clinical outcomes in CHD children. Despite these observations, iron deficiency usually goes undiagnosed in children due to nonspecific clinical presentations and reliance on incomplete screening methods [6,8]. Routine testing of the serum iron profile can thus become instrumental in the early identification and intervention of iron deficiency anaemia in this population. Early recognition and timely management improve cardiac efficiency as well as overall physical and developmental outcomes. The current study proposes assessing the serum iron profile in children with CHD presenting to a tertiary care hospital.

METHODS & MATERIALS

This cross-sectional study was conducted among 91 children with CHD attending the Outpatient and Inpatient Departments of Paediatrics at ICMH, Dhaka, Bangladesh, from July 2023 to June 2024. Participants were selected through purposive sampling. Children aged 1 month to 12 years with echocardiographically confirmed CHD were included. Written informed consent was taken from their legal guardians before participation. Children with hemolytic disorders, previous cardiac surgery, recent iron supplementation, or systemic illnesses resulting in anemia were excluded. Data collection was done through a pre-tested semistructured questionnaire by interviewing the caregivers, physical examination, and review of medical records of the children. Information included demographic details, type of CHD, nutritional status, anemia, and feeding practices. Laboratory investigations included complete blood count and serum iron profile (iron, ferritin, and total iron-binding capacity). Iron deficiency was defined as serum ferritin <12 ng/mL (<5 years), <15 ng/mL (≥5 years), or <30 ng/mL with infection; iron deficiency anemia as Hb <11 g/dL with corresponding biochemical findings. Data were analyzed using SPSS version 26 and $p < 0.05$ was considered statistically significant. Ethical approval was obtained from the ICMH Ethical Review Committee.

RESULTS

Table I shows that the participants were categorized into three age groups: 1–6 months (32.97%), 7–12 months (30.77%), and >12 months (36.26%). The mean age of the population was 12.7 months, ranging from 1 to 32 months.

Table I
Age distribution of the study population (*n* = 91).

Age in months	Number	Percentage (%)
1–6	30	32.97
7–12	28	30.77
>12	33	36.26
Total	91	100
Mean	12.7	1–32 months

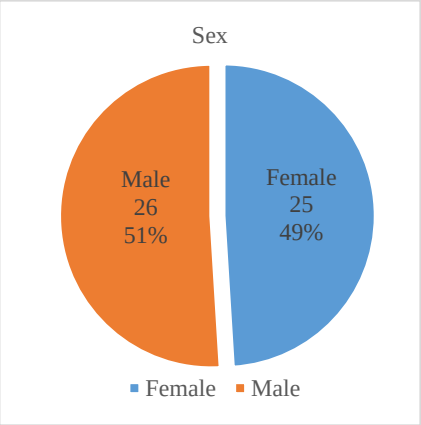

Figure 1 Sex distribution of the study population (*n*=91).

Figure 1 shows that 51% of the study population is male and 49% female child.

Table II summarizes the clinical characteristics of the study population. Among the participants, 39 had anemia, 18 had cyanosis, and 17 had heart failure. The mean height/length was 72.96 ± 13.13 cm, and mean weight was 8.98 ± 2.60 kg. Nutritional assessment showed mean WAZ, HAZ, and WHZ scores of -2.19 ± 1.48, -1.52 ± 1.04, and -1.69 ± 1.73, respectively, with 47 children wasted and 36 stunted. Features of acute illness were present in 27 children. Exclusive breastfeeding was reported in 48 children, and 33 received iron-containing appropriate complementary feeding.

Table II
Clinical characteristics of the study population (n = 91).

Clinical Feature	Number / Value
Anemia	39
Cyanosis	18
Heart Failure	17
Mean Height/Length (cm)	72.96 ± 13.13
Mean Weight (kg)	8.98 ± 2.60
Mean WAZ score	-2.19 ± 1.48
Mean HAZ score	-1.52 ± 1.04
Mean WHZ score	-1.69 ± 1.73
Child Wasted	47
Child Stunted	36
Features of acute illness (fever, cough, respiratory distress)	27
EBF (Exclusive Breastfeeding)	48
Iron-containing Appropriate Complementary Feeding	33

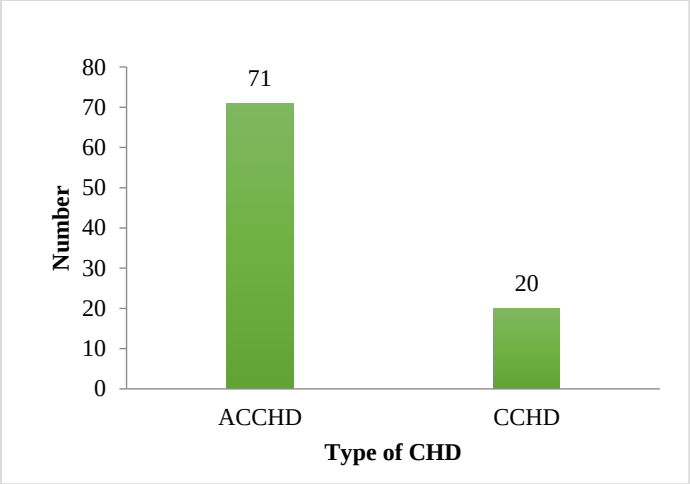

Figure 2 Types of CHD of the study population (*n* = 91).

Figure 2 shows that the number of ACHD is 71 and the number of CCHD is 20, respectively. *Table III* shows the types of congenital heart disease in the study population. VSD was the most common (36; 39.56%), followed by ASD (21; 23.07%) and TOF (13; 14.28%). Other types included PDA (7; 7.69%), VSD & ASD (5; 5.49%), VSD & PS (3; 3.35%), PDA & ASD (2; 2.19%), PAPVC (2; 2.19%), Truncus Arteriosus (1; 1.09%), and TGA (1; 1.09%).

Table III
Specific types of CHD of the study population (n = 91).

Specific Type of CHD	Number	Percentage (%)
VSD	36	39.56
ASD	21	23.07
TOF	13	14.28
PDA	7	7.69
VSD & ASD	5	5.49
VSD & PS	3	3.35
PDA & ASD	2	2.19
PAPVC	2	2.19
Truncus Arteriosus	1	1.09
TGA	1	1.09

Table IV shows the mean and range of iron parameters in the study population. Serum iron was 57.59 ± 34.49 µg/dl (range: 10–180), serum ferritin was 125.25 ± 141.34 ng/ml (range: 12–509), and TIBC was 322.15 ± 71.85 µg/dl (range: 180–528).

Table IV
Mean serum Iron, serum ferritin and TIBC (*n* = 91).

Parameter	Mean ± SD	Range (min–max)
Serum Iron	57.59 ± 34.49 µg/dl	10–180
Serum Ferritin	125.25 ± 141.34 ng/ml	12–509
TIBC	322.15 ± 71.85 µg/dl	180–528

Table V shows that among acyanotic CHD patients, 33 (46.5%) had normal serum iron and 38 (53.5%) had iron deficiency. Among cyanotic CHD patients, 7 (35.0%) had normal serum iron and 13 (65.0%) had iron deficiency, with a total of 91 patients and a p value of 0.36.

Table V
Serum Iron level among congenital heart disease patients (*n* = 91).

Serum Iron Status (µg/dl)	Acyanotic CHD n (%)	Cyanotic CHD n (%)	Total	p value
Normal	33 (46.5)	7 (35.0)	40	0.36
Deficiency	38 (53.5)	13 (65.0)	51	
Total	71 (100)	20 (100)	91	-

Table VI demonstrates that normal serum ferritin level for acyanotic congenital heart disease is 31 (43.7%) and 06 (30.0%) for cyanotic group. Deficiency of serum ferritin for acyanotic congenital heart disease is 40 (56.3%) and 14 (70.0%) for the cyanotic group among 54 congenital heart disease patients.

Table VI
Serum ferritin level among congenital heart disease patients (*n* = 91).

Serum Ferritin (ng/ml)	Acyanotic CHD n (%)	Cyanotic CHD n (%)	Total	p value
Normal	31 (43.7)	6 (30.0)	37	0.27
Deficiency	40 (56.3)	14 (70.0)	54	
Total	71 (100)	20 (100)	91	-

Table VII shows that normal TIBC levels were present in 40.8% of acyanotic and 40% of cyanotic CHD cases. High TIBC was the most common finding in both groups—52.1% in acyanotic and 50% in cyanotic patients. Low TIBC was seen in a small proportion of children (7.1% vs. 10%). Overall, the distribution of TIBC levels was similar between the two groups, with no significant difference (p = 0.9).

Table VII
Serum TIBC level among congenital heart disease patients (*n* = 91).

Serum TIBC (µg/dl)	Acyanotic CHD n (%)	Cyanotic CHD n (%)	Total	p value
Normal	29 (40.8)	8 (40.0)	37	
High	37 (52.1)	10 (50.0)	47	0.9
Low	5 (7.1)	2 (10.0)	7	
Total	71 (100)	20 (100)	91	-

DISCUSSION

The mean age of children with congenital heart disease (CHD) in this study was 12.7 months, ranging from 1 to 32 months. About one-third were aged 1–6 months, 30.77% were 7–12 months, and 36.26% were older than 12 months. Previous studies on children with cyanotic CHD reported a mean age of around 8 months, with most under 12 months [12]. Compared to these findings, the present cohort was older and had a higher proportion of children above 12 months, suggesting possible delayed referral or late presentation, which could be related to regional healthcare access, awareness, or early detection challenges. The sex distribution was nearly equal, with 51% male and 49% female, which is consistent with reports showing minimal sex bias in CHD prevalence [13]. Clinically, 42.9% of children had anaemia, 19.8% had cyanosis, and 18.7% had heart failure. The mean height/length was 72.96 ± 13.13 cm, and the mean weight was 8.98 ± 2.60 kg. Nutritional assessment revealed mean WAZ –2.19 ± 1.48, HAZ –1.52 ± 1.04, and WHZ –1.69 ± 1.73, with 51.6% of children wasted and 39.6% stunted. A meta-analysis of children with CHD reported pooled prevalences of wasting (~24.8%) and stunting (~24.4%) [2]. The higher rates observed in this cohort indicate a substantial nutritional burden. It may be influenced by socioeconomic factors, delayed intervention, increased metabolic demands or more severe cardiac lesions. Features of acute illness were present in a significant proportion of children, and exclusive breastfeeding was reported in less than half of the participants, with only a minority receiving iron-containing complementary feeding. These are highlighted here that suboptimal nutritional practices, which could contribute to growth retardation, poor immunity and hematologic deficits, emphasising the need for focused nutritional interventions in pediatric CHD care. Acyanotic lesions predominated, while cyanotic lesions accounted for a smaller proportion. Ventricular septal defect (VSD) was the most common lesion (39.56%). It is followed by atrial septal defect (ASD, 23.07%) and tetralogy of Fallot (TOF, 14.28%). On the other hand, global analyses also report that acyanotic lesions predominate, with VSD and ASD being the most frequent [14]. This distribution is consistent with the worldwide epidemiology of CHD, emphasising that isolated septal defects remain the most prevalent congenital cardiac abnormalities, which may have implications for early surgical intervention and iron deficiency risk. Biochemical assessment revealed a mean serum iron of 57.59 ± 34.49 µg/dl, ferritin 125.25 ± 141.34 ng/ml, and TIBC 322.15 ± 71.85 µg/dl. Lower mean serum iron and ferritin in children with CHD were reported in other studies [15]. Serum iron deficiency was observed in over half of children with acyanotic lesions and nearly two-thirds of those with cyanotic lesions, reflecting the higher prevalence of iron deficiency in cyanotic CHD [16]. Ferritin deficiency was also substantial, with 56.3% in acyanotic and 70% in cyanotic lesions, suggesting marked depletion of iron stores. Elevated TIBC was observed in roughly half of the children in both lesion types, reflecting a compensatory response to iron deficiency [17]. These results indicate that children with congenital heart disease attending a tertiary care hospital exhibit significant alterations in their serum iron profile.

LIMITATIONS

The study was limited by its purposive sampling, small sample size, absence of a control group, and lack of inflammatory marker assessment, which may affect accurate interpretation of iron status.

CONCLUSION

In conclusion, this study shows that children with congenital heart disease have a high prevalence of iron deficiency, with more than half exhibiting low serum iron and ferritin levels and many showing elevated TIBC. Although cyanotic patients had slightly higher rates of deficiency than acyanotic patients, the differences were not statistically significant.

RECOMMENDATIONS

Future research might involve larger, multicenter studies with control groups and include assessment of inflammatory markers alongside iron parameters. Studies could also evaluate long-term effects of iron supplementation on growth and clinical outcomes in children with CHD.

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CONFLICT OF INTEREST

None declared

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A Study of the Outcome of Anastomotic Urethroplasty as a Delayed Management of Traumatic Posterior Urethral Injury

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ABSTRACT

Background: Pelvic fracture-associated posterior urethral injuries are complex reconstructive problems that require delayed surgical repair. Anastomotic urethroplasty remains the gold standard, although its outcomes are multifactorial. This study was aimed at assessing the surgical outcomes and the predictors of failure after delayed anastomotic urethroplasty for post-traumatic posterior urethral strictures. **Materials & Methods:** This observational study was conducted at Dhaka Medical College Hospital from March 2017 to March 2018, including 50 adult male patients who had complete post-traumatic posterior urethral obliteration and underwent delayed anastomotic urethroplasty. A transperineal approach with spatulated mucosa-to-mucosa anastomosis was done for all cases, with the addition of inferior pubectomy when the urethral gap exceeded 3 cm. Surgical success was defined as asymptomatic voiding with adequate flow and no radiological narrowing. Patients were followed up after 3, 6, and 12 months with uroflowmetry and urethrography. Data were entered and analyzed using SPSS version 26. **Results:** The mean patient age was 32.8±13.9 years, with road traffic accidents accounting for 74% of injuries. Mean stricture length was 2.7±0.9 cm, and mean time to repair was 12.4±3.1 weeks. Surgical success was achieved in 86% of patients, with overall complications occurring in 36%. Stricture length >3 cm (adjusted OR 8.74, p=0.005) and performance of inferior pubectomy (adjusted OR 3.62, p=0.048) were independent predictors of surgical failure. Mean postoperative Qmax was significantly higher in successful repairs compared to failures (20.4±3.9 vs 12.8±2.5 ml/s, p<0.001). **Conclusion:** Delayed anastomotic urethroplasty provides good results in post-traumatic posterior urethral strictures, with a success rate of 86%. The failure rate is higher in longer strictures and in cases requiring inferior pubectomy. Proper patient selection and planning are essential.

Keywords: *Posterior urethral stricture, Anastomotic urethroplasty, Inferior pubectomy.*

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INTRODUCTION

Injuries to the posterior urethra are serious complications of pelvic injuries. The estimated incidence is approximately 5-10% of pelvic fractures, or 0.6-1 per 100,000 population annually [1]. PUI predominantly occurs in young males following high-energy trauma, arising commonly from road traffic accidents, falls from height, and industrial crush injuries [2]. The mechanism typically involves disruption at the bulb membranous junction due to shearing forces when the fixed membranous urethra is displaced relative to the mobile bulbar urethra during pelvic ring disruption [3]. The resultant complete urethral distraction defect leads to stricture formation with significant morbidity if left untreated, including urinary retention, recurrent infections, renal impairment, and devastating impact on quality of life [4]. The management of posterior urethral injuries has changed significantly in recent decades. Whereas the approach of immediate primary realignment used to be recommended, contemporary data indicate that the results of delayed repair after a period of initial suprapubic diversion are better in terms of lower incontinence and erectile dysfunction rates [5]. Today, consensus exists for the initial use of suprapubic cystostomy urinary diversion, usually followed by delayed definitive reconstructive surgery, after resolution of pelvic hematoma and fracture stabilization, typically 3-6 months after injury [6]. This staged approach permits resolution of inflammation, accurate estimation of stricture characteristics, and optimization of conditions for surgical reconstruction [7]. Anastomotic urethroplasty via the perineal approach is considered the gold standard treatment for post-traumatic posterior urethral strictures. Success rates have been reported from 83-97% in specialized centers [8,9]. The surgical principle is the complete excision of fibrotic tissue and the creation of a tension-free, spatulated mucosa-to-mucosa anastomosis over an indwelling catheter [10]. In longer defects, ancillary maneuvers include bulbar urethral mobilization, crural separation, and inferior pubectomy to bridge the urethral gap without tension [11]. Notwithstanding the high overall success rates, factors such as stricture length, prior urethral manipulation, and complexity of reconstruction have been associated with higher failure and complication rates [12]. Given the complexity of the anatomy in posterior urethral reconstruction and recognized complications that include restricture, erectile dysfunction, urinary incontinence, and urethrocutaneous fistula, comprehensive outcome analysis is required to help devise the best surgical strategies and patient counseling [13]. Stricture length has emerged as a critical determinant, since the management of longer defects mandates extended dissection and ancillary procedures, resulting in increased technical difficulty and risk for complications [14]. The contribution of surgical approach complexity, such as the requirement for inferior pubectomy when bridging longer gaps, toward functional outcomes has not been fully realized, particularly in settings from developing countries where injury patterns and patient demographics may vary from those seen in Western cohorts [15]. This study evaluates the results of delayed anastomotic urethroplasty for completely obliterated post-traumatic posterior urethral strictures, looking into success rates, complication profiles, and identifying independent predictors of surgical failure.

METHODS & MATERIALS

This observational study was carried out in the Department of Urology, Dhaka Medical

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College Hospital, from March 14, 2017, to March 13, 2018. 50 consecutively selected adult male patients with post-traumatic, completely obliterated posterior urethral stricture who underwent delayed anastomotic urethroplasty were included in the study. Clinical notes and operative sheets were used to document the following: the mechanism of injury, age, stricture length (in centimeters), time from injury to urethroplasty (in weeks), and operative approach (simple perineal versus perineal urethroplasty with inferior pubectomy). A transperineal approach was used for all procedures: an inverted Y perineal incision was used to mobilize the bulbar urethra, the fibrotic segment was removed, and a tension-free, spatulated mucosa-to-mucosa anastomosis was constructed over a 16 Fr silicone catheter. When the urethral gap was more than about 3 cm, an inferior pubectomy was carried out to achieve a tension-free repair, and suprapubic diversion was maintained until a satisfactory pericatheter urethrogram was obtained. Surgical success was defined as asymptomatic voiding with adequate urinary flow and no radiological narrowing; complications included wound infection, restricture, erectile dysfunction, urethrocutaneous fistula, and urinary incontinence. Patients were monitored at 3, 6, and 12 months with uroflowmetry, urethrography, and symptom review when necessary. Data were entered and analyzed using SPSS version 26. Descriptive statistics were generated for all variables, chi-square tests were used to evaluate associations between categorical predictors and outcome, independent samples t tests were used for continuous variables like Qmax, and multivariable logistic regression was used to find independent predictors of surgical failure. A p-value < 0.05 was considered statistically significant.

RESULTS

Table I represents the demographic and clinical baseline characteristics of 50 adult male patients who enrolled in the study. The mean age was 32.8±13.9 years, with over half (52%) of the patients aged between 18 and 30 years. Road traffic accidents were the most common mechanism of injury in 74%, followed by falls from height in 18% and crush injuries in 8%. Mean stricture length was 2.7±0.9 cm, with the majority (44%) having strictures measuring 2-3 cm, while 32% had strictures exceeding 3 cm. The mean interval from initial injury to definitive repair was 12.4±3.1 weeks. A simple perineal approach was used in 76% cases, while 24% needed a perineal approach with inferior pubectomy in order to achieve tension-free anastomosis for longer urethral gaps.

Table I
Baseline and Clinical Characteristics of Study Participants (n = 50).

Variable	Category / Values	(n), (%) / Mean ± SD
Age (years) (Mean ± SD)	-	32.8 ± 13.9
Age group (years)	18-30	26 (52%)
	31-45	14 (28%)
	>45	10 (20%)
Mechanism of injury	Road traffic accident	37 (74%)
	Fall from height	9 (18%)
	Crush injury	4 (8%)
Stricture length (cm) (Mean ± SD)	-	2.7 ± 0.9
	<2 cm	12 (24%)
	2–3 cm	22 (44%)
	>3 cm	16 (32%)
Time from injury to repair (weeks) (Mean ± SD)	-	12.4 ± 3.1
Surgical approach	Simple perineal	38 (76%)
	Perineal + inferior pubectomy	12 (24%)

Table II summarizes the surgical outcomes and complications following delayed anastomotic urethroplasty in the study cohort. A success rate of 86% was observed, with only 14% having surgical failure that required further intervention. The complication profile revealed the most frequent adverse outcome to be urinary incontinence at 12%, followed by erectile dysfunction at 8%, urethrocutaneous fistula at 8%, wound infection at 6%, and restricture at 6%. The overall complication rate was 36%, though many complications were minor and managed conservatively. Of note, the mean postoperative Qmax improved substantially to 19.3±4.6 ml/s.

Table II
Postoperative Outcomes Following Delayed Anastomotic Urethroplasty.

Outcome	(n)	(%)
Success	43	86%
Failure	7	14%
Wound infection	3	6%
Restricture	3	6%
Erectile dysfunction	4	8%
Urethrocutaneous fistula	4	8%
Urinary incontinence	6	12%
Overall complications (any)	18	36%
Postoperative Qmax (ml/s) (Mean ± SD)	19.3 ± 4.6	

Table III depicts a very significant relation between stricture length and failure rate of surgery ($\chi^2 = 11.57$; $p = 0.003$). Patients with a stricture less than 2 cm had all 12 cases (100%) successful, with no failures. In patients with stricture lengths measuring 2-3 cm, failure was very minimal at 4.5% (1 in 22). However, for those patients with stricture lengths larger than 3 cm, the rate of failure is markedly increased to 37.5% (6 in 16).

Tables III
Association Between Stricture Length and Surgical Failure (χ^2 Test).

Stricture Length	Success (n = 43)	Failure (n = 7)
<2 cm	12	0
2-3 cm	21	1
>3 cm	10	6
Total	43	7

$\chi^2 = 11.57$; $p = 0.003$

Table IV demonstrates that there is a statistically significant relationship between the complexity of the surgical approach and the appearance of complications: χ^2=5.61; p=0.018. Among the cases of simple perineal urethroplasty, complications arose among 10 patients, whereas in patients with the more complex perineal approach with inferior pubectomy, this rate was much higher (8 of 12 patients).

Table IV
Association Between Type of Surgery and Complication Rate.

Surgical Approach	Complications Present	No Complications
Simple perineal	10	28
Perineal + inferior pubectomy	8	4
Total	18	32

$\chi^2 = 5.61$; $p = 0.018$

Table V denotes a very significant difference in postoperative maximum flow rates when comparing successful versus failed surgical repairs: t = 5.24; p < 0.001. Those patients with successful urethroplasty had a mean Qmax of 20.4 ± 3.9 ml/s, suggesting restoration of near-normal voiding function. Conversely, the mean Qmax for those with surgical failure was a significantly lower 12.8 ± 2.5 ml/s.

Table V
Comparison of Qmax Between Successful and Failed Repairs.

Outcome	Mean Qmax (ml/s)	SD
Success (n = 43)	20.4	3.9
Failure (n = 7)	12.8	2.5

$t = 5.24$; $p < 0.001$

Multivariable logistic regression analysis in Table 6 shows independent predictors of failure of surgery after adjustment for potential confounders. Stricture length of more than 3 cm was the strongest independent predictor of failure, with an 8.74-fold increased odds of failure of surgery compared with strictures of less than 3 cm in length (95% confidence interval 1.92-39.8; p = 0.005). The performance of inferior pubectomy further independently predicted an increased risk of failure, with an adjusted odds ratio of 3.62 (95% confidence interval 1.01-12.9; p = 0.048). In contrast, advanced age (>45 years) and prolonged time to surgery (>16 weeks) were not independently associated with failure after adjusting for other variables (*Table VI*).

Table VI
Multivariate Logistic Regression Predicting Surgical Failure.

Predictor	Adjusted OR	95% CI	p-value
Stricture length >3 cm	8.74	1.92-39.8	0.005
Inferior pubectomy performed	3.62	1.01-12.9	0.048
Age >45 years	1.28	0.22-7.34	0.78
Time to surgery (>16 weeks)	1.54	0.39-6.05	0.53

DISCUSSION

This study demonstrates that delayed anastomotic urethroplasty yields favorable outcomes for post-traumatic posterior urethral restrictures in our studies, with an 86% success rate comparable to the success rates of 83-97% reported by Koraitim et al. [16]. Our findings are in keeping with contemporary evidence that anastomotic urethroplasty represents the gold standard for complete posterior urethral distraction defects after pelvic trauma [17]. The mean age of 32.8 years reflects a typical demographic of young, working-age males sustaining high-energy pelvic trauma, consistent with Horiguchi et al. who demonstrated a peak in the third and fourth decades of life [18]. Injuries due to road traffic accidents accounted for 74% of cases, slightly higher than the 50-60% figure common in many developed settings where injury mechanisms are more heterogeneous [19]. This likely reflects the high relative burden of road traffic injury and occupational risk in Bangladesh, emphasizing a need for the implementation of targeted injury prevention strategies. The mean stricture length of 2.7 cm, slightly longer than the 1.6-2.0 cm reported by Mehmood et al., suggests more severe initial trauma or delayed presentation, although still amenable to single-stage perineal reconstruction in most cases [20]. Stricture length >3 cm emerged as the strongest independent predictor of failure (OR 8.74, p = 0.005), in keeping with Alberca et al. that longer defects present greater technical and biological challenges [21]. Such cases often require more extensive urethral

mobilization and ancillary maneuvers, including corporeal separation and inferior pubectomy, to achieve a tension-free anastomosis [22]. Success rates in prior series are reported to decline from >95% for defects <2 cm to 75-85% for defects >3 cm [23]. Our analysis demonstrates that inferior pubectomy was independently associated with higher failure risk (OR 3.62, p = 0.048) should be interpreted as a marker of reconstructive complexity rather than an inherently deleterious maneuver. Inferior pubectomy is typically reserved for the most challenging defects; multicenter data suggest that when performed with meticulous technique, pubectomy-based approaches can still yield excellent long-term outcomes despite higher early complication rates [24,25]. The overall complication rate in our cohort was 36%, but the overwhelming majority of these were complications manageable with conservative or minimally invasive measures. Urinary incontinence occurred in 12% of patients, within the reported range of 5-21% [26]. The majority of cases appeared to be mild and responded to behavioral and pelvic floor interventions, and none required sphincter prosthesis. Erectile dysfunction was observed in 8% of patients, lower than many series reporting 30-75% [27]. This comparatively favorable rate likely reflects a younger population, less severe associated pelvic injuries, or underreporting due to sociocultural reluctance to disclose sexual issues. The use of validated erectile function instruments would likely provide a more accurate estimate. Functional outcomes were promising, with a mean postoperative Qmax of 19.3 ml/s. The notable difference between the successful (20.4 ml/s) and failed repairs (12.8 ml/s, $p < 0.001$) further argues for uroflowmetry as a functional, objective outcome measure. Previous literature suggests that Qmax > 15 ml/s, with a normal flow curve, strongly predicts anatomical success and that large decrements in flow correlate with restricture [28]. However, flow studies should supplement, not supplant, imaging or endoscopy, as early or focally narrowed strictures may pass undetected by uroflowmetry alone [29]. The lack of significant associations between failure and either age >45 years or increased time to urethroplasty is consistent with Hofer et al. and Davenport et al. that, within reasonable limits, other anatomical variables such as stricture length and degree of pelvic distortion are more important predictors of outcome than age or exact timing of repair [30,31]. The 14% failure rate, though acceptable and comparable to published data, illustrates continued refinement in technique and case selection. Failures often reflect residual scar, anastomotic tension, or progressive fibrosis, all of which emphasize complete excision of diseased tissue and strict adherence to tension-free principles [32]. Most postoperative restrictures after a well-performed anastomotic urethroplasty respond favorably to a single direct vision internal urethrotomy, whereas a minority require redo anastomotic urethroplasty, which still can achieve high success in experienced hands [33,34].

LIMITATIONS

The limitations of this study include its single-center design, with a relatively modest sample size of 50 patients, which may limit the generalizability of the findings to broader populations. A maximum follow-up duration of 12 months may be inadequate for the detection of late restricture recurrence, as some series report continued failures beyond one year post-operatively.

CONCLUSION

Delayed anastomotic urethroplasty is an effective treatment modality for post-traumatic posterior urethral strictures, with an 86% success rate in our study. However, stricture length greater than 3 cm and need for inferior pubectomy independently predict surgical failure, emphasizing meticulous preoperative assessment and surgical planning. While overall results are encouraging, a complication rate of 36% highlights the importance of thorough counseling regarding potential adverse effects, including incontinence, erectile dysfunction, and restricture formation. Continued refinement in surgical technique, patient selection, and postoperative surveillance protocols will further improve results in this challenging patient population.

RECOMMENDATIONS

Future studies will need to be prospective, multicenter trials with larger sample sizes and longer follow-up to fully delineate the long-term durability of repairs and late complication rates. Furthermore, comparative studies examining different surgical techniques, such as vessel-sparing approaches and variations in ancillary maneuver utilization, may highlight strategies to minimize complications yet maintain success rates.

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Distribution of eGFR Across Age, Sex, and Rh Factor Subgroups among Chronic Kidney Disease Patients in a Tertiary Care Hospital

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ABSTRACT

Introduction: Chronic kidney disease (CKD) is a progressive condition marked by a gradual decline in kidney function, often leading to end-stage renal disease if not detected and managed early. Estimating glomerular filtration rate (eGFR) is a key clinical tool for assessing kidney function and staging CKD. **Methods & Materials:** This cross-sectional observational study was conducted in department of Nephrology, National Institute of Kidney Diseases & Urology, Dhaka, Bangladesh, from January 2022 to June 2022, to evaluate the distribution of estimated glomerular filtration rate (eGFR) among chronic kidney disease (CKD) patients based on age, sex, and Rh factor. A total of 100 adult patients (≥18 years) with clinically diagnosed CKD (Stages 1–5) were included. **Result:** In this study of 100 CKD patients, the majority were over 60 years of age (45%) and male (59%), with most being Rh positive (86%). A clear decline in mean eGFR was observed with increasing age, from 58.9 mL/min/1.73 m² in the 18–40 age group to 33.7 mL/min/1.73 m² in those over 60. Females had a slightly higher mean eGFR than males, and Rh-negative patients had lower mean eGFR compared to Rh-positive patients. Most patients were in CKD stages 3b (26%) and 4 (28%), with advanced stages more prevalent in older individuals. **Conclusion:** This study found that eGFR declined with age, especially after 60 years. Females had slightly higher mean eGFR than males, though not significant. Rh-negative patients showed lower eGFR than Rh-positive, indicating a potential association needing further study.

Keywords: *eGFR, Chronic Kidney Disease, Rh Factor Subgroups, End-Stage Renal Disease*

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INTRODUCTION

Chronic kidney disease (CKD) is a progressive and irreversible condition characterized by the gradual loss of kidney function over time. It represents a significant global health concern due to its high prevalence, substantial burden on healthcare systems, and association with increased morbidity and mortality. The global prevalence of CKD is estimated to be over 13%, with higher rates observed in low- and middle-income countries due to limited access to early detection and treatment services [1]. In Bangladesh, CKD is becoming increasingly prevalent, particularly among individuals with comorbidities such as hypertension and diabetes mellitus [2]. The estimated glomerular filtration rate (eGFR) serves as a vital indicator of kidney function and is widely used to classify and monitor the progression of CKD. The eGFR is calculated using formulas such as the Modification of Diet in Renal Disease (MDRD) and the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations, which incorporate serum creatinine levels, age, sex, and race [3]. Decreases in eGFR reflect worsening kidney function and are predictive of adverse outcomes, including progression to end-stage renal disease (ESRD) and cardiovascular events [4]. Age is a well-established determinant of kidney function. eGFR declines naturally with aging due to structural and functional changes in the kidney, such as nephron loss and glomerulosclerosis [5]. Studies have shown that elderly populations are disproportionately affected by CKD, and the rate of decline in eGFR is often faster in older individuals [6]. In fact, the risk of CKD doubles with each decade after the age of 40 [7]. Hence, understanding the age-related distribution of eGFR is essential for tailoring preventive and therapeutic strategies, especially in geriatric patients. Sex-related differences in kidney function and CKD progression have also been well documented. Generally, males tend to have higher eGFR values than females due to differences in muscle mass and hormonal influences [8]. However, females often experience slower progression of CKD compared to males, possibly due to protective effects of estrogen on renal hemodynamics [9]. Understanding sex-specific patterns in eGFR distribution can inform more individualized clinical care and highlight potential biological or environmental contributors to disease progression. Although ABO and Rh blood groups have traditionally been associated with transfusion medicine and obstetrics, emerging evidence suggests potential associations between blood group antigens and non-hematologic conditions, including cardiovascular and renal diseases [10]. Among these, the Rh factor specifically Rh-positive and Rh-negative status has received limited attention in nephrology research. Some studies have proposed a correlation between Rh status and the susceptibility or severity of certain chronic diseases, possibly mediated through immune or endothelial mechanisms [11]. However, data on the relationship between Rh factor and kidney function, particularly eGFR, remains scarce and inconclusive. In the context of developing countries like Bangladesh, where CKD often remains undiagnosed until advanced stages, such studies are crucial for raising awareness, guiding policy decisions, and optimizing resource allocation. In the context of developing countries like Bangladesh, where CKD often remains undiagnosed until advanced stages, such studies are crucial for raising awareness, guiding policy decisions, and optimizing resource allocation. This study aims to assess distribution of eGFR across age, sex, and

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rh factor subgroups among chronic kidney disease patients in a tertiary care hospital.

METHODS & MATERIALS

This cross-sectional observational study was conducted in Department of Nephrology, National Institute of Kidney Diseases & Urology, Dhaka, Bangladesh, from January 2022 to June 2022, to evaluate the distribution of estimated glomerular filtration rate (eGFR) among chronic kidney disease (CKD) patients based on age, sex, and Rh factor. A total of 100 adult patients (≥18 years) with clinically diagnosed CKD (Stages 1–5) were included, following the KDIGO 2012 guidelines. Patients with acute kidney injury, those undergoing dialysis or post-renal transplant, pregnant women, and individuals with hematological disorders affecting blood group typing were excluded. Data were collected through patient interviews and medical records, including age, sex, CKD stage, eGFR (calculated using the CKD-EPI equation), and Rh blood group status. Data analysis was done by SPSS version 26.0. All participants provided informed written consent before enrollment.

RESULTS

Nearly half (45%) of the patients were aged >60 years. Males accounted for 59% of the study population. The majority (86%) were Rh positive (*Table I*).

Table I
Demographic Profile of the Study Population (*n* = 100).

Characteristics	Frequency (n)	Percentage (%)
Age Group		
18–40 years	18	18.0%
41–60 years	37	37.0%
>60 years	45	45.0%
Sex		
Male	59	59.0%
Female	41	41.0%
Rh Factor		
Rh Positive	86	86.0%
Rh Negative	14	14.0%

A declining trend in eGFR was observed with increasing age. Patients >60 years showed the lowest mean eGFR (33.7 mL/min/1.73 m²), indicating more advanced renal dysfunction (*Table II*).

Table II
Distribution of Mean eGFR Across Age Groups.

Age Group	Mean eGFR (mL/min/1.73 m²)	Standard Deviation (SD)
18–40 years	58.9	±9.8
41–60 years	45.6	±10.5
>60 years	33.7	±8.2

Female patients had a slightly higher mean eGFR compared to males, though the difference was small and not statistically significant (*Table III*).

Table III
Mean eGFR According to Sex.

Sex	Mean eGFR (mL/min/1.73 m²)	Standard Deviation (SD)
Male	42.9	±10.1
Female	44.3	±9.5

The majority of patients were in Stage 3b (26%) and Stage 4 (28%) of CKD. Advanced kidney disease (Stage 5) was present in 16% of patients (*Table IV*).

Table IV
Distribution of eGFR by CKD Stage.

CKD Stage	eGFR Range (mL/min/1.73 m²)	Frequency (n)	Percentage (%)
Stage 1	≥90	2	2.0%
Stage 2	60–89	10	10.0%
Stage 3a	45–59	18	18.0%
Stage 3b	30–44	26	26.0%
Stage 4	15–29	28	28.0%
Stage 5 (ESRD)	<15	16	16.0%

Rh-negative individuals had a slightly lower mean eGFR than Rh-positive individuals. The clinical and statistical significance of this difference warrants further investigation (*Table V*).

Table V
eGFR Distribution by Rh Factor.

Rh Factor	Mean eGFR (mL/min/1.73 m²)	Standard Deviation (SD)
Rh Positive	44.1	±9.7
Rh Negative	40.5	±10.8

Older patients (>60 years) had higher frequencies of advanced CKD (Stages 4 and 5). Early stages (1 and 2) were more commonly seen in the younger age groups (*Table VI*).

Table VI
Cross-tabulation of CKD Stage by Age Group.

CKD Stage	18–40 yrs	41–60 yrs	>60 yrs	Total (n)
Stage 1	1	1	0	2
Stage 2	3	5	2	10
Stage 3a	4	7	7	18
Stage 3b	4	10	12	26
Stage 4	5	9	14	28
Stage 5	1	5	10	16
Total	18	37	45	100

This table shows the distribution of Rh phenotypes with their corresponding genotypes, frequencies, and estimated mean eGFR values among chronic kidney disease patients, highlighting variations across subgroups (*Table VII*).

Table VII
Distribution of eGFR Across Rh Phenotype and Genotype Subgroups in Chronic Kidney Disease Patients.

Phenotype	Genotype (Fisher–Race)	Genotype (Weiner)	Frequency (%)	Estimated mean eGFR (mL/min/1.73 m²)
CC DD ee	CDe / CDe	R1 R1	38.60	42 ± 12
Cc DD ee	CDe / cDe	R1 r	29.20	45 ± 13
CC DD EE	CDe / CDE	R1 R2	22.20	38 ± 11
cc dd ee	cde / cde	rr	4.51	33 ± 10
Cc Dd Ee	CDE / cde	R2 r	1.91	40 ± 12
CC DD EE	CDE / CDE	R2 R2	1.57	35 ± 11

DISCUSSION

This study investigated the distribution of estimated glomerular filtration rate (eGFR) across different age groups, sexes, and Rh blood group subtypes among patients with chronic kidney disease (CKD). Our findings highlight key demographic and biological variations in renal function, aligning with and extending existing literature on CKD epidemiology. The present study showed that eGFR declines significantly with age, with patients >60 years exhibiting the lowest mean eGFR (33.7 ± 8.2 mL/min/1.73 m²). This is consistent with global data indicating that kidney function deteriorates naturally with aging due to nephron loss, glomerulosclerosis, and tubulointerstitial fibrosis [5]. The United States NHANES study also demonstrated a steady decline in eGFR with age, with CKD being most prevalent in the elderly population [6]. Similarly, Coresh et al. noted that individuals over 60 had a significantly higher prevalence of CKD stages 3–5, reinforcing the findings of our study [12]. In terms of sex distribution, females had a slightly higher mean eGFR than males (44.3 vs. 42.9 mL/min/1.73 m²), though not statistically significant. This observation mirrors that of Wetzels et al., who found women to have marginally higher eGFR values despite having smaller muscle mass and lower serum creatinine [8]. Moreover, studies have suggested that estrogen may confer a protective effect on the kidneys, slowing the progression of CKD in women [9]. However, despite this protective effect, women may be underdiagnosed due to lower baseline creatinine, highlighting the need for sex-specific diagnostic considerations [13]. Regarding CKD stage distribution, our findings revealed that most patients were in Stage 3b (26%) and Stage 4 (28%), followed by Stage 5 (16%). This pattern is consistent with data from a multi-center study in India where the majority of CKD patients were also found in moderate-to-severe stages, primarily due to late diagnosis and limited access to nephrology care [14]. Similarly, the SEEK study (Screening and Early Evaluation of Kidney Disease) from South Asia reported that over half of diagnosed CKD cases were already in stage 3 or higher at the time of presentation [15]. A novel aspect of our study was the evaluation of eGFR in relation to Rh blood group, where Rh-negative patients exhibited a lower mean eGFR (40.5 ± 10.8) compared to Rh-positive individuals (44.1 ± 9.7). Although the clinical significance of this finding remains uncertain, a study by Khalid et al. suggested a potential association between Rh-negative status and higher risks of metabolic and vascular conditions, which are known risk factors for CKD [11]. While most existing literature has focused on ABO blood groups and their relation to cardiovascular and renal disease, the role of the Rh factor in renal pathophysiology remains underexplored [16]. This study shows that eGFR varies across Rh phenotypes and genotypes in CKD patients. The highest mean eGFR was observed in Cc DD ee (45 ± 13 mL/min/1.73 m²) and the lowest in cc dd ee (33 ± 10), indicating that genotype may influence renal function. Although the Rh system has been little studied in CKD, prior research suggests genetic factors affect disease progression [17-19].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community

CONCLUSION

This study highlights the variation in eGFR distribution among chronic kidney disease patients based on age, sex, and Rh factor in a tertiary care hospital setting. A significant decline in eGFR was observed with increasing age, particularly among patients over 60 years. While females showed slightly higher mean eGFR than males, the difference was not statistically significant. Notably, Rh-negative patients exhibited lower eGFR levels compared to Rh-positive counterparts, suggesting a possible association that warrants further investigation.

RECOMMENDATION

Routine screening for kidney function using eGFR should be emphasized, especially in older adults and high-risk groups. Clinicians should consider age, sex, and possibly Rh factor as relevant variables when assessing CKD risk and progression. Further large-scale, multicenter studies are recommended to explore the potential role of Rh factor in renal function and disease susceptibility.

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CONFLICT OF INTEREST

None declared

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Diagnostic Accuracy for Breast Lump by Core Biopsy without Image Guidance

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ABSTRACT

Introduction: Breast lumps are a common clinical presentation, and accurate tissue diagnosis is essential for appropriate management. Core needle biopsy (CNB) is widely accepted as a reliable diagnostic tool; however, in resource-limited settings, biopsies are often performed without image guidance for palpable lesions. **Aim of the Study:** To evaluate the diagnostic accuracy of core biopsy without image guidance in patients presenting with palpable breast lumps. **Methods & Materials:** This prospective observational study was conducted at Holy Family Red Crescent Medical College & Hospital and Dhaka Cancer and General Hospital Ltd from December 2023 to November 2025. A total of 100 patients with palpable breast lumps underwent unguided core (Tru-Cut) biopsy. Histopathological findings were compared with final diagnoses obtained from surgical excision and/or follow-up. Diagnostic performance parameters were calculated using standard statistical methods. **Results:** The mean age of patients was 43.22 ± 11.80 years. Malignant lesions accounted for 58% of cases, with invasive ductal carcinoma being the most common. On comparison with the final diagnosis, core biopsy showed 100% sensitivity, 59.2% specificity, 50.0% positive predictive value, 100% negative predictive value, and an overall diagnostic accuracy of 71%. The association between core biopsy results and final diagnosis was statistically significant ($p < 0.05$). **Conclusion:** Unguided core biopsy demonstrates excellent sensitivity and negative predictive value for the diagnosis of palpable breast lumps and remains a valuable diagnostic modality in settings where image guidance is unavailable.

Keywords: *Breast lump, Core needle biopsy, Diagnostic accuracy, Breast cancer.*

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INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and remains a major cause of morbidity and mortality [1]. Accurate tissue diagnosis of breast lumps is essential for timely treatment plan and improved survival outcomes. Histopathological confirmation is the gold standard, and core needle biopsy (CNB) has become a minimally invasive technique that provides reliable tissue samples[2]. Traditionally, CNB is performed under image guidance most using ultrasonography, stereotactic mammography, or magnetic resonance imaging to ensure precise targeting of lesions [3]. However, in many resource-limited settings, freehand CNB without image guidance continues to be practiced, particularly for palpable breast lumps [4]. International studies have consistently demonstrated the diagnostic accuracy of CNB. In the United States, systematic reviews have shown sensitivity rates above 90% and specificity approaching 100% [5]. Similarly, European multicenter studies confirm CNB as a safe and effective alternative to open surgical biopsy [6]. In contrast, research from South Asia and Africa highlights the adaptability of freehand CNB in low-resource environments. A Bangladeshi study showed that freehand CNB achieved high diagnostic accuracy for palpable breast lumps in Bangladesh [4]. Additional regional studies have further shown that sensitivity and specificity comparable to image-guided techniques [7]. A prospective study also confirmed the reliability of Tru-Cut biopsy for breast lumps [8], Comparative studies between fine-needle aspiration cytology (FNAC) and CNB further highlight the superiority of CNB. FNAC, though inexpensive and widely available, often suffers from inadequate sampling and interpretive limitations [9]. Meta-analyses show CNB has significantly higher sensitivity than FNAC, with similar specificity [6]. Studies from India and Bangladesh confirm that CNB provides larger tissue cores, enabling receptor studies and grading, which FNAC cannot reliably achieve [7]. African studies, such as those from Nigeria, demonstrate that CNB remains feasible even in resource-limited hospitals, with diagnostic accuracy sufficient to guide treatment [6]. Global reviews emphasize that while image-guided CNB is the recommended standard, freehand CNB remains a pragmatic alternative where imaging facilities are scarce [5]. This dichotomy reflects broader healthcare inequities: high-income countries prioritize technological precision, while low-income regions adapt techniques to local realities. Importantly, CNB reduces the need for open surgical biopsy, thereby minimizing patient morbidity and healthcare costs [2]. Concerns remain regarding sampling errors and operator dependency, but evidence suggests that with adequate training, freehand CNB can achieve diagnostic accuracy comparable to image-guided methods [4,7]. Given the global burden of breast cancer and the diversity of healthcare contexts, it is crucial to validate diagnostic techniques across settings. By systematically evaluating the diagnostic accuracy of CNB without image guidance, clinicians can establish evidence-based protocols that balance accessibility with reliability, ultimately improving breast cancer detection worldwide. Therefore, this study aimed to evaluate the diagnostic accuracy of core biopsy without image guidance in the assessment of breast lumps.

METHODS & MATERIALS

This prospective observational study was conducted at Holy Family Red Crescent Medical College & Hospital and Dhaka Cancer and General Hospital Ltd from December 2023 to November 2025. A total of 100 patients presenting with palpable breast lumps were enrolled after obtaining informed consent. Unguided core (Tru-Cut) biopsy was performed by 1st author using 14G core needle size standard technique without imaging guidance, and multiple (7-9) cores were obtained from each lump for histopathological evaluation. Demographic, clinical, and procedural data were recorded, and biopsy results were compared with final diagnoses established

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by surgical excision or follow-up. Statistical analysis was performed using SPSS software to calculate sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. The study protocol was reviewed and approved by the Institutional Ethical Review Board, ensuring compliance with ethical standards.

Inclusion Criteria

- Patients presenting with palpable breast lumps during the study period
- Patients who provided written informed consent for participation and biopsy procedure.
- Patients who underwent unguided core (Tru-Cut) biopsy as part of diagnostic evaluation.

Exclusion Criteria

1. Patients with non-palpable breast lesions requiring image-guided biopsy.
2. Patients with previously diagnosed breast carcinoma or those already on treatment.
3. Patients with incomplete clinical data or missing biopsy specimens.
4. Patients who refused consent or declined participation.
5. Cases where biopsy material was inadequate or non-diagnostic.

RESULTS

The mean age of the study population was 43.22 ± 11.80 years, with ages ranging from a minimum of 20 years to a maximum of 80 years. The largest proportion of patients belonged to the 30–39 years age group (34%), followed by 40–49 years (27%). Patients aged ≥60 years constituted 10% of the cohort (*Table I*).

Table I
Baseline demographic characteristics of the study population (*n* = 100).

Variable	Value
Age, mean ± SD (years)	43.22 ± 11.80
Age range (years)	20 – 80
<30 years	9 (9.0%)
30–39 years	34 (34.0%)
40–49 years	27 (27.0%)
50–59 years	20 (20.0%)
≥60 years	10 (10.0%)

The mean lump length was 2.41 ± 0.84 cm (range: 1.0–5.0 cm), while the mean lump width was 2.62 ± 1.00 cm (range: 1.0–6.0 cm). The mean lump area measured 6.99 ± 5.70 cm², with values ranging from 1.0 cm² to 30.0 cm², representing the widest variability among clinical measurements (*Table II*).

Table II
Clinical characteristics of breast lumps (*n* = 81*).

Variable	Mean ± SD	Range
Lump length (cm)	2.41 ± 0.84	1.0 – 5.0
Lump width (cm)	2.62 ± 1.00	1.0 – 6.0
Lump area (cm²)	6.99 ± 5.70	1.0 – 30.0

**Data missing in 19 cases*

The mean number of cores obtained per case was 7.6 ± 3.2, ranging from 1 to 14 cores. The largest core length had a mean of 1.54 ± 0.57 cm, while the smallest core length averaged 0.49 ± 0.36 cm. Most cases (94%) were sampled with a single-site core biopsy, and the mean number of blocks prepared was 2.18 ± 1.13 (*Table III*).

Table III
Core biopsy procedural characteristics (*n* = 100).

Variable	Value
Number of cores taken, mean ± SD	7.6 ± 3.2
Single core biopsy	94 (94.0%)
Multiple cores taken	6 (6.0%)
Largest core length (cm), mean ± SD	1.54 ± 0.57
Smallest core length (cm), mean ± SD	0.49 ± 0.36
Core size ratio, mean ± SD	2.18 ± 1.13
Blocks prepared, mean ± SD	2.18 ± 1.13

Malignant lesions constituted the majority, with invasive ductal carcinoma being the most frequent diagnosis. Benign conditions included mastitis, fibroadenoma, papilloma, and benign breast tissue. Overall, 58% of cases were malignant and 42% were benign on core biopsy histology (*Table IV*).

Table IV
Histopathological diagnosis on core biopsy (*n* = 100).

Diagnosis	n (%)
Invasive ductal carcinoma (including NOS)	47 (47.0%)
Invasive lobular carcinoma	1 (1.0%)
Mixed ductal & lobular carcinoma	2 (2.0%)
Mucinous carcinoma	1 (1.0%)
Ductal carcinoma in situ (DCIS)	3 (3.0%)
Fibroadenoma	4 (4.0%)
Papilloma ± atypia	4 (4.0%)
Phyllodes tumor	1 (1.0%)
Mastitis (acute/chronic/granulomatous)	29 (29.0%)
Benign breast tissue / others	8 (8.0%)
Unknown	2 (2.0%)

Among malignant cases, Grade II tumors were most common (34%), followed by Grade I (12%) and Grade III (4%). Lymphovascular invasion (LVI) was present in 16% of cases, while perineural invasion (PNI) was observed in 8% (*Table V*).

Table V
Tumor grade and pathological risk features (n = 100).

Variable	*n* (%)
Histological grade	
Not applicable	50 (50.0%)
Grade I	12 (12.0%)
Grade II	34 (34.0%)
Grade III	4 (4.0%)
Lymphovascular invasion (LVI)	
Present	16 (16.0%)
Absent	84 (84.0%)
Perineural invasion (PNI)	
Present	8 (8.0%)
Absent	92 (92.0%)

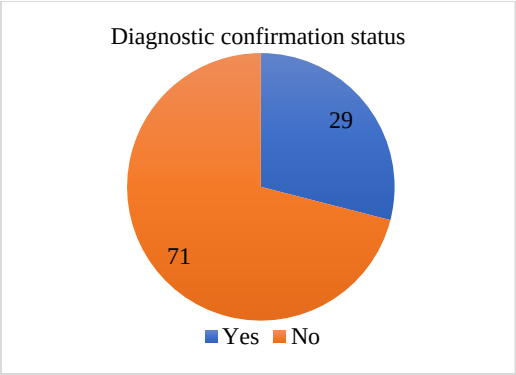

Figure 1 Diagnostic confirmation status.

Final diagnosis was confirmed in 29% of cases, while 71% showed no malignant confirmation on reference standard evaluation (*Figure 1*). Core biopsy correctly identified all confirmed malignant cases (true positives = 29), with no false-negative results. However, 29 cases were false positives, where core biopsy suggested malignancy but the final diagnosis was benign. True-negative results accounted for 42 cases (*Table VI*).

Table VI
Comparison of core biopsy results with final diagnosis.

Core biopsy result	Final malignant	Final benign	Total
Malignant	29 (TP)	29 (FP)	58
Benign	0 (FN)	42 (TN)	42
Total	29	71	100

The sensitivity of unguided core biopsy was 100%, while the specificity was 59.2%. The positive predictive value was 50.0%, and the negative predictive value was 100%. The overall diagnostic accuracy was 71% (*Table VII*).

Table VII
Diagnostic performance of core biopsy without image guidance.

Diagnostic parameter	Value
Sensitivity	100%
Specificity	59.2%
Positive predictive value (PPV)	50.0%
Negative predictive value (NPV)	100%
Overall diagnostic accuracy	71.0%

DISCUSSION

The present study assessed the diagnostic accuracy of unguided core biopsy for breast lumps in a cohort of 100 patients. By analyzing demographic, clinical, procedural, histopathological, and diagnostic performance parameters, we provide a comprehensive evaluation of this technique in a real-world setting. Our findings are consistent with published literature, particularly in demonstrating high sensitivity and negative predictive value, but modest specificity and positive predictive value. In our study, the mean age of patients was 43.2 years, with the largest proportion belonging to the 30–39 year age group (34%). This age distribution aligns with a study by Hassan et al. (2022), who found a mean age of 42 years with peak incidence in the fourth decade, and Hoq et al. (2021), who similarly reported clustering of cases in the 30–40-year range [10,1]. The predominance of younger women reflects the demographic profile of breast lump presentations in South Asian populations, contrasting with Western cohorts, where peak incidence is often in the fifth and sixth decades. This suggests regional differences in breast cancer epidemiology, possibly influenced by genetic, reproductive, and environmental factors. Our cohort demonstrated mean lump dimensions of 2.4 cm in length and 2.6 cm in width, with a mean area of 7.0 cm². These values are comparable to those reported by Nwafor et al. (2018), who found average lump sizes of 2–3 cm in Nigerian women [11]. The variability in lump area (range 1–30 cm²) highlights the heterogeneity of clinical presentations. Larger lump sizes are often associated with delayed presentation, a common issue in resource-limited settings. This reinforces the importance of accessible diagnostic modalities such as unguided core biopsy, which can be performed even in peripheral centers without imaging facilities. We obtained a mean of 7.6 cores per case, with most patients (94%) undergoing single-site biopsy. The largest core length averaged 1.5 cm, while the smallest was 0.5 cm. These findings are consistent with Noor et al. (2025), who reported a mean of 4–8 cores per case [12]. Our study confirms that an unguided biopsy can yield sufficient tissue for histopathological evaluation, although the absence of imaging guidance may increase variability in sample quality. The mean of 2.2 blocks prepared per case further supports the adequacy of tissue for diagnosis. Malignant lesions constituted 58% of cases in our study, with invasive ductal carcinoma being the most frequent (47%). Benign conditions included mastitis (29%), fibroadenoma (4%), papilloma (4%), and phyllodes tumor (1%). A similar study by Wright et al. (2025) reported invasive ductal carcinoma in 45% of cases, and lee et al. (2021) found mastitis and fibroadenoma as common benign mimics [13,14]. The predominance of ductal carcinoma is consistent across global literature. At the same time, the relatively high proportion of mastitis in our cohort reflects the diagnostic challenges posed by inflammatory lesions in tropical populations. This explains the higher false-positive rate observed in our study. Among malignant cases, Grade II tumors were most common (34%), followed by Grade I (12%) and Grade III (4%). Lymphovascular invasion was present in 16% and perineural invasion in 8%. These findings are in line with Dooijeweert et al. (2019), who also reported Grade II predominance in 34% of cases, and Mahmud et al. (2025), who found LVI in 15% of malignant biopsies [15,2]. The predominance of intermediate-grade tumors suggests that unguided biopsy can reliably capture histological grading features, although assessment of invasion may be limited by sampling error. This highlights the importance of correlating with excision specimens for definitive staging. Final malignant confirmation was achieved in 29% of cases, while 71% were benign on reference standard evaluation. This discrepancy highlights the tendency of unguided biopsy to overcall malignancy, particularly in benign inflammatory lesions. Similar findings were reported by Hoq et al. (2021), who noted frequent false positives in mastitis and papillomas [1]. Our results emphasize the importance of cautious interpretation of unguided biopsy, especially in settings where confirmatory imaging or excision may not be immediately available. Our study demonstrated sensitivity of 100%, specificity of 59.2%, PPV of 50%, NPV of 100%, and overall accuracy of 71%. These values are strikingly consistent with published literature: Saha et al. (2016) reported sensitivity 100%, specificity 62%, accuracy 74% [16]; Ciatto et al. (2025) reported sensitivity 94.2%, specificity 68% [17]. Another study by Karim et al. (2020) reported a 97% sensitivity, 96% specificity, 97% positive predictive value, and 100% negative predictive value(18). Across studies, unguided core biopsy consistently achieves very high sensitivity and NPV, confirming its reliability for ruling out malignancy. However, specificity and PPV remain modest, reflecting the diagnostic pitfalls of benign lesions mimicking carcinoma. This pattern underscores the role of unguided biopsy as a screening tool rather than a definitive diagnostic modality. A major strength of our study is the comprehensive analysis of multiple parameters, including demographics, clinical features, procedural details, histopathology, grading, and diagnostic accuracy. The inclusion of 100 patients provides a robust sample size, and the absence of false negatives highlights the reliability of unguided biopsy in excluding malignancy. Furthermore, our study reflects real-world practice in resource-limited settings, enhancing its external validity.

LIMITATION

The study was limited by the absence of routine image guidance and incomplete final diagnostic confirmation in all cases.

CONCLUSION

Core needle biopsy without image guidance is a highly sensitive and practical diagnostic tool for the histopathology of palpable breast lumps. Although specificity is comparatively lower, the technique reliably excludes malignancy and provides adequate tissue for histopathological evaluation and for further IHC(Immunohistochemistry). In resource-constrained healthcare settings, unguided core biopsy can effectively reduce the need for open surgical biopsy and facilitate early clinical decision-making.

RECOMMENDATION

Unguided core biopsy can be adopted as a standard initial diagnostic approach for palpable breast lumps in resource-limited centers, provided that procedures are performed by trained clinicians. Where available, suspicious or equivocal cases should be further evaluated with image-guided biopsy or surgical excision. Future multicenter studies with larger sample sizes and complete histological follow-up are recommended to further validate diagnostic accuracy and improve specificity.

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Study of Pattern of Injuries in Cases of Fall from Height – A Cross Sectional Study

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ABSTRACT

Background: Falls from height (FFH) represent a major public health concern, particularly in developing countries like Bangladesh. FFH accounts for significant morbidity and mortality globally, with injury patterns and severity influenced by factors such as fall height, impact surface, and body orientation. **Aim:** This study aimed to analyze the correlation between fall height and injury severity, identify demographic and environmental risk factors, and assess medical responses and outcomes among FFH victims in Bangladesh. **Methods & Materials:** An observational cross-sectional study was conducted across major hospital in Dhaka over 18 months. Data were collected from 80 FFH victims through interviews, medical records, and clinical evaluations. **Results:** The study included participants aged 1–85 years (mean: 27.75 ± 18.49 years). FFH predominantly affected males (56.25%) and unemployed individuals (42.5%). Most falls occurred at home (37.5%) and from low to moderate heights (83% below 11 feet). Fractures (84%), scalp swellings (27.5%), and abrasions (41.3%) were the most common injuries. Severity was significantly associated with fall height ($p < 0.0001$). **Conclusion:** FFH remains a significant cause of injury in Bangladesh, with demographic and environmental factors influencing outcomes. Improved safety protocols, public awareness, and accessible emergency care are critical for mitigating the impact of FFH. Further research is warranted to explore long-term outcomes and tailored interventions for high-risk populations.

Keywords: *Fall from height, Pattern, Severity of Injuries.*

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INTRODUCTION

Falls from height (FFH) are a major cause of injury and death worldwide, particularly in developing countries like Bangladesh. FFH occurs when individuals fall from elevated locations such as rooftops, balconies, staircases, scaffolds, trees, and agricultural structures. The severity of injuries depends on factors including the height of the fall, body position during impact, the surface struck, and the biomechanical characteristics of affected body parts.[1]

In Bangladesh, FFH is a significant public health concern in both urban and rural areas. In cities, rapid construction growth has increased workplace accidents, especially among construction workers who often fall from scaffolds, ladders, and unfinished buildings. These incidents frequently result in serious injuries such as head trauma, limb fractures, and spinal cord damage, often due to inadequate safety measures, poor equipment maintenance, and insufficient worker training. [2]

In rural regions, FFH commonly occurs during agricultural activities, particularly when farmers climb palm or coconut trees for harvesting. Such falls often cause severe head and spinal injuries due to impact with hard ground surfaces. [3]

Vulnerable groups, including children and the elderly, are also at high risk. Children frequently fall from windows, balconies, or furniture during play, while elderly individuals face increased risk due to reduced balance, slower reflexes, and age-related physical decline. Despite increasing awareness, inadequate enforcement of safety regulations continues to contribute to high FFH-related injury and fatality rates in Bangladesh.[4]

Objectives

General Objective:

To determine the association between pattern of injury with fall from different level of height.

Specific Objectives:

1. To analyze the demographic distribution of falls from height (FFH) victims.
2. To determine the correlation between fall height and the severity of injuries sustained.
3. To identify any threshold heights at which the risk of specific injury types or severity levels increases significantly.
4. To assess the role of environmental factors and surface types in influencing injury patterns

METHODS & MATERIALS

This is Observational Cross-Sectional Study. This research was conducted in the Department of Forensic Medicine, Sir Salimullah Medical College, in collaboration with emergency department of Dhaka Medical College Hospital & Shaheed Suhrawardy Medical College, Sher-E-Bangla Nagar, Dhaka. In this study, the sampling technique was convenient sampling.

Study period: 18 months (From 1st January 2023 to 30th June 2024).

Materials

Questionnaire and checklist was used to collect data from victims of fall from height.

Measurement:

Height was measured by self-reporting.

Inclusion Criteria:

1. Individuals who have sustained injuries from falls from height.
2. Patients come at emergency department of the hospital due to fall from height.
3. Both male and female patients of all ages.
4. Incidents occurring in both urban and rural settings in Bangladesh.
5. Willingness to participate: Patients/their guardians must consent to participate in the study

Exclusion Criteria:

1. Victims of falls with incomplete medical records or unclear details of the fall incident.

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2. Patients not willing to participate or whose guardians do not consent.
3. Falls that occur as a result of vehicular accidents or other traumatic events unrelated to height.

Sampling

A convenient sampling method was employed for the study.

Ethical approval:

Prior to the study conduct, the research protocol was sought approval from the Institutional review board (IRB) of Sir Salimullah Medical College. Ref no. 59.14.0000.131.000.18.0000.22.173. The study protocol, questionnaire and informed consent form as well as the methodology of the study was reviewed by Institutional review board(IRB).

Consent procedure:

Permission was taken from the Department of Forensic medicine. Every eligible participant was informed about the study and its objectives. Informed written consent was signed by all the participants.

Operational Definition

Fall from height: Injury sustained by a person after landing on the ground following a fall from an elevated place. Categorized into ranges:-

1. Low (1-3 meters)
2. Moderate (4-30 meters)
3. High (above 30 meters)

Severity of Injuries: it will be calculated by AIS, ISS & GCS.

Abbreviated injury scale: It is an anatomical based coding system to classify & describe the severity of injuries. It also represents the threat to life associated with the injury. It is range from 1 (minor)–6 **(**Un survivable).

RESULTS

The study results revealed the injury pattern of fall from height cases of 80 cases so that their injuries, locations and fatality can be revealed.

Age distribution of participants

A total of 80 participants were included in the study. The ages of participants ranged from 1 year to 85 years, with a mean age of 27.75 years (M=27.75) and a standard deviation of 18.49 years (SD=18.49). This indicates that there is a wide age variation among the participants, as evidenced by the range and standard deviation (*Table I***)**.

Table I
Distribution of participants according to age.

	N	Minimum age	Maximum age	Mean age	Std. Deviation
Age	80	1	85	27.75	18.49

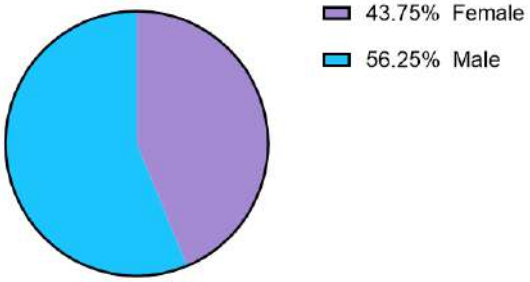

Figure 1 Gender Distribution

Analysis of Gender Distribution of the participants

Figure 1 illustrates the gender distribution of participants in the study as a pie chart. The majority of participants were male, comprising 56.25% of the sample. Female participants accounted for the remaining 43.75%. The chart visually represents the slightly higher proportion of male participants compared to females, highlighting a moderate gender imbalance in the sample.

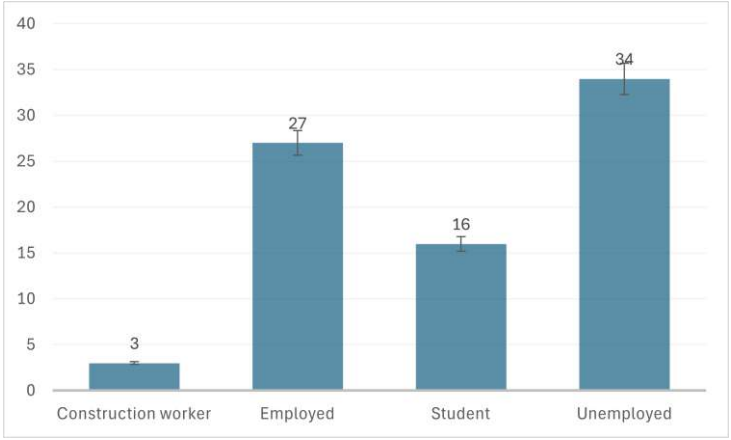

Figure 2 Participants Current profession to engage with in this study

Current profession of the participants

Figure 2 illustrates the distribution of participants across four occupational categories: Construction Worker, Employed, Student, and Unemployed. The Unemployed group was the largest, comprising 42.50% (34 participants), followed by the Employed group at 33.75% (27 participants). Students accounted for 20.00% (16 participants), while Construction Workers represented the smallest category at 3.75% (3 participants).

Place of fall of the participant

Table II presents the frequency and percentage distribution of falls reported by participants across different locations. Among the total of 80 respondents, 37.5% experienced falls at home, making it the most common location for falls. The workplace was the second most frequent location for falls, accounting for 36.3% of responses.

Table II
Frequency and percentage distribution of falls reported by participants.

Location of fall	n	Frequency	Percent
Home	80	30	37.5
Public area		21	26.3
Workplace		29	36.3
Total		80	100.0

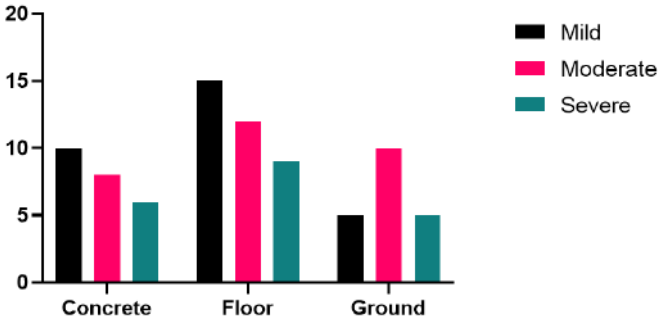

Figure 3 Frequencies of injuries across three surface types

For Concrete (8). Severe injuries, depicted in teal, were highest on the Floor (9), with Concrete and Ground both recording fewer cases (6 and 5, respectively). The Floor surface had the highest overall frequencies across all injury severities, while the Ground surface showed the fewest. This visualization suggests no clear association between surface type and injury severity, consistent with the chi-square test results (*Figure 3*).

Analysis of Injury Severity by Type of Incident

This table presents the distribution of injury severities (Mild, Moderate, Severe) across three types of incidents: Accidental, Homicidal, and Suicidal. These results highlight that the distribution of injury severity significantly differs for Accidental and Suicidal incidents, whereas no significant pattern is observed for Homicidal cases (Figurt *III*).

Table III
Types and Injury Severity and by Incident.

Type	Mild	Moderate	Severe	Chi-Square (df)	p-value
Accidental	50	20	4	27.04 (2)	< 0.0001
Homicidal	2	1	1	0.67 (2)	0.715
Suicidal	0	0	2	4.00 (1)	0.046

Distribution of various types of soft tissue injuries

Table IV illustrates the frequency distribution of various types of soft tissue injuries, including abrasions, incised wounds, lacerations, bruises, and penetrating wounds. Abrasions were the most frequently reported type of injury, with 34 occurrences, accounting for a significant proportion of the total cases. Lacerations and incised wounds were reported with comparable frequencies, 23 and 12 cases, respectively. Bruises were reported in 10 cases, while penetrating wounds were the least frequent, with only 1 reported instance. These data suggest that abrasions, lacerations, and incised wounds are the most prevalent types of injuries in the sample population, potentially indicating the dominance of blunt and sharp force trauma mechanisms. Multiple responses were allowed in questionnaire.

Table IV
The frequency distribution of various types of soft tissue injuries.

Type of Injury	Frequency	Percent (%)
Abrasion	34	42.5
Incised Wound	12	15.0
Laceration	23	28.8
Bruise	10	12.5
Penetrating Wound	1	1.3
Total	80	100

Distribution of head injuries of the participants

Table V summarizes the distribution of head injuries, including swelling of the scalp, skull fractures, and intracranial hemorrhages, based on frequency, percent, and valid percent. For **swelling of the scalp**, it was present in 27.5% of cases (n = 22), while 72.5% of cases (n = 58) showed no swelling. This indicates that swelling of the scalp is relatively common among the reported injuries. In contrast, **skull fractures** were much less frequent, with only 7.5% of cases (n = 6) exhibiting a fracture, while the majority (92.5%, n = 74) did not have a skull fracture. Similarly, **intracranial hemorrhages** were observed in 7.5% of cases (n = 6), with 92.5% of cases (n = 74) showing no hemorrhage. These findings are significant for understanding the prevalence of specific types of head injuries in the study population.

Table V
Distribution of Head Injuries.

Type of Injury	Response	Frequency (n)	Percent (%)
Swelling of Scalp	No	58	72.5
	Yes	22	27.5
Skull Fracture	No	74	92.5
	Yes	6	7.5
Intracranial Hemorrhage	No	74	92.5
	Yes	6	7.5
Total		80	100.0

DISCUSSION

The present study examined 80 participants aged between 1 and 85 years, with a mean age of 27.75 ± 18.49 years, demonstrating substantial age diversity. This broad age range provided insight into perspectives across multiple life stages and allowed for a more inclusive understanding of medicolegal and fall-related issues. Compared with previous studies that focused on narrower age ranges, the current study offers improved generalizability. However, the wide variation also limits the ability to identify age-specific trends, indicating that future research should categorize participants into defined age groups for more precise analysis. [5]

The age distribution showed uneven representation across age groups, with the highest proportion of participants in the 26–30 years group, followed by the 0–5 and 36–40 years categories. The least represented groups were older adults, particularly those aged 61–65 and above 70 years, while some age groups had no participants. This suggests greater participation of younger individuals, possibly reflecting early-career professionals or dependents frequently exposed to clinical or domestic environments. Similar patterns have been observed in previous studies, although many had more consistent age representation, likely due to differences in sampling methods and study designs. [6]

Gender distribution revealed a moderate male predominance, with males accounting for 56.25% of participants compared to 43.75% females. This aligns with existing literature indicating that males are more frequently involved in falls from height, possibly due to occupational exposure, involvement in high-risk physical activities, and sociocultural factors that increase risk-taking behavior. [7]

The occupational distribution showed significant variation, with the largest proportion of participants being unemployed, followed by employed individuals and students, while construction workers formed a small percentage. Statistical analysis confirmed significant differences in distribution, suggesting that falls from height are not restricted to high-risk occupations such as construction. Instead, they frequently occur in domestic and general workplace settings. The lower representation of construction workers contrasts with traditional assumptions and may reflect regional occupational trends or improved safety regulations in high-risk industries. [8]

Analysis of fall locations revealed that most incidents occurred at home, closely followed by workplaces, while public areas accounted for fewer cases. These findings emphasize that both domestic and occupational environments are critical areas for fall prevention strategies. Household falls may result from unsafe environmental conditions or age-related vulnerability, while workplace falls often arise from occupational hazards and inadequate safety compliance. [9]

Regarding fall height, most incidents occurred from lower heights, particularly between 1 and 7 feet, indicating that falls during routine daily activities are most common. Although falls from higher heights were less frequent, they are often associated with more severe injuries. This highlights the importance of implementing safety measures in everyday environments to reduce fall incidence. [10]

Injury pattern analysis demonstrated a significant association between injury type and occurrence. Fractures were the most common injuries, followed by head and spinal injuries. The predominance of abrasions and lacerations highlights the need for preventive strategies targeting blunt trauma. Preventive measures such as non-slip flooring, protective equipment, improved safety protocols, and increased awareness can help reduce injury risk. Overall, the study underscores the multifactorial nature of falls from height and emphasizes the need for targeted, location-specific, and demographic-based fall prevention strategies. [11]

CONCLUSION

This study highlights the significant public health burden of falls from height (FFH) in Bangladesh, emphasizing their occurrence across diverse settings, from homes to workplaces. It established a clear correlation between fall height and injury severity, revealing that even low-height falls can result in significant injuries, including fractures, head trauma, and spinal injuries. These findings underscore the necessity for targeted preventive measures, including safety protocols, public education, and policy reforms.

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ETHICAL CONSIDERATION

Ethical issues (including plagiarism, data fabrication, double publication) were completely obliged by the authors.

CONFLICT OF INTEREST

There is no conflict of interest.

AUTHORS CONTRIBUTION

All the authors contributed equally to the study.

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Effect of Metformin on Anti-Mullerian Hormone Level in Infertile Women with Polycystic Ovary Syndrome

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a common endocrine disorder and major cause of anovulatory infertility, often associated with metabolic dysfunction. Anti-Mullerian hormone (AMH), typically elevated in PCOS, may be modulated by metformin therapy, though existing evidence remains inconsistent. **Objective:** The aim of the study was to evaluate the effect of metformin on serum Anti-Mullerian Hormone levels in infertile women with Polycystic Ovary Syndrome. **Methods & Materials:** This prospective interventional study at the Department of Obstetrics and Gynaecology, Bangladesh Medical University (BMU), Dhaka, Bangladesh, from January to December 2025, included 80 infertile women with PCOS. Participants received three months of oral metformin, and serum AMH was measured pre- and post-treatment. Demographic and clinical data were collected, and AMH changes, BMI-stratified effects, and correlations with baseline AMH were analyzed using SPSS 25.0 ($p < 0.05$). **Results:** Among 80 infertile women with PCOS (mean age 29.1 ± 4.5 years), most were overweight or obese (65.0%), with menstrual irregularity in 72.5% and hyperandrogenism in 65%. Baseline AMH was 8.4 ± 2.1 ng/mL and decreased to 6.1 ± 1.8 ng/mL after 3 months of metformin (mean reduction 2.3 ± 1.2, $p < 0.001$), with 77.5% showing a decrease. AMH reduction was greatest in obese participants, and baseline AMH positively correlated with BMI ($r = 0.41$) and AMH reduction ($r = 0.52$), all $p < 0.001$. **Conclusion:** Metformin effectively reduces elevated serum AMH levels in infertile women with PCOS, with greater reductions observed in those with higher BMI.

Keywords: *Polycystic Ovary Syndrome, Metformin Therapy, Anti-Mullerian Hormone.*

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INTRODUCTION

Polycystic ovary syndrome (PCOS) represents a leading cause of endocrine disorders and anovulatory infertility in women. Affecting approximately 5% to 10% of women, it stands as the most frequently encountered gynecological endocrine condition among adolescents and women of reproductive age [1]. The syndrome is defined by three primary features: hyperandrogenism (HA), ovulatory dysfunction (OD), and polycystic ovarian morphology (PCOM), with the diagnosis requiring the presence of at least two of these criteria [2]. Women with PCOS frequently experience reproductive complications, including irregular menstrual cycles and infertility, which often drive them to seek medical attention. Beyond reproductive challenges, PCOS is associated with multiple metabolic disturbances, placing affected women at higher risk for insulin resistance, impaired glucose metabolism, dyslipidemia, and increased susceptibility to cardiovascular disease [2].

Anti-Mullerian hormone (AMH) is a dimeric glycoprotein that belongs to the transforming growth factor B (TGF-B) family and is produced exclusively by the granulosa cells of primary, preantral, and small antral ovarian follicles. The serum levels of AMH reflect the size of the ovarian follicular pool. In women, AMH secreted from antral and small antral follicles plays an essential role in the early recruitment of follicles, their growth, selection of dominant follicles, and final maturation during folliculogenesis [3]. Studies have shown that women with PCOS have serum AMH concentrations two to three times higher than those of healthy women. Compared with other markers such as inhibin, estradiol, or follicle-stimulating hormone, AMH is considered a more reliable indicator of ovarian function and follicular reserve [4]. In addition, AMH acts in a paracrine manner within the ovary, independent of gonadotropin signaling, with its levels closely reflecting the number of small antral follicles present.

Metformin, a widely used antihyperglycemic agent, has been introduced as a therapeutic option for women with PCOS. Evidence indicates that metformin can restore regular menstrual cycles and enhance ovulatory function in affected women. Recognized as a primary treatment for insulin resistance, metformin improves insulin sensitivity, reduces androgen levels, and promotes normalization of ovulatory cycles. Its clinical benefits in PCOS include regulation of menstrual cycles, induction of ovulation, and improved fertility potential [5]. These effects are thought to occur through increased hepatic production of sex hormone-binding globulin (SHBG), reduced adrenal and ovarian androgen secretion, and enhanced ovarian responsiveness [6]. Given the role of insulin resistance in PCOS and the associated elevation in AMH, metformin has been hypothesized to mitigate insulin resistance and thereby influence AMH levels in these women [7,8].

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Despite this, the effect of metformin on serum AMH concentrations in women with PCOS remains uncertain [9]. Research findings are inconsistent, with some studies demonstrating reductions in AMH following metformin therapy, while others report no significant changes [10]. Nonetheless, improvements in metabolic parameters such as body weight and insulin sensitivity may indirectly benefit reproductive function. Furthermore, there is a lack of comprehensive systematic reviews or meta-analyses assessing the effects of metformin on AMH, particularly within specific populations, including women in Bangladesh. This highlights the need for further research to evaluate the effect of metformin on serum Anti-Mullerian Hormone levels in infertile women with Polycystic Ovary Syndrome.

Objective

To evaluate the effect of metformin on serum Anti-Mullerian Hormone levels in infertile women with Polycystic Ovary Syndrome.

METHOD & MATERIALS

This prospective interventional study was conducted at the Department of Obstetrics and Gynaecology, Bangladesh Medical University (BMU), Dhaka, Bangladesh, from January to December 2025. A total of 80 infertile women diagnosed with Polycystic Ovary Syndrome (PCOS) were enrolled to evaluate the effects of metformin therapy on serum Anti-Mullerian Hormone (AMH) levels.

Inclusion Criteria:

- Women diagnosed with PCOS based on the Rotterdam criteria.
- Infertile women seeking treatment for conception.
- Age between 20 and 40 years.
- Willingness to participate and provide informed consent.
- Baseline serum AMH measurement available before starting metformin therapy.

Exclusion Criteria:

- Women with other endocrine disorders (e.g., thyroid dysfunction, hyperprolactinemia, Cushing's syndrome).
- History of ovarian surgery or pelvic inflammatory disease.
- Current use of hormonal medications or insulin sensitizers other than metformin.
- Pregnant or lactating women.
- Known hypersensitivity to metformin.
- Severe hepatic, renal, or cardiovascular disease.

Participants were enrolled using purposive sampling, and the diagnosis of PCOS was confirmed according to the Rotterdam criteria, requiring at least two of the following: oligo/anovulation, clinical and/or biochemical hyperandrogenism, or polycystic ovarian morphology on ultrasound. Baseline demographic and clinical data, including age, body mass index (BMI), menstrual pattern, presence of clinical hyperandrogenism, and duration of infertility, were recorded. BMI was calculated as weight in kilograms divided by height in meters squared (kg/m²) and categorized according to WHO criteria.

All participants received oral metformin at standard therapeutic doses for three months while maintaining their usual diet and physical activity. Serum AMH levels were measured at baseline and after 3 months using a standardized enzyme-linked immunosorbent assay (ELISA). The primary outcome was the change in serum AMH levels following metformin therapy, while secondary outcomes included the proportion of participants showing decreased, unchanged, or increased AMH, stratified AMH changes according to BMI, and correlations between baseline AMH, BMI, and magnitude of AMH reduction.

Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequency and percentage. Paired t-tests were used to compare pre- and post-treatment AMH levels. Stratified analyses were performed according to BMI categories, and Pearson correlation coefficients assessed associations between baseline AMH, BMI, and AMH reduction. A p-value < 0.05 was considered statistically significant. Written informed consent was obtained from all participants, and confidentiality was maintained throughout the study.

RESULTS

Table I shows the baseline demographic and clinical characteristics of the 80 infertile women with polycystic ovary syndrome. The majority of participants were aged 26–30 years (36/80, 45.0%), followed by 31–35 years (20/80, 25.0%), 20–25 years (16/80, 20.0%), and >35 years (8/80, 10.0%). Regarding BMI, 37 participants (46.2%) were overweight, 23 (28.8%) were obese, and 20 (25.0%) had normal weight. Menstrual irregularity was present in 58 participants (72.5%), and clinical hyperandrogenism was observed in 52 participants (65%). The mean duration of infertility was 3.2 ± 1.4 years, and the baseline serum AMH level was 8.4 ± 2.1 ng/mL.

Table I
Baseline Demographic and Clinical Characteristics of Study Participants (n = 80).

Variable		Frequency (n)	Percentage (%)
Age Group (years)	20–25	16	20.0
	26–30	36	45.0
	31–35	20	25.0
	>35	8	10.0
	Mean ± SD (years)	29.1 ± 4.5	
BMI Category	Normal (18.5–24.9)	20	25.0
	Overweight (25–29.9)	37	46.2
	Obese (≥30)	23	28.8
	Mean ± SD (kg/m²)	27.5 ± 3.9	
Menstrual irregularity	Present	58	72.5
	Absent	22	27.5
Clinical hyperandrogenism	Present	52	65
	Absent	28	35
Duration of infertility (years)		3.2 ± 1.4	
Baseline AMH (ng/mL)		8.4 ± 2.1	

Table II presents the mean serum AMH levels before and after 3 months of metformin therapy. The mean AMH significantly decreased from 8.4 ± 2.1 ng/mL at baseline to 6.1 ± 1.8 ng/mL after treatment (mean difference 2.3 ± 1.2 ng/mL, $p < 0.001$).

Table II
Pre- and Post-Treatment Serum AMH Levels (*n* = 80).

Parameter	Baseline (Mean ± SD)	After 3 Months (Mean ± SD)	Mean Difference	p-value
AMH (ng/mL)	8.4 ± 2.1	6.1 ± 1.8	2.3 ± 1.2	<0.001

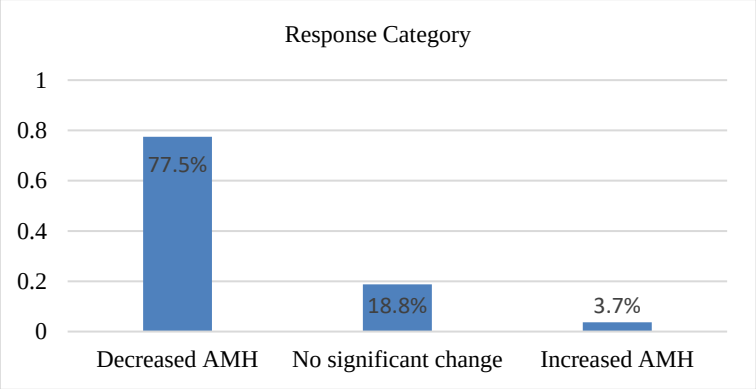

Figure I Response of Serum AMH to Metformin Therapy (*n* = 80).

Figure I illustrate the response of serum AMH to metformin therapy. Most participants (62/80, 77.5%) experienced a decrease in AMH, 15 participants (18.8%) had no significant change, and 3 participants (3.7%) showed an increase.

Table III shows the stratified analysis of AMH change according to BMI category. Obese participants exhibited the greatest reduction in AMH levels (8.7 ± 2.3 to 5.9 ± 1.7 ng/mL, p < 0.001), followed by overweight (8.3 ± 2.0 to 6.2 ± 1.9 ng/mL, p < 0.001) and normal weight participants (7.8 ± 1.9 to 6.5 ± 1.6 ng/mL, p = 0.004).

Table III
Serum AMH Change According to BMI Category (*n* = 80).

BMI Category	n	Baseline AMH (Mean ± SD)	After Treatment (Mean ± SD)	Mean Reduction	p-value
Normal weight (18.5–24.9 kg/m²)	20	7.8 ± 1.9	6.5 ± 1.6	1.3	0.004
Overweight (25–29.9 kg/m²)	37	8.3 ± 2.0	6.2 ± 1.9	2.1	<0.001
Obese (≥30 kg/m²)	23	8.7 ± 2.3	5.9 ± 1.7	2.8	<0.001

Table IV shows the correlation of baseline AMH with BMI and with the magnitude of AMH reduction. Baseline AMH was positively correlated with BMI (r = 0.41, p < 0.001) and with AMH reduction (r = 0.52, p < 0.001), indicating that participants with higher baseline AMH levels tended to have higher BMI and greater AMH reduction after metformin therapy.

Table IV
Correlation Between Baseline AMH and BMI, and AMH Reduction (*n* = 80).

Variable Pair	Correlation Coefficient (r)	p-value
Baseline AMH vs BMI	0.41	<0.001
Baseline AMH vs AMH Reduction	0.52	<0.001

DISCUSSION

Polycystic Ovary Syndrome is a common endocrine disorder and a leading cause of anovulatory infertility in women of reproductive age, characterized by hyperandrogenism, ovulatory dysfunction, and metabolic disturbances. Anti-Mullerian Hormone serves as an important marker of ovarian follicular activity and is typically elevated in women with this condition, reflecting altered folliculogenesis. The findings of the present study demonstrate that metformin therapy is associated with a significant reduction in serum AMH levels among infertile women with Polycystic Ovary Syndrome, with greater reductions observed in those with higher body mass index and baseline AMH levels. These results highlight the potential role of metformin not only in improving metabolic parameters but also in modulating ovarian hormonal dynamics, emphasizing its clinical relevance in the management of infertility related to Polycystic Ovary Syndrome.

In the present study, the baseline demographic and clinical characteristics of the 80 infertile women with PCOS indicated that the majority were aged 26–30 years (45.0%), with a mean age of 29.1 ± 4.5 years. Most participants were overweight (46.2%) or obese (28.8%), with a mean BMI of 27.5 ± 3.9 kg/m². Menstrual irregularity and clinical hyperandrogenism were observed in 72.5% and 65% of participants, respectively. These findings are consistent with previous reports, such as Kayali et al., who found that a high proportion of infertile women with PCOS were overweight or obese (74.0%) and exhibited menstrual irregularity and hyperandrogenism [11], and Sachdeva et al., who similarly reported that most infertile PCOS women were overweight or obese [12], reinforcing the well-established association between PCOS and increased adiposity. The mean duration of infertility in our cohort was 3.2 ± 1.4 years, and the baseline AMH level was 8.4 ± 2.1 ng/mL, reflecting the typical reproductive and hormonal profile

observed in infertile women with PCOS. Collectively, these results corroborate existing evidence that PCOS in infertile women is frequently associated with overweight or obesity, menstrual disturbances, and hyperandrogenism.

Metformin therapy for 3 months in this study resulted in a significant reduction in serum AMH levels, with mean AMH decreasing from 8.4 ± 2.1 ng/mL at baseline to 6.1 ± 1.8 ng/mL post-treatment (mean difference 2.3 ± 1.2 ng/mL, $p < 0.001$). These findings are consistent with Foroozanfard et al., who reported a significant decline in AMH from 10.0 ± 3.75 ng/mL to 7.8 ± 3.7 ng/mL ($p = 0.008$) after 8 weeks of metformin therapy in a cohort of 30 infertile women with PCOS [13], demonstrating the short-term efficacy of metformin in lowering AMH levels. Similarly, Zhou et al., in a systematic review and meta-analysis of 14 studies encompassing approximately 257 women with PCOS, observed an overall significant decrease in AMH following metformin treatment, with the greatest reductions occurring in younger women and those receiving therapy for ≤6 months [14]. Collectively, these results support the notion that metformin effectively reduces elevated AMH levels in infertile women with PCOS, likely reflecting its impact on follicular activity and ovarian function.

The majority of women in the present study experienced a decrease in serum AMH levels after metformin therapy, while a smaller proportion showed no significant change or an increase. These findings are consistent with Tomova et al., who reported that women with PCOS treated with metformin for 6 months exhibited significant reductions in AMH among clinical responders, whereas non-responders occasionally showed increases, reflecting the heterogeneity in ovarian response [15]. Similarly, Mehdinezhad et al., in meta-analyses of multiple clinical trials, found that most women with PCOS experienced significant decreases in AMH following metformin treatment, particularly with short-term therapy comparable to the present study [16]. These observations indicate that metformin effectively reduces elevated AMH levels in most infertile women with PCOS, while a smaller subset may exhibit stable or increased levels, likely due to individual differences in metabolic profile and ovarian responsiveness.

Metformin therapy in the current study also led to significant reductions in serum AMH across all BMI categories, with the greatest reduction observed in obese participants, followed by overweight and normal-weight groups. These findings align with Zhou et al., whose meta-analyses reported overall significant decreases in AMH after metformin treatment and highlighted that baseline metabolic and demographic factors, including BMI, can influence the magnitude of AMH reduction [14], reflecting variability across patient subgroups. Similarly, Kriseman et al. reported that BMI interacts with AMH regulation in women with PCOS, with higher BMI associated with altered AMH dynamics, suggesting that body composition may modulate ovarian response to interventions like metformin [17]. Collectively, these observations support the notion that the degree of AMH reduction following metformin therapy is influenced by BMI, with greater decreases seen in women with higher adiposity.

In this study, baseline serum AMH was positively correlated with BMI ($r = 0.41$, $p < 0.001$) and with the magnitude of AMH reduction following metformin therapy ($r = 0.52$, $p < 0.001$), indicating that women with higher baseline AMH tended to have higher BMI and experienced greater declines in AMH. These findings are consistent with Kriseman et al., who reported a significant inverse correlation between AMH and BMI in women with PCOS [17], highlighting that adiposity influences ovarian hormone levels. Similarly, Misra et al. observed that BMI modulates AMH levels across PCOS subgroups, with lean PCOS women showing stronger correlations, suggesting that body composition can affect ovarian function and hormonal markers [18]. Additionally, Foroozanfard et al. demonstrated that higher BMI was associated with larger decreases in AMH after metformin treatment [13], supporting the notion that baseline metabolic status can influence both AMH levels and the response to therapy. Collectively, these studies corroborate the present findings, emphasizing that BMI plays a significant role in determining baseline AMH and its modulation following metformin treatment in women with PCOS.

LIMITATIONS

This study had some limitations:

- It was a single-center study. A larger, multi-center study is needed to reach more definitive conclusions.
- The study's limited geographic scope may introduce sample bias, potentially affecting the broader applicability of the findings.

CONCLUSION

Polycystic Ovary Syndrome is commonly associated with elevated AMH levels and impaired ovarian function in infertile women. In this study, metformin therapy effectively reduced serum AMH levels, with most participants showing a decrease while a smaller proportion exhibited no change or an increase. The reduction in AMH was observed across all BMI categories, with greater decreases in women with higher adiposity. Baseline AMH levels were positively associated with BMI and the magnitude of AMH reduction, indicating that women with higher initial AMH and body mass tended to respond more robustly. These findings suggest that metformin has a significant modulatory effect on ovarian hormonal activity in infertile women with PCOS, and that individual characteristics such as BMI may influence treatment response.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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Elevated Neutrophil-to-Lymphocyte Ratio in First Trimester of Pregnancy – Is a Predictor for Development of Pre-Eclampsia

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ABSTRACT

Background: Pre-eclampsia is a major cause of maternal and perinatal morbidity and mortality, particularly in developing countries. Early identification of high-risk women remains challenging. The neutrophil-to-lymphocyte ratio (NLR), an inexpensive and readily available inflammatory marker derived from routine blood tests, has emerged as a potential predictor of adverse pregnancy outcomes. This study aimed to evaluate the role of first-trimester NLR in predicting the development of pre-eclampsia. **Methods & Materials:** This prospective observational study was conducted in the Department of Obstetrics and Gynaecology at Bangladesh Medical University (BMU), Dhaka, from January to December 2025. A total of 120 pregnant women in their first trimester (≤13 weeks) were enrolled consecutively. Socio-demographic and clinical data were recorded and complete blood counts were performed to calculate NLR. Participants were followed until delivery for the development of pre-eclampsia. Statistical analysis was performed using SPSS version 25, with $p < 0.05$ considered significant. **Results:** The mean age of participants was 26.8 ± 4.9 years. Elevated NLR (>3.5) was observed in 33.3% of women. Overall, 31 women (25.8%) developed pre-eclampsia. The incidence increased significantly with rising NLR values, from 11.1% in the <2.5 group to 45.0% in the >3.5 group ($p = 0.002$). Women with elevated NLR had nearly fourfold higher odds of developing pre-eclampsia (OR = 3.82; 95% CI: 1.61–9.05). **Conclusion:** First-trimester NLR is a simple, cost-effective and significant predictor of pre-eclampsia. Incorporating NLR into routine antenatal screening may facilitate early risk stratification and improve maternal outcomes.

Keywords: *Neutrophil-to-lymphocyte ratio, Pre-eclampsia, First trimester, Inflammation, Pregnancy, Predictive marker.*

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INTRODUCTION

Pre-eclampsia is a common hypertensive disorder of pregnancy and remains a leading cause of maternal and perinatal morbidity and mortality worldwide, particularly in low- and middle-income countries [1]. It complicates approximately 5–10% of pregnancies and is associated with serious adverse outcomes, including preterm birth, fetal growth restriction, placental abruption, eclampsia and maternal organ dysfunction [2]. Despite advances in antenatal care, early identification of women at risk remains challenging, especially in resource-constrained settings where access to advanced biochemical markers and imaging modalities is limited [3]. Therefore, simple, affordable and readily available predictors are needed to facilitate early risk stratification and timely intervention.

The pathophysiology of pre-eclampsia is complex and multifactorial, involving abnormal placentation, endothelial dysfunction and an exaggerated systemic inflammatory response [4]. Increasing evidence suggests that inflammation plays a central role in disease development. During normal pregnancy, physiological changes in the immune system occur; however, excessive inflammatory activation may contribute to impaired placental perfusion and vascular dysfunction, ultimately leading to hypertensive complications [5]. Hematological parameters reflecting systemic inflammation have thus gained attention as potential early markers for predicting pre-eclampsia [6].

The neutrophil-to-lymphocyte ratio (NLR), calculated from routine complete blood count parameters, has emerged as a novel and cost-effective indicator of systemic inflammatory status [7]. Elevated neutrophil counts reflect acute inflammatory activation, whereas decreased lymphocyte counts indicate relative immunosuppression or stress and the combined ratio provides a more stable measure of inflammatory burden [8]. Several studies have demonstrated an association between increased NLR and adverse cardiovascular, metabolic and obstetric outcomes. In pregnancy, higher NLR levels have been linked with gestational hypertension and pre-eclampsia, suggesting its potential utility as an early predictive biomarker [9, 10].

Early detection during the first trimester is particularly important, as it allows closer surveillance, preventive strategies such as low-dose aspirin therapy and improved maternal and fetal outcomes [11]. Because complete blood count testing is routinely performed in antenatal clinics, NLR could serve as a practical screening tool without additional cost or specialized equipment, making it especially suitable for busy tertiary hospitals and developing healthcare systems [12].

Therefore, this study aimed to evaluate the

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association between first-trimester neutrophil-to-lymphocyte ratio and the subsequent development of pre-eclampsia and to determine its potential role as an early, simple and reliable predictor among pregnant women attending a tertiary care hospital.

METHODS & MATERIALS

This prospective observational study was conducted in the Department of Obstetrics and Gynaecology at Bangladesh Medical University (BMU), Dhaka, Bangladesh, from January 2025 to December 2025. A total of 120 pregnant women attending the antenatal clinic during the first trimester (≤13 weeks of gestation) were enrolled consecutively after obtaining informed written consent. Women aged 18–40 years with singleton pregnancies were included. Exclusion criteria comprised a history of chronic hypertension, pre-existing diabetes mellitus, renal or hepatic disease, autoimmune or inflammatory disorders, hematological diseases, thyroid disorders, acute or chronic infections, multiple gestations, previous pre-eclampsia, current use of corticosteroids or anti-inflammatory drugs and incomplete follow-up or missing laboratory data, as these conditions could influence inflammatory markers and pregnancy outcomes. Baseline socio-demographic and clinical information, including age, parity, body mass index (BMI), blood pressure and antenatal history, was recorded using a structured questionnaire and clinical examination. Venous blood samples were collected during the first trimester for complete blood count analysis using an automated hematology analyzer. Absolute neutrophil and lymphocyte counts were obtained and the neutrophil-to-lymphocyte ratio (NLR) was calculated by dividing the neutrophil count by the lymphocyte count. Participants were followed prospectively through routine antenatal visits until delivery for the development of pre-eclampsia, which was diagnosed according to standard criteria as new-onset hypertension (≥140/90 mmHg after 20 weeks of gestation) with proteinuria (≥300 mg/24 hours or ≥1+ on dipstick). The primary outcome was the association between first-trimester NLR and the subsequent development of pre-eclampsia. Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 25.0. Continuous variables were expressed as mean ± standard deviation and categorical variables as frequency and percentage. Group comparisons were performed using the independent t-test and chi-square test and logistic regression analysis was conducted to determine odds ratios with 95% confidence intervals. A p value of <0.05 was considered statistically significant.

RESULTS

Table I presents the socio-demographic characteristics of the 120 enrolled pregnant women. The majority of participants were aged 21–25 years (32.5%), followed by 26–30 years (28.3%), while only 7.5% were older than 35 years. More than half of the women were from urban areas (55.8%). Slightly over half were primigravida (50.8%), with the remainder multigravida (49.2%). Most participants had regular antenatal care visits (60.8%), whereas 39.2% attended irregularly.

Table I
Socio-demographic Characteristics of the Study Participants (*n* = 120).

Variables	Frequency (n)	Percentage (%)
Age group (years)		
≤20	17	14.2
21–25	39	32.5
26–30	34	28.3
31–35	21	17.5
>35	9	7.5
Residence		
Urban	67	55.8
Rural	53	44.2
Parity		
Primigravida	61	50.8
Multigravida	59	49.2
Booking status		
Regular ANC	73	60.8
Irregular ANC	47	39.2

Table II shows the baseline clinical and laboratory characteristics of the participants during the first trimester. The mean age was 26.8 ± 4.9 years and the average BMI was 24.6 ± 3.7 kg/m². The mean systolic and diastolic blood pressures were 112.4 ± 9.6 mmHg and 71.8 ± 7.8 mmHg, respectively. The mean hemoglobin level was 10.9 ± 1.2 g/dL and the total WBC count was 8.7 ± 2.1 ×10⁹/L. The mean neutrophil and lymphocyte counts were 6.1 ± 1.8 and 2.3 ± 0.9, respectively. Regarding inflammatory status, 36 women (30.0%) had an NLR <2.5, 44 (36.7%) had 2.5–3.5 and 40 (33.3%) showed elevated NLR >3.5.

Table II
Baseline Clinical and Laboratory Characteristics in the First Trimester (*n* = 120).

Variables	Mean ± SD / n (%)
Age (years)	26.8 ± 4.9
BMI (kg/m²)	24.6 ± 3.7
Systolic BP (mmHg)	112.4 ± 9.6
Diastolic BP (mmHg)	71.8 ± 7.8
Hemoglobin (g/dL)	10.9 ± 1.2
Total WBC count (×10⁹/L)	8.7 ± 2.1
Neutrophil count	6.1 ± 1.8
Lymphocyte count	2.3 ± 0.9

NLR categories	
<2.5	36 (30.0)
2.5–3.5	44 (36.7)
>3.5	40 (33.3)

Table III illustrates the incidence of pre-eclampsia according to first-trimester NLR categories. Overall, 31 out of 120 women (25.8%) developed pre-eclampsia. The frequency of pre-eclampsia increased progressively with higher NLR values, occurring in only 11.1% of women with NLR <2.5, 20.5% in the 2.5–3.5 group and rising markedly to 45.0% among those with NLR >3.5. This trend was statistically significant (p = 0.002).

Table III
Incidence of Pre-eclampsia According to First-Trimester NLR Category (*n* = 120).

NLR category	Developed Pre-eclampsia n (%)	No Pre-eclampsia n (%)	Total	p value
<2.5	4 (11.1)	32 (88.9)	36	
2.5–3.5	9 (20.5)	35 (79.5)	44	
>3.5	18 (45.0)	22 (55.0)	40	
Total	31 (25.8)	89 (74.2)	120	0.002*

Table IV demonstrates the association between elevated first-trimester NLR and the development of pre-eclampsia. Women with NLR >3.5 had a significantly higher risk of developing pre-eclampsia, with 18 cases compared to 22 in the non–pre-eclampsia group, yielding nearly fourfold increased odds (OR = 3.82, 95% CI: 1.61–9.05; p = 0.002). Although higher BMI (≥25 kg/m²), primigravidity and age >30 years showed increased odds ratios, these associations were not statistically significant. These findings suggest that elevated NLR is an independent and significant predictor of pre-eclampsia.

Table IV
Association Between Elevated NLR (>3.5) and Development of Pre-eclampsia.

Variables	Pre-eclampsia (n=31)	No Pre-eclampsia (n=89)	Odds Ratio (OR)	95% CI	p value
NLR >3.5	18	22	3.82	1.61–9.05	0.002
BMI ≥25 kg/m²	14	25	2.09	0.91–4.77	0.08
Primigravida	19	42	1.63	0.72–3.69	0.24
Age >30 years	11	19	1.96	0.80–4.82	0.13

DISCUSSION

The present prospective observational study evaluated the role of the first-trimester neutrophil-to-lymphocyte ratio (NLR) as an early predictor of pre-eclampsia among 120 pregnant women. Overall, 25.8% of participants developed pre-eclampsia and the incidence increased progressively with rising NLR values. Women with NLR >3.5 demonstrated a markedly higher occurrence of pre-eclampsia (45.0%) compared with those with NLR 2.5–3.5 (20.5%) and <2.5 (11.1%), with a statistically significant association (p = 0.002). Logistic regression further showed nearly fourfold increased odds (OR = 3.82), indicating that elevated NLR is an independent predictor of adverse hypertensive outcomes in pregnancy.

These findings are consistent with the growing evidence linking systemic inflammation to the pathogenesis of pre-eclampsia. Sultana et al. reported a significant association between elevated NLR and pre-eclampsia in a case–control study, emphasizing its usefulness as a simple inflammatory marker [13]. Similarly, Sabry et al. demonstrated higher NLR and platelet indices among pre-eclamptic women, supporting the role of inflammatory hematological parameters in disease prediction [14]. Khan et al. also identified NLR as a reliable marker for both clinical prediction and disease severity evaluation, which aligns with our observation of increased risk among women with higher NLR levels [15].

Endothelial dysfunction and neutrophil activation are key mechanisms in pre-eclampsia. Wazib et al. found a correlation between neutrophil elastase levels and NLR, suggesting that increased neutrophil activity contributes to vascular injury [16]. Our higher mean neutrophil counts (6.1 ± 1.8) and elevated NLR categories further reinforce this inflammatory basis. Additionally, Liao et al. and Liu et al. reported that peripheral blood parameters, particularly neutrophil-related indices, could predict both occurrence and severity of pre-eclampsia, findings that parallel our results [17,18].

Several studies have emphasized the predictive utility of first-trimester hematological markers. Mensah et al. demonstrated that NLR, along with platelet indices, had good predictive value for pre-eclampsia in a teaching hospital setting, while Srinivasa et al. highlighted NLR as an early, inexpensive screening parameter [19,20]. Tekin et al. also confirmed that first-trimester clinical and laboratory findings, including inflammatory markers, are helpful in early risk stratification [21]. Furthermore, Seyhanli et al. showed that first-trimester inflammatory indexes such as NLR and PLR were significantly associated with later development of pre-eclampsia, supporting our strategy of early measurement [22].

More recently, Liang et al. developed a comprehensive first-trimester predictive model incorporating multiple indicators, where inflammatory markers improved prediction accuracy [23]. Our findings similarly suggest that NLR could be integrated into routine antenatal screening models, especially in resource-limited settings where advanced biomarkers may not be available. Given that complete blood count testing is routinely performed, NLR offers a cost-effective and easily accessible alternative without additional financial burden.

In summary, the present study corroborates previous evidence that elevated first-trimester NLR reflects systemic inflammation and is significantly associated with the subsequent development of pre-eclampsia. The progressive rise in incidence from 11.1% to 45.0% across NLR categories and the nearly fourfold increased risk highlight its clinical relevance. Therefore, NLR may serve as a simple, affordable and practical early screening tool for identifying high-risk pregnancies and enabling closer

monitoring and timely preventive interventions.

LIMITATIONS

This study has several limitations that should be considered while interpreting the findings. It was conducted at a single tertiary care center with a relatively small sample size of 120 participants, which may limit the generalizability of the results to the wider population. Although efforts were made to exclude confounding conditions, unmeasured factors such as nutritional status, subclinical infections and other inflammatory states might have influenced NLR values. Additionally, NLR was assessed only once during the first trimester and serial measurements could have provided a better understanding of dynamic inflammatory changes throughout pregnancy.

CONCLUSION

In conclusion, the present study demonstrates that an elevated first-trimester neutrophil-to-lymphocyte ratio is significantly associated with the subsequent development of pre-eclampsia. Women with higher NLR values showed a markedly increased risk, suggesting that NLR can serve as a simple, inexpensive and readily available early screening marker. Incorporating NLR into routine antenatal evaluation may help identify high-risk pregnancies for closer monitoring and timely preventive interventions, ultimately improving maternal and fetal outcomes.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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Identifying Risk Factors Associated with Mortality in Critically Ill Ventilated Infants at a Tertiary Care Setting

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ABSTRACT

Background: Critically ill infants requiring mechanical ventilation face a high risk of mortality, especially in resource-limited settings. Identifying modifiable risk factors is crucial to improving survival outcomes. **Objective:** To evaluate risk factors associated with mortality among ventilated infants in a tertiary care hospital. **Methods & Materials:** This observational study was conducted in the Department of Intensive Care Unit of Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh, from January 2020 to December 2020. This study included 50 critically ill young infants up to 2 months of age who required mechanical ventilation. Among these infants, 37 (74.0%) died during the study period, while 13 (26.0%) survived. **Results:** The study showed no significant differences in age, gestational age, birth weight, or sex distribution between the two groups. Higher initial ventilatory settings, including FiO_2 >80%, PIP >18 cmH_2O, and PEEP >5 cmH_2O, were significantly associated with death ($p<0.01$). Hypernatremia (Na^+ >145 mmol/L) also showed a significant association with mortality ($p=0.039$). However, severe respiratory distress before extubation and ventilation duration >5 days were significantly associated with poor outcomes. Multivariable regression analysis confirmed initial high PIP, low bicarbonate, severe respiratory distress, and prolonged ventilation as independent predictors of mortality. **Conclusion:** Infants on mechanical ventilation with high initial settings, metabolic acidosis, severe respiratory distress, and prolonged ventilation have increased mortality risk. Early recognition and management of these factors may improve survival outcomes.

Keywords: *Neonatal Mortality, Mechanical Ventilation, Respiratory Distress, NICU, Risk Factors.*

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INTRODUCTION

Infant mortality remains a major global health concern, especially in low- and middle-income countries. Infant mortality rate defined as the probability of dying between birth and age one, is a key indicator of child health progress [1]. Globally, infant mortality has declined significantly dropping from an estimated 8.9 million deaths in 1990 to approximately 4.5 million in 2015 [2].

In Bangladesh, although progress has been made, reduction in infant mortality has not kept pace with the decrease in under-five mortality. From 1993 to 2014, infant mortality dropped from 87 to 38 deaths per 1,000 live births [3,4]. However, this decline is slower than the reduction in under-five mortality which dropped from 133 to 46 per 1,000 over the same period [3].

A large population-based survey across 56 countries from 1990 to 2002 highlighted key factors that contribute to infant mortality worldwide. These include being a firstborn child, having a short birth interval, male sex, multiple gestation, and living in rural settings. Additionally, infants born to mothers with lower levels of education or those living far from health services are at a greater risk of dying in their first year [5,6].

Neonatal mortality is a significant contributor to infant deaths. According to the Health Bulletin 2017 of the Directorate General of Health Services (DGHS), the neonatal mortality rate in Bangladesh was reported as 19 per 1,000 live births (SVRS 2016) and 28 per 1,000 live births (BDHS 2014) [4]. Globally, the leading causes of neonatal mortality include preterm birth, birth asphyxia, sepsis, and pneumonia [7,8]. Although the exact causes of neonatal deaths are sometimes unclear, studies consistently identify sepsis, asphyxia, birth injuries, neonatal tetanus, prematurity, congenital anomalies, and undetermined factors as major contributors [9]. In developing countries, preterm birth, infections, and birth asphyxia remain the predominant causes, with mortality rates ranging between 40% and 60% [10,11].

Mechanical ventilation (MV) is commonly used in the management of critically ill infants, especially those with severe respiratory infections. Although MV itself is not a direct cause of complications, it is an essential intervention in cases of severe respiratory failure, which can be associated with multiple organ dysfunction [12,13]. While MV can increase the risk of secondary complications such as ventilator-associated pneumonia, these are often consequences of the underlying illness rather than the ventilation itself [14,15]. MV remains a vital therapy that provides crucial respiratory support to critically ill infants and is not a cause of additional infections that might complicate the clinical course [16].

Several studies have reported that respiratory failure from respiratory illnesses is the most common indication for mechanical ventilation in pediatric patients, including infants up to two months of age. [17-19] Factors such as age, weight, clinical condition, and severity of illness all influence the outcomes of mechanical ventilation. Extended stays in the pediatric intensive care unit (PICU) and the need for invasive procedures can increase the risk of nosocomial infections, contributing to higher mortality rates, particularly in those with respiratory disorders [17,20].

Despite significant advancements in healthcare, infant mortality remains shaped by a complex interplay of risk factors. Understanding these risk factors is essential for designing effective interventions to reduce infant mortality and improve child health outcomes worldwide.

Objectives

The objective of this study was to evaluate the risk factors associated with mortality among ventilated infants in a tertiary care hospital.

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METHODS & MATERIALS

This observational study was conducted in the Department of Intensive Care Unit of Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh, from January 2020 to December 2020. In this study, we included 50 critically ill young infants up to 2 months of age who required mechanical ventilation in the Intensive Care Unit of Dhaka Shishu Hospital.

Inclusion criteria

- All critically ill young infants (age 0 day to 2 months)
- Infants who received mechanical ventilation in the Intensive Care Unit of Dhaka Shishu Hospital
- Infants whose parents or guardians were willing to participate

Exclusion criteria

- Young infants who required ventilation for surgical intervention
- Young Infants with cyanotic congenital heart disease
- Infants with congenital malformations were excluded from our study.

Data Collection Procedure

Legal guardians or parents of infants were asked to be included in the present study. A written consent was obtained after an explanation of the study procedure. The study included fifty young infants who were consecutively placed on mechanical ventilation. Before initiation, investigations such as ABG, chest X-ray, and other relevant tests were performed. Infants were continuously monitored using clinical assessments and devices like cardiac monitors and pulse oximetry. Ventilator parameters, including respiratory rate, PIP, PEEP, FiO_2, and inspiratory time, were set according to each patient and adjusted based on clinical signs, chest X-rays, and ABG results. After 2 hours of ventilation, ABG was done to adjust the parameters. Then, subsequent parameters (PIP, PEEP, Rate of ventilation, FiO2) on mechanical ventilation were modified according to the need for 20 oxygenation and ventilation through SpO2 and blood gas analysis. Patients were extubated when clinically stable, both hemodynamically & neurologically, having self-respiration, maintaining oxygen saturation, normal chest X-ray & with low ventilator parameters or after gradual weaning. All infants were observed for complications and followed until extubation or death.

Ethical Considerations

Ethical approval was obtained from the Ethical Review Committee of Bangladesh Shishu Hospital & Institute. Informed consent was taken from patients or their legal guardians before enrollment. Confidentiality of patient information was strictly maintained and data were used solely for research purposes.

Statistical Analysis

Quantitative data was expressed as mean and standard deviation, and qualitative data was expressed as frequency distribution and percentage. The Odds ratio, chi-square test, student "t" test, and multiple logistic regressions were used to analyze the data. A p-value <0.05 was considered significant. Statistical analysis was performed by using SPSS 25 (Statistical Package for Social Sciences) for Windows version 10.

RESULTS

In the present study, we initially enrolled 50 critically ill young infants up to 2 months of age who required mechanical ventilation. During the study, nearly three-fourths of the patients, 37 (74.0%), died, while 13 infants (26.0%) survived. The present study was done to identify risk factors associated with mortality in critically ill ventilated infants.

Table I shows that 27 patients in the death group and 7 in the survival group were aged ≤15 days. Most patients in both groups had a gestational age >34 weeks, 30 (81.1%) and 12 (92.3%) in the death and survival groups, respectively, with no statistically significant difference between the groups ($p > 0.05$). Low birth weight (<2500 g) was observed in 20 (54.1%) patients in the death group and 4 (30.8%) in the survival group, again showing no significant difference ($p > 0.05$). Male infants were predominant in both groups, comprising 59.5% of the death group and 76.9% of the survival group; however, the difference was not statistically significant ($p > 0.05$).

Table I
Demographic characteristics of the study patients (*n*=50).

Demographic Variables	Death (n=37) n (%)	Survival (n=13) n (%)	Odds ratio (95% CI)	P-value
Age				
≤15 days	27 (73)	7 (53.8)		
16-30 days	7 (18.9)	2 (15.4)		
31-45 days	2 (5.4)	3 (23.1)		
>45 days	1 (2.7)	1 (7.7)		
Mean±SD (days)	14.2±10.1	20.2±18.2		0.145[ns]
Gestational age				
<34 weeks	7 (18.9)	1 (7.7)	2.8(0.31-25.26)	0.321[ns]
>34 weeks	30 (81.1)	12 (92.3)		
Weight				
<2500 gm	20 (54.1)	4 (30.8)	2.6(0.69-10.15)	0.148[ns]
>2500 gm	17 (45.9)	9 (69.2)		
Sex				
Male	22 (59.5)	10 (76.9)	0.44 (0.10-1.87)	0.216[ns]
Female	15 (40.5)	3 (23.1)		

ns= non-significant, [a]P value reached from unpaired t-test, s= significant, [b]P value reached from Fisher's exact test

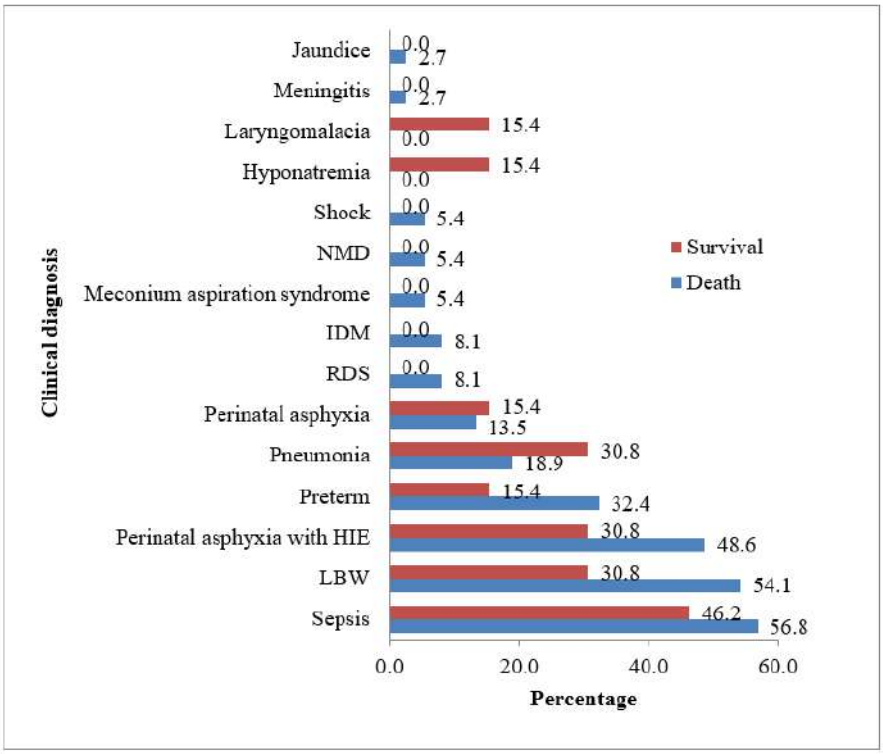

Figure 1 Clinical diagnosis of the study patients (n=50).

Figure 1 shows that the majority of 21(56.8%) patients had sepsis in the death group and 6(56.2%) in the survival group. Twenty (54.1%) patients were low birth weight in the death group and 4(30.8%) in the survival group, followed by 48.6% & 30.8% had prerinatal asphyxia in the death and survival group, respectively. Clinical diagnoses were not statistically significant (p>0.05) between the two groups.

Table II shows that among the ventilated infants, several initial clinical and biochemical parameters were significantly associated with mortality. A higher initial fraction of inspired oxygen (FiO_2 >80%) was observed in 97.3% of deaths compared to 46.2% of survivors (OR: 42, 95% CI: 4.35–405.14; p = 0.001). Similarly, peak inspiratory pressure (PIP >18 cmH_2O) and positive end-expiratory pressure (PEEP >5 cmH_2O) were significantly higher among non-survivors, both showing strong associations with mortality (PIP OR: 35, p = 0.001; PEEP OR: 13, p = 0.002). Infants with bicarbonate (HCO_3) levels <15 mmHg and base excess (BE) values <-10 had significantly higher mortality (HCO_3 OR: 7.88, p = 0.003; BE OR: 4.98, p = 0.019), reflecting a correlation between metabolic acidosis and adverse outcomes. Furthermore, hypernatremia (serum sodium >145 mmol/L) was significantly more common among those who died (89.2% vs. 61.5%), and was associated with reduced odds of survival (OR: 0.19, 95% CI: 0.04–0.89; p = 0.039).

Table II
Relation between initial FiO2, PIP, PEEP, HCO3, BE, serum sodium and outcome of ventilated patients (*n*=50).

Parameters	Death (n=37) n (%)	Survival (n=13) n (%)	Odds Ratio (95% CI)	P-value
FiO_2 (%)				
>80	36 (97.3%)	6 (46.2%)	42 (4.35–405.14)	0.001[s]
<80	1 (2.7%)	7 (53.8%)		
PIP (cmH_2O)				
>18.0	32 (86.4%)	2 (15.4%)	35 (5.95–208.14)	0.001[s]
<18.0	5 (13.6%)	11 (84.6%)		
PEEP (cmH_2O)				
>5.0	26 (70.3%)	2 (15.4%)	13 (2.46–68.60)	0.002[s]
<5.0	11 (29.7%)	11 (84.6%)		
HCO_3 (mmHg)				
<15	26 (70.3%)	3 (23.1%)	7.88 (1.81–34.28)	0.003[s]
>15	11 (29.7%)	10 (76.9%)		
BE				
<-10	28 (75.7%)	5 (38.5%)	4.98 (1.30–19.31)	0.019[s]
>-10	9 (24.3%)	8 (61.5%)		
Serum sodium (mmol/L)				
>145	33 (89.2)	8 (61.5)	0.19 (0.04–0.89)	0.039[s]
<135	4 (10.8)	5 (38.5)		

s= significant, P value reached from Fisher's exact test.

Table III shows that metabolic acidosis before ventilation was significantly associated with mortality, with 75.7% of deaths occurring in infants with this condition compared to 38.5% of survivors (OR: 4.07, 95% CI: 1.09–15.20; p = 0.019). A similar pattern was observed before extubation/death, where metabolic acidosis was present in 51.4% of those who died versus 15.4% of survivors (OR: 5.81, 95% CI: 1.13–29.89; p = 0.024). Before ventilation, severe respiratory distress was present in 35.1% of those who died and 30.8% of survivors, showing no significant difference (OR: 1.21; p = 0.775). In contrast, severe respiratory distress before extubation/death was more common in non-survivors (43.2%) than in survivors (7.7%), and this difference was statistically significant (OR: 9.14, 95% CI: 1.07–77.80; p = 0.04).

Table III
Relation between acidosis, respiratory distress, and outcome (*n*=50).

Acidosis	Death (n=37)		Survival (n=13)		Odds ratio (95% CI)	P value
	n	(%)	n	(%)		
Before ventilation						
Metabolic acidosis	28	(75.7)	5	(38.5)	4.07 (1.09-15.20)	[a]0.019[s]
Respiratory acidosis	3	(8.1)	1	(7.7)	1.06 (0.10-11.18)	[b]0.725[ns]
Before extubation/ death						
Metabolic acidosis	19	(51.4)	2	(15.4)	5.81 (1.13-29.89)	[b]0.024[s]
Respiratory acidosis	5	(13.5)	1	(7.7)	1.88 (0.20-17.74)	[b]0.503[ns]
Respiratory Distress						
Before Ventilation						
Severe	13	(35.1)	4	(30.8)	1.21 (0.31–4.73)	[b]0.775[ns]
Moderate	24	(64.9)	9	(69.2)		
Before Extubation/Death						
Severe	16	(43.2)	1	(7.7)	9.14 (1.07–77.80)	[b]0.04[s]
Moderate	21	(56.8)	12	(92.3)		

s= significant, ns= not significant, [a]P value reached from Chi square test, [b]P value reached from Fisher's exact test.

In *Table IV*, a heart rate >130 bpm was observed in 45.9% of neonates who died, compared to 30.8% of survivors. However, this difference was not statistically significant (OR: 1.91, 95% CI: 0.49–7.33; p = 0.344). Only 13.5% of non-survivors had HR >130 bpm before death, while just 7.7% of survivors had elevated HR at extubation. Again, this difference was not statistically significant (OR: 1.87, 95% CI: 0.19–17.74; p = 0.583). Delayed CRT (>3 seconds) was found in 27.0% of deaths and 15.4% of survivors (OR: 2.03, 95% CI: 0.38–10.84; p = 0.404), showing no significant association. Delayed CRT was more frequent in the death group (32.4%) than in survivors (7.7%). However, this association did not reach statistical significance (OR: 5.76, 95% CI: 0.66–49.59; p = 0.111).

Table IV
Relation between heart rate, CRT, and outcome of ventilated patients (*n*=50).

Heart Rate (bpm)	Death (n=37) n (%)	Survival (n=13) n (%)	Odds Ratio (95% CI)	P Value
Before Ventilation				
>130	17 (45.9%)	4 (30.8%)	1.91 (0.49–7.33)	[a]0.344[ns]
<130	20 (54.1%)	9 (69.2%)		
Before Extubation/Death				
>130	5 (13.5%)	1 (7.7%)	1.87 (0.19–17.74)	[a]0.583[ns]
<130	32 (86.5%)	12 (92.3%)		
CRT (sec)				
Before Ventilation				
Delayed (>3 sec)	10 (27.0%)	2 (15.4%)	2.03 (0.38-10.84)	[b]0.404[ns]
Normal (<3 sec)	27 (73.0%)	11 (84.6%)		
Before Extubation/Death				
Delayed (>3 sec)	12 (32.4%)	1 (7.7%)	5.76 (0.66–49.59)	[b]0.111[ns]
Normal (<3 sec)	25 (67.6%)	12 (92.3%)		

ns= not significant, [a]P-value reached from chi-square test, [b]P-value reached from Fisher's exact test.

Table V shows that neonates ventilated for more than 5 days had a significantly higher mortality rate (43.2%) compared to survivors (7.7%). This association was statistically significant (OR: 9.14, 95% CI: 1.07–77.80; p = 0.04). Although a greater proportion of deaths (67.6%) occurred in those with ICU stays longer than 7 days compared to survivors (46.2%), the association was not statistically significant (OR: 2.43, 95% CI: 0.66–8.82; p = 0.177).

Table V
Relation between duration of ventilation and ICU stay and outcome (*n*=50).

Duration of Ventilation (days)	Death (n=37) n (%)	Survival (n=13) n (%)	Odds Ratio (95% CI)	P-value
>5	16 (43.2%)	1 (7.7%)	9.14 (1.0744–77.803)	0.04[s]
<5	21 (56.8%)	12 (92.3%)		
Duration of ICU Stay (days)				
>7	25 (67.6%)	6 (46.2%)	2.43 (0.66–8.82)	0.177[ns]
<7	12 (32.4%)	7 (53.8%)		

s= significant, ns=non-significant, P-value reached from Fisher's exact test

Table VI shows that initial high PIP, low bicarbonate, severe respiratory distress, and duration of ventilation (>5 days) were identified as significant independent predictors of mortality in neonates ($p<0.05$). These factors may serve as important markers for early identification of high-risk patients and tailoring of intensive care strategies. Other variables were not found to be significantly ($p>0.05$) associated with death in patients.

Table VI
Multivariable regression analysis for prediction of death (*n*=50).

	Adjusted	95% CI		P value
	OR	Lower	Upper	
Initial PIP (>18)	10.090	5.133	96.029	0.003[s]
Initial PEEP (>5)	15.274	0.925	69.638	0.056[ns]
Initial FiO2 (>80)	17.068	0.747	39.177	0.076[ns]
Initial HCO3 (<15)	6.855	1.012	46.407	0.049[s]
Initial BE (<-10)	1.444	0.229	9.092	0.695[ns]
Hyponatraemia	0.227	0.042	1.215	0.083[ns]
Metabolic acidosis	0.746	0.137	4.059	0.737[ns]
Severe respiratory distress	10.031	1.053	95.557	0.045[s]
Duration of ventilation (>5 days)	11.919	1.333	86.573	0.027[s]

s= significant, ns= not significant, p value reached from multivariate analysis by binary logistic regression analysis, OR=Odds Ratio.

DISCUSSION

In the present study, a total of 50 infants were included during the study period, and male predominance was observed among the participants. This finding is consistent with similar studies conducted in other developing countries, which reported male predominance of 63% in Pakistan, 57.8% in South Africa, 63.3% in India, and 58.3% in Ethiopia [21-25].

Globally, the leading contributors to neonatal morbidity and mortality include preterm birth, perinatal asphyxia, and neonatal infections [26,27]. In our cohort, the disease patterns for which infants were transferred to the ICU and subsequently required mechanical ventilation included low birth weight (54.1% in the death group vs. 30.8% in the survival group), perinatal asphyxia (13.5% in the death group vs. 15.4% in the survival group), neonatal sepsis (56.8% in the death group vs. 46.2% in the survival group), respiratory distress syndrome (8.1% in the death group), meconium aspiration syndrome (8.1% in the death group), and pneumonia (18.9% in the death group vs. 30.8% in the survival group). These findings are partially aligned with a study by Demisse et al., where the most frequently observed complications were hypothermia (71%) and neonatal sepsis (67.9%) [25]. Notably, our sepsis rates are significantly higher compared to studies in Pakistan (20.3%) [20] and South Africa (21%) [22], as well as Nigeria (16.9%), Nepal (34.5%), and another study from Ethiopia conducted at SPHMMC (22.7%) [24,28,29].

Regarding birth weight, 54.1% of neonates in our study were classified as LBW (<2500 g), which is comparable to reports from Pakistan (37.7%) and Tanzania (29%), though slightly lower than South Africa (52.5%) and India (60%) [21-24]. The prevalence of LBW in developing countries is closely linked to multiple maternal and socioeconomic factors, including poverty, inadequate prenatal care, maternal infections, malnutrition, and anemia [30].

In the present study, the overall infant mortality rate was notably high at 74%. In comparison, Demisse et al reported a significantly lower neonatal mortality rate of 14.3% (95% CI: 11.9–16.9) [25], which aligns with findings from studies conducted in South Africa (13.8%) and Nigeria (14.2%) [22,29]. However, this rate is higher than those reported from SPHMMC in Addis Ababa (23.2%) and Bangladesh (20.6%) [27,31]. In contrast, even lower mortality rates were observed in studies from Pakistan and Nepal, at 6.2% and 4.6%, respectively [28,32].

More than half (56.8%) of the deaths in our study occurred within the first five days of admission. While Demisse et al. noted that 62.7% of neonatal deaths took place within 24 hours of admission [25], and this trend is consistent with studies from Nigeria (55%) and Tanzania (56.7%) [29,33]. These early fatalities underscore the importance of immediate and aggressive neonatal care, as the initial hours after birth are critical for survival. Lamberti et al., in a study involving older neonates (mean age 6 months), reported a mortality rate of 2.3%, including a death in a 1.7-kg neonate with perinatal asphyxia (PA) [34]. Similarly, Williams et al., in a large series of 2000 Blalock-Taussig shunt cases over six decades, documented an overall mortality rate of 14% [35].

In this study, multivariable regression analysis identified several factors that were independently and significantly associated with increased risk of mortality. These included an initial peak inspiratory pressure (PIP) >18 cmH_2O, low serum bicarbonate (<15 mmol/L), severe respiratory distress, and a duration of mechanical ventilation exceeding five days ($p<0.05$). These parameters can serve as early warning indicators for clinicians to identify neonates at elevated risk and intervene accordingly. A study by Demisse et al identified hypothermia, sepsis, and perinatal asphyxia as significant predictors of neonatal mortality through multivariate analysis [25]. Another study by Iqbal et al. conducted a multiple regression analysis on ten variables that were found to be significant in univariate analysis, including gestational age <34 weeks, birth weight <2500 g, shock, apnea, sepsis, pulmonary hemorrhage, neutropenia, thrombocytopenia, and pH <7.1. The analysis identified gestational age <34 weeks, presence of shock, neutropenia, pulmonary hemorrhage, and a pH <7.1 as significant independent predictors of mortality in mechanically ventilated neonates [36]. These findings are consistent with those reported in several previous studies [37-39]. Other studies have further reinforced the association between neonatal hypothermia, intraventricular hemorrhage (IVH), and mortality [40,41].

Additionally, a study from China highlighted that the majority of deaths in preterm infants occur in those with the lowest gestational age. The primary causes of mortality in this group included apnea, respiratory distress syndrome (RDS), necrotizing enterocolitis (NEC), IVH, infections, and asphyxia [42]. These findings are consistent with the multifactorial nature of prematurity-related complications that contribute to early neonatal mortality.

CONCLUSION

This study highlights several critical risk factors associated with mortality in ventilated infants in a tertiary care setting. The study findings indicate that specific ventilatory parameters, such as high initial PIP, elevated FiO_2, and increased PEEP, along with metabolic parameters, including low bicarbonate levels and metabolic acidosis, are strongly associated with poor outcomes. Additionally, clinical signs such

as severe respiratory distress before extubation and prolonged duration of mechanical ventilation emerged as significant independent predictors of mortality. These results underscore the importance of early recognition and prompt intervention targeting modifiable risk factors.

Further study with a prospective and longitudinal study design, including a larger sample size, needs to be done to validate the findings of our study.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Correlation between Sonographic Features of Thyroid Nodules Based on Thyroid Imaging Reporting and Data System (TIRADS) Classification and Fine Needle Aspiration Cytology (FNAC) Results

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ABSTRACT

Introduction: Thyroid nodules are common, with most being benign, but a small proportion carries a risk of malignancy. Accurate risk stratification is essential to guide management and avoid unnecessary invasive procedures. Fine-needle aspiration cytology (FNAC) is the gold standard for diagnosis, while the Thyroid Imaging Reporting and Data System (TIRADS) standardizes ultrasound evaluation and estimates malignancy risk. **Methods & Materials:** This cross-sectional observational study was conducted in the Department of Radiology & Imaging, Combined Military Hospital (CMH), Dhaka, over six months from January 2024 to June 2024. A total of 160 patients with thyroid nodules detected on ultrasonography (USG) were the study subjects. Data were analyzed using SPSS version 23.0. **Result:** Among 160 patients, most were female (80%) with a mean age of 41.6 ± 12.8 years, and the majority presented with painless neck swelling (82.5%). On ultrasonography, 25% of nodules were TIRADS 2, 30% TIRADS 3, 27.5% TIRADS 4, and 17.5% TIRADS 5. FNAC showed 67.5% benign, 8.8% indeterminate, 6.2% follicular neoplasm, 7.5% suspicious, and 10% malignant nodules. Malignancy risk increased with higher TIRADS grades, and TIRADS demonstrated high sensitivity (83.3%), specificity (81.2%), accuracy (81.9%), and NPV (94.7%), confirming its reliability for malignancy risk stratification. **Conclusion:** This study demonstrated a strong correlation between sonographic features of thyroid nodules, as classified by TIRADS, and FNAC results, with diagnostic performance showing high sensitivity, specificity, and negative predictive value. The malignancy risk increased with higher TIRADS grades, confirming the utility of TIRADS as a reliable, non-invasive risk stratification tool.

Keywords: *Thyroid Nodules, Thyroid Imaging Reporting and Data System, Fine Needle Aspiration Cytology*

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INTRODUCTION

Thyroid nodules are a common clinical finding, with a prevalence of 4–7% on physical examination and up to 50% on ultrasonography. While most nodules are benign, a small proportion carry the risk of malignancy, making accurate risk stratification essential. Thyroid nodules are frequently detected incidentally during imaging studies, and their reported prevalence largely depends on the method of detection. When assessed by palpation alone, prevalence ranges from 4 to 7%, whereas high-resolution ultrasonography identifies nodules in 20 to 76% of the adult population [1,2]. Nodules detected through radiographic studies are termed "thyroid incidentalomas" [2,3]. The correlation between imaging findings and prevalence reported at surgery or autopsy ranges from 50 to 65% [4]. The primary goal in evaluating a thyroid nodule is to rule out malignancy. Reported malignancy rates vary widely among clinically or radiologically detected nodules, with the global average prevalence of malignancy, as determined by invasive procedures, ranging from 4.0 to 6.5% [5,6]. With the widespread use of ultrasound, increased access to ultrasound-guided fine-needle aspiration cytology (FNAC), and advancements in functional imaging such as 18F-FDG FDG-PET, the incidental detection of thyroid nodules is rising. However, the clinical benefit of this is debated, as most nodules are benign [7,8]. Some studies suggest that although the incidence of thyroid nodules discovered during 18 FDG-PET is low (1–2%), their malignant potential may be as high as 27%, indicating the need for prompt evaluation [9]. The American Thyroid Association defines thyroid nodules as "discrete lesions within the thyroid gland, radiologically distinct from surrounding thyroid parenchyma" [10]. Epidemiological data indicate that nodules occur approximately four times more frequently in women than men, likely due to hormonal influences, as nodule growth and the development of new nodules have been linked to pregnancy and multiparity [2,11]. Thyroid nodules may occasionally cause thyroid dysfunction or compressive symptoms, but their clinical significance primarily lies in excluding malignancy. The Thyroid Imaging Reporting and Data System (TIRADS), proposed by Horvath et al., classifies nodules based on ultrasound features to better select those requiring FNAC, thus minimizing unnecessary procedures. This system also standardizes terminology among radiologists and endocrinologists globally. This study aimed to assess the correlation between TIRADS-classified thyroid nodules and cytopathological findings.

METHODS & MATERIALS

This cross-sectional observational study was conducted in the Department of Radiology & Imaging, Combined Military Hospital (CMH), Dhaka, over six months from January 2024 to June 2024, after obtaining ethical clearance from the institutional review board. A total of 160 patients with thyroid nodules detected on ultrasonography (USG) and graded according to the Thyroid Imaging Reporting and Data System (TIRADS) who were scheduled for fine needle aspiration cytology (FNAC) were included using simple random sampling. Patients with normal thyroid scans (TIRADS 1), proven cases of thyroid malignancy (TIRADS 6), or those unwilling to participate were excluded. After obtaining informed written consent, relevant clinical information, physical findings, and investigation reports were recorded. High-resolution ultrasonography was performed using a GE machine with a high-frequency probe, and findings were documented. All data were collected through a semi-structured

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questionnaire, checked and verified for consistency, and analyzed using SPSS version 23.0. Data were presented as proportions for categorical variables and as mean ± standard deviation or median with interquartile range for continuous variables. Baseline characteristics were compared using Student's t-test and Pearson's chi-square test, and a p-value of <0.05 was considered statistically significant.

RESULTS

Most patients were between 30–39 years (27.5%) and ≥50 years (26.3%), with a marked female predominance (80%). The most common presenting symptom was a painless anterior neck swelling (82.5%), which is consistent with the typical presentation of thyroid nodules in the general population (*Table I*).

Table I
Demographic and Clinical Characteristics of Study Population (*n*=160).

Characteristics	Frequency (%)
Age group (years)	
<30	36 (22.5)
30–39	44 (27.5)
40–49	38 (23.7)
≥50	42 (26.3)
Sex	
Male	32 (20.0)
Female	128 (80.0)
Presenting symptoms	
Painless neck swelling	132 (82.5)
Painful swelling	16 (10.0)
Dysphagia	8 (5.0)
Hoarseness	4 (2.5)

Nearly one-third of the nodules were classified as TIRADS 3 (30%), followed by TIRADS 4 (27.5%). A smaller proportion (17.5%) were highly suspicious (TIRADS 5). This distribution suggests that most nodules detected were benign or probably benign, as seen in other population-based studies (*Table II*).

Table II
Distribution of Thyroid Nodules According to TIRADS Classification (*n*=160).

TIRADS Category	Frequency (%)
TIRADS 2 (Benign)	40 (25.0)
TIRADS 3 (Probably Benign)	48 (30.0)
TIRADS 4 (Suspicious)	44 (27.5)
TIRADS 5 (Highly Suspicious)	28 (17.5)

Most FNAC results were benign (67.5%), with 10% of nodules confirmed as malignant. Indeterminate lesions (Bethesda III and IV) accounted for 15% of cases, aligning with the expected prevalence in thyroid cytology reporting (*Table III*)

Table III
Distribution of FNAC Results Based on Bethesda System (*n*=160).

FNAC Category (Bethesda)	Frequency (%)
Category II (Benign)	108 (67.5)
Category III (AUS/FLUS)	14 (8.8)
Category IV (Follicular Neoplasm/SFN)	10 (6.2)
Category V (Suspicious for Malignancy)	12 (7.5)
Category VI (Malignant)	16 (10.0)

There was a clear trend of increasing malignancy with higher TIRADS categories. While 95% of TIRADS 2 nodules were benign, 35.7% of TIRADS 5 nodules were malignant. The association between TIRADS classification and FNAC results was statistically significant (p < 0.001), confirming the diagnostic value of TIRADS as a malignancy risk stratification tool (*Table IV*).

Table IV
Correlation Between TIRADS Classification and FNAC Results.

TIRADS	Benign (Cat II)	AUS/FLUS (Cat III)	SFN (Cat IV)	Suspicious (Cat V)	Malignant (Cat VI)	p-value
TIRADS 2	38 (95.0%)	2 (5.0%)	0	0	0	<0.001*
TIRADS 3	42 (87.5%)	4 (8.3%)	2 (4.2%)	0	0	
TIRADS 4	22 (50.0%)	6 (13.6%)	4 (9.1%)	6 (13.6%)	6 (13.6%)	
TIRADS 5	6 (21.4%)	2 (7.1%)	4 (14.3%)	6 (21.4%)	10 (35.7%)	

TIRADS showed high sensitivity (83.3%) and specificity (81.2%) in predicting malignant nodules, with a negative predictive value of 94.7%, indicating that it reliably ruled out malignancy in lower categories. These findings are comparable to prior studies, reinforcing TIRADS as a robust and cost-effective screening tool before FNAC (*Table V*).

Table V
Diagnostic Performance of TIRADS in Predicting Malignancy (*n*=160).

Parameter	Value (%)
Sensitivity	83.3
Specificity	81.2
Positive Predictive Value (PPV)	55.6
Negative Predictive Value (NPV)	94.7
Accuracy	81.9

DISCUSSION

In this study of 160 thyroid nodules, a clear association was observed between higher TIRADS categories and increased risk of malignancy on FNAC. The diagnostic performance was favorable, with sensitivity 83.3%, specificity 81.2%, negative predictive value (NPV) 94.7%, positive predictive value (PPV) 55.6%, and overall accuracy 81.9%. These results were comparable to prior regional and international studies. Nighat et al. reported in a study of 201 patients that TIRADS showed a sensitivity of 77.8%, specificity 75.5%, PPV 53.8%, NPV 90.2%, and accuracy 76.1%, which is slightly lower than our findings, suggesting that our cohort may have had fewer false negatives in lower-risk TIRADS categories [12]. Similarly, Safina et al. evaluated 243 patients and found sensitivity 84.0%, specificity 78.2%, PPV 50.0%, and NPV 95.0%, which closely matched our results, especially with respect to sensitivity and NPV [13]. These findings reinforce that TIRADS is a dependable system for stratifying thyroid nodules in South Asian populations. Meta-analyses have reported a wide range of diagnostic performance values. Kim et al. reviewed 67 studies involving over 76,000 nodules and reported that ACR-TIRADS TR5 had a sensitivity of 63.5% and specificity of 89.6% [14]. Similarly, Yang et al. conducted a network meta-analysis and reported pooled sensitivity ranging from 68–82% and specificity from 71–81% across multiple risk stratification systems [15]. Our results fall within or slightly above these ranges, especially regarding sensitivity, indicating that our ultrasound interpretation and selection criteria for FNAC may have optimized case detection. Zahoor et al. compared TIRADS and FNAC with histopathology in 360 solitary nodules and reported that FNAC had very high sensitivity (98.5%) but low specificity (27%), while TIRADS specificity was higher at 44.6% [16]. In comparison, our study showed better specificity (81.2%), meaning we had fewer false positives, thus reducing unnecessary interventions. Another study by Mumtaz et al. reported FNAC sensitivity of 95.3%, specificity of 86.3%, and accuracy of 90.6%, again suggesting FNAC is a highly reliable confirmatory tool, consistent with our findings, where FNAC confirmed most TIRADS 4–5 nodules as malignant [17].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

This study demonstrated a strong correlation between sonographic features of thyroid nodules, as classified by TIRADS, and FNAC results, with diagnostic performance showing high sensitivity, specificity, and negative predictive value. The malignancy risk increased with higher TIRADS grades, confirming the utility of TIRADS as a reliable, non-invasive risk stratification tool to guide FNAC decision-making.

RECOMMENDATION

Based on the study results, it is recommended that TIRADS classification be routinely applied in the evaluation of thyroid nodules to stratify malignancy risk. Nodules classified as low-risk (TIRADS 2–3) may be safely monitored, reducing unnecessary FNAC procedures, whereas high-risk nodules (TIRADS 4–5) should undergo prompt FNAC to ensure early detection and management of malignancy. Future research should include multi-center studies with histopathologic confirmation to further validate TIRADS accuracy and optimize thyroid nodule management protocols.

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CONFLICT OF INTEREST

None declared.

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Prevalence and Clinical Profile of Chronic Rhinosinusitis Among Patients Attending in ENT OPD of a Tertiary Care Hospital

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ABSTRACT

Background: Chronic Rhinosinusitis (CRS) is a prevalent inflammatory disease of the nose & paranasal sinuses, causing immense suffering for millions of people around the world, thereby putting a significant burden on healthcare systems globally. This study was undertaken to evaluate the prevalence and clinical profile of patients with CRS in an ENT OPD. **Methods & Materials:** This cross-sectional observational study was performed at Combined Military Hospital, Jashore, Bangladesh from July 2024 to December 2025, among 120 patients diagnosed with CRS. Sociodemographic, lifestyle, comorbidities, symptoms, endoscopic, and paranasal sinus computed tomography scans were all included in the data collection. SPSS version 26 was used to enter and analyze all of the data. **Results**: The average age was 36.8 ± 12.9 years, and 56.7% of the population was male. The percentage of people who lived in cities was higher (68.3%). Nasal obstruction (90%), nasal discharge (80%), and post-nasal drip (69.2%) were the most common clinical complaints. CRS without nasal polyps had a higher rate (72.5%), while CRS with nasal polyps had a lower percentage (27.5%). Bilateral sides had a higher proportion (73.3%). AR coexisting with CRS was shown to be more common (38.3%), followed by smokers (23.3%). The maxillary (71.7%), ethmoidal (60%), and CT sinuses had higher percentages. **Conclusion:** Rhinological blockage and discharge are the most common symptoms of CRS, which is highly prevalent in tertiary care settings. A comprehensive investigation with a multidisciplinary treatment approach is emphasized by the high comorbidity prevalence of non-polyploid CRS and the equal prevalence on both sides.

Keywords: *Chronic Rhinosinusitis, Nasal mucosa, Nasal polyps*

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INTRODUCTION

Chronic rhinosinusitis (CRS) is a common inflammatory condition of the nasal and paranasal mucosa, with persistent symptoms for longer than 12 weeks in duration [1]. It is among the most common diseases found in the practice of medicine and contributes to the socioeconomic burden of healthcare expenditure and lost productivity due to quality-of-life alteration, found to affect 5 to 15% of the global population in the current understanding of the condition's impact and relevance [2]. There are complex multifactorial mechanisms in the CRS, including the role of environment, the immune system, and genetic factors. Clinical classification of the condition has been done into two main categories, namely those suffering from chronic rhinosinusitis with nasal polyps (CRSwNP) and those without nasal polyps (CRSsNP), which clearly follow diverse mechanisms of pathology and management courses [3,4]. However, the symptoms that confirm the condition include nasal blockage, nasal discharge, facial pain or pressure, as well as a reduction in the sensation of smell, which must be further validated by evidence through nasal endoscopy or computed tomography scan findings [5]. There seems to be a clear requirement for proper characterization despite the criteria being well defined. The epidemiology of CRS can be observed to have variations in different regions of the world depending on the levels of pollution, prevalence of allergic sensitivity, and the availability of medical facilities [6]. There is a lack of data in the developing world about the extent of the problem and the spectrum of cases in the context of CRS in the context of a referral institution in the country [7]. Various risk factors have been identified for the development of CRS, which include smoking, allergies, asthma, anatomical issues, and states of immunodeficiency [8]. Comorbidities tend to coexist in patients with CRS, making patient management a significant concern. New evidence has indicated the important roles of lifestyle changes and managing comorbidities in the overall management of CRS patients [9]. The role played by the tertiary care hospital acts as a referral center for cases that are complex and difficult to manage. These hospitals may have a different disease spectrum than the ones handled in the primary healthcare system. The assessment and establishment of the healthcare profile among the patients with CRS would be beneficial to understand the disease severity and the management requirements [10]. This study aimed to determine the prevalence, identify, and comprehensively describe the clinical profile of patients with chronic rhinosinusitis who visited an ear, nose, and throat specialist's outpatient department at a Bangladeshi tertiary care hospital.

METHODS & MATERIALS

The study was a cross-sectional observational study undertaken at Combined Military Hospital, Jashore, Bangladesh from July 2024 to December 2025 over a period of 12 months. The study population was composed of patients attending the outpatient department, having clinical features suggestive of Chronic Rhinosinusitis, in which a total population of 120 was enrolled after obtaining informed written consent from the patients along with clearance from the Institutional Review Board. Patients aged 16 years and above of both sexes, presenting with the following prominent symptoms of Rhinosinusitis, such as nasal obstruction, presence of nasal discharge, facial pain & pressure, loss of smell in varying amounts for a period not less than 12 weeks, were chosen for the study. The patient was judged to have Chronic Rhinosinusitis based on the definition set by the "European Position Paper on Rhinosinusitis & Nasal Polyps," along with

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nasal endoscopic & computed tomograms of the paranasal sinuses. Patients with Acute Rhinosinusitis less than 12 weeks, in case of an episode of Acute Exacerbation in the preceding four weeks, those with a History of Sinonasal surgery in the preceding six months, Sinonasal malignancy, cases with Immune conditions, Patient being pregnant, & those not willing to participate in the study were not chosen for this study on Rhinosinusitis. The data was collected by using a structured proforma, in which parameters studied were Sociodemographics regions such as age, sex, residence, & occupations, & lifestyle areas such as Smoking status, Medical conditions comprising Allergic Rhinitis, Bronchial Asthma, Diabetes mellitus, & Hypertension, Family history of "Atopy," detailed "symptom profile," & "duration," & all patients were subjected to detailed "Nasal Endoscopic Examination with 0 degree rigid endoscope to observe mucosal edema, presence & character of nasal polyps, character & amount of nasal discharge, & areas related to anatomy," & then non-contrast "computed tomogram of the paranasal sinuses to observe involvement & disease extent." The data obtained was quantified by using suitable computer programs & represented in the form of frequencies, percentages, means, & Standard Deviations.

RESULTS

Table I shows that most patients suffering from CRS were from the age group 25-34 years (28.3%), with an average age of 36.8 ± 12.9 years. 56.7% of patients were male, and 43.3% were female. Urban population (68.3%) was higher than the rural population, pointing towards possible correlations between CRS and environmental exposures. The occupational class identified service holders (35%) and students (16.7%) as most affected.

Table I
Socio-Demographic Characteristics of Study Participants (n = 120).

Variable	Category	Frequency (n)	Percentage (%)
Age group (years)	16-24	22	18.3
	25-34	34	28.3
	35-44	28	23.3
	45-54	20	16.7
	≥55	16	13.4
	Mean ± SD	36.8 ± 12.9	-
Sex	Male	68	56.7
	Female	52	43.3
Residence	Urban	82	68.3
	Rural	38	31.7
Occupation	Student	20	16.7
	Service holder	42	35
	Business	16	13.3
	Homemaker	28	23.3
	Others	14	11.6

Table II revealed that 31.7% have exposure to smoking (23.3% current smokers and 8.4% former smokers), which can be considered a highly influential and modifiable risk factor. Total patient group (38.3%) has a comorbid condition of allergic rhinitis. Bronchial asthma is seen in 12.5% of total patients. Systemic diseases such as hypertension in 14.2% and diabetes mellitus in 11.7% can be considered important, in addition to a family history of atopy in 26.7%.

Table II
Lifestyle Factors and Comorbid Conditions Among CRS Patients.

Variable	Category	n (%)
Smoking status	Non-smoker	82 (68.3)
	Current smoker	28 (23.3)
	Former smoker	10 (8.4)
Allergic rhinitis history	Present	46 (38.3)
	Absent	74 (61.7)
Bronchial asthma	Yes	15 (12.5)
Diabetes mellitus	Yes	14 (11.7)
Hypertension	Yes	17 (14.2)
Family history of atopy	Present	32 (26.7)

Table III unveiled that nasal obstruction (90%) and rhinorrhea (80%) were the common nasal symptoms. Post-nasal drip (69.2%), facial pain/pressure (56.7%), and headaches (65%) indicated the common pain-related symptomatology. Olfactory dysfunction was prevalent (30%), with hyposmia/anosmia. Other symptomatology, including sneezing (26.7%) and cough (19.2%) suggested an inflammatory and an airway disease process.

Table III
Clinical Symptom Profile of Chronic Rhinosinusitis.

Symptom	Frequency (n)	Percentage (%)
Nasal obstruction	108	90
Nasal discharge	96	80
Post-nasal drip	83	69.2

Facial pain/pressure	68	56.7
Headache	78	65
Hyposmia/anosmia	36	30
Sneezing	32	26.7
Chronic cough	23	19.2

Table IV demonstrated that the majority 39.2% of the patients suffered from the same symptoms for longer than 1 year, while (32.5%) of the patients had symptoms for longer than 6 months to 1 year. CRS without nasal polyps was observed in 72.5% of the patients, while in the remaining 27.5%, the diagnosis was CRS with polyps. Bilateral distribution of the diseases in 73.3% of the patients indicated the spread of the inflammation in the sinuses, while in the remaining 26.7%, which showed unilateral distribution, one has to rule out the focal conditions.

Table IV
Duration of Symptoms and Clinical Classification.

Variable	Category	n (%)
Duration of symptoms	12 weeks-6 months	34 (28.3)
	>6 months-1 year	39 (32.5)
	>1 year	47 (39.2)
Type of CRS	CRS without nasal polyps (CRSsNP)	87 (72.5)
	CRS with nasal polyps (CRSwNP)	33 (27.5)
Laterality	Bilateral	88 (73.3)
	Unilateral	32 (26.7)

Table V shows mucosal edema in 68.3% of cases, which was mostly due to inflammation. Presence of purulent discharge was found in 46.7% of cases. Septal deviation was observed in 40% cases, which was an important variation with possible role in disease etiology. CT scans revealed maxillary sinus disease in 71.7% cases, followed by ethmoid, frontal, and sphenoid sinuses in 60%, 28.3%, and 18.3% cases, respectively.

Table V
Endoscopic and Radiological Findings.

Finding	Category	n (%)
Nasal endoscopy	Mucosal edema	82 (68.3)
	Purulent discharge	56 (46.7)
	Nasal polyps	33 (27.5)
	Septal deviation	48 (40)
CT PNS findings	Maxillary sinus involvement	86 (71.7)
	Ethmoid sinus involvement	72 (60)
	Frontal sinus involvement	34 (28.3)
	Sphenoid sinus involvement	22 (18.3)

There were multiple responses.

DISCUSSION

This study demonstrated the prevalence and clinical spectrum of CRS in a tertiary care center and provided inferences on the demographic and diagnostic profile of the disease. The mean age of 36.8 ± 12.9 years, which predominated in the age group of 25-34 years, agrees with Smith et al., who stated the productivity of the affected classes of people in the community, thereby creating a considerable socioeconomic burden [11]. The male predominance of 56.7% in our study concurs with that of Kim et al., but variations do exist in the gender ratio in the general population [12].

Urban dominance (68.3%) implies linkages with air pollutants, exposure to allergens, and associated lifestyle factors. Mady et al. showed that the rise of urbanization has been linked with air quality deterioration and the rise of CRS [13]. The occupational pattern indicating service holders, students being predominantly affected, draws attention not only to its burden but also to its effects on the working-age group. A significant exposure to smoking was also found to be prevalent in the CRS patients, and it was observed to be 31.7%. This further supports the existing body of evidence related to the pathogenesis of sinonasal inflammation, dysfunction of cilia, and vulnerability to infections due to exposure to tobacco smoke [14]. This also supports the concept reported by Bousquet et al., as the association with allergic rhinitis was found to be 38.3%, and the association with bronchial asthma was found to be 12.5% in the study [15]. This symptom complex, which consists of nasal obstruction (90%) and rhinorrhoea (80%), closely mirrors the main characteristics associated with CRS and largely impacts quality of life. A reduction in olfactory sensation, or hyposmia, found in 30% of patients, relates to a symptom that has been substantially overlooked, which largely impacts nutritional intake, awareness, and psychiatric well-being [16]. The presence of facial pain at 56.7% and cough at 19.2% differs significantly, leading to specific symptom management. The dominance of CRSsNP (72.5%) over CRSwNP (27.5%) found in this study is consistent with Cao et al., although phenotypic variations occur according to geographical location [17]. These phenotypes have different characteristics of inflammation, where CRSwNP is predominantly eosinophilic with a higher rate of recurrence after treatment. Bilateral involvement in 73.3% suggests widespread inflammation, although unilateral disease always requires investigation for neoplastic or fungal infection [18]. Endoscopic examination showed mucosal edema (68.3%) and the presence of purulent discharge (46.7%) as dominant signs. This is evident in diagnosing CRS. Septal deviation in 40% of the cases is a contributing anatomical lesion potentially causing obstruction in the ostiomeatal complex and poor sinus ventilation [19]. CT scan studies showed that the maxillary sinus was involved in 71.7% of the cases. This clearly showed that sinus

anatomy contributes to the gravitation of fluids in the dependent areas. A high prevalence of 60% in the case of the ethmoid sinus highlights its association with obstruction in the ostiomeatal complex and spread of infection to other sinuses [20]. Comorbidities, such as hypertension in 14.2% and diabetes mellitus in 11.7%, make it essential to take special precautions while managing treatment, as these factors can affect treatment modalities, as well as outcomes. A family history of atopy in 26.7% points towards genetic susceptibility, implying a complex pathophysiological cause in both genetic and environmental elements [21]. The presentation with symptoms for longer than 6 months in 71.7% of cases would indicate issues with the initial diagnosis, lack of awareness, and the initial care delivered. It again underlines the nervous system of educating the primary care physicians better about the diagnosis of CRS and the criteria for referral. The clinical profile as presented in this case would be useful for forming the foundation for the managerial approach and patient education in the tertiary level of care.

LIMITATIONS

This study might not be accurately representative of the overall population, considering it comprises a single-center study with a limited sample size. Additionally, because the study is hospital-based, intervention bias may exist, and patients may have been selected for evaluation in a tertiary care center.

CONCLUSION

Individuals attending the tertiary care facility have a significant prevalence of rhinosinusitis chronicus, primarily in the younger to middle-aged age range, with a similar predisposition in men. Nasal blockage and discharge are the main symptoms of this illness. Changes in quality of life and smell have a significant effect. The etiological homogeneity is diminished by the high prevalence of relationship with smoking exposure and allergic rhinitis, necessitating a more comprehensive workup and therapy approach. A particular management approach is required due to the majority of patients' lack of nasal polyps, their propensity to be bilaterally distributed, and their maxillary predilection.

RECOMMENDATIONS

Larger multicentric studies with follow-up periods will aid in the evaluation of treatment responsiveness, prognostic variables, and the impact of specific therapies on illness progression and quality of life.

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CONFLICT OF INTEREST

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Functional Outcome of Anterior Cruciate Ligament Reconstruction by Hamstring Tendon Autograft using Femoral Endobutton and Tibial Post Fixation

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ABSTRACT

Background: ACL rupture is a common disabling injury in young, active people, leading to knee instability, delayed return to sport or work, and potential early osteoarthritis. Arthroscopic ACL reconstruction with hamstring autograft is widely used, and femoral EndoButton fixation is reliable, but optimal tibial fixation remains debated, particularly for maintaining early stability during rehabilitation. This study aimed to assess functional outcomes and early complications after hamstring autograft ACL reconstruction using femoral EndoButton and tibial post fixation. **Methods & Materials:** This prospective observational study was conducted at NITOR, Dhaka (2024–2025), enrolling consecutive skeletally mature patients with clinically unstable, MRI-confirmed ACL rupture undergoing arthroscopic hamstring autograft reconstruction with femoral EndoButton and tibial post fixation. Functional outcomes (IKDC, Lysholm) and activity level (Tegner) were recorded preoperatively and at 6 weeks, 3 months, and 6 months; stability, range of motion, and complications were documented, with late adverse events noted up to 12 months when available. Data were analyzed in SPSS v26 using descriptive statistics and paired or repeated-measures comparisons of score changes over time. **Results:** Among 40 patients (mean age 28.6 ± 6.9 years, 85% male), non-contact sports pivoting injury was the commonest mechanism (62.5%), and MRI showed complete ACL tear in 90% with frequent concomitant meniscal injury (57.5%) and chondral lesions (22.5%). Most reconstructions used a 4-strand semitendinosus ± gracilis graft (95%) with a mean diameter of 8.1 ± 0.6 mm, predominantly via transportal femoral tunneling (87.5%). Functional outcomes improved steadily, with IKDC increasing from 44.9 ± 11.7 preoperatively to 75.6 ± 9.1 at 6 months, and Lysholm from 52.6 ± 13.9 to 88.3 ± 8.6; Tegner rose from a median of 3 to 5. Postoperative course was uncomplicated in 72.5%, with minor numbness/dysesthesia (12.5%), superficial infection (5.0%), arthrofibrosis (5.0%), and suspected graft failure (2.5%), and no deep infections. **Conclusion:** Arthroscopic ACL reconstruction using a hamstring autograft with femoral EndoButton and tibial post fixation produced significant early improvements in IKDC, Lysholm, and Tegner scores, with low complication rates. These findings support the technique as a safe and effective option for restoring function in symptomatic ACL-deficient knees.

Keywords: *Anterior cruciate ligament reconstruction, Hamstring tendon autograft, EndoButton femoral fixation, and Tibial post fixation*

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INTRODUCTION

Anterior cruciate ligament (ACL) rupture is a significant injury among young, active individuals, as it compromises knee stability, delays return to sport or work, and may accelerate post-traumatic osteoarthritis even after surgical intervention [1,2]. Population-level data from the United States indicate a substantial increase in ACL reconstruction utilization over time, reflecting both improved injury recognition and expanded surgical access across age and sex groups [1]. Comparable registry-based evidence from Europe confirms that ACL reconstruction remains prevalent at the national level, with distinct epidemiologic patterns by age and sex that inform service planning and outcome benchmarking [2]. Mechanistically, most ACL ruptures occur during non-contact pivoting, cutting, and landing activities in multidirectional sports, while a considerable proportion also results from high-energy trauma. This injury profile is particularly relevant in South Asian contexts, where football, cricket, and road-traffic incidents frequently contribute to knee trauma presentations [3].

The primary objectives of ACL reconstruction are to restore functional stability, reduce symptomatic instability, and facilitate a safe return to pre-injury activity levels. Hamstring tendon autograft is commonly utilized due to its favorable donor-site characteristics and adaptability in graft sizing and configuration. Recent comparative studies demonstrate that both hamstring and bone-patellar tendon-bone autografts yield favorable mid- to long-term outcomes, with specific trade-offs in anterior knee pain, kneeling discomfort, and rotational stability depending on surgical technique, fixation method, and rehabilitation protocol [4,5]. Clinical outcomes are frequently assessed using validated patient-reported measures such as the IKDC and Lysholm scores, which have shown significant postoperative improvement in prospective cohorts employing hamstring grafts with cortical suspensory femoral fixation in regional settings [4]. However, functional outcomes are influenced by multiple factors beyond graft selection, including fixation strategy, tunnel positioning, and perioperative

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management, all of which are critical for graft incorporation and early mechanical stability.

Femoral cortical suspension devices, such as EndoButton-based fixation, are widely adopted due to their technical reproducibility and robust femoral-side fixation. In contrast, tibial fixation is frequently regarded as the "weak link," given the diversity of available devices and ongoing debate regarding the optimal construct, particularly when early rehabilitation necessitates secure initial fixation [6]. Biomechanical studies continue to investigate alternative tibial fixation methods, including post-based and hybrid techniques, to enhance resistance to cyclic loading and minimize slippage in clinical practice [7]. In Bangladesh, there is a notable lack of high-quality prospective outcome data on ACL reconstruction using hamstring autograft with femoral EndoButton and tibial post fixation, especially from high-volume public institutions. Therefore, the present study aims to evaluate functional outcomes and early complications following arthroscopic ACL reconstruction using hamstring tendon autograft with femoral EndoButton and tibial post fixation at NITOR, Dhaka, Bangladesh.

METHODS & MATERIALS

This prospective observational study was conducted at the National Institute of Traumatology and Orthopaedic Rehabilitation (NITOR), Dhaka, Bangladesh, over a 1-year period (2024–2025). Consecutive patients with symptomatic anterior cruciate ligament rupture who underwent arthroscopic ACL reconstruction using a hamstring tendon autograft, femoral EndoButton fixation, and tibial post fixation were enrolled. Inclusion criteria comprised skeletally mature patients with clinical instability and MRI-confirmed ACL tear who consented to follow-up; patients with prior ipsilateral knee surgery, multiligament injuries requiring reconstruction, periarticular fractures, active infection, or advanced degenerative changes were excluded.

Semitendinosus with or without gracilis was harvested and prepared as a multi-strand graft; standard arthroscopic tunnel preparation was performed, femoral fixation was achieved with an EndoButton, and tibial fixation was secured using post fixation, screw with washer or equivalent system, with meniscal and chondral procedures performed when indicated. Functional outcomes were assessed preoperatively and at 6 weeks, 3 months, and 6 months postoperatively using the IKDC subjective score and Lysholm score, with activity level recorded by the Tegner scale; clinical stability testing, range of motion, and complications were documented at each visit, with late adverse events captured up to 12 months when available. Data were analyzed using descriptive statistics (SPSS, v. 26.0); change in functional scores over time was tested using paired or repeated-measures methods as appropriate.

RESULTS

Table I summarizes baseline characteristics of the 40 patients, showing a predominantly young cohort, 87.5% were aged 18–35 years, with a mean age of 28.6 ± 6.9 years, and most were male, 34 (85.0%). Mean BMI was 24.3 ± 2.8 kg/m², manual workers and students formed the largest occupational groups, 13 (32.5%) and 12 (30.0%), and the right knee was more commonly operated, 22 (55.0%). Dominant-leg involvement was noted in 24 (60.0%), the median injury-to-surgery interval was 32 weeks (IQR 20–52), and recurrent instability was frequent, with 28 (70.0%) reporting at least 3 giving-way episodes.

Table I
Baseline demographic and clinical characteristics of patients undergoing ACL reconstruction (*n* = 40).

Variable	Category	n (%)
Age (years)	18-35	35 (87.5)
	36-50	5 (12.5)
	>50	0 (0.0)
	Mean ± SD	28.6 ± 6.9
Sex	Male	34 (85.0)
	Female	6 (15.0)
BMI (kg/m²)	Mean ± SD	24.3 ± 2.8
Occupation	Student	12 (30.0)
	Manual worker	13 (32.5)
	Service/office	10 (25.0)
	Athlete	5 (12.5)
Operated side	Right	22 (55.0)
	Left	18 (45.0)
Dominant leg involved		24 (60.0)
Time from injury to surgery (weeks)	Median (IQR)	32 (20–52)
Giving-way episodes	None	3 (7.5)
	1–2	9 (22.5)
	3–5	14 (35.0)
	>5	14 (35.0)

Table II presents injury mechanism and MRI findings, where non-contact pivoting sports injuries were the leading cause, 25 (62.5%), followed by road traffic accidents, 8 (20.0%). MRI confirmed complete ACL tears in 36 (90.0%) cases, and concomitant meniscal pathology was common, present in 23 (57.5%), most often medial meniscal injury, 14 (35.0%). Chondral lesions were identified in 9 (22.5%), and associated low-grade MCL sprain was noted in 6 (15.0%).

Table II
Injury mechanism and preoperative MRI findings among study participants (*n* = 40).

Variable	Category	n (%)
Mechanism of injury	Non-contact pivoting sports (football, cricket, etc.)	25 (62.5)
	Road traffic accident	8 (20.0)
	Fall or twisting during daily activity	7 (17.5)

MRI: ACL tear type	Complete tear	36 (90.0)
	Partial tear with clinical instability	4 (10.0)
MRI: Meniscus injury	None	17 (42.5)
	Medial only	14 (35.0)
	Lateral only	6 (15.0)
	Both medial and lateral	3 (7.5)
	MRI: Chondral lesion present	9 (22.5)
	Associated MCL sprain (Grade I–II)	6 (15.0)

Table III outlines operative and graft characteristics, with spinal anesthesia used in 29 (72.5%) cases, mean tourniquet time 61.5 ± 12.4 minutes, and mean operative time 88.2 ± 18.7 minutes. Most reconstructions used semitendinosus plus gracilis grafts, 37 (92.5%), predominantly configured as 4-strand grafts, 38 (95.0%), with a mean graft diameter of 8.1 ± 0.6 mm. Transportal femoral tunneling was most common, 35 (87.5%), fixed-loop EndoButtons were used in 28 (70.0%), tibial post fixation was performed in all cases, and more than half required no concomitant procedure, 21 (52.5%), while partial meniscectomy and meniscal repair were performed in 10 (25.0%) and 9 (22.5%), respectively.

Table III
Intraoperative details, graft characteristics, fixation methods, and concomitant procedures (*n* = 40).

Variable	Category	n (%)
Anesthesia	Spinal	29 (72.5)
	General	11 (27.5)
Tourniquet time (min), mean ± SD		61.5 ± 12.4
Operative time (min), mean ± SD		88.2 ± 18.7
Tendons harvested	ST+G	37 (92.5)
	ST only	3 (7.5)
Graft configuration	4-strand	38 (95.0)
	5-strand	2 (5.0)
Graft diameter (mm), mean ± SD		8.1 ± 0.6
Femoral tunnel technique	Transportal	35 (87.5)
	Outside-in	5 (12.5)
EndoButton type	Fixed loop	28 (70.0)
	Adjustable loop	12 (30.0)
Tibial fixation (Post fixation used)		40 (100)
Tibial post type	Screw + washer	34 (85.0)
	Post system	6 (15.0)
Concomitant procedures	None	21 (52.5)
	Partial meniscectomy	10 (25.0)
	Meniscal repair	9 (22.5)
Chondroplasty performed		6 (15.0)

Table IV shows consistent improvement in functional outcomes over follow-up, with IKDC rising from 44.9 ± 11.7 preoperatively to 75.6 ± 9.1 at 6 months, and Lysholm improving from 52.6 ± 13.9 to 88.3 ± 8.6 over the same period. Activity level also improved, with Tegner increasing from a median of 3 (IQR 2–4) preoperatively to 5 (IQR 4–6) by 6 months.

Table IV
Functional outcome scores over follow-up after ACL reconstruction (*n* = 40).

Outcome	Pre-op	6 weeks	3 months	6 months
IKDC (0–100), mean ± SD	44.9 ± 11.7	56.3 ± 10.8	67.8 ± 9.9	75.6 ± 9.1
Lysholm (0–100), mean ± SD	52.6 ± 13.9	69.1 ± 11.6	80.2 ± 10.1	88.3 ± 8.6
Tegner (0–10), median (IQR)	3 (2–4)	3 (2–4)	4 (3–5)	5 (4–6)

Table V summarizes postoperative complications, indicating that most patients had an uncomplicated course, 29 (72.5%) reported no complication. The most frequent minor issue was harvesting site numbness or dysesthesia, 5 (12.5%), while superficial infection occurred in 2 (5.0%), arthrofibrosis` requiring intensified physiotherapy occurred in 2 (5.0%), and suspected graft failure was uncommon, 1 (2.5%), with no deep infections recorded.

Table V
Postoperative complications and adverse events following ACL reconstruction (*n* = 40).

Complication	Frequency (n)	Percentage (%)
Superficial infection (managed with antibiotics, dressings)	2	5.00
Deep infection	0	0.00
Hemarthrosis requiring aspiration	1	2.50
Persistent effusion beyond 6 weeks	2	5.00
Harvest site numbness or dysesthesia	5	12.50
Arthrofibrosis requiring intensive physiotherapy	2	5.00
Tibial post region irritation, symptomatic	2	5.00
Suspected graft failure by 12 months	1	2.50
No complication	29	72.50

DISCUSSION

In this prospective cohort, arthroscopic anterior cruciate ligament (ACL) reconstruction using a hamstring autograft with femoral EndoButton and tibial post fixation resulted in early functional recovery. The International Knee Documentation Committee (IKDC) score improved from 44.9 to 75.6, and the Lysholm score increased from 52.6 to 88.3 by six months, with a median Tegner activity level rising from 3 to 5. These outcomes align with current evidence indicating that hamstring-based ACL reconstruction provides significant short-term patient-reported improvements and facilitates a gradual return to recreational activity, particularly when fixation is stable and rehabilitation protocols are structured. Long-term studies further demonstrate that hamstring autograft ACL reconstruction can maintain satisfactory outcomes beyond the early postoperative period, although degenerative changes and secondary injuries increasingly influence later results [8].

Regarding fixation, the use of suspensory femoral fixation in this cohort is consistent with large comparative analyses that report similar clinical outcomes across various femoral fixation methods, despite minor differences in laxity measurements. Network meta-analyses indicate that interference screw constructs may offer slight advantages in certain stability parameters, but cortical buttons and cross-pin systems generally yield comparable patient-reported outcomes, supporting the clinical acceptability of EndoButton-based constructs in standard practice [9-11]. Comparative studies have found no significant functional disadvantage for EndoButton compared to cross-pin fixation, reinforcing that suspensory femoral fixation can achieve reliable clinical results when tunnel placement, graft preparation, and tensioning are optimized [12]. Evidence from randomized and pooled studies suggests that both fixed-loop and adjustable-loop devices provide similar functional outcomes, which is pertinent since most cases in this cohort utilized fixed-loop EndoButtons [13,14]. In resource-limited settings, these findings imply that consistent surgical technique and standardized rehabilitation protocols may be more critical than minor differences between commonly used button designs.

The high prevalence of concomitant meniscal injury (57.5%) and chondral lesions (22.5%) observed in this cohort is likely related to delayed reconstruction, as indicated by a median injury-to-surgery interval of 32 weeks. Data from both regional and high-income settings demonstrate that longer intervals between injury and ACL reconstruction are associated with increased meniscal and cartilage pathology, as well as reduced opportunities for meniscal preservation [15,16]. This case mix may have contributed to lower six-month IKDC scores compared to cohorts undergoing earlier intervention. These findings underscore a key clinical implication for Bangladesh: enhancing referral pathways and minimizing surgical delays may decrease secondary intra-articular damage, preserve meniscal tissue, and potentially improve long-term knee health.

The observed early suspected graft failure rate of 2.5% should be interpreted with caution due to the limited duration of primary follow-up; however, this rate is consistent with expected early outcomes. Meta-analyses indicate that hamstring autografts are associated with slightly higher failure rates compared to bone-patellar tendon-bone grafts, though the absolute differences are minimal and patient-reported functional outcomes are often comparable. This evidence supports the continued use of hamstring autografts in cases where donor-site morbidity, kneeling requirements, and patient preference are significant considerations [17,18]. As many participants were manual workers or students, it is essential to base return-to-sport or return-to-demanding-work decisions on objective criteria, since delayed return and achievement of adequate strength symmetry significantly reduce the risk of reinjury [19].

The observed complication patterns were within acceptable limits, with no deep infections and predominantly minor morbidity. Current literature indicates that anterior cruciate ligament reconstruction (ACLR) infections are infrequent and highlights the significance of preventive measures, such as meticulous graft handling and, in some protocols, topical antibiotic graft presoaking, which has been linked to a reduced risk of infection in hamstring grafts [20,21]. The 5% incidence of arthrofibrosis, managed through intensified physiotherapy, aligns with reported ranges. Recent analyses emphasize the necessity of early restoration of motion, strict adherence to rehabilitation protocols, and vigilant monitoring of patients predisposed to stiffness [22]. Harvest-site numbness or dysesthesia (12.5%) remains a recognized morbidity associated with hamstring harvest. Published data confirm that saphenous nerve sensory disturbance is not uncommon, generally improves over time, and is pertinent for patient counselling and refinement of incision and harvest techniques [23].

LIMITATIONS

This was a single-center observational study with a small sample and no comparison group, so causal inferences and generalizability are limited. Functional outcomes were mainly short-term (6 months) with incomplete longer follow-up, and unmeasured rehabilitation adherence or activity exposure may have influenced results.

CONCLUSION

Arthroscopic anterior cruciate ligament (ACL) reconstruction utilizing a hamstring tendon autograft with femoral EndoButton and tibial post fixation at NITOR demonstrated significant improvements in IKDC, Lysholm, and Tegner scores at six months, with predominantly minor complications. These results indicate that this fixation construct is an effective and safe approach for early functional recovery in patients with symptomatic ACL-deficient knees. The findings also highlight the necessity of structured rehabilitation and extended follow-up to validate long-term durability and return-to-activity outcomes.

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CONFLICT OF INTEREST.

None declared

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Antibiotic Resistance Patterns and Molecular Determinants of Fluoroquinolone Resistance Among Urinary Escherichia coli Isolates – A Comparison of Disc Diffusion and MIC Methods

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ABSTRACT

Background: Urinary tract infections remain one of the major public health concerns worldwide, for which Escherichia coli (E. coli) is the predominant causative organism. The study aims to assess the resistance patterns of E. coli in urinary, identify fluoroquinolone-associated gyrA mutations, and evaluate their association with phenotypic resistance profiles. **Methods & Materials:** This cross-sectional study was conducted at Sir Salimullah Medical College and Mitford Hospital, Dhaka, from January to December 2020. 229 urine samples collected by purposive sampling were analyzed for this study. Identification of the bacterial isolates was performed by standard biochemical tests; antimicrobial susceptibility testing was done according to CLSI guidelines by disc diffusion and agar dilution methods to determine the MIC. Detection of mutations in the gyrA gene that confer resistance to quinolones was performed with the use of the PCR-RFLP methodology, with HinfI restriction enzyme digestion targeting codons 83 and 87. **Results:** Among the 138 culture-positive samples, E. coli constituted 81.8% of the total isolates. The overall fluoroquinolone resistance rate was 52.2% as determined by the disc diffusion method. The ciprofloxacin MICs were ≥4 µg/ml in 43.4% of the isolates as determined by MIC testing. Molecular analysis detected gyrA mutations in 55.7% of all E. coli isolates. 37.1% mutations were shown at both Ser83 and Asp87 codons. 92.1% of isolates with gyrA mutations showed a phenotypic ciprofloxacin resistance that established a strong genotype-phenotype correlation. Only double mutations were associated with higher MIC values (≥8 µg/ml) and a complete resistance phenotype, while single mutations were associated with lower MIC ranges (0.25-4 µg/ml). **Conclusion:** This study documents high fluoroquinolone resistance rates among urinary E. coli isolates, largely driven by double mutations in the gyrA gene. These findings highlight the clinical relevance of molecular surveillance in guiding empirical treatment decisions due to its close association with resistance phenotypes.

Keywords: *Escherichia coli, Fluoroquinolone resistance, gyrA mutations, Urinary tract infection, PCR-RFLP*

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INTRODUCTION

Urinary tract infections are among the most common bacterial infections worldwide, with approximately 150 million cases annually, placing a significant burden on healthcare systems [1]. *E. coli* remains the most dominant uropathogen, causing the majority of community-acquired infections, and a high proportion of hospital-acquired episodes further solidifies its dominance within both ambulatory and inpatient parameters [2]. This is attributed to its vast arsenal of virulence factors and inherent adaptability, which enable its persistence and global clinical relevance. An increasingly antimicrobial-resistant nature of uropathogenic *E. coli* populations has emerged as a significant therapeutic challenge, especially in developing countries where widespread antibiotic availability and frequent misuse expedite the emergence of resistance [3]. Fluoroquinolones, such as ciprofloxacin and levofloxacin, have long been used as first-line agents for the management of urinary tract infection, based on their broad antimicrobial spectrum, strong tissue penetration, and convenient oral dosing characteristics [4]. Their bactericidal action is via inhibition of bacterial DNA gyrase and topoisomerase IV, enzymes that are considered important for DNA supercoiling and chromosomal replication [5]. However, increasing and often inappropriate fluoroquinolone consumption is being paralleled by rising resistance rates worldwide, with surveillance reports noting resistance levels of 15-50% across different regions and particularly high rates in South Asia [6]. Resistance of *E. coli* to fluoroquinolones is mediated through complex mechanisms involving chromosomal mutations, efflux pump activation, and plasmid-borne resistance determinants [7]. Chromosomal alterations within the quinolone resistance-determining regions of target genes constitute a core mechanism for high-level resistance. The most critical mutation hotspots within the gyrA gene encoding the A subunit of DNA gyrase involve codons 83 and 87, with amino acid substitutions like Ser83Leu and Asp87Asn commonly reported [8]. Such modifications decrease the affinity of fluoroquinolones for their target and thus reduce drug efficacy. Accumulation of multiple mutations is strongly associated with rising minimum inhibitory concentrations and increased risk of therapeutic failure [9]. Indeed, reliable antimicrobial susceptibility testing is still crucial for appropriate patient management and to inform the development of effective antimicrobial stewardship programs. Disc diffusion techniques are still widely used because of their ease and low cost, while minimum inhibitory concentration testing provides more accurate quantification of drug activity and better prediction of clinical outcome [10]. Recent developments in molecular diagnostics have facilitated the use of PCR-based restriction fragment length polymorphism analysis to rapidly detect resistance-conferring mutations and improve epidemiological typing capability [11]. There is a need to understand genotype-phenotype relationships to enable the prediction of treatment outcomes and to inform evidence-based antibiotic policies. It is within this context, the study aims to determine local resistance patterns among urinary *E. coli* isolates, to determine fluoroquinolone-related gyrA mutations, and to assess their association with the

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corresponding phenotypic resistance profile.

METHODS & MATERIALS

This cross-sectional study was conducted in the Department of Microbiology at Sir Salimullah Medical College and Mitford Hospital, Dhaka, over a 12-month period from January to December 2020. The study population consisted of patients of all ages and both sexes attending the microbiology department from both inpatient and outpatient units for urine culture and antibiotic susceptibility testing. Individuals with clinically suspected urinary tract infection (UTI) were eligible for inclusion, while patients who had taken antibiotics within the preceding 14 days, those on current antibiotic therapy, and catheterized urine samples were excluded. A total of 229 urine samples were ultimately collected through purposive sampling. Clinical and demographic information, including age, sex, duration of hospitalization, and prior antibiotic history, was collected using a structured questionnaire. Written informed consent was obtained from each participant or their guardian, and ethical approval was granted by the Ethical Review Committee of Sir Salimullah Medical College and Mitford Hospital. Approximately 10 ml of midstream urine was collected under aseptic conditions. Primary culture was performed on MacConkey agar and Blood agar, followed by incubation at 37°C for 24 hours [12]. Bacterial isolates were identified through standard biochemical tests using Kligler Iron Agar, Simmons' citrate agar, and Motility-Indole-Urea media [13]. Antimicrobial susceptibility testing was performed on Mueller-Hinton agar following CLSI guidelines [14]. Detection of gyrA gene mutations associated with quinolone resistance was performed using PCR-RFLP [15]. DNA was extracted using the Monarch genomic DNA purification kit [16]. A 164-bp fragment of the gyrA gene encompassing codons 83 and 87 was amplified using allele-specific primers. PCR was carried out in a 25 µl reaction mixture, and amplification products were subjected to HinfI restriction enzyme digestion [17]. Electrophoresis on a 3 percent agarose gel was used for the interpretation of band patterns, allowing discrimination between wild-type and mutated alleles at Ser83 and Asp87. ATCC E. coli 25922 served as the control strain [18]. All collected data were entered and analyzed using SPSS version 26.

RESULTS

Table I represents the overall culture yield and distribution of bacterial pathogens isolated from 229 urine samples. Out of these, 138 samples (60.2%) showed positive bacterial growth, and *E. coli* was the predominant isolate at 81.8%, followed by *Klebsiella* species (8.7%), *Pseudomonas* (6.5%), and other less common organisms.

Table I
Rate of Growth Yielded from Urine Culture and Distribution of Organisms Isolated (*n*=229).

Variable	Category	No. of Isolates	Percentage
Growth Yield	Positive	138	60.2%
	Negative	91	39.7%
Bacterial Isolates (n=138)	E. coli	113	81.8%
	Klebsiella	12	8.7%
	Pseudomonas	9	6.5%
	Citrobacter	2	1.4%
	Proteus	1	0.7%
	Staphylococcus aureus	1	0.7%

Table II shows the overall susceptibility pattern of 113 *E. coli* strains against 16 different antimicrobial agents. Of note are the high resistance rates to nalidixic acid, at 72.6%; aztreonam, 71.7%; amoxiclav, 69%; and cefuroxime, 67.3%. On the other hand, carbapenems (imipenem and meropenem), and amikacin, had resistance rates of less than 15%. For most antibiotics, the proportion in the intermediate category was low, indicating well-delineated susceptible and resistant populations.

Table II
Antibiotic Susceptibility pattern among *E. Coli* (*n*=113).

Antimicrobial Agents	Sensitive (n) (%)	Intermediate (n) (%)	Resistant (n) (%)
Mecillinam (10 µg)	66 (58.4%)	3 (2.7%)	44 (38.9%)
Ceftazidime (30µg)	40 (35.4%)	4 (3.5%)	69 (61.1%)
Cefuroxime (30µg)	31 (27.4%)	6 (5.3%)	76 (67.3%)
Ceftriaxone (30µg)	48 (42.5%)	4 (3.5%)	61 (54%)
Cefixime (5µg)	39 (34.5%)	6 (5.3%)	68 (60.2%)
Nalidixic Acid (30µg)	26 (23%)	5 (4.4%)	82 (72.6%)
Ciprofloxacin (5µg)	48 (42.5%)	6 (5.3%)	59 (52.2%)
Levofloxacin (5µg)	76 (67.3%)	2 (1.8%)	35 (31%)
Nitrofurantoin (300µg)	86 (76.1%)	0 (0%)	27 (23.9%)
Gentamicin (10µg)	83 (73.5%)	4 (3.5%)	26 (23%)
Amikacin (30µg)	96 (85%)	3 (2.7%)	14 (12.4%)
Co-trimoxazole (1.25/23.75µg)	50 (27.4%)	6 (5.3%)	57 (50.4%)
Amoxiclav (20/10µg)	31 (27.4%)	4 (3.5%)	78 (69%)
Meropenem (10µg)	105 (92.9%)	0 (0%)	8 (7.1%)
Imepenem (10µg)	100 (88.5%)	0 (0%)	13 (11.5%)
Aztreonam (30µg)	30 (26.5%)	2 (1.8%)	81 (71.7%)

Table III represents the distribution of ciprofloxacin minimum inhibitory concentration (MIC) values amongst the *E. coli* isolates by the agar dilution method. MIC values showed a bimodal distribution pattern, where the peaks at high concentrations represent resistant populations (16 µg/ml: 20.4%, 8 µg/ml: 16.8%), while those at lower concentrations represent susceptible strains (0.015 µg/ml: 9.7%, 0.007 µg/ml: 7.9%), reflecting the distinct genetic basis for resistance mechanisms.

Table III
MIC values of ciprofloxacin by agar dilution method (*n*=113).

MIC value of Ciprofloxacin (µg/ml)	n	%
16 µg/ml	23	20.4%
8 µg/ml	19	16.8%
4 µg/ml	7	6.2%
2 µg/ml	6	5.3%
1 µg/ml	2	1.7%
0.5 µg/ml	4	3.5%
0.25 µg/ml	11	9.7%
0.12 µg/ml	9	7.9%
0.06 µg/ml	6	5.3%
0.03 µg/ml	6	5.3%
0.015 µg/ml	11	9.7%
0.007 µg/ml	9	7.9%

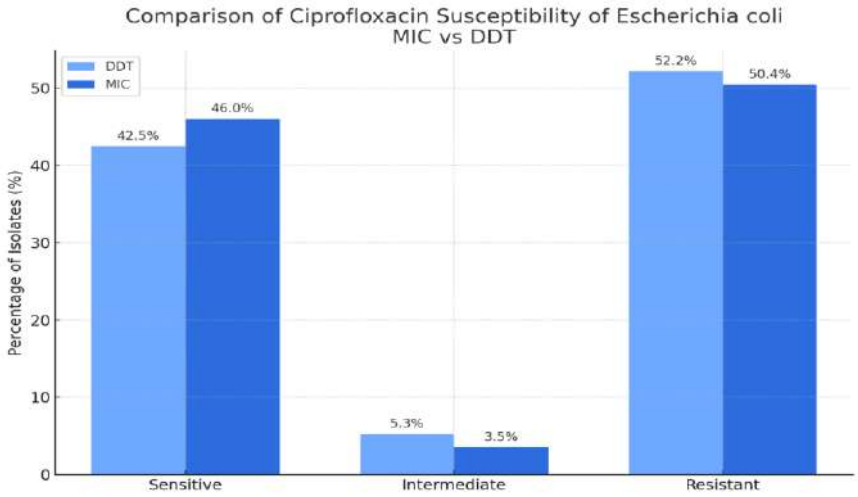

Figure 1 Comparison of susceptibility of *E. coli* against ciprofloxacin by agar dilution method (MIC) and disc diffusion technique (DDT) (*n*=113)

Figure 1 compares ciprofloxacin susceptibility of 113 urinary *E. coli* isolates by disc diffusion and MIC methods, showing broadly concordant categorizations, with MIC classifying slightly more isolates as sensitive and fewer as resistant, and minimal intermediate susceptibility in both assays.

Table IV shows the differential resistance patterns between ciprofloxacin-resistant and ciprofloxacin-sensitive *E. coli* isolates. Remarkably, all ciprofloxacin-resistant isolates demonstrated concurrent resistance to nalidixic acid at 100%, probably indicating related resistance mechanisms. Cross-resistance was particularly evident with β-lactams and aztreonam, while carbapenems retained activity against both groups.

Table IV
Comparison of antibiotic resistance profile between ciprofloxacin-resistant and ciprofloxacin-sensitive Escherichia coli isolates (*n*=113).

Antimicrobial agents	Ciprofloxacin resistant (n=61)	Ciprofloxacin sensitive (n=52)
Mecillinam (10 µg)	28 (45.9%)	19 (36.5%)
Ceftazidime (30µg)	37 (60.7%)	36 (69.2%)
Cefuroxime (30µg)	46 (75.4)	36 (69.2%)
Ceftriaxone (30µg)	30 (49.2%)	35 (67.3%)
Cefixime (5µg)	43 (70.5%)	31 (59.6%)
Nalidixic Acid (30µg)	61 (100%)	26 (50%)
Levofloxacin (5µg)	16 (26.2%)	21 (40.4%)
Nitrofurantoin (300µg)	19 (31.1%)	8 (15.4%)
Gentamicin (10µg)	9 (14.8%)	21 (40.4%)
Amikacin (30µg)	5 (8.2%)	12 (23.1%)
Co-trimoxazole (1.25/23.75µg)	35 (57.4%)	28 (53.8%)
Amoxiclav (20/10µg)	44 (72.1%)	38 (73.1%)
Meropenem (10µg)	3 (4.9%)	5 (9.6%)
Imepenem (10µg)	4 (6.6%)	9 (17.3%)
Aztreonam (30µg)	45 (73.8%)	38 (73.1%)

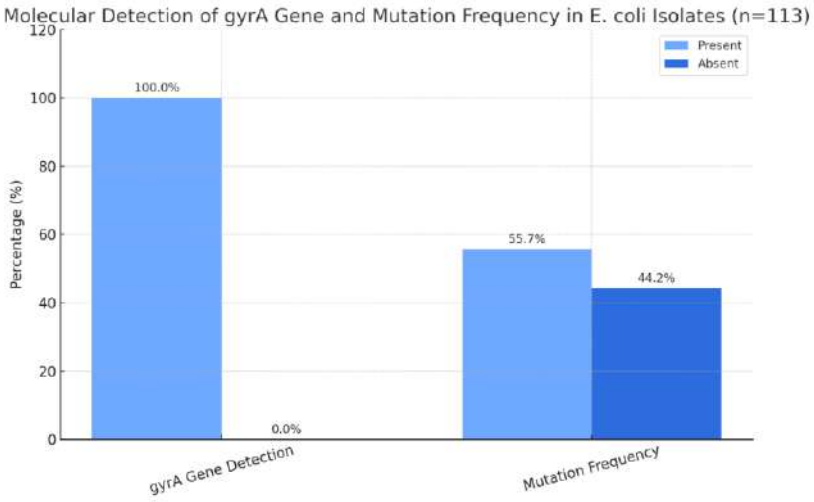

Figure 2 Molecular detection and mutation frequency of the gyrA gene in *E. coli* isolates (*n*=113).

Figure 2 depicts the molecular detection results, indicating that 55.7% of *E. coli* isolates carried gyrA gene mutations, while 44.2% exhibited a wild-type genotype. The high percentage of mutated strains points out the wide dissemination of chromosomally mediated fluoroquinolone resistance within the study population and underlines the value of molecular surveillance in understanding the epidemiology of resistance.

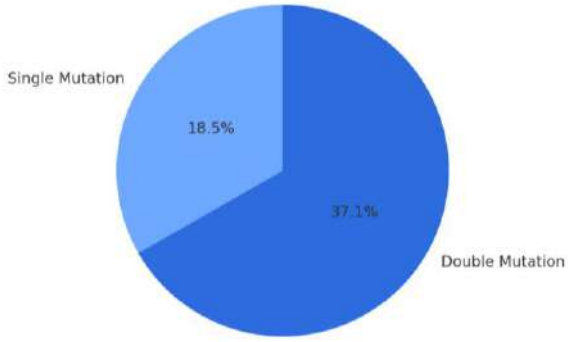

Figure 3 Type of gyrA Mutation gene among the *E. coli* Isolates.

Figure 3 reveals the kinds of gyrA mutations identified, showing that double mutations at both Ser83 and Asp87 codons were predominant, at 37.1% of mutated strains, while single mutations solely at Ser83 occurred in 18.5%.

Table V indicates the association between gyrA mutations and ciprofloxacin susceptibility phenotypes. Among resistant isolates, 37.2% had double mutations at both codons, while 12.4% had single Ser83 mutations.

Table V
Association of gyrA gene mutation and ciprofloxacin susceptibility of *E. coli* (*n*=113).

Ciprofloxacin susceptibility pattern	Mutations at specific codon		
	Ser83 (n) (%)	Asp87 (n) (%)	Both Ser83 and Asp 87 (n) (%)
Sensitive	5 (4.4%)	0	0
Intermediate	2 (1.8%)	0	0
Resistant	14 (12.4%)	0	42 (37.2%)

Table VI exhibits the specific amino acid substitution patterns with corresponding ciprofloxacin MIC values. Single-site Ser 83 mutations associated with MIC values ranging from 0.25-2 µg/ml, indicating low-level resistance. In contrast, double mutations at both Ser83 and Asp87 exclusively correlated with MICs ≥8 µg/ml, showing high-level resistance.

Table VI
Amino-acid changes in gyrA genes of Escherichia coli and corresponding MIC of Ciprofloxacin (*n*=63).

Substitution site	No. of Isolates	Mutation observed in *E. coli* isolates at specific MIC of ciprofloxacin (µg/ml)						
		0.25	0.5	1	2	4	8	16
Single site mutation 21 (Ser 83)	21	5	2	5	7	2	-	-
Single site mutation (Asp 87)	0	-	-	-	-	-	-	-
Both site mutations (Ser 83 & Asp 87)	42	-	-	-	-	-	19	23

Table VII shows the antibiotic resistance profiles between single-mutated and double-mutated *E. coli* strains. Double-mutated strains were more resistant to a wide array of antibiotic classes, especially the fluoroquinolone class: 100% ciprofloxacin-resistant versus 76.2% in single mutants; and nalidixic acid, 100% versus 90.5%. Resistance patterns of non-fluoroquinolone antibiotic classes, however, remained largely unchanged, indicating that they may depend on distinct mechanisms of resistance.

Table VII
Comparison of antibiotic resistance between single-mutated and double-mutated Escherichia coli strains (*n*=63).

Antimicrobial Agents	Single-strain mutation (n=21)	Double-mutated strains (n=42)
Mecillinam (10 µg)	15 (71.4%)	28 (66.7%)
Ceftazidime (30µg)	19 (90.5%)	40 (95.2%)
Cefuroxime (30µg)	18 (85.7%)	40 (95.2%)
Ceftriaxone (30µg)	19 (90.5%)	39 (92.9%)
Cefixime (5µg)	20 (95.2%)	39 (92.9%)
Nalidixic Acid (30µg)	19 (90.5%)	42 (100%)
Ciprofloxacin (5µg)	16 (76.2%)	42 (100%)
Levofloxacin (5µg)	14 (66.7%)	12 (28.6%)
Nitrofurantoin (300µg)	8 (38.1%)	17 (40.5%)
Gentamicin (10µg)	11 52.4%)	17 (40.5%)
Amikacin (30µg)	4 (19%)	11 (26.2%)
Co-trimoxazole (1.25/23.75µg)	20 (95.2%)	41 (97.6%)
Amoxiclav (20/10µg)	17 (81%)	38 (90.5%)
Meropenem (10µg)	3 (14.3%)	5 (11.9%)
Imepenem (10µg)	4 (19%)	9 (21.4%)
Aztreonam (30µg)	18 (85.7%)	41 (97.6%)

Table VIII summarizes the ciprofloxacin susceptibility of different genetic backgrounds. Mutated strains showed 49.5% resistance, compared with only 1.7% resistance among strains without mutations, making the gyrA mutation the major prevailing resistance mechanism. Additionally, double mutations presented total resistance at 100%, while single mutations demonstrated partial penetrance with 66.7% resistance, exemplifying the incremental nature of mutation-mediated resistance. These data highlight the predictive value of genotypic characterization.

Table VIII
Comparative Analysis of Ciprofloxacin Susceptibility Patterns Between Mutated vs Non-Mutated Strains, Single vs Double gyrA mutations, and overall gyrA mutation status in Escherichia coli (*n*=113).

Variable	Category	Ciprofloxacin susceptibility pattern		
		Susceptible n (%)	Intermediate n (%)	Resistant n (%)
E. coli strains	Mutated	5 (4.4%)	2 (1.7%)	56 (49.5%)
	Non mutated	47 (41.6%)	2 (1.7%)	1 (0.8%)
E. coli strains	Single Mutation (n=21)	5 (23.8%)	2 (1.7%)	14 (66.7%)
	Double Mutation (n=42)	0	0	42 (100%)
	-	**Sensitive**		**Resistant**
gyrA gene mutation	Present (n=63)	5 (7.9%)		58 (92.1%)
	Absent (n=50)	47 (94%)		3 (6%)

DISCUSSION

This study provides a comprehensive overview of the dynamics of antimicrobial resistance and fluoroquinolone resistance mechanisms among urinary *E. coli* isolates in Bangladesh and uncovers their resistance patterns. The study confirms *E. coli* as the predominant uropathogen, constituting 81.8% of culture-positive urinary tract infections, which is consistent with Khanal et al. [19]. However, the antibiogram shows a disturbingly high level of resistance among isolates. High levels of resistance to nalidixic acid (72.6%), cefuroxime (67.3%), and ciprofloxacin (52.2%) are consistent with Ruiz et al. and Sahm et al. [20,21]. These contrasts reveal the differential global evolution of antimicrobial resistance shaped by patterns of antibiotic consumption, regulatory oversight, and healthcare infrastructure. These molecular data led chromosomal mutations as the main driver of fluoroquinolone resistance, with mutations of gyrA present in 55.7% of the tested isolates. This prevalence contrasts the situation reported by Hoseinzadeh et al., where plasmid-mediated quinolone resistance determinants stand for a significant percentage of the resistance phenotypes [22]. Particularly noteworthy is the preponderance of double mutants involving Ser83 and Asp87 (37.1% of mutated isolates), a hallmark of high-level resistance and clinical failure. Azargun et al. reported similar identified Ser83Leu and Asp87Asn as the two most common changes in the Iranian population, further emphasizing a geographical spreading of mutation patterns carrying pivotal therapeutic consequences [23]. The strong genotype-phenotype correlation depicted here, where 92.1% of mutated isolates turned out as resistant, underlines very well the predictive value of molecular markers. The overt linkage of double mutants to MIC values of at least 8 µg/ml further illustrates the stepwise acquisition of mutations as resistance progresses, a process well described in in vitro selections and clinical isolates [24]. The lack of isolates with only Asp87 mutations further supports the idea that Ser83 changes are often the first evolutionary event, due to particularly favorable fitness dynamics. The study also shows meaningful concordance between disc diffusion and MIC methods, supporting continued use of disc diffusion in routine diagnostic workflows, while recognizing the higher precision of MIC testing for pharmacokinetic-pharmacodynamic

optimization and more nuanced clinical decision-making [25]. The observed bimodal MIC distribution underlines genetic segmentation between wild-type populations and mutated resistant strains. Cross-resistance patterns further complicate clinical management. Indeed, ciprofloxacin-resistant isolates often showed resistance to β-lactams and trimethoprim-sulfamethoxazole, reflecting selective pressure that co-favors multidrug resistance pathways shaped by antibiotic overuse and horizontal gene transfer [26]. Notably, carbapenems remained highly effective, with resistance below 10%, consistent with global evidence supporting their standing as last-line agents [27]. Aminoglycosides and nitrofurantoin also maintained considerable activity and, hence, can continue to play a role as therapeutic alternatives in fluoroquinolone-resistant infections. Clinically and programmatically, these findings support reconsideration of empirical fluoroquinolone therapy in settings with similar resistance landscapes. Local susceptibility patterns need to be incorporated into the treatment algorithms, and rapid molecular diagnostics targeting gyrA mutations may enable early therapeutic precision with reduced unnecessary antibiotic exposure [28]. From the broader public health perspective, the findings shed light on systemic gaps in antimicrobial stewardship, regulatory control, diagnostic capacity, and community-level education that perpetuate the high burden of resistance [29]. The decreasing usefulness of existing antibiotics also highlights the need to examine new therapeutics, such as phage therapy and immunomodulatory strategies [30].

LIMITATIONS

Because of the cross-sectional design, temporal trends in resistance evolution could not be assessed, and other possible resistance mechanisms were not investigated, including parC mutations, efflux pump expression, and plasmid-mediated quinolone resistance genes.

CONCLUSION

This study detected alarmingly high rates of fluoroquinolone resistance among urinary *E. coli* isolates, which were mainly due to double mutations in codons 83 and 87 within the gyrA gene. A strong genotype-phenotype correlation establishes molecular screening as a useful tool for predicting resistance patterns. Extensive multidrug resistance warrants re-evaluation of empirical treatment policies and determines the crucial role of an antimicrobial stewardship program. These results reiterate the importance of continuing surveillance and molecular characterization to support rational antibiotic policies in combating the growing menace of antimicrobial resistance.

RECOMMENDATIONS

Whole-genome sequencing approaches should be used to comprehensively characterize all resistance mechanisms and clonal relationships among resistant strains in future studies. Multicenter longitudinal surveillance with diverse patient populations and healthcare settings should, therefore, provide more representative national resistance data.

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Clinicodemographic and Stricture-Related Factors Influencing Surgical Outcomes Following One-Stage Versus Staged Buccal Mucosal Graft Urethroplasty

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ABSTRACT

Introduction: Anterior urethral stricture is a common urological disorder that is often diagnosed and is characterised by the fibrotic tissue formation and narrowing of the urethral canal which leads to obstructive voiding symptoms, urinary infections, and a decrease in quality of life. **Methods & Materials:** This quasi, experimental study was carried out in Department of Urology, National Institute of Kidney Diseases & Urology (NIKDU), Dhaka, for one year from 15 June 2023 to 14 June 2024. The target population of the study was 84 male patients admitted with long, segment anterior urethral stricture. The data were analysed using SPSS Statistics for Windows, version 26.0. **Result:** The mean age was 38.48 ± 11.90 years in Group A and 37.64 ± 10.52 years in Group B (p = 0.596). Mean stricture length in overweight patients was 7.16 ± 3.83 cm in Group A and 6.67 ± 4.19 cm in Group B (p = 0.559), while in obese patients it was 9.25 ± 4.18 cm and 10.67 ± 3.95 cm, respectively (p = 0.113). Per-operative parameters showed significantly shorter operative time in Group A (180.47 ± 3.63 min) versus Group B (254.52 ± 8.02 min; p < 0.0001) and lower blood loss (502.38 ± 31.14 ml vs. 619.76 ± 58.91 ml; p < 0.0001), while blood transfusion requirement was comparable (8 [19%] vs. 13 [30%]; p = 0.208). Stricture site distribution was also similar, with the penile urethra most common in Group A (35.7%) and bulbo-penile urethra in Group B (35.7%; p = 0.194). **Conclusion:** In a comparative study of one, stage and staged buccal mucosal graft urethroplasty in patients with long, segment anterior urethral strictures, it was found that the two groups were similar with respect to age, BMI, stricture length, and anatomical site of the urethral stricture.

Keywords: *Urethroplasty, Urethral Stricture, BMI.*

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INTRODUCTION

Anterior urethral stricture disease is a common urological disorder that causes the narrowing of the urethral lumen due to fibrosis. This eventually leads to obstructive lower urinary tract symptoms, recurrent urinary tract infections, urinary retention, and a substantial loss in the quality of life [1]. The challenge of dealing with urethral stricture disease is most severe in the developing countries. There, patients often come only when the disease is at an advanced stage, have aetiologically infectious factors, and frequently receive several endoscopic treatments [2]. Long segment anterior urethral strictures are among the most difficult types of cases for surgical repair due to their length, complexity, and the risk of recurrence being higher. Currently, urethroplasty is the only definitive treatment for anterior urethral strictures and the most preferred procedure due to its higher long, term success rate in comparison with minimally invasive strategies like urethral dilation and direct vision internal urethrotomy (DVIU), particularly for long or recurrent strictures [3]. Nonetheless, the results of urethroplasty continue to differ markedly in spite of the development of surgical techniques and that of flap materials. Depending on the type of patients, condition of the stricture, and surgical procedure, success rates as high as 70% to more than 90% have been reported [4]. By studying the factors that influence the outcomes, one can help improve the pre, operative planning and patient counselling. It has been demonstrated that clinicodemographic variables like age, body mass index (BMI), smoking status, and comorbidities may affect the results of surgery after urethral reconstruction. Aging has been linked to less efficient tissue healing and higher rates of recurrence in some studies, whereas others indicate that old age by itself should not be a reason to avoid urethroplasty [5]. Becoming overweight has been identified as one of the possible risk factors in the light of changes in wound healing processes, surgeries being more difficult, and a greater chance of perioperative morbidity [6]. Moreover, systemic conditions such as diabetes mellitus could potentially be detrimental to graft take and urethral healing due to microvascular compromise [7]. Stricture, related factors contribute just as significantly in determining the success of the surgery. Length of stricture is among the commonly reported predictors of result, with longer strictures showing greater incidences of recurrence after reconstruction [8]. The cause of the disease also has a major impact on the prognosis; inflammation, infection, and lichen sclerosusrelated strictures are linked with worse outcomes than idiopathic or traumatic strictures [9]. Furthermore, the site of anatomical involvement, the number of previous interventions, and whether pan, urethral disease is present contribute to the complexity of surgery and hence the effect on long, term results. For long, segment anterior urethral strictures, substitution urethroplasty with buccal mucosal grafts is currently the most preferred reconstructive procedure due to the graft's resilient epithelial nature, the simple harvesting process, and good long, term results [4]. Nevertheless, the decision between one, stage and staged operations still depends quite a lot on stricture length, tissue quality, infection status, and patient, related factors. This study aimed to evaluate clinicodemographic and stricture-related factors influencing surgical outcomes following one-stage versus staged buccal mucosal graft urethroplasty in patients with long-segment anterior urethral strictures.

METHODS & MATERIALS

This quasi, experimental study took place at the Department of Urology, National Institute of Kidney Diseases & Urology (NIKDU), Dhaka, over the duration of one year from 15 June 2023 to 14 June 2024. The study population were male patients with long, segment anterior urethral stricture admitted to the hospital. A

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purposive sampling method was used, and the total number of patients was 84, 42 patients in each group. Group A was the one, stage buccal mucosal graft urethroplasty group and Group B was the staged buccal mucosal graft urethroplasty group. Male patients aged between 18 and 60 years with anterior urethral stricture length more than 2 cm were included in the study. Patients who had urethroplasty, post, traumatic urethral stricture, genitourinary malignancy, or were younger than 18 years or older than 60 years were not included in the study. All the data were collected and processed in IBM SPSS Statistics for Windows, version 26.0. Continuous variables were expressed as mean standard deviation, whereas categorical variables were presented as counts and percentages. The Chi, square test was applied to assess the differences in qualitative variables between the groups. At the same time, the Independent Sample t, test was used for quantitative variables. A p, value less than 0.05 was considered statistically significant. Before the start of the research, ethical approval for the study was secured from the Ethical Committee of the National Institute of Kidney Diseases & Urology (NIKDU), Dhaka.

RESULTS

Most patients in both groups were in the 21-40 years age group in the current study which was 52.38% in Group A and 45.24% in Group B. Patients aged 41, 60 years were 40.48% in Group A and 50.00% in Group B, while only few participants were aged 18, 20 years in both groups. The average age of the patients was 38.48± 11.90 years in Group A and 37.64± 10.52 years in Group B. The difference in age distribution between the two groups was not statistically significant p = 0.596) (*Table I*).

Table I
Distribution of the Study Subjects According to Age (*n* = 84).

Age group (Years)	Group A (n = 42)	Group B (n = 42)	*p* value
18–20	3 (7.14%)	2 (4.76%)	0.596
21–40	22 (52.38%)	19 (45.24%)	
41–60	17 (40.48%)	21 (50.00%)	
Mean ± SD	38.48 ± 11.90	37.64 ± 10.52	-

Data expressed as frequency, percentage, and Mean ± SD. p-value obtained using the Chi-square test. Group A: One-stage buccal mucosal graft urethroplasty. Group B: Staged buccal mucosal graft urethroplasty

In the overweight category (BMI 25–<30 kg/m²), the mean stricture length was 7.16 ± 3.83 cm in Group A and 6.67 ± 4.19 cm in Group B, with no statistically significant difference (p = 0.559). Among obese patients (BMI ≥30 kg/m²), the mean stricture length was higher in both groups; however, the difference between Group A (9.25 ± 4.18 cm) and Group B (10.67 ± 3.95 cm) was not statistically significant (p = 0.113). Overall, no significant association was observed between BMI and mean stricture length in either group $p > 0.05$ (*Table II*).

Table II
Relationship of BMI with Mean Stricture Length in Study Subjects (*n* = 84).

BMI category (kg/m²)	Mean stricture length (cm) Group A (n = 42)	Mean stricture length (cm) Group B (n = 42)	*p* value
Overweight (25–<30)	7.16 ± 3.83	6.67 ± 4.19	0.559
Obese (≥30)	9.25 ± 4.18	10.67 ± 3.95	0.113
Mean ± SD	8.91 ± 4.24	10.24 ± 4.28	0.156

Data expressed as Mean ± SD. p-value obtained using the Independent Sample t-test. Group A: One-stage buccal mucosal graft urethroplasty. Group B: Staged buccal mucosal graft urethroplasty

The mean operation time was significantly shorter in Group A compared to Group B (180.47 ± 3.63 minutes vs. 254.52 ± 8.02 minutes; $p < 0.0001$). Similarly, mean intra-operative blood loss was significantly lower in Group A than in Group B (502.38 ± 31.14 ml vs. 619.76 ± 58.91 ml; $p < 0.0001$). Although the requirement for blood transfusion was lower in Group A (19%) compared to Group B (30%), this difference was not statistically significant (p = 0.208). It is noteworthy that the operation time, blood loss, and blood transfusion requirement in Group B represent the cumulative values of both stage I and stage II procedures (*Table III*).

Table III
Comparison of Per-operative Parameters of the Study Subjects (*n* = 84).

Per-operative parameter	Group A (n = 42)	Group B (n = 42)	*p* value
Operation time (min)	180.47 ± 3.63	254.52 ± 8.02	<0.0001
Blood loss (ml)	502.38 ± 31.14	619.76 ± 58.91	<0.0001
Blood transfusion required (units)	8 (19.0%)	13 (30.0%)	0.208

Data expressed as Mean ± SD and frequency (%). p-value obtained using the Independent Sample t-test. Group A: One-stage buccal mucosal graft urethroplasty. Group B: Staged buccal mucosal graft urethroplasty

In Group A, the site most frequently involved was the penile urethra (35.7%), then the bulbo, penile urethra (23.8%) and the bulbar urethra (21.4%). In Group B, the bulbo, penile urethral involvement was the most common (35.7%) followed by the penile urethra (21.4%) and the bulbo, penile urethra with meatal involvement (21.4%). Patients with bulbar urethral strictures constituted 21.4% of Group A and 9.5% of Group B. The difference in the distribution of stricture sites between the two groups was not statistically significant p = 0.194 (*Table IV*).

Table IV
Distribution of the Study Subjects According to Site of Involvement (n = 84).

Site of involvement	Group A (n = 42)	Group B (n = 42)	*p* value
Bulbar urethra	9 (21.4%)	4 (9.5%)	0.194
Penile urethra	15 (35.7%)	9 (21.4%)	
Bulbo-penile urethra	10 (23.8%)	15 (35.7%)	
Penile urethra + meatus	3 (7.1%)	5 (11.9%)	
Bulbo-penile urethra + meatus	5 (11.9%)	9 (21.4%)	

Data expressed as frequency and percentage. p-value obtained using the Chi-square test. Group A: One-stage buccal mucosal graft urethroplasty Group B: Staged buccal mucosal graft urethroplasty.

DISCUSSION

The majority (52.48% and 45.24%) of the study subjects were in the age group of 21-40 years. Mean±SD age was 38.48±11.90 years and 37.64±10.52. Another study found a mean age of 38.4 years in their study, which is similar to this study [10]. Mean±SD length of stricture was 8.91±4.24 cm and 10.24±4.28 cm in both groups, respectively. But significant relationship between BMI and length of the urethral stricture in this study, which is dissimilar to the findings of one other study showing obese patients had significantly longer urethral strictures (Mean 6.7±4.7) cm than non-obese patients (p<0.001) [11]. Maybe it is due to geographical variation or aetiology affecting the stricture. The stricture was in the bulbar urethra (21.4% and 9.5%), penile urethra (35.7% and 21.4%), bulbo-penile (23.8% and 35.7%), penile with meatal (7.1% and 11.9%) and bulbo-penile with meatal (11.9% and 21.4%). There were no significant (p=0.195) differences in stricture location between groups, where a different study informed that the majority of strictures (58.6%) involved the bulbar urethra [11]. The incidence of different site involvement may be due to geographical variations. This study revealed operation time (180.47± 3.63 vs 254.52 ±8.02) was significantly (p<0.0001) less in one-Stage Buccal Mucosal Graft Urethroplasty than staged Buccal Mucosal Graft Urethroplasty, as in the staged procedure patient had to face the surgical procedure twice. Per-operative bleeding (502.38±31.14 vs 619.76±58.91) ml was also very significantly (p<0.0001) less in one-Stage Buccal Mucosal Graft Urethroplasty than staged Buccal Mucosal Graft Urethroplasty, the latter one included two surgical procedures. Bleeding was estimated by the deduction of the dry mop's weight from wet ones, and also by measuring from the suction bottle. There was a different study had also reported mean operative time was 162.7±12.156 minutes to 181.36±7.429 minutes in BMG urethroplasty [12]. They measured intraoperative blood loss by the decrease in haemoglobin after surgery up to (1.79±1.009 mg/dl). Another study revealed that the surgical time varied from 130 to 424 minutes, with the mean surgical time being 211 minutes in various types of urethroplasties [13]. In this study, the distribution of the sites of anterior urethral stricture was similar between the two groups. (p = 0.194). In Group A, penile urethral involvement was most common (35.7%), followed by bulbo-penile (23.8%) and bulbar strictures (21.4%). Group B, on the other hand, mostly had bulbo, penile strictures (35.7%), while penile urethral strictures and bulbo, penile strictures with meatal involvement were 21.4% each. Hence, it may be inferred that those who had staged urethroplasty were more likely to have multi, segment or complex disease. Palminteri et al. found that penile and bulbo, penile strictures account for a large share of long, segment anterior urethral strictures requiring substitution urethroplasty, which is in line with the high occurrence of these sites in both groups of our study [2]. Barbagli et al. exposed that the bulbo, penile area is mostly affected in long strictures hence the repair trip which was also seen in group B was of complicated nature [4]. Kulkarni et al. reported that penile and pan, urethral strictures are more likely to be associated with longer disease duration and severe spongiofibrosis, which usually determines the decision to do a staged repair [9]. Furthermore, Kinnaird et al. pointed out that the involvement of different urethral segments is a common feature of long strictures and does not, by itself, predict surgical failure. This is in line with the similar distribution of the two groups in our study [8].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

Between one, stage and staged buccal mucosal graft urethroplasty groups, patients with long, segment anterior urethral strictures had similar age, BMI, stricture length, and site. One, stage urethroplasty resulted in a significantly shorter operative time and less blood loss, however, transfusion rates were similar. These data suggest that the one, stage repair has perioperative benefits not impacted by baseline clinicodemographic or stricture, related factors.

RECOMMENDATION

Stage buccal mucosal graft urethroplasty should probably be the first choice for patients who are suitable and have long, segment anterior urethral strictures because it involves less operative time and blood loss, among other factors. A thorough preoperative evaluation of stricture features and patient factors should determine the surgical approach, and staged surgeries are to be kept for very complicated or extensive strictures when the tissue quality or length does not allow single, stage reconstruction.

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Outcome of Voice Therapy in Treatment of Benign Laryngeal Lesions

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ABSTRACT

Introduction: Benign laryngeal lesions, such as vocal nodules, polyps, cysts, and Reinke's edema, constitute some of the most common voice disorders and have a great impact on people's daily communication and quality of life. Voice therapy is considered First, line, non, surgical method of treatment, which aims to reduce phono traumatic behavior, improve vocal technique and achieve functional voice. **Methods & Materials:** A prospective observational study was carried out at the Department of Otolaryngology Head & Neck Surgery, Specialized ENT Hospital of SAHIC, over the period from January 2025 to December 2025. The data were processed by means of SPSS version 26.0. **Result:** Voice therapy with a structure had a profound impact on the reduction of VHI scores in all types of lesions ($p < 0.001$). The greatest impact was seen in vocal nodules where the average VHI fell from 49.1 to 31.9. Laryngoscopic examination demonstrated that the lesions had fully or partly disappeared in 89.7% of the cases, and the nodules had the biggest rate of fully going away while Reinkes edema had a less good response. **Conclusion:** This study shows that a structured voice therapy is an effective and safe non, surgical treatment for benign laryngeal lesions. There was a substantial improvement in voice, related quality of life reflected by a significant decrease in the scores of Voice Handicap Index and majority of the patients also had positive laryngoscopic changes. Vocal nodules responded best to therapy, however Reinkes edema kept on displaying lesser but still significant improvements.

Keywords: *Benign Laryngeal Lesions, Voice Therapy, Voice Handicap Index*

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INTRODUCTION

Benign laryngeal lesions (BLLs) including vocal nodules, polyps, cysts, Reinke's edema, and contact granulomas are common voice disorders that significantly affect vocal quality, professional communication, and quality of life. The overall worldwide proportion of people with voice disorders in the general population is believed to be between 3% and 9%, with the highest levels found in such voice, demanding professions as teachers, singers, and call center workers [1]. Voice disorders due to benign lesions account for nearly 40% to 60% of diagnosed laryngeal pathologies among the patients who come with voice complaints [2]. With low awareness about voice health and high exposure to risk factors such as smoking, air pollution, and poor vocal hygiene, South Asian countries BLLs are rarely diagnosed. Research from India and Pakistan shows that benign lesions make up 50%70% of the cases among patients with hoarseness and voice disorders [3,4]. Surgical interventions have been the principal mode of treatment traditionally. However, the role of voice therapy as an important non, invasive modality in the management of benign vocal fold lesions is becoming more and more recognized. Voice therapy, generally administered by a speech, language pathologist with expertise in voice disorders, intends to change harmful vocal habits. The therapy also aims at refining vocal technique and thus, helping to maintain good vocal hygiene. It includes both direct and indirect approaches, such as vocal function exercises, resonant voice therapy, and the teaching of vocal conservation. Evidence, based practice recently highlighted the importance of behavioral interventions in not only symptom relief but also in preventing recurrence after surgery. A study was designed to randomize patients to different treatment arms, and it was found that voice therapy was equally effective as phonosurgery for certain lesions in terms of long, term vocal outcomes. Also, pre, operative voice therapy has been demonstrated to enhance the results of surgery and shorten the healing time [5]. The effectiveness of voice therapy is largely determined by a thorough and individualized assessment and goal, setting, a good compliance to the treatment protocols, and a strong multidisciplinary collaboration of otolaryngologists and voice specialists [6]. Although it has advantages, voice therapy is still rarely used in some clinical settings, mainly due to the unawareness or shortage of professionals trained in this field [7]. Technological improvements in laryngeal imaging and voice signal analysis techniques have significantly facilitated the evaluation of treatment outcomes and tracking of lesions. Besides that, the expanding use of telepractice has greatly facilitated access to voice therapy and has demonstrated similar effectiveness to face, to, face sessions [8]. Voice therapy is an important tool in the non, surgical treatment of benign laryngeal lesions. It helps to alleviate symptoms and improve voice, thus lessening the need for surgery and preventing the recurrence of lesions. This paper will investigate the success and different uses of voice therapy as a method of treatment for benign laryngeal lesions with the support of current research and clinical practice guidelines.

METHODS & MATERIALS

This prospective observational study was held at the Department of Otolaryngology Head & Neck Surgery, Specialized ENT Hospital of SAHIC, from January 2025 to December 2025. 68 patients with benign laryngeal lesions were the subject of the study. The study participants' demographic and clinical profiles were documented after obtaining the participants' written consents. An institutional ethics committee at SAHIC issued ethical clearance for the study. Voice Handicap Index (VHI) and video

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laryngoscopy assessments were performed for all patients before and after the structured voice therapy sessions. The data management and statistical analyses were done using SPSS 26.0. Appropriate statistical tests were chosen to analyze the data: the means and standard deviations were shown for continuous variables, and frequencies and percentages for categorical variables. Comparisons of pre, and post, treatment VHI scores were done using paired t, tests, and associations between lesion types and laryngoscopic findings were determined using chi, square tests. A p, value of less than 0.05 denoted statistical significance.

RESULTS

Among the participants, females outnumbered males (55.9% vs 44.1%), which may reflect higher voice-related concerns or greater healthcare-seeking behavior in females. The majority were in the 26–35 years age group (36.8%), followed by 36–45 years (26.5%). Only 5.9% of participants were over 55 years old (*Table I*).

Table I
Demographic Profile of Participants (*n* = 68).

Variable	Number	Percentage
Gender		
Male	30	44.1
Female	38	55.9
Age group (years)		
18–25	12	17.6
26–35	25	36.8
36–45	18	26.5
46–55	9	13.2
>55	4	5.9

Vocal nodules were the most frequently observed lesion (41.2%), followed by polyps (29.4%) and cysts (16.2%). Reinke's edema was the least common (13.2%). This pattern aligns with prior studies that show voice misuse or overuse is a leading cause of nodules and polyps, while Reinke's edema is less prevalent but often associated with smoking or long-term vocal abuse (*Table II*).

Table II
Distribution of Benign Laryngeal Lesions (*n* = 68).

Lesion Type	Number	Percentage
Vocal nodules	28	41.2
Vocal polyps	20	29.4
Vocal cysts	11	16.2
Reinke's edema	9	13.2

Structured voice therapy led to a significant reduction in VHI scores across all lesion types ($p < 0.001$). The largest reduction was seen in vocal nodules (-18.1 points), indicating a substantial improvement in perceived voice handicap. Vocal polyps and cysts also showed marked improvement (-16.7 and -17.2 points, respectively). Participants with Reinke's edema had the highest baseline VHI (52.1 ± 10.3), reflecting greater functional impairment, and showed a mean reduction of 16.9 points, demonstrating that even more severe lesions benefit from voice therapy. Overall, the mean VHI decreased from 49.1 to 31.9. (*Table III*).

Table III
Pre- and Post-Therapy Voice Handicap Index (VHI) Scores (*n* = 68).

Lesion Type	Pre-Therapy VHI Mean ± SD	Post-Therapy VHI Mean ± SD	Mean Difference	p-value
Vocal nodules	48.5 ± 8.4	30.4 ± 7.2	-18.1	<0.001
Vocal polyps	50.2 ± 9.1	33.5 ± 8.0	-16.7	<0.001
Vocal cysts	45.8 ± 7.6	28.6 ± 6.5	-17.2	<0.001
Reinke's edema	52.1 ± 10.3	35.2 ± 9.5	-16.9	<0.001
Overall	49.1 ± 8.9	31.9 ± 7.7	-17.2	<0.001

Laryngoscopic assessment showed that 89.7% of lesions had complete or partial resolution after therapy. Vocal nodules demonstrated the highest rate of complete resolution (50%), while Reinke's edema had the lowest (22.2%), indicating that edema is less responsive to conservative voice therapy. Partial resolution was most frequent in cysts (63.6%) and Reinke's edema (55.6%). Only 10.3% of lesions showed no change, emphasizing the effectiveness of structured voice therapy across most benign lesions. The differences in laryngoscopic outcomes among lesion types were statistically significant ($p < 0.05$) (*Table IV*).

Table IV
Laryngoscopic Changes After Voice Therapy (*n* = 68).

Lesion Type	Complete Resolution	Partial Resolution	No Change	p-value (χ^2)
Vocal nodules	14 (50.0%)	12 (42.9%)	2 (7.1%)	0.003
Vocal polyps	8 (40.0%)	10 (50.0%)	2 (10.0%)	0.005
Vocal cysts	3 (27.3%)	7 (63.6%)	1 (9.1%)	0.012
Reinke's edema	2 (22.2%)	5 (55.6%)	2 (22.2%)	0.021
Overall	27 (39.7%)	34 (50.0%)	7 (10.3%)	<0.001

Overall, 80.9% of participants showed good response, reflecting marked improvement in voice quality and lesion reduction. Vocal nodules responded best (92.9%), while Reinke's edema had the lowest good response rate (55.6%), likely due to chronic edema changes that are slower to resolve. Moderate response was observed in 19.1% of participants, while no participant had poor response, confirming the efficacy of voice therapy in benign lesions. Differences between lesion types were statistically significant ($p < 0.05$) (*Table V*).

Table V
Response to Voice Therapy by Lesion Type (*n* = 68).

Lesion Type	Good Response (%)	Moderate Response (%)	Poor Response (%)	p-value
Vocal nodules	26 (92.9)	2 (7.1)	0 (0)	0.001
Vocal polyps	16 (80.0)	4 (20.0)	0 (0)	0.004
Vocal cysts	8 (72.7)	3 (27.3)	0 (0)	0.010
Reinke's edema	5 (55.6)	4 (44.4)	0 (0)	0.028
Overall	55 (80.9)	13 (19.1)	0 (0)	<0.001

Both males and females experienced significant reduction in VHI scores ($p < 0.001$). The mean improvement was similar between genders (-17.2 vs -17.3), indicating that voice therapy is equally effective in both males and females, independent of baseline lesion type or severity (*Table VI*).

Table VI
Improvement in VHI by Gender (*n* = 68).

Gender	Pre-Therapy VHI Mean ± SD	Post-Therapy VHI Mean ± SD	Mean Difference	p-value
Male	48.7 ± 9.1	31.5 ± 7.9	-17.2	<0.001
Female	49.5 ± 8.7	32.2 ± 7.6	-17.3	<0.001

DISCUSSION

With respect to demographic characteristics, females constituted a higher proportion of participants (55.9%) than males, and the majority were aged 26–35 years. This reflects a population actively engaged in professional and social voice use. Roy et al. reported a higher prevalence of voice disorders among females and working-age adults, attributing this to increased vocal load and greater health-seeking behavior among women [1]. Similarly, Cohen et al. observed that patients presenting to voice clinics were predominantly young to middle-aged adults with occupational voice demands [9]. Regarding lesion distribution, vocal nodules were the most common lesion (41.2%), followed by polyps and cysts, with Reinke's edema being least frequent. In a large clinical review, Rosen and Murry identified vocal nodules and polyps as the most frequent benign vocal fold lesions, primarily related to phonotrauma, while Reinke's edema was less common and more strongly associated with smoking and chronic irritation [10]. Johns also emphasized that nodules are particularly prevalent in patients with voice misuse, whereas Reinke's edema represents a more chronic inflammatory process [11]. The lesion pattern observed in our study mirrors these established etiological associations. In terms of voice-related quality of life, our study demonstrated a statistically significant reduction in VHI scores across all lesion types ($p < 0.001$), with the largest improvement observed in vocal nodules (-18.1 points). Schindler et al. reported significant reductions in VHI scores following voice therapy in patients with benign vocal fold lesions, even when laryngoscopic resolution was incomplete [12]. Similarly, Cohen et al. documented clinically meaningful VHI improvement after behavioral voice therapy, emphasizing its impact on patients' perceived vocal handicap [9]. Compared to these studies, the magnitude of VHI reduction in our cohort was substantial, indicating robust subjective benefit from structured therapy. Laryngoscopic outcomes revealed complete or partial resolution in 89.7% of lesions, with vocal nodules showing the highest complete resolution rate (50%) and Reinke's edema the lowest (22.2%). Schindler et al. noted minimal structural resolution on videostroboscopy despite symptomatic improvement, whereas later studies reported partial or complete lesion regression, particularly for nodules, following intensive therapy programs [12, 13]. The higher resolution rates in our study may be attributable to strict therapy adherence and lesion selection, though the limited response of Reinke's edema aligns with its known chronic pathology. When assessing overall response by lesion type, 80.9% of participants demonstrated a good response, with vocal nodules responding best (92.9%). Nakagawa et al. reported that voice therapy alone led to significant improvement in many patients with vocal polyps, allowing avoidance of surgery in selected cases [14]. However, they also noted that response varied by lesion type and chronicity. Our findings support this lesion-specific responsiveness, particularly highlighting the favorable prognosis of nodules with conservative management. Finally, analysis by gender showed comparable VHI improvement in males and females. This observation is consistent with Schindler et al., who found no gender-based difference in post-therapy VHI improvement [12].

LIMITATIONS

The single, center study design and relatively small sample size (n = 68) may reduce the extent to which the results can be generalized. Without a control group, it is not entirely possible to assign all the positive changes solely to voice therapy as spontaneous recovery or placebo effects may still exist. The evaluation of results was based mainly on the subjective Voice Handicap Index, while objective acoustic or aerodynamic voice measures were not part of the study.

CONCLUSION

The present paper reveals that organized voice therapy is indeed an effective and safe non, surgical treatment for benign laryngeal lesions. A remarkable change was noted in the voice quality of life of the patients as is clear from the profound decline in Voice Handicap Index scores, besides that, there were also positive laryngoscopic changes in most of the cases. Vocal nodules reacted the most to the treatment, whereas Reinkes edema got the least response but the changes were still clinically significant.

RECOMMENDATION

As a result of the findings of this research, it is suggested that structured voice therapy be considered the primary treatment for patients suffering from benign laryngeal lesions, especially vocal nodules. Prompt voice therapy referral could lessen symptoms, enhance the patient's quality of life through better voice, and even reduce the necessity for surgery. To provide more robust evidence for these interventions and to clarify protocols that are specific to different lesions, it is suggested that future research be carried out with a larger number of participants, a longer duration of follow, up, and the use of objective voice parameters.

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Anthropometric Estimation of Stature, Morphological Face Height, and Maximum Facial Breadth, and Determination of Craniofacial Morphometric Types among Adult Rakhain Females in Bangladesh

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ABSTRACT

Background: Accurate craniofacial anthropometry is crucial for forensic identification, surgical planning, and anthropological studies. However, normative craniofacial data for the Rakhain ethnic minority in Bangladesh are lacking. The study aimed to estimate stature, morphological face height, and maximum facial breadth from craniofacial measurements and to determine craniofacial morphometric types among adult Rakhain females. **Methods & Materials**: A cross-sectional study was conducted among 100 adult Rakhain females aged 25–45 years in Cox's Bazar, Bangladesh. Seventeen craniofacial parameters and stature were measured. Multiplication factors were derived, and craniofacial indices were calculated. Pearson's correlation and Bland-Altman agreement analyses were performed. **Results**: The mean stature was 158.17 ± 3.87 cm. Morphological face height showed a weak but significant correlation with stature (r = 0.224, p = 0.025). Mandible height and nasal height were moderately associated with facial height. Head circumference and biocular width significantly predicted facial breadth, while maximum cranial breadth and nasal width were not significant predictors. Multiplication factors provided highly accurate stature and face height estimates, with minor underestimation noted for facial breadth. The population was predominantly mesocephalic (56.6%) and mesorrhine (72.38 ± 7.54), with a wide-jaw facial morphology in 71.9% of cases. **Conclusion**: The study establishes important baseline anthropometric data for adult Rakhain females, demonstrating the need for ethnic-specific standards in forensic and clinical practice in Bangladesh.

Keywords: *Anthropometry, Rakhain Ethnicity, Stature Estimation, Craniofacial Indices, Forensic Identification*

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INTRODUCTION

Reliable craniofacial estimation stands as a fundamental pillar in forensic anthropology, bioarchaeology, maxillofacial surgery planning, and disaster victim identification. When biological remains are fragmented or degraded, anthropometric markers, especially craniofacial features, persist as durable identifiers, serving critical forensic and medical purposes [1,2]. Globally, mass disasters continue to produce thousands of unidentified victims annually, necessitating accurate, durable biometric frameworks. Facial and cranial structures, due to their high postmortem resilience, have been prioritized by INTERPOL protocols for disaster victim identification [3]. In this context, craniofacial anthropometry is indispensable not only for reconstructive identification but also for enabling personalized prosthesis and surgical interventions after traumatic incidents. Despite these needs, significant regional data gaps persist. Bangladesh, with a population exceeding 165 million and comprising over 160 recognized ethnic subgroups, has developed anthropometric reference standards for less than 10% of its ethnic minorities. Prior studies have largely focused on Bengali males or select tribal groups like the Garo and Chakma females, with Rakhain females remaining virtually unexamined [4,5]. No published dataset to date has systematically derived multiplication factors or craniofacial morphometric type distributions specific to the Rakhain population. This absence of ethnic-specific biometric databases undermines the effectiveness of forensic identification and surgical planning for minority populations in Bangladesh, directly clashing with global calls under Sustainable Development Goal 3 (SDG-3) for equitable health standards. Stature estimation from craniofacial dimensions is rooted in the premise that stature, morphological face height, and maximum facial breadth are high-heritability, low-environmental-noise traits [6]. These traits stabilize early during skeletal maturation and remain relatively resistant to postnatal environmental modifications, making them reliable predictors in both regression-based and multiplication-factor anthropometric models. Moreover, the craniofacial variables selected-such as maximum cranial length, nasal height, and mandibular breadth-are based on their early ossification timing and their palpability even under suboptimal field conditions [7]. These measurements are not only straightforward to collect but also crucial in resource-limited forensic scenarios where imaging or sophisticated technologies may not be available. Beyond simple linear dimensions, craniofacial indices such as the cephalic index, facial index, nasal index, auricular index, biocular width index, and zygomandibular index offer integrated, scale-free measures that condense complex three-dimensional craniofacial shapes into manageable two-dimensional ratios [8]. These indices are highly valuable in anthropometric and forensic research because they facilitate standardized inter-population comparisons without being confounded by absolute body size. However, regional findings across South Asia have shown inconsistent correlations between craniofacial measurements and stature. Studies from India, Pakistan, and Thailand have reported stature versus facial height correlation coefficients ranging widely from 0.30 to 0.60 [9]. This methodological heterogeneity-arising from differences in age groups, sexes, instruments, and measurement protocols-

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complicates direct extrapolation of these findings to Bangladeshi ethnic minorities. Compounding the issue, many regional studies have relied solely on correlation coefficients without validating predictive models through Bland-Altman agreement analyses or residual diagnostics, risking overestimation of model performance [10,11]. Accurate craniofacial datasets are not only pivotal for forensic sciences but are increasingly recognized as critical to clinical applications. In sleep medicine and orthodontic practice, individualized cephalometric profiles have demonstrated utility in the prediction and management of obstructive sleep apnea [12]. Moreover, preoperative cephalometric traits such as mandibular retrognathism and increased lower facial height have been shown to predict the surgical response to multilevel sleep apnea surgeries [13]. Establishing normative craniofacial values thus supports a wide spectrum of healthcare-from forensic identification to corrective jaw surgeries and sleep-apnea management-especially in previously unprofiled minority populations. Given this background, the present study aims to establish multiplication factors for predicting stature, morphological face height, and maximum facial breadth from 17 craniofacial measurements among adult Rakhain females in Bangladesh. Additionally, the study seeks to classify predominant craniofacial morphometric types within this ethnic cohort based on six key anthropometric indices. In addressing these objectives, this research not only fills a significant ethnic and methodological gap but also contributes to the broader forensic and clinical capacities necessary for achieving equitable healthcare and disaster response preparedness in Bangladesh.

METHODS & MATERIALS

This cross-sectional study with analytical components was conducted among adult Rakhain females residing in Chawfaldondi village and the Sadar Upazila of Cox's Bazar District in the Chittagong Division of Bangladesh. Data collection was carried out between March 2018 and February 2019, and data analysis was conducted at the Department of Anatomy, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh. The study recruited 100 adult Rakhain females between 25 and 45 years of age to ensure completion of skeletal ossification and to avoid postmenopausal height changes, based on known biological standards of epiphyseal fusion and aging effects. Inclusion criteria were Bangladeshi residency, Rakhain ethnicity, female sex, and age within the specified range. Participants were excluded if they had a history of mixed ethnicity within three generations, congenital craniofacial anomalies, craniofacial trauma, prior orthodontic or reconstructive surgery, malocclusion, significant endocrine or neurological disorders, or current pregnancy. Institutional Review Board (IRB) approval from BSMMU was obtained prior to data collection. Written informed consent was secured from all participants after explaining the study in Bangla; thumb impressions were collected for illiterate participants. Data were collected through direct face-to-face interviews and physical anthropometric measurements, documented on structured data sheets. Convenience sampling was employed, relying on community support and voluntary participation. Participant recruitment and cooperation were facilitated through local Rakhain leaders and community volunteers. The physical measurements included stature and seventeen craniofacial parameters, following standardized anthropometric protocols. Instruments used were a spreading caliper for curved surface distances, a digital sliding caliper for shorter linear measurements, a flexible measuring tape for head circumference, a measuring steel plate, and a measuring steel tape for stature assessment. Landmark identification was performed using a black eye pencil after careful palpation. All measurements were performed between 9 AM and 4 PM to minimize diurnal variation. Each variable was measured twice, and the average was used for analysis, with 2 mm systematically deducted from spreading caliper readings to account for instrument error. Stature was measured as the vertical distance from the vertex of the head to the floor, with participants standing barefoot against a wall in the Frankfurt horizontal plane. Craniofacial measurements included maximum cranial length, maximum cranial breadth, morphological face height, maximum facial breadth, mandible height, mandible breadth, nasal height, nasal width, mouth width, intercanthal width, biocular width, head circumference, and various facial depth measures (upper, middle, and lower third). Measurements were obtained following anatomical landmarks and internationally accepted definitions. Multiplication factors were calculated by dividing the measured stature, morphological face height, or maximum facial breadth by the corresponding craniofacial measurement. Mean multiplication factors (MMF) were subsequently derived. These factors enabled estimation of stature, facial height, and facial breadth from the selected craniofacial variables. Craniofacial indices-cephalic index, facial index, nasal index, auricular index, biocular-face width index, and zygomandibular index-were also calculated using standard formulas to determine morphometric types. Statistical analysis was conducted using SPSS version 22. Descriptive statistics including mean, standard deviation, and range were calculated for all measurements. Data normality was tested using the Shapiro-Wilk test. Pearson's correlation coefficients were computed to evaluate the strength of association between stature and craniofacial measurements, as well as between morphological face height or maximum facial breadth and relevant craniofacial dimensions. To assess the agreement between estimated and measured values, Bland-Altman plots were constructed. Differences between measured and estimated values were plotted against their mean, with 95% of the differences expected to fall within ±2 standard deviations of the mean difference. A significance level of $p < 0.05$ was considered statistically significant.

RESULTS

Table I summarizes the descriptive statistics of stature and selected craniofacial measurements among adult Rakhain females. The mean stature was found to be 158.17 ± 3.87 cm, with a range between 149.10 cm and 168.10 cm. Among craniofacial measurements, the maximum cranial length averaged 18.16 ± 0.85 cm, while the maximum cranial breadth had a mean of 15.16 ± 0.56 cm. Morphological face height and maximum facial breadth showed mean values of 10.67 ± 0.55 cm and 13.28 ± 1.03 cm, respectively. The mandible measurements revealed a mean mandible height of 3.84 ± 0.33 cm and a mandible breadth of 10.78 ± 0.35 cm. Nasal height and nasal width were recorded at means of 4.93 ± 0.38 cm and 3.55 ± 0.24 cm, respectively. Other facial dimensions such as left upper face depth, left maxillary depth, and left mandibular depth showed mean values of 10.08 ± 0.56 cm, 11.45 ± 0.58 cm, and 14.09 ± 0.58 cm, respectively. Measurements related to mouth and ear dimensions, including mouth width (4.61 ± 0.38 cm), left ear length (6.26 ± 0.45 cm), and left ear width (3.06 ± 0.28 cm), were also reported. Additionally, intercanthal width and biocular width demonstrated means of 3.42 ± 0.33 cm and 9.39 ± 0.58 cm, respectively. The mean head circumference among the participants was measured at 55.76 ± 1.28 cm.

Table I
Descriptive statistics (range, mean, standard deviation) for stature and selected craniofacial measurements among adult Rakhain females (n = 100).

Measurement	Range (cm)	Mean ± SD (cm)
Stature	149.10–168.10	158.17 ± 3.87
Maximum cranial length (g–op)	16.20–20.00	18.16 ± 0.85
Maximum cranial breadth (eu–eu)	14.00–16.50	15.16 ± 0.56
Morphological face height (n–gn)	9.38–12.00	10.67 ± 0.55
Maximum facial breadth (zy–zy)	11.00–16.00	13.28 ± 1.03
Mandible height (sto–gn)	2.97–4.55	3.84 ± 0.33
Mandible breadth (go–go)	10.00–11.50	10.78 ± 0.35
Nasal height (n–sn)	4.00–5.89	4.93 ± 0.38
Nasal width (al–al)	2.91–4.13	3.55 ± 0.24
Left upper face depth (n–t)	9.00–11.50	10.08 ± 0.56
Left maxillary depth (sn–t)	10.00–13.00	11.45 ± 0.58
Left mandibular depth (gn–t)	13.00–15.50	14.09 ± 0.58
Mouth width (ch–ch)	3.83–5.55	4.61 ± 0.38
Left ear length (sa–sba)	5.09–7.39	6.26 ± 0.45
Left ear width (pra–pa)	2.32–3.77	3.06 ± 0.28
Intercanthal width (en–en)	2.69–4.27	3.42 ± 0.33
Biocular width (ex–ex)	8.53–10.30	9.39 ± 0.58
Head circumference (on–op)	50.00–57.00	55.76 ± 1.28

Table II presents the correlation coefficients and significance levels for the associations between selected craniofacial measurements and stature, morphological face height, and maximum facial breadth among adult Rakhain females. Morphological face height showed a weak but statistically significant positive correlation with stature (r = 0.224, p = 0.025), while maximum cranial length, maximum cranial breadth, and other measurements demonstrated non-significant associations with stature. Morphological face height itself correlated significantly with mandible height (r = 0.509, p < 0.001), nasal height (r = 0.474, p < 0.001), and left ear length (r = 0.221, p = 0.028), whereas maximum cranial length and head circumference did not show significant correlations. In relation to maximum facial breadth, significant positive correlations were observed with biocular width (r = 0.217, p = 0.031) and head circumference (r = 0.302, p = 0.002), indicating that individuals with wider biocular distances and larger head circumferences tended to have broader facial widths. No significant correlations were noted between maximum facial breadth and other measurements such as maximum cranial breadth, nasal width, or mouth width.

Table II
Pearson correlation coefficients (r) and p-values for the association between each craniofacial variable and (i) stature, (ii) morphological face height, and (iii) maximum facial breadth in adult Rakhain females (n = 100).

Cranio-facial measurement	Stature r (p)	Morphological face height r (p)	Maximum facial breadth r (p)
Maximum cranial length (g-op)	+0.110 (0.276)	+0.148 (0.137)	—
Maximum cranial breadth (eu-eu)	+2.982 (0.768)	—	–0.077 (0.436)
Morphological face height (n-gn)	+0.224 (**0.025**)	—	—
Maximum facial breadth (zy-zy)	–1.756 (0.862)	—	—
Mandible height (sto-gn)	+2.327 (0.818)	+0.509 (<**0.001**)	—
Mandible breadth (go-go)	–0.032 (0.729)	—	+0.071 (0.484)
Nasal height (n-sn)	+0.122 (0.220)	+0.474 (<**0.001**)	—
Nasal width (al-al)	–0.055 (0.568)	—	–0.100 (0.325)
Left upper-face depth (n-t)	+0.045 (0.699)	—	—
Left maxillary depth (sn-t)	+1.035 (0.919)	—	—
Left mandibular depth (gn-t)	+0.110 (0.278)	—	—
Mouth width (ch-ch)	–0.045 (0.664)	—	–0.161 (0.108)
Left ear length (sa-sba)	–0.055 (0.602)	+0.221 (**0.028**)	—
Left ear width (pra-pa)	–1.221 (0.904)	—	–1.077 (0.915)
Inter-canthal width (en-en)	+0.995 (0.982)	—	+0.188 (0.233)
Bi-ocular width (ex-ex)	+0.167 (0.095)	—	+0.217 (**0.031**)
Head circumference (on-op)	+0.045 (0.663)	+0.161 (0.109)	+0.302 (**0.002**)

Table III presents the mean multiplication factors (MMF) and the corresponding mean estimated values for stature, morphological face height, and maximum facial breadth based on selected craniofacial measurements. In part (a), related to stature estimation, multiplication factors ranged from 2.93 ± 0.11 for head circumference to 52.16 ± 5.06 for left ear width. The estimated mean statures derived from various craniofacial measurements closely approximated the measured mean stature of 158.17 ± 3.87 cm, with estimated values ranging from 158.31 cm to 159.60 cm. In part (b), focused on morphological face height estimation, estimated means from source measurements such as maximum cranial length, nasal height, mandible height, left ear length, and head circumference were very close to the measured mean of 10.67 ± 0.55 cm, with estimated values between 10.67 cm and 10.72 cm. Similarly, part (c) illustrates the estimation of maximum facial breadth, where the estimated mean values obtained from measurements like maximum cranial breadth, intercanthal width, biocular width,

nasal width, mouth width, mandible breadth, left ear width, and head circumference ranged from 11.97 cm to 12.11 cm, compared to the measured mean of 13.28 ± 1.03 cm.

Table III
Mean multiplication factors (MMF ± SD) and mean estimated versus measured values for (a) stature, (b) morphological face height, and (c) maximum facial breadth.

a. Estimation of stature (measured mean = 158.17 ± 3.87 cm)		
Source measurement	**MMF ± SD**	**Estimated mean ± SD (cm)**
Maximum cranial length	8.73 ± 0.44	158.50 ± 7.46
Maximum cranial breadth	10.47 ± 0.46	158.38 ± 5.86
Morphological face height	14.86 ± 0.78	158.54 ± 8.18
Maximum facial breadth	11.98 ± 0.97	159.11 ± 12.32
Mandible height	41.50 ± 3.77	159.32 ± 13.54
Mandible breadth	14.67 ± 0.61	158.33 ± 5.17
Nasal height	32.26 ± 2.46	159.03 ± 12.16
Nasal width	44.81 ± 3.36	158.92 ± 10.84
Left upper-face depth	15.74 ± 0.93	158.63 ± 8.80
Left maxillary depth	13.85 ± 0.77	158.57 ± 8.01
Left mandibular depth	11.24 ± 0.51	158.41 ± 6.52
Mouth width	34.56 ± 3.02	159.24 ± 13.05
Left ear length	25.38 ± 1.99	158.99 ± 11.34
Left ear width	52.16 ± 5.06	159.50 ± 14.49
Inter-canthal width	46.62 ± 4.61	159.60 ± 15.18
Bi-ocular width	16.88 ± 0.79	158.44 ± 6.93
Head circumference	2.93 ± 0.11	158.31 ± 4.60
(b) Estimation of morphological face height (measured mean = 10.67 ± 0.55 cm)		
Source measurement	**MMF ± SD**	**Estimated mean ± SD (cm)**
Maximum cranial length	0.59 ± 0.04	10.69 ± 0.50
Nasal height	2.17 ± 0.15	10.71 ± 0.82
Mandible height	2.79 ± 0.21	10.72 ± 0.91
Left ear length	1.71 ± 0.14	10.71 ± 0.76
Head circumference	0.20 ± 0.01	10.67 ± 0.31
(c) Estimation of maximum facial breadth (measured mean = 13.28 ± 1.03 cm)		
Source measurement	**MMF ± SD**	**Estimated mean ± SD (cm)**
Maximum cranial breadth	0.79 ± 0.03	12.01 ± 0.44
Inter-canthal width	3.54 ± 0.34	12.01 ± 0.53
Bi-ocular width	1.28 ± 0.06	12.11 ± 1.15
Nasal width	3.40 ± 0.24	12.06 ± 0.82
Mouth width	2.62 ± 0.22	12.06 ± 0.99
Mandible breadth	1.11 ± 0.04	12.00 ± 0.39
Left ear width	3.96 ± 0.37	12.10 ± 1.10
Head circumference	0.22 ± 0.01	11.97 ± 0.35

Table IV presents the descriptive statistics for six craniofacial indices measured among adult Rakhain females. The cephalic index ranged from 72.54 to 85.49, with a mean value of 78.55 ± 2.90, indicating a predominant mesocephalic head type in the population. The facial index varied widely between 64.69 and 101.00, with a mean of 80.84 ± 7.54, reflecting considerable diversity in facial height relative to width. The biocular-face width index ranged from 57.61 to 84.82, with a mean value of 71.06 ± 5.66, while the auricular index, measuring ear proportions, demonstrated a mean of 48.10 ± 5.06 within a range of 37.66 to 61.82. The nasal index, reflecting nasal width relative to height, showed a broad range from 51.14 to 90.51 and a mean of 72.38 ± 7.54, suggesting a predominance of mesorrhine nasal morphology. Finally, the zygomandibular index, describing the proportion of jaw width, had a mean value of 81.67 ± 6.62, with values ranging from 64.52 to 99.09.

Table IV
Descriptive statistics of craniofacial indices among adult Rakhain females (*n* = 100).

Index	**Range**	**Mean ± SD**
Cephalic index	72.54–85.49	78.55 ± 2.90
Facial index	64.69–101.00	80.84 ± 7.54
Biocular-face width index	57.61–84.82	71.06 ± 5.66
Auricular index	37.66–61.82	48.10 ± 5.06
Nasal index	51.14–90.51	72.38 ± 7.54
Zygomandibular index	64.52–99.09	81.67 ± 6.62

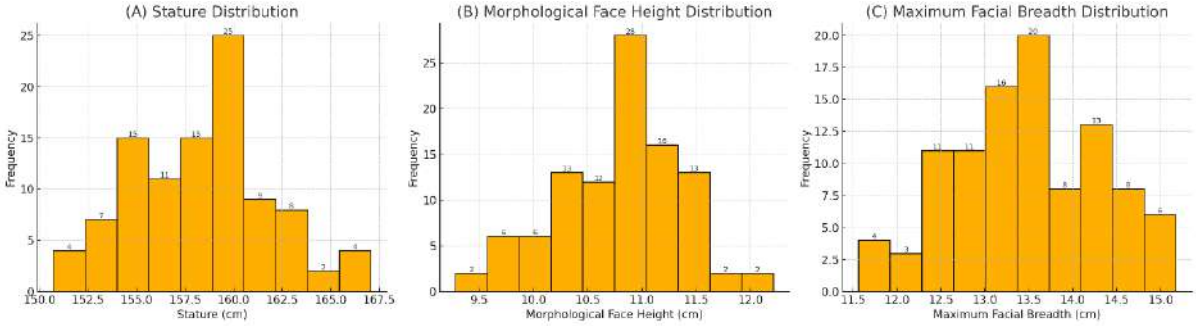

Figure 1 Frequency Distributions of Key Measurements among Adult Rakhain Females (*n*=100).

The frequency distributions of stature, morphological face height, and maximum facial breadth among adult Rakhain females were presented in *Figure 1*. The majority of participants had a stature ranging between 153 cm and 163 cm, reflecting a concentration around the mean of 158.17 ± 3.87 cm. Similarly, morphological face height exhibited a distribution predominantly between 10.0 cm and 11.5 cm, consistent with the mean value of 10.67 ± 0.55 cm. Maximum facial breadth showed a slightly wider dispersion, with most values clustering between 12.0 cm and 14.0 cm, aligning with the mean of 13.28 ± 1.03 cm.

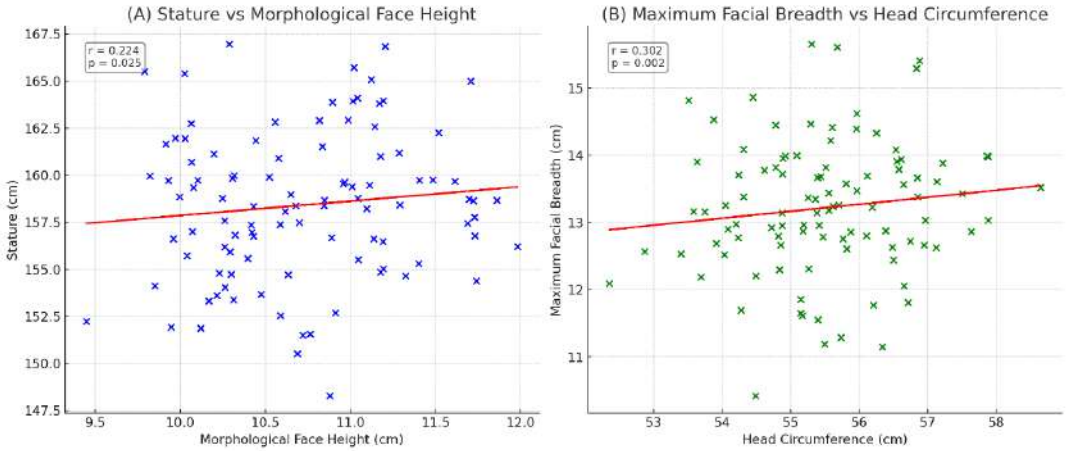

Figure 2 Significant Correlations between Key Craniofacial Measurements (*n*=100).

Figure 2 illustrates the significant correlations observed between selected craniofacial measurements and key anthropometric outcomes. A weak but statistically significant positive correlation (r = 0.224, p = 0.025) was observed between morphological face height and stature, indicating that individuals with greater facial height tended to have higher stature measurements. In addition, a moderate and statistically significant positive correlation (r = 0.302, p = 0.002) was noted between head circumference and maximum facial breadth, suggesting that broader facial widths were associated with larger head circumferences.

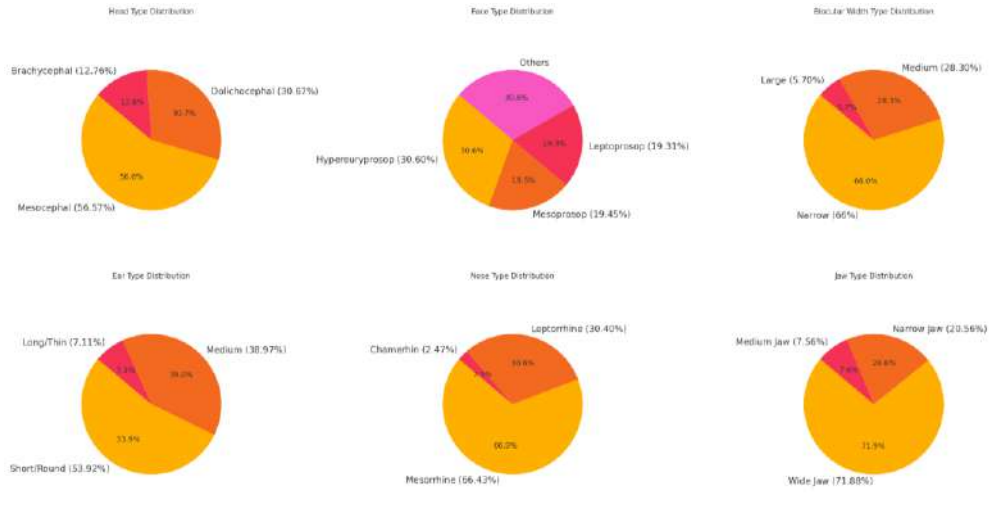

Figure 3 Distribution of Craniofacial Morphometric Types among Adult Rakhain Females (*n*=100).

The distribution of craniofacial morphometric types among adult Rakhain females is depicted in Figure 3 through a series of pie charts. The most common head type was mesocephal, comprising 56.57% of the sample, followed by dolichocephal (30.67%) and brachycephal (12.76%). In terms of facial morphology, hypereuryprosop (broad face) was the predominant type (30.60%), with mesoprosop (19.45%) and leptoprosop (19.31%) types also represented. A majority (66%) exhibited narrow biocular width, whereas medium and large types accounted for 28.30% and 5.70%, respectively. Regarding ear morphology, short or round ears were most common (53.92%), followed by medium-sized (38.97%) and long, thin ears (7.11%). Nasal morphology was predominantly mesorrhine (66.43%), with a notable presence of leptorrhine types (30.40%). Finally, jaw morphology analysis revealed that wide jaws were overwhelmingly predominant (71.88%), suggesting a characteristic craniofacial trait within this ethnic population (*Figure 3*).

DISCUSSION

This study offers a crucial contribution to craniofacial anthropometry by generating normative data for adult Rakhain females, an ethnically distinct yet understudied group in Bangladesh. The observed mean stature of 158.17 ± 3.87 cm among the participants falls between the slightly taller values reported for Bengali females and lower ranges seen in indigenous groups such as the Garo females of Bangladesh (152.79 ± 5.62 cm) [4]. The mean maximum cranial length (18.16 ± 0.85 cm) and breadth (15.16 ± 0.56 cm) displayed tight clustering, suggesting strong developmental stability, consistent with findings among Gujarati females, who similarly showed limited variability in cranial dimensions [14]. Meanwhile, morphological face height (10.67 ± 0.55 cm) and maximum facial breadth (13.28 ± 1.03 cm) exhibited greater dispersion, an expected feature observed in both South Indian and Bangladeshi indigenous groups, underscoring the variable nature of midfacial vertical and horizontal proportions even within genetically homogeneous groups [4,15]. Regarding associations with stature, morphological face height demonstrated a statistically significant but weak positive correlation ($r = 0.224$, $p = 0.025$), whereas cranial length and breadth were not significantly related. This finding supports earlier studies among North Indian populations, where facial height parameters were more predictive of stature than cranial dimensions, and aligns with the Bangladeshi Garo study where maximum facial breadth had minimal predictive value [16,17]. Notably, the non-significance of maximum cranial breadth resonates with other observations in stature prediction models that caution against assuming direct skull-to-body size proportionality across populations [18]. The determinants of morphological face height further reinforced the functional significance of lower-face structures: mandible height ($r = 0.509$) and nasal height ($r = 0.474$) emerged as moderately strong predictors. Additionally, the minor but significant role of left ear length mirrors patterns in other anthropometric surveys where auricular dimensions modestly contributed to facial proportionality assessments [19]. In contrast, the determinants of maximum facial breadth revealed head circumference ($r = 0.302$) and biocular width ($r = 0.217$) as significant contributors, while canonical surrogates like maximum cranial breadth and nasal width remained non-significant. These finding parallels evidence from large anthropometric surveys in China, where facial width was more tightly linked to biocular distance than to overall skull width, and supports Nigerian data demonstrating facial breadth scaling better with head circumference than isolated cranial measurements [7,20]. The multiplication-factor based estimates for stature and facial dimensions exhibited strong performance. For stature, estimates from 17 craniofacial variables deviated by less than ±1.4 cm from the measured mean, echoing similar levels of accuracy observed in Bangladeshi Garo females and Nigerian studies using foot-based multiplication factors [4,21]. Morphological face height estimations were nearly perfect, deviating only between 10.67 cm and 10.72 cm across predictors, demonstrating high robustness. However, maximum facial breadth consistently showed underestimation (~1–1.3 cm lower than measured values), a trend also noted in foot and craniofacial multiplication studies where breadth-related variables exhibited systematic bias [22]. In terms of multiplication factor magnitudes, the current findings showed a wide range for stature estimation (2.93 to 52.16), driven by the relative size of the source variable. Lower magnitude and low standard deviation (≤0.21) factors for facial height and breadth confirm previous observations that ratios involving smaller linear dimensions offer greater stability and reliability [4,22]. Craniofacial indices further illustrated the distinctive profile of Rakhain females. A mean cephalic index of 78.55 ± 2.90 classified the group as predominantly mesocephalic, closely matching findings from Gujarati females (77.20) and Latvian populations showing mesocephaly as a common trait [8,14]. The nasal index (72.38 ± 7.54) aligned with a mesorrhine nasal type, comparable to patterns reported among South Indian and North-East Asian groups (15,20). The relatively wide variability of facial and zygomandibular indices underscores internal diversity, consistent with observations that facial height-to-width ratios are among the most fluctuating metrics in both Indian and European populations [8,14]. Finally, morphometric-type distribution analysis provided additional anthropological insights. Head shapes were predominantly mesocephal (56.6%), with a substantial dolichocephal (30.7%) subgroup, closely paralleling the Gujarati population distributions [14]. Facial morphology favored hypereuryprosopic (30.6%) types, again aligning with Indian and South-East Asian reports. Furthermore, a narrow biocular width (66%) and wide-jaw (zygomandibular) morphology (71.9%) were defining features of the Rakhain craniofacial profile, resonating with observations from East Asian mandibular studies where broad lower facial structures were typical [23]. Overall, the present study not only establishes valuable ethnic-specific biometric standards for the Rakhain community but also highlights the complex interplay of craniofacial structures with stature and facial dimensions. It emphasizes the necessity of population-specific models for forensic, surgical, and anthropometric applications, avoiding the pitfalls of indiscriminate application of foreign-derived standards.

LIMITATIONS

The study was limited by its modest sample size, restricted geographic coverage within Cox's Bazar, and manual measurement techniques, which, despite standardization, may introduce minor operator-dependent errors. Additionally, the exclusion of individuals with mixed ancestry may slightly limit the generalizability of findings to the entire Rakhain population.

CONCLUSION

This study provides the first comprehensive anthropometric profile of adult Rakhain females in Bangladesh, focusing on stature, craniofacial measurements, and morphometric types. The findings confirm that morphological face height is a significant, though weak, predictor of stature, while mandible height, nasal height, head circumference, and biocular width are key determinants of facial dimensions. The multiplication-factor method demonstrated excellent agreement for stature and face height estimation, though minor systematic underestimations were observed for facial breadth, highlighting the need for population-specific calibration. Craniofacial indices classified the majority as mesocephalic and mesorrhine, with a predominant hypereuryprosopic facial shape and wide-jaw configuration. These results underscore the necessity of

establishing ethnic-specific biometric databases to improve forensic identification, surgical planning, and anthropological research in Bangladesh.

RECOMMENDATION

Future studies should aim to expand the sample size across different age groups and regions to verify the representativeness of these findings among broader Rakhain and related populations. Incorporating three-dimensional imaging and automated measurement systems could enhance the precision and reproducibility of craniofacial data. Moreover, longitudinal studies exploring age-related craniofacial changes and their impact on stature prediction models are recommended. Finally, establishing normative databases for other indigenous Bangladeshi groups will further strengthen the national forensic and medical anthropometric frameworks.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

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Angiographic Profile and Lesion Complexity in NSTEMI – Insights from a Comparative Analysis of Revascularization Strategies

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ABSTRACT

Introduction: Non–ST-elevation myocardial infarction (NSTEMI) is a common presentation of acute coronary syndrome and is frequently associated with multivessel coronary artery disease (MVD), which increases the risk of adverse cardiovascular outcomes. **Methods & Materials:** This cohort study was conducted at the Department of Cardiology, Ibrahim Cardiac Hospital & Research Institute, over a 19-month period from December 01, 2022, to June 30, 2024. Data were analyzed using Statistical Package for Social Sciences (SPSS) version 25.0. **Result:** The two patient groups were comparable in age, gender, and BMI, with chest pain being the predominant symptom and similar hemodynamic parameters observed ($p > 0.05$). Killip Class III heart failure was significantly more frequent in the Culprit-only PCI group ($p = 0.020$). Both groups showed minimal left main artery involvement, while significant LAD and LCx lesions were comparable. The Complete PCI group had a higher prevalence of RCA lesions (33% vs. 23.4%, $p = 0.046$). Angiographically, three-vessel disease and thrombus burden were significantly greater in the Culprit-only PCI group (TVD: 34.3% vs. 23.5%, $p = 0.025$; thrombus: $p = 0.005$). **Conclusion:** In patients with NSTEMI and multivessel coronary artery disease, the choice of revascularization strategy is primarily influenced by the extent and complexity of coronary lesions rather than patient demographics. Complete PCI was more frequently undertaken in those with less severe disease and lower thrombus burden, whereas culprit-only PCI was favored for patients with more complex anatomy and higher clinical risk.

Keywords: *Angiographic Profile, Lesion Complexity, Revascularization Strategies, NSTEMI*

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INTRODUCTION

Non-ST-elevation myocardial infarction (NSTEMI) accounts for a substantial percentage of acute coronary syndromes (ACS) and is commonly seen in conjunction with multivessel coronary artery disease (MVD). In comparison to patients with single-vessel coronary artery disease, NSTEMI patients with MVD have a propensity for recurrent ischemic events, heart failure, and late mortality [1]. NSTEMI patients have a typical underlying angiography showing diffuse atherosclerosis, complex lesions, and varying severity of coronary artery obstruction, thus making the selection of revascularization approaches more complex and challenging to manage. Lesion complexity identified on coronary angiography plays a critically important role in defining the efficacy of percutaneous coronary interventions (PCI). In order to predict the complexity of coronary anatomy, the SYNTAX score and its variants have been developed, incorporating the complexity of the lesion in terms of location, morphology, bifurcation, calcification, and chronic total occlusion [2]. Higher SYNTAX scores have been consistently found to be predictive of adverse cardiac events and outcomes after PCI in patients with ACS, thereby underlining the importance of comprehensive assessment on coronary angiograms for risk stratification in these patients [3]. A therapeutic dilemma is posed for patients with NSTEMI and MVD regarding the extent of revascularization as a therapeutic approach for these patients. Culprit vessel-only revascularization has classically been preferred for these patients due to a larger contrast volume requirement and a longer procedural time and a possible risk of complications with more extensive invasive approaches. However, this may be a contributing cause for future events and ischemia as a result of incompletely revascularized lesions in these patients with NSTEMI and MVD [4,5]. On the other hand, the focus on complete revascularization, or the treatment of all significant coronary lesions, has gained more attention as a potentially more favorable approach. Although there is good randomized data in the STEMI population to support the success of complete revascularization, the evidence in the NSTEMI population remains relatively scarce [6]. However, several studies in the NSTEMI group have found lower event rates for all-cause mortality, myocardial infarction, and repeat revascularization with the complete revascularization group as compared to the culprit PCI group [7]. The complexity of the lesions affects the ease and potential benefit of full revascularization. Angiographic complexity, like long lesions, bifurcation lesions, severe calcifications, and chronic occlusions, makes procedures challenging and possibly increases procedural risk, especially among patients with a high Syntax score [8]. Residual Syntax score, which is an index of the lesion complexity left after PCI, has been recognized as an independent predictor of outcomes, and this underlines the importance not only of MVD, but also the level of complexity, in determining prognosis [9]. This study aimed to compare the angiographic profile and lesion complexity of NSTEMI patients

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undergoing complete versus culprit-only PCI.

METHODS & MATERIALS

The cohort study, was carried out in the Department of Cardiology, Ibrahim Cardiac Hospital & Research Institute, for a period of 19 months starting from 01 December 2022 to 30th June 2024. A total of 354 consecutive patients admitted with their initial episode of Non-STEMI and confirmed to have multivessel disease through angiography were selected through informed consent and ethical clearance obtained from the Ethical Review Committee of the Institute. The patients were divided into two groups depending on revascularization techniques. In Group I, 179 patients underwent complete revascularization in a single sitting through PCI, while in Group II, 175 patients with only culprit vessels underwent PCI. The inclusion criteria included patients who are above 18 years old regardless of sex with initial Non-STEMI. Patients with cardiogenic shock, myocardial infarction, previous PCI or coronary artery bypass, SYNTAX score>32, valvular heart disease, or systemic illnesses such as collagen vascular disease, amyloid, or malignancies would be excluded. The study would be conducted using a semi-structured predesigned questionnaire. The analysis would be done using the Software for Statistical Package for the Social Sciences version 25.0. The continuous variables would be represented using the average and standard deviation, while the categorical variables would be shown using the frequency, using the Students t-test, and Chi-square test, respectively. The p-value would be set at 0.05.

RESULTS

The age distribution was similar in the two patient populations, with an average age of approximately 58 years (p = 0.665). Gender distribution was comparable, showing a male predominance in both groups (p = 0.991), and there were no differences in BMI data as well p = 0.451 (*Table I*).

Table I
Comparison of demographic characteristics between the study groups.

Demographic characteristics	Group		p-value
	Complete PCI (n = 179)	Culprit Only PCI (n = 175)	
Age (years)	58.5 ± 10.4	57.9 ± 10.9	0.665[#]
Sex			
Male	138(77.1)	135(77.1)	0.991[*]
Female	41(22.9)	40(22.9)	
BMI (kg/m^2)			
Underweight (<18.5)	2 (1.1)	3 (1.7)	0.451[*]
Normal weight (18.5-24.9)	75 (41.9)	87 (49.7)	
Overweight (25-29.9)	77 (43.0)	63 (36.6)	
Obese (30-39.9)	25 (14.0)	22 (12.6)	

Figures in the parentheses indicate corresponding %; [*]Chi-squared Test □^{2}) was done to analyze the data. [#]Data were analyzed using an Unpaired t-Test and were presented as mean ± SD.

Chest pain was a common complaint among patients in both groups (p = 0.894). The prevalence of shortness of breath was marginally lower in the Complete PCI cohort compared to the Culprit-only PCI cohort (p = 0.091). The mean duration from the onset of MI was 1.3 days for both groups (p = 0.555). There were no significant differences in pulse and both systolic and diastolic blood pressures among the hemodynamic variables between both groups (p = 0.099, p = 0.661, and p = 0.733, respectively). Of note, the incidence of Killip Class III heart failure was significantly higher in the Culprit-only PCI arm compared to the Complete PCI arm p = 0.020 (*Table II*).

Table II
Comparison of clinical characteristics between the study groups.

Clinical variables	Group		p-value
	Complete PCI (n = 179)	Culprit-only PCI (n = 175)	
History & presenting symptoms			
Chest pain	179(100.0)	174(99.4)	0.894[**]
Shortness of breath	71(39.7)	85(48.6)	0.091[*]
Duration of NSTEMI (days)	1.3 ± 0.45	1.3 ± 0.47	0.555[#]
Pulse (bpm)	79.4 ± 19.2	76.4 ±14.5	0.099[#]
Systolic (mmHg)	127.9 ±20.8	126.9 ±20.4	0.661[#]
Diastolic (mmHg)	77.6 ± 10.3	77.3 ±10.1	0.733[#]
Killip Class on admission			
Class I	96(53.6)	95(54.3)	0.020[*]
Class II	79(44.1)	64(36.6)	
Class III	4(2.2)	16(9.1)	

Figures in the parentheses indicate corresponding %; [*]Chi-squared Test □^{2}) was done to analyze the data. [#]Data were analyzed using an Unpaired t-Test and were presented as mean ± SD.

Both cohorts showed a substantial freedom from lesions within the left main artery. About 18% of patients in the Complete PCI group and 21.7% of patients in the Culprit-only PCI group showed significant lesions within the left anterior descending (LAD) artery (p = 0.365). More than one-quarter of patients in both cohorts showed significant lesions within the left circumflex (LCx) (p = 0.810). But the Complete PCI group showed a significantly higher percentage of significant lesions within the right coronary artery (RCA) (33%) than those in the Culprit-only PCI group (23.4%) p = 0.046 (*Table III*).

Table III
Comparison of lesion characteristics between the study groups.

Percentage of lesions*	Group		p-value
	Complete PCI (n = 179)	Culprit-only PCI (n = 175)	
LM			
Significant	0(0.0)	(0.0)	Not computable
Insignificant	179(100.0)	175(100.0)	
LAD			
Significant	32(17.9)	38(21.7)	0.365
Insignificant	147(82.1)	137(78.3)	
LCx			
Significant	47(26.3)	44(25.1)	0.810
Insignificant	132(73.7)	131(74.9)	
RCA			
Significant	59(33.0)	41 (23.4)	0.046
Insignificant	120(67.0)	134 (76.6)	

*Figures in the parentheses indicate corresponding %; *Chi-squared Test^2) was done to analyze the data.*

Analysis of the angiographic information showed that there were significantly more patients with three-vessel disease (TVD) within the Culprit-only PCI group (34.3%) compared with the Complete PCI group (23.5%) (p = 0.025). Furthermore, the thrombus burden was also greater within the Culprit-only group p = 0.005 (*Table IV*).

Table IV
Comparison of angiographic comments between the study groups.

Angiographic findings	Group		p-value
	Complete PCI (n = 179)	Culprit-only PCI (n = 175)	
Number of vessels involved			
DVD	137(76.5)	115(65.7)	0.025*
TVD	42(23.5)	60(34.3)	
Thrombus burden	56(31.3)	80(45.7)	0.005*

*Figures in the parentheses indicate corresponding %; *Chi-square Test^2) was done to analyze data.*

DISCUSSION

In this cohort study involving NSTEMI patients with multivessel disease who underwent either complete or culprit-only PCI, the distribution of their demographic characteristics is well balanced at baseline between the two groups. The mean age was similarly distributed in the complete PCI (58.5 ± 10.4 years) and culprit-only PCI groups (57.9 ± 10.9 years), without any statistically significant difference. There was male predominance in both groups, amounting to 77.1%, which reflects the already identifiable pattern in the epidemiological studies of coronary artery disease among South Asian populations. This has been reported by Bangalore et al., citing a mean age of approximately 60 years, with over 70% male representation among the patients undergoing multivessel PCI for NSTEMI [5]. Likewise, the ACUITY trial substudy demonstrated no significant age or sex differences between revascularization strategies in NSTEMI, supporting the demographic comparability observed in our study [10]. Body mass index categories were also evenly distributed between groups, consistent with findings from contemporary registries showing a high prevalence of overweight and obesity among ACS patients in South Asia and other regions [11]. Clinical presentation and hemodynamic parameters were largely similar between groups. Nearly all patients presented with chest pain, and the duration of NSTEMI before intervention did not differ significantly. However, one thing that stood out was the marked difference in the Killip class at admission. Killip class III was seen to be higher in the culprit-only PCI group (9.1%) compared to the complete PCI group (2.2%), indicating instability among patients undergoing culprit-only PCI. This is consistent with what was observed by the SWEDEHEART registry study, where Killip class had been found to be higher among patients preferring aggressive strategies for NSTEMI because of the risks associated with process [12]. This was further observed by Shishehbor et al., where patients with initial signs of cardiac failure are often not subjected to complete revascularization procedures but instead undergo culprit-only PCI procedures because of risks associated with procedure [13]. Angiographic lesion patterns were different among both groups. Significant RCA lesion patterns were higher among the complete PCI group (33.0%) compared to the culprit-only group where it stood at 23.4%, involving statistical significance. No significant differences were observed for LAD or LCx involvement. Palmerini et al. reported that non-LAD lesions, particularly RCA disease, are more frequently addressed during complete revascularization strategies, as they are often technically less complex and associated with lower procedural risk [3]. The absence of significant left main disease in both groups reflects appropriate patient selection and is consistent with guideline-directed exclusion of high SYNTAX score anatomy from PCI-based strategies [14]. Regarding overall angiographic burden, double-vessel disease was significantly more prevalent in the complete PCI group (76.5%), whereas triple-vessel disease was more common in the culprit-only PCI group (34.3%). Additionally, thrombus burden was significantly higher in the culprit-only PCI group (45.7% vs. 31.3%). These findings suggest that patients with more extensive disease and higher thrombus load were preferentially treated with culprit-only PCI. Similar trends were reported by Bainey et al., who demonstrated that NSTEMI patients with higher anatomical complexity and thrombus burden were less likely to undergo complete revascularization during index hospitalization [15]. Furthermore, Généreux et al. showed that higher residual disease burden and thrombotic complexity influenced revascularization completeness and were independently associated with adverse outcomes [16].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

In NSTEMI patients with multivessel disease, the revascularization strategy is largely determined by angiographic severity and lesion complexity rather than demographic factors. Complete PCI was more commonly performed in patients with less extensive disease and lower thrombus burden, while culprit-only PCI was preferred in those with greater anatomical complexity and clinical instability.

RECOMMENDATION

Revascularization strategy in NSTEMI patients with multivessel disease should be individualized based on comprehensive angiographic assessment, including lesion complexity, thrombus burden, and extent of vessel involvement. Complete PCI may be considered in clinically stable patients with lower anatomical complexity, while culprit-only PCI should be reserved for those with higher lesion complexity or clinical instability.

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Association of Serum Apolipoprotein B-Apolipoprotein A-I Ratio with Renal Function Decline in Patients with Chronic Kidney Disease

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ABSTRACT

Background: Dyslipidemia is common in chronic kidney disease (CKD) and contributes to accelerated atherosclerosis and disease progression. The serum apolipoprotein B/apolipoprotein A-I (ApoB/ApoA-I) ratio is an established marker of atherogenic risk; however, its role in predicting renal function decline in CKD patients remains inadequately explored, particularly in South Asian populations. **Objective:** To evaluate the association between serum ApoB/ApoA-I ratio and renal function decline in patients with chronic kidney disease. **Methods & Materials:** This prospective cohort study was conducted at IOJH Hospital, Dhaka, Bangladesh, from January 2023 to December 2024. A total of 80 CKD patients were enrolled using purposive sampling. Renal function decline was defined as a ≥25% reduction in eGFR or progression to a higher CKD stage during follow-up. Data were analyzed using SPSS version 23.0. **Results:** The mean age of participants was 52.6 ± 11.4 years, with a male predominance (62.5%). The mean ApoB/ApoA-I ratio was significantly higher in patients who experienced renal function decline compared to those who did not ($p<0.001$). The ApoB/ApoA-I ratio showed a significant negative correlation with eGFR ($p<0.001$). After adjustment for age, sex, diabetes, hypertension, and baseline eGFR, a higher ApoB/ApoA-I ratio remained an independent predictor of renal function decline ($p=0.002$). **Conclusion:** An elevated serum ApoB/ApoA-I ratio is independently associated with accelerated renal function decline in CKD patients. This ratio may serve as a simple and useful biomarker for risk stratification and early intervention in chronic kidney disease.

Keywords: *Apolipoprotein A-I, Apolipoprotein B, Chronic kidney disease, Dyslipidemia, eGFR, Renal function decline.*

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INTRODUCTION

Chronic kidney disease (CKD) is a growing global public health problem, affecting approximately 10–13% of the adult population worldwide and contributing substantially to morbidity, mortality, and healthcare costs [1,2]. The burden of CKD is particularly pronounced in low- and middle-income countries, including Bangladesh, due to the rising prevalence of diabetes mellitus, hypertension, population aging, and limited access to early diagnostic and preventive care [3]. Progressive decline in renal function ultimately leads to end-stage kidney disease (ESKD), which is associated with poor quality of life and increased cardiovascular mortality [4]. Cardiovascular disease (CVD) remains the leading cause of death among patients with CKD, exceeding the risk of progression to ESKD in many cases [5]. Traditional cardiovascular risk factors alone cannot fully explain the markedly increased cardiovascular burden observed in CKD patients. Consequently, non-traditional risk factors, such as chronic inflammation, oxidative stress, endothelial dysfunction, and abnormalities in lipid metabolism, have gained increasing attention [6]. Dyslipidemia in CKD is characterized by qualitative and quantitative alterations in lipoproteins rather than simple elevations in total cholesterol levels. Typical lipid abnormalities include elevated triglycerides, increased levels of small dense low-density lipoprotein (LDL) particles, and reduced high-density lipoprotein (HDL) functionality [7]. Apolipoproteins, the protein components of lipoproteins, provide a more accurate representation of atherogenic and anti-atherogenic lipid particles. Apolipoprotein B (ApoB) reflects the total number of atherogenic lipoproteins, including LDL and very-low-density lipoprotein, whereas apolipoprotein A-I (ApoA-I) is the main structural protein of HDL and plays a protective role through reverse cholesterol transport [8]. The ApoB/ApoA-I ratio has emerged as a robust marker of cardiovascular risk, outperforming traditional lipid parameters in predicting atherosclerotic events in both the general population and high-risk groups [9]. This ratio reflects the balance between atherogenic and anti-atherogenic forces and has been shown to correlate with endothelial dysfunction, inflammation, and plaque burden [10]. In recent years, interest has grown in exploring the role of the ApoB/ApoA-I ratio beyond cardiovascular outcomes, particularly its association with renal disease progression. Emerging evidence suggests that dyslipidemia may directly contribute to renal injury through mechanisms such as lipid accumulation in glomerular and tubular cells, promotion of oxidative stress, and activation of pro-inflammatory pathways [11]. Several observational studies have reported associations between adverse lipid profiles and accelerated decline in estimated glomerular filtration rate (eGFR) in CKD patients [12]. However, data focusing specifically on apolipoprotein-based markers, especially the ApoB/ApoA-I ratio, remain limited and inconsistent, with most studies conducted in Western or East Asian populations. In Bangladesh, research on apolipoprotein profiles in CKD patients is scarce, and the prognostic significance of the ApoB/ApoA-I ratio for renal function decline has not been well established. Given ethnic differences in lipid metabolism, cardiovascular risk, and CKD progression, locally generated evidence is essential [13]. Identifying simple, cost-effective biomarkers that can predict renal function deterioration may facilitate early risk stratification and targeted interventions. Therefore, this prospective cohort study was

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designed to evaluate the association between the serum ApoB/ApoA-I ratio and renal function decline in patients with chronic kidney disease attending a tertiary care hospital in Bangladesh.

METHODS & MATERIALS

This prospective cohort study was conducted at IOJH Hospital, Dhaka, Bangladesh, from January 2023 to December 2024. A total of 80 patients diagnosed with chronic kidney disease (CKD) were enrolled using purposive sampling. CKD was defined according to the kidney disease: Improving Global Outcomes (KDIGO) guidelines as evidence of kidney damage or reduced estimated glomerular filtration rate (eGFR <60 mL/min/1.73 m²) persisting for at least three months. Patients were recruited from both outpatient and inpatient nephrology services.

Inclusion criteria: Adult patients aged ≥18 years with established CKD stages 2–5, who provided informed written consent, were included in the study. Participants were required to have a stable clinical status at enrollment and available baseline laboratory investigations, including serum apolipoprotein B and apolipoprotein A-I levels.

Exclusion criteria: Patients with acute kidney injury, nephrotic syndrome, active infection, chronic liver disease, malignancy, pregnancy, or a history of renal transplantation were excluded. Individuals receiving lipid-lowering therapy within the preceding three months were also excluded to avoid confounding effects on apolipoprotein levels.

Study procedure: Baseline demographic data, clinical history, and comorbid conditions were recorded using a structured questionnaire. Blood samples were collected after an overnight fast for biochemical analysis. Serum ApoB and ApoA-I levels were measured using standardized immunoassay methods, and the ApoB/ApoA-I ratio was calculated. Renal function was assessed by serum creatinine and eGFR at baseline and during follow-up.

Data analysis: Data were analyzed using SPSS version 23.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. Associations between the ApoB/ApoA-I ratio and renal function decline were assessed using correlation analysis and multivariate regression, with statistical significance set at $p < 0.05$.

RESULT

A total of 80 patients with chronic kidney disease were included in the final analysis. The mean age of the study population was 52.6 ± 11.4 years, with most patients belonging to the 41–60-year age group (45.0%). Male participants constituted 62.5% of the cohort. Hypertension (70.0%) and diabetes mellitus (55.0%) were the most common comorbidities. At baseline, a majority of patients were in CKD stage 3 (42.5%), followed by stage 4 (31.2%), stage 2 (15.0%), and stage 5 (11.3%) *Table I.*

Table I
Baseline demographic and clinical characteristics of the study population (*n*=80)

Variables	n/Mean	%/SD
Age (years)	52.6	±11.4
Male sex	50	62.5%
Hypertension	56	70.0%
Diabetes mellitus	44	55.0%
CKD stage 2	12	15.0%
CKD stage 3	34	42.5%
CKD stage 4	25	31.2%
CKD stage 5	9	11.3%

The baseline biochemical profile showed a mean serum creatinine level of 2.18 ± 0.86 mg/dL and a mean eGFR of 41.3 ± 16.7 mL/min/1.73 m². The mean serum ApoB and ApoA-I levels were 98.4 ± 21.6 mg/dL and 112.7 ± 24.1 mg/dL, respectively, resulting in a mean ApoB/ApoA-I ratio of 0.87 ± 0.19. Higher ApoB/ApoA-I ratios were observed in patients with advanced CKD stages (*Table II*).

Table II
Baseline biochemical parameters of the study population.

Parameters	Mean	SD
Serum creatinine (mg/dL)	2.18	0.86
eGFR (mL/min/1.73 m²)	41.3	16.7
ApoB (mg/dL)	98.4	21.6
ApoA-I (mg/dL)	112.7	24.1
ApoB/ApoA-I ratio	0.87	0.19

During the follow-up period, renal function decline was documented in 38 (47.5%) patients, defined as a ≥25% reduction in eGFR or progression to a higher CKD stage. Patients with renal function decline had a significantly higher mean ApoB/ApoA-I ratio compared to those without decline (0.96 ± 0.18 vs. 0.78 ± 0.16; $p < 0.001$) (*Table III*).

Table III
Comparison of the ApoB/ApoA-I ratio between patients with and without renal function decline.

Renal function status	ApoB/ApoA-I ratio (Mean ± SD)	p-value
Decline present (n=38)	0.96 ± 0.18	<0.001
No decline (n=42)	0.78 ± 0.16	

Data analysis test: Independent samples t-test

A greater proportion of patients with elevated ApoB/ApoA-I ratios (≥0.90) experienced renal deterioration (68.4%) compared to those with lower ratios (28.6%) *Table IV*.

Table IV
Distribution of renal function decline according to ApoB/ApoA-I ratio category.

ApoB/ApoA-I ratio	Renal decline	
	Present	**Absent**
<0.90 (n = 42)	12 (28.6%)	30 (71.4%)
≥0.90 (n = 38)	26 (68.4%)	12 (31.6%)

p-value: 0.001, Data analysis test: Chi-square test.

Correlation analysis demonstrated a significant negative relationship between the ApoB/ApoA-I ratio and baseline eGFR ($r = -0.42$, $p < 0.001$), indicating that a higher atherogenic burden was associated with poorer renal function. The ratio also showed a modest but significant association with annual eGFR decline ($r = -0.36$, $p = 0.002$) *Table V*.

Table V
Correlation of ApoB/ApoA-I ratio with renal function parameters.

Variables	Correlation coefficient (r)	p-value
Baseline eGFR	−0.42	<0.001
Annual eGFR decline	−0.36	0.002

Data analysis test: Pearson correlation.

Multivariate logistic regression analysis revealed that an elevated ApoB/ApoA-I ratio was an independent predictor of renal function decline after adjustment for age, sex, diabetes mellitus, hypertension, and baseline eGFR (adjusted OR = 2.74; 95% CI: 1.32–5.68; p = 0.007). Diabetes mellitus and lower baseline eGFR were also significantly associated with renal deterioration, whereas age and sex did not show independent significance (*Table VI*).

Table VI
Multivariate logistic regression analysis for predictors of renal function decline.

Variables	Adjusted OR (95% CI)	p-value
ApoB/ApoA-I ratio (high)	2.74 (1.32–5.68)	0.007
Diabetes mellitus	2.11 (1.01–4.42)	0.047
Hypertension	1.38 (0.64–2.98)	0.409
Baseline eGFR (low)	3.26 (1.54–6.91)	0.002

Data analysis test: Multivariate logistic regression.

DISCUSSION

This prospective cohort study demonstrated a significant association between an elevated serum apolipoprotein B/apolipoprotein A-I (ApoB/ApoA-I) ratio and accelerated renal function decline in patients with chronic kidney disease (CKD). Nearly half of the study participants experienced deterioration of renal function during follow-up, and those patients had significantly higher ApoB/ApoA-I ratios compared to individuals with stable kidney function. These findings support the growing evidence that atherogenic dyslipidemia plays an important role not only in cardiovascular morbidity but also in the progression of CKD. The observed negative correlation between the ApoB/ApoA-I ratio and baseline eGFR indicates that patients with poorer renal function tend to have a more atherogenic lipid profile. This observation is consistent with earlier studies reporting progressive lipid abnormalities with advancing CKD stages [14,15]. Reduced activity of lipoprotein lipase, impaired HDL maturation, and increased oxidative modification of lipoproteins in CKD may explain the elevation of ApoB-containing particles and reduction in ApoA-I levels [16]. Our findings align with previous studies that highlighted the superiority of apolipoprotein-based indices over traditional lipid parameters in predicting adverse outcomes. The ApoB/ApoA-I ratio reflects the balance between atherogenic and anti-atherogenic lipoproteins and is a strong predictor of cardiovascular events and mortality [17,18]. Emerging data suggest that similar mechanisms may contribute to renal damage. Lipid accumulation in mesangial and tubular epithelial cells promotes inflammation, fibrosis, and glomerulosclerosis, thereby accelerating renal function decline [19]. The significantly higher proportion of renal deterioration among patients with an ApoB/ApoA-I ratio ≥0.90 in the present study underscores the potential clinical utility of this marker for risk stratification. Similar associations have been reported in cohort studies from Japan and Europe, where higher ApoB/ApoA-I ratios were linked to faster eGFR decline and increased incidence of end-stage kidney disease [20,21]. However, evidence from South Asian populations has been limited. Given ethnic differences in lipid metabolism and cardiovascular risk profiles, our findings provide important region-specific data. Multivariate analysis confirmed that a high ApoB/ApoA-I ratio was an independent predictor of renal function decline even after adjustment for age, sex, diabetes mellitus, hypertension, and baseline eGFR. Diabetes mellitus and lower baseline eGFR were also significant predictors, which is consistent with established literature identifying these factors as key determinants of CKD progression [22]. The lack of independent association of age and sex in the adjusted model suggests that metabolic factors may have a stronger influence on short-term renal outcomes in this cohort. The pathophysiological link between dyslipidemia and CKD progression is multifactorial. Atherogenic lipoproteins can induce endothelial dysfunction, reduce

nitric oxide bioavailability, and activate pro-inflammatory cytokines, leading to microvascular injury within the kidney [23]. In contrast, ApoA-I and functional HDL exert anti-inflammatory and antioxidant effects that may protect against renal injury. Therefore, an elevated ApoB/ApoA-I ratio may reflect an imbalance that favors renal damage. From a clinical perspective, measuring the ApoB/ApoA-I ratio is relatively simple and may offer incremental prognostic value over conventional lipid profiles, particularly in CKD patients whose standard lipid levels may appear deceptively normal [24]. Early identification of high-risk individuals could enable intensified lifestyle modifications and pharmacological interventions aimed at optimizing lipids and protecting the kidneys. Nevertheless, this study has some limitations. The sample size was modest, and the follow-up duration was relatively short, which may limit the generalizability of the findings. Additionally, inflammatory markers and direct measures of HDL functionality were not assessed. Despite these limitations, the prospective design and adjustment for major confounders strengthen the validity of the results. In conclusion, the present study provides evidence that an elevated ApoB/ApoA-I ratio is independently associated with renal function decline in CKD patients. Incorporating apolipoprotein-based markers into routine assessments may improve risk stratification and guide preventive strategies in chronic kidney disease, particularly in resource-limited settings such as Bangladesh [25].

LIMITATIONS

This study was limited by its relatively small sample size and single-center design, which may restrict generalizability. The follow-up duration was short, and inflammatory biomarkers and HDL functionality were not assessed, which may have limited the mechanistic interpretation of the findings.

CONCLUSION

This prospective cohort study demonstrates that an elevated serum apolipoprotein B/apolipoprotein A-I ratio is independently associated with accelerated renal function decline in patients with chronic kidney disease. The ApoB/ApoA-I ratio may serve as a simple and effective biomarker for early risk stratification. Incorporating apolipoprotein-based assessment into routine clinical evaluation could support timely preventive and therapeutic strategies in CKD management.

RECOMMENDATION

Routine assessment of the ApoB/ApoA-I ratio should be considered in patients with chronic kidney disease for early risk stratification. Larger, multicenter studies with longer follow-up and interventional evaluation of lipid-modifying strategies are recommended to confirm clinical utility.

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Gestational Diabetes Mellitus and Fetomaternal Outcomes in a Tertiary Hospital – Risk-Stratified Obstetric and Neonatal Complications, and Predictors of NICU Admission

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is associated with severe maternal and newborn problems, which contribute significantly to perinatal morbidity. Understanding fetomaternal outcomes in certain healthcare settings is critical for developing effective management strategies. **Methods & Materials:** This prospective observational study was conducted at Popular Medical College, Dhaka, Bangladesh, between July 2022 and June 2023 including 120 pregnant women with GDM who gave birth at a tertiary care hospital. Data were entered and analyzed using SPSS version 26, including descriptive statistics, chi-square tests, and logistic regression, which were used to identify factors linked with poor newborn outcomes. **Results:** The average maternal age was 29.8 ± 4.6 years, and 61.7% were multigravida. Treatment options included diet alone (43.3%) or diet plus insulin (56.7%). Maternal problems included pregnancy-induced hypertension (21.7%), preeclampsia (15%), and polyhydramnios (18.3%). The cesarean section rate was 53.3%. Neonatal problems included macrosomia (23.3%), hypoglycemia (21.7%), respiratory distress syndrome (15%), and NICU hospitalization (28.3%). Insulin-treated individuals had significantly higher rates of cesarean birth (73.5% vs 26.9%, p=0.001), macrosomia (32.4 vs 11.5%, p=0.006), and NICU hospitalization (38.2% vs 15.4%, p=0.005). Independent predictors of NICU admission included maternal age ≥35 years (OR=1.92), BMI ≥30 kg/m² (OR=2.38), insulin administration (OR=2.76), poor glycemic control (OR=3.12), and premature delivery (OR=2.54). **Conclusion:** GDM is associated with high maternal and newborn morbidity, especially in women who require insulin therapy. Advanced maternal age, obesity, and poor glycemic control all predict poor newborn outcomes, highlighting the importance of careful monitoring and tertiary-level care for high-risk GDM pregnancies.

Keywords: *Gestational diabetes mellitus, Fetal-maternal outcomes, Neonatal complications, Macrosomia.*

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INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most frequent metabolic disorders observed during pregnancy, with a worldwide prevalence of about 14% of pregnancies, and rates differing dramatically among different populations according to varying definitions [1]. GDM is a condition associated with glucose intolerance that is observed for the first-time during pregnancy as a result of relative insulin secretory dysfunction against the background of the enhanced metabolic demands of the pregnant state [2]. The worldwide prevalence of GDM has gradually increased over the last two decades, along with the rise in the proportion of obese and type 2 diabetes mellitus cases among the population at large [3]. The pathophysiology that affects GDM has been explained by complex modifications in insulin resistance, impaired β-cell function, and placental hormonal effects that lead to anomalies in glucose regulation [4]. With pregnancy, there has been an influence of hormonal changes, which involves an excess of human placental lactogen, progesterone, cortisol, and tumor necrosis factor-alpha, thereby leading to an increase in insulin resistance, mainly in the second and third trimesters of pregnancy [5]. Also, patients have not managed an insulin response that counteracts insulin resistance, thereby leading to hyperglycemia and eventually GDM. The maternal and infant consequences of GDM remain important and well-clarified in recent obstetric literature. These maternal complications include pregnancies with hypertension, preeclampsia, polyhydramnios, urinary tract infections, and Caesarean section deliveries [6]. The intrauterine hyperglycemic conditions result in elevated glucose exposure to the fetus, which presents with hyperinsulinemia as a result of insulin resistance, culminating in intrauterine metabolic disorders of macrosomia, trauma, neonatal hypoglycemia, respiratory distress syndrome, and hyperbilirubinemia [7]. Additionally, mothers as well as children exposed to GDM exhibit lifetime risks of chronic metabolic complications, including gestational diabetes mellitus, type 2 diabetes, and cardiovascular diseases [8]. The different managerial approaches for GDM include medical nutrition therapy, diet and lifestyle changes, self-blood sugar monitoring, and pharmacotherapy when these changes do not lead to blood sugar control by dietary means alone [9]. As yet, insulin therapy has remained the mainstay for pharmacologic control, although there has been an increasing trend for its use in some centers with the aid of oral hypoglycemics [10]. Despite advances in screening and care algorithms, what has and continues to be an unanswered question regarding GDM involves how best to avoid adverse outcomes for mother and fetus. Understanding the spectrum and frequency of obstetric and neonatal complications related to GDM in a particular health setting is an essential step in the creation of interventions and the quality of perinatal care [11]. This study aimed to assess the fetomaternal outcome in women with GDM and the effects of various treatment strategies, and determine the predictors of poor outcomes in the newborn in a tertiary care setting.

METHODS & MATERIALS

This prospective observational study was carried out at Popular Medical College, Dhaka, Bangladesh, between July 2022 and June 2023, including 120 pregnant women diagnosed with gestational diabetes mellitus. The inclusion criteria included pregnant women diagnosed with GDM according to the criteria of the International Association of Diabetes and Pregnancy Study Groups by means of the 75g oral

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glucose tolerance test, having a singleton pregnancy, being between 24 and 28 weeks pregnant at the time of diagnosis, having received antenatal care and being a patient of the study institution at the time of delivery, and voluntarily seeking informed consent. The exclusion criteria were pre-existing cases of diabetes mellitus types 1 and 2 diagnosed before pregnancy, multiple pregnancies including twins or other multiples, pregnancies with pre-existing congenital anecdotes identified by ultrasound scan among the fetuses, cases among women with other important medical conditions that would independently influence some pregnancy outcome provisions including hypertension and other cases of renal diseases and cases with other immune conditions like autoimmune diseases, cases with pregnancies complicated by cases of placenta preva and cases of abruptio placentae. Demographic details, obstetric details, family details regarding diabetes, and anthropometric details were collected. The patients were treated as per the hospital protocol with Medical Nutrition Therapy or with Medical Nutrition Therapy along with Insulin Therapy as per glycemic parameters. Obstetric parameters regarding maternal complications during the antenatal period, type of delivery, as well as post-delivery complications were collected. Newborn parameters such as Birth Weight, Apgar Score, and the requirement for admission to the Neonatal Intensive Care Unit were collected. Data analysis was carried out using the SPSS software version 26. Chi-Square test, along with Logistic Regression analysis, was employed for the identification of risk factors associated with adverse maternal as well as fetal outcomes with a significance level of 0.05.

RESULTS

Table I shows a mean maternal age of 29.8±4.6 years, with 60% of these women falling within the 25 -34 years age range. Participants were multigravid in 61.7% of cases. On average, GDM was diagnosed at 26.9 ± 3.4 weeks. The average BMI was 27.6±3.1 kg/m², showing overweight. Family history of diabetes was positive in 40% of the cases. Treatment modalities used were comparable, with 43.3% managed on diet alone while 56.7% needed additional insulin, thus indicating variable degrees of glycemic dysregulation.

Table I
Socio-demographic and Baseline Clinical Characteristics of Mothers with GDM (*n* = 120).

Variable	Category	n (%) / Mean ± SD
Age (years)	Mean ± SD	29.8 ± 4.6
	<25 years	24 (20)
	25-34 years	72 (60)
	≥35 years	24 (20)
Parity	Primigravida	46 (38.3)
	Multigravida	74 (61.7)
Gestational age at diagnosis (weeks)	Mean ± SD	26.9 ± 3.4
BMI (kg/m²)	Mean ± SD	27.6 ± 3.1
Family history of diabetes	Yes	48 (40)
	No	72 (60)
Treatment modality	Diet only	52 (43.3)
	Diet + insulin	68 (56.7)

As indicated in *Table II*, antenatal and intrapartum complications were common among study participants. Pregnancy-induced hypertension was found in 21.7%, with the onset of preeclampsia in 15%. Polyhydramnios, because of fetal hyperglycemia-induced osmotic diuresis, was found in 18.3%. Preterm labor occurred in 16.7% of cases. Recurrent urinary tract infections, because of glycosuria-induced susceptibility, were found in 11.7%. Intrapartum conditions were shoulder dystocia in 5%, and post-partum hemorrhage in 8.3%.

Table II
Antenatal and Intrapartum Maternal Complications (*n* = 120).

Complication	n (%)
Pregnancy-induced hypertension	26 (21.7)
Preeclampsia	18 (15)
Polyhydramnios	22 (18.3)
Recurrent urinary tract infection	14 (11.7)
Preterm labor (<37 weeks)	20 (16.7)
Shoulder dystocia	6 (5.0)
Postpartum hemorrhage	10 (8.3)

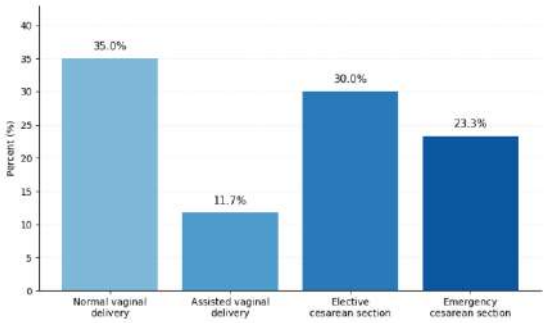

Figure 1 Mode of Delivery Among Mothers with GDM.

Figure 1 illustrates that only 35% achieved normal vaginal delivery, while 11.7% required assisted vaginal delivery. There was, however, a very high rate of delivery via cesarean section: 53.3% in total; 30% being elective and 23.3% being emergency, which is well in excess of the national averages.

Table III unveiled the existence of morbidity, as the average weight of the newborns was 3.42±0.56kg. Macrosomia occurred in 23.3% of newborns, while the incidence of low birth weight was 11.7%, indicating variable glycemic control. Hypoglycemia in newborns occurred in 21.7%, directly due to hyperinsulinemia. Respiratory distress syndrome occurred in 15%, due to the deferred maturation process of the lungs. NICU admission was necessary in 28.3% of newborns. Hyperbilirubinemia developed in 18.3% of the study population, while perinatal mortality was seen in 3.3%.

Table III
Neonatal Outcomes and Complications (*n* = 120).

Neonatal outcome	n (%) / Mean ± SD
Birth weight (kg), Mean ± SD	3.42 ± 0.56
Macrosomia (≥4.0 kg)	28 (23.3)
Low birth weight (<2.5 kg)	14 (11.7)
Neonatal hypoglycemia	26 (21.7)
Respiratory distress syndrome	18 (15)
NICU admission	34 (28.3)
Hyperbilirubinemia	22 (18.3)
Perinatal mortality	4 (3.3)

Table IV showed that poor outcomes were even more significant in insulin-treated patients. The rate of caesareans in the insulin group was spectacularly high compared to the control group (73.5% vs 26.9%, p = 0.001). The prevalence of preeclampsia, macrosomia, incidents of infant hypoglycemia, and NICU admissions in insulin-treated cases was notably high compared to the control group, pointing towards severe disease, and not treatment-induced side effects, as these were preeclampsia (20.6% vs 7.7%), macrosomia (32.4% vs 11.5%), neonatal hypoglycemia (29.4% vs 11.5%), and NICU admission (38.2% vs 15.4%).

Table IV
Comparison of Fetomaternal Outcomes by Treatment Modality (Diet vs Insulin).

Outcome	Diet only (n=52)	Diet + Insulin (n=68)	p-value
Cesarean delivery	14 (26.9)	50 (73.5)	0.001
Preeclampsia	4 (7.7)	14 (20.6)	0.048
Macrosomia	6 (11.5)	22 (32.4)	0.006
Neonatal hypoglycemia	6 (11.5)	20 (29.4)	0.014
NICU admission	8 (15.4)	26 (38.2)	0.005

Table V demonstrated five independent predictors for NICU admission. Older maternal age of 35+ years (OR=1.92, p =0.046) and BMI of 30+ kg/m² (OR=2.38, p =0.009) stood as mother-related predictors. Insulin-induced GDM (OR=2.76, p =0.002) and uncontrolled diabetes (OR=3.12, p<0.001) were distinctly linked with unfavorable outcomes in the infant. Preterm birth remained an independent predictor (OR= 2.54, p =0.007).

Table V
Logistic Regression Analysis of Factors Associated with Adverse Neonatal Outcome (NICU Admission).

Predictor	Adjusted OR	95% CI	p-value
Maternal age ≥35 years	1.92	1.01-3.65	0.046
BMI ≥30 kg/m²	2.38	1.24-4.58	0.009
Insulin-treated GDM	2.76	1.45-5.24	0.002
Poor glycemic control	3.12	1.62-6.02	<0.001
Preterm delivery	2.54	1.28-5.01	0.007

DISCUSSION

This study demonstrates significant maternal and newborn morbidity, emphasizing the clinical importance of this frequent pregnancy condition. The sociodemographic distribution in our study, with a median maternal age of 29.8 years and 20% of women aged ≥ 35 years, confirms the association reported by Kalra et al. between high maternal age and the risk for GDM [12]. The high prevalence of multigravida (61.7%) and median BMI at 27.6 kg/m² confirms the association between parity, obesity, and the risk for GDM [13]. The high frequency (40%) of positive family history emphasizes the genetic predisposition to problems with glucose metabolism, as the risk for GDM was found to be much higher in the presence of diabetes in first-degree family members [14]. Our studies revealed a high incidence of pregnancy-induced hypertension (21.7%) and preeclampsia (15%), which is expected as there is a doubled risk of hypertensive disorders among women with GDM pregnancies relative to normoglycemic women, as reported by Bryson et al. [15]. Moreover, polyhydramnios was observed to occur in 18.3% instances that were attributed to the osmotic diuresis/polyuria associated with fetal hyperglymia as a direct result of glycemic dysregulation [16]. The high rate of cesarean sections, at 53.3%,

stands out as much higher compared to the recommended rate by the WHO that does not exceed 15% because "fears" related to shoulder dystocia because of macrosomia, cephalopelvic disproportion, the inability to reassure the patient regarding the fetal condition, and the inadequacy of previous induction attempts have all contributed to the rate [17]. Shang et al. support the high rate of cesarean sections that range from 40-60% within the population with GDM in tertiary centers [18]. Neonatal complications are also common in this study. The incidence of 23.3% for macrosomia is consistent with that of 15-30% described by Catalano et al. among pregnancies with GDM due to fetal hyperinsulinemia-induced excessive fetal growth [19]. The incidence of 21.7% among neonates with hypoglycemia can be anticipated due to the abrupt loss of glucose delivery at birth despite persisting fetal hyperinsulinemia [20]. The 28.3% incidence of NICU admissions signifies the magnitude of resources needed that are devoted to neonates with GDM. The comparison of the treatment modalities showed a poorer outcome in those requiring insulin, which might be a result of the severity of the disease. Women requiring insulin showed inadequate glycemic control despite diet alone, which shows that the women have more disturbances in the metabolic functions [21]. The result from the logistic regression analysis shows glycemic control as the predictor for the outcome (OR=3.12, p-value<0.001). The recognition of maternal obesity (BMI ≥ 30 kg/m²) as an independent risk factor for adverse newborn outcomes (OR=2.38) highlights the cumulation of various metabolic abnormalities [22]. Insulin resistance, inflammation, and adipokine abnormalities contributed by maternal obesity cumulatively add adverse impacts during pregnancy, aside from GDM. Conversely, increased maternal age (≥ 35 years) was again an independent predictor for NICU admission, contributed by the aging placenta with higher complication risks [23]. These observations make significant contributions to the diagnosis and diversions of attention for women with GDM. Those with co-existing risk factors of obesity, older age, insulin use, and uncontrolled glycemic levels should receive intensive care monitoring and should give birth within institutions capable of managing neonatal complications.

LIMITATIONS

This single-center study with a limited sample size may not represent the broader GDM population across diverse healthcare settings and geographic regions. The lack of long-term follow-up prevented assessment of postpartum maternal glucose metabolism and childhood developmental outcomes in offspring exposed to intrauterine hyperglycemia.

CONCLUSION

This study found a considerable impact of GDM on the mother as well as the infant, as evident by the high incidence of gestational hypertension, preeclampsia, operative delivery, macrosomia, infant hypoglycemia, and NICU admissions in our tertiary center dataset. Outcomes in women requiring insulin treatment remained decidedly poorer, which is an index of the severity of dysregulation and not because of the treatment modalities used. Multivariate predictors of severe outcomes in the infant included high maternal age at delivery, maternal obesity, insulin use, high glucose levels, and prematurity. These results emphasize the paramount value of early GDM testing and the importance of tailored prenatal management to ensure the best possible fetomaternal and perinatal outcomes.

RECOMMENDATIONS

Multicenter prospective studies with larger sample sizes are needed to validate these findings and develop robust risk prediction models for adverse outcomes. Long-term follow-up studies evaluating postpartum progression to type 2 diabetes in mothers and metabolic health trajectories in offspring would provide valuable insights for preventive interventions.

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CONFLICT OF INTEREST

None declared.

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Association between Pancreatic Cancer and Diabetes Mellitus among Bangladeshi Patients – A Retrospective Study

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ABSTRACT

Background: Pancreatic cancer is a highly lethal malignancy, and an increasing body of evidence suggests a complex bidirectional relationship between pancreatic cancer and diabetes mellitus (DM). Diabetes may act both as a risk factor and as an early manifestation of pancreatic cancer. However, data from South Asian populations, particularly Bangladesh, remain limited. Aim of the study: To evaluate the association between diabetes mellitus and pancreatic cancer among Bangladeshi patients and to assess the impact of diabetes-related and clinical factors on disease characteristics and stage at presentation. **Methods & Materials:** This retrospective observational study included 150 patients with confirmed pancreatic cancer. Patients were categorized into two groups: those with diabetes mellitus (n = 57) and those without diabetes mellitus (n = 93). Socio-demographic data, clinical characteristics, tumor features, and laboratory parameters were extracted from medical records. Diabetes-related variables included type, duration, glycemic control, and treatment. Comparative analyses were performed using appropriate statistical tests. Unadjusted odds ratios were calculated to assess risk factors, and multivariable logistic regression was conducted to identify independent predictors of advanced pancreatic cancer (Stage III–IV). **Result:** The mean age was significantly higher among patients with diabetes compared to those without diabetes (66.4 ± 9.1 vs. 59.2 ± 11.3 years; $p < 0.001$). Smoking was less prevalent in the diabetic group (33.3% vs. 46.2%; $p = 0.028$), while chronic pancreatitis was more frequent (12.3% vs. 4.3%; $p = 0.031$). Tumor location, stage distribution, metastasis at diagnosis, and CA 19-9 levels did not differ significantly between groups. Among diabetic patients, 89.5% had type 2 diabetes, and 50.9% had new-onset diabetes (<3 years). Poor glycemic control (HbA1c ≥7%) was observed in 63.2%. Multivariable analysis demonstrated that diabetes mellitus was independently associated with advanced-stage pancreatic cancer (adjusted OR 1.88; 95% CI: 1.08–3.29; $p = 0.025$), along with age ≥50 years, obesity, and chronic pancreatitis. Longer duration of diabetes was significantly associated with more advanced cancer stage ($p = 0.039$). **Conclusion:** Diabetes mellitus is significantly associated with advanced pancreatic cancer among Bangladeshi patients, particularly in older individuals and those with obesity or chronic pancreatitis. New-onset and longer-duration diabetes appear to be important clinical markers in pancreatic cancer. Early evaluation of pancreatic pathology in patients with diabetes may facilitate timely diagnosis and improved outcomes.

Keywords: *Pancreatic cancer; Diabetes mellitus; New-onset diabetes; Risk factors; Bangladesh; Retrospective study*

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INTRODUCTION

Pancreatic cancer is a highly lethal malignancy characterized by aggressive progression and poor prognosis, with pancreatic ductal adenocarcinoma (PDAC) comprising the majority of cases [1]. Diabetes mellitus (DM), particularly type 2 diabetes (T2DM), is a chronic metabolic disorder marked by hyperglycemia and insulin resistance, frequently co-occurring with pancreatic neoplasia and implicated as both a risk factor and early clinical manifestation of the disease [2,3]. Globally, the incidence and mortality of pancreatic cancer have increased over recent decades, with age-standardized incidence rates approaching approximately 6 per 100,000 population in 2021. High fasting plasma glucose and other metabolic risk factors significantly contribute to the disease burden of pancreatic cancer. [4,5]. In Bangladesh, age-standardized mortality from pancreatic cancer has been estimated at approximately 1.15 per 100,000 population, based on WHO-derived national statistics, while the prevalence of diabetes mellitus in the general population is about 7.8%. [6,7]. Meta-analyses indicate a dose-response relationship between fasting blood glucose and pancreatic cancer risk, with risk increasing continuously across the spectrum from prediabetes to overt diabetes, and each increment in blood glucose associated with a higher likelihood of pancreatic cancer development [8]. Beyond glycemia, metabolic syndrome components such as obesity, dyslipidemia, and chronic inflammation further interact with glucose dysregulation to enhance pancreatic oncogenic risk [9]. The association between pancreatic cancer and diabetes mellitus is complex and bidirectional. Long-standing T2DM is associated with a ~1.5–2.0× increased risk of pancreatic cancer, likely mediated by chronic hyperinsulinemia, insulin resistance, elevated fasting glucose, and associated inflammatory pathways [2,3]. Conversely, pancreatic tumors can induce new-onset diabetes (NODM) by disrupting insulin secretion and glucose homeostasis, with 40–70% of patients exhibiting diabetes at the time of diagnosis [10, 11]. 68% of pancreatic cancer patients had diabetes compared to approximately 20–23% of non-cancer controls, emphasizing both the high prevalence of diabetes in this population and the potential mechanistic interplay between the two conditions [10]. Mechanisms linking diabetes and pancreatic carcinogenesis include insulin and insulin-like growth factor signaling promoting cell proliferation, chronic low-grade inflammation fostering DNA damage, and metabolic derangements facilitating a tumor-permissive microenvironment [5, 12]. These mechanisms highlight the bidirectional relationship between diabetes and pancreatic cancer, where diabetes may contribute to both the initiation and

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progression of pancreatic neoplasia, and pancreatic tumors can further exacerbate glycemic dysregulation [3]. Despite recognition of this association, several gaps persist. There is little evidence from Bangladesh on clinical patterns, duration of diabetes or risk stratification [6, 10]. Moreover, diagnostic delays and barriers to early detection in low-resource settings like Bangladesh may confound observed associations. Challenges include low awareness, limited access to advanced imaging or biomarker screening, and inadequate integration of metabolic and oncologic care pathways. This retrospective study aims to clarify the prevalence of diabetes mellitus in Bangladeshi pancreatic cancer patients, characterize the proportion of new-onset versus long-standing diabetes, and identify demographic and clinical factors associated with this comorbidity.

METHODS & MATERIALS

This retrospective observational study was conducted at National Gastroliver Institute & Hospital, Mohakhali, Dhaka, Bangladesh, and included patients diagnosed with pancreatic cancer between January 2023 to December 2024. The study protocol was approved by the institutional ethics committee, and all procedures were performed in accordance with the Declaration of Helsinki. A total of 150 patients with pancreatic cancer were included in the study. Patients were categorized into two groups based on the presence or absence of diabetes mellitus: pancreatic cancer with DM (n = 57) and pancreatic cancer without DM (n = 93).

Inclusion and Exclusion Criteria

Inclusion Criteria

Patients were eligible if they met all of the following criteria:

1. Histologically or radiologically confirmed pancreatic cancer.
2. Age ≥18 years at diagnosis.
3. Complete medical records available, including demographic, clinical, and laboratory data.
4. For the diabetes group: documented diagnosis of diabetes mellitus according to ADA criteria.

Exclusion Criteria

Patients were excluded if they had:

1. History of other primary malignancies or secondary pancreatic tumors.
2. Incomplete or missing medical records.
3. Chronic systemic illnesses likely to confound study outcomes (e.g., severe liver or renal disease).
4. Received neoadjuvant chemotherapy or radiotherapy prior to baseline data collection.

Data Collection Procedure

Data were collected retrospectively from the medical records of patients diagnosed with pancreatic cancer. A structured data extraction form was used to systematically record socio-demographic variables, including age, sex, residence, and smoking status, as well as clinical characteristics such as body mass index, family history of cancer, and comorbidities, including chronic pancreatitis. Tumor-related information, including location (head, body, or tail), stage at diagnosis (I–IV), presence of metastasis, and serum CA 19-9 levels, was also documented. For patients with diabetes mellitus, additional data regarding the type of diabetes, duration, and glycemic control (HbA1c), and anti-diabetic treatment were obtained. All data were carefully reviewed and cross-checked by two independent researchers to ensure accuracy and completeness, with discrepancies resolved through discussion with a senior investigator. Patient identifiers were removed to maintain confidentiality, and the finalized data were entered into a secure electronic database for statistical analysis.

Statistical Analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) and compared using Student's t-test or one-way ANOVA, as appropriate. Categorical variables were presented as frequencies and percentages and compared using the Chi-square test or Fisher's exact test. The association between risk factors and diabetes status was estimated using unadjusted odds ratios (ORs) with 95% confidence intervals (CIs). Multivariable logistic regression analysis was performed to identify independent predictors of advanced pancreatic cancer (Stage III–IV), adjusting for potential confounders including age, sex, obesity, smoking, diabetes mellitus, and chronic pancreatitis. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study protocol was approved by the Institutional Review Board of [Institution Name] (Approval No. XXX). Patient confidentiality was strictly maintained, and all data were anonymized. Due to the retrospective nature of the study, the requirement for informed consent was waived.

RESULT

Among 150 pancreatic cancer patients, 38.00% had diabetes. Most were ≥50 years (80.00%), with a higher proportion in the diabetic group (86.00% vs 76.00%, p = 0.048), and mean age was higher in diabetics (66.40 ± 9.10 vs 59.20 ± 11.30, p < 0.001). Males predominated (54.67%), urban residents comprised 58.67%, and smoking was more common in non-diabetics (46.24% vs 33.33%, p = 0.028) *Table 1*.

Table I
Socio-demographic characteristics of the study population (*n* = 150).

Variable	Pancreatic Cancer with DM (n = 57)	Pancreatic Cancer without DM (n = 93)	Total (*n* = 150)	p-value
Age (years)				
<50	8(14.04)	22(23.66)	30(20.00)	0.048
≥50	49 (85.96)	71 (76.34)	120 (80.00)	
Mean ± SD	66.4 ± 9.1	59.2 ± 11.3	62.0 ± 10.6	<0.001
Gender				
Male	31 (54.39)	51 (54.84)	82 (54.67)	0.88
Female	26 (45.61)	42 (45.16)	68 (45.33)	
Residence				
Urban	36 (63.16)	52 (55.91)	88 (58.67)	0.41
Rural	21 (36.84)	41 (44.09)	62 (41.33)	
Smoking status				
Smoker	19 (33.33)	43 (46.24)	62 (41.33)	0.028
Non-smoker	38 (66.67)	50 (53.76)	88 (58.67)	

Tumor location was predominantly in the pancreatic head (68.42% in diabetics vs 63.44% in non-diabetics, p = 0.20). Most patients presented at advanced stages (III–IV, 75.44% vs 72.04%). Metastasis at diagnosis was observed in approximately 53.00%, and mean CA 19-9 levels were comparable between groups (405.20 ± 336.40 vs 392.80 ± 324.10 U/mL, p = 0.68) *Table II*.

Table II
Clinical and tumor characteristics of pancreatic cancer patients among the study population.

Characteristic	With DM (n = 57)		Without DM (n = 93)		p-value
	n	%	n	%	
Tumor location					
Head of pancreas	39	68.42	59	63.44	0.2
Body/tail	18	31.58	34	36.56	
Cancer stage					
Stage I–II	14	24.56	26	27.96	0.69
Stage III–IV	43	75.44	67	72.04	
Metastasis at diagnosis	31	54.39	49	52.69	0.75
Mean CA 19-9 (U/mL)	405.2 ± 336.4		392.8 ± 324.1		0.68

Among 57 pancreatic cancer patients with diabetes, the majority (89.47%) had type 2 DM, and 50.88% had new-onset diabetes (<3 years). Duration of diabetes was <1 year in 31.58%, 1–5 years in 35.09%, and >5 years in 33.33%. Poor glycemic control (HbA1c ≥7%) was present in 63.16%, with 57.89% on oral hypoglycemics and 42.11% receiving insulin therapy (*Table III*).

Table III
Diabetes mellitus characteristics among pancreatic cancer patients (*n* = 57).

Variable	Frequency (n)	Percentage (%)
Type of diabetes		
Type 2 DM	51	89.47
New-onset DM (<3 years)	29	50.88
Duration of DM		
<1 year	18	31.58
1–5 years	20	35.09
>5 years	19	33.33
Poor glycemic control (HbA1c ≥7%)	36	63.16
Anti-diabetic treatment		
Oral hypoglycemic agents	33	57.89
Insulin therapy	24	42.11

Among pancreatic cancer patients, smoking was more frequent in non-diabetics (46.24% vs 33.33%, OR 0.58, p = 0.041), while obesity (BMI ≥25 kg/m²) was higher in diabetics (45.61% vs 34.41%, OR 1.60, p = 0.041). Family history of cancer showed no significant difference. Chronic pancreatitis was more common in diabetics (12.28% vs 4.30%, OR 3.14, p = 0.031) *Table IV*.

Table IV
Comparison of risk factors between pancreatic cancer patients with and without diabetes mellitus.

Risk Factor	DM Group n (%)	Non-DM Group n (%)	Unadjusted OR (95% CI)	p-value
Smoking	19 (33.33)	43 (46.24)	0.58 (0.30–0.98)	0.041
Obesity (BMI ≥25 kg/m²)	26 (45.61)	32 (34.41)	1.60 (0.83–3.05)	0.041
Family history of cancer	9 (15.79)	11 (11.83)	1.40 (0.55–3.52)	0.48
Chronic pancreatitis	7 (12.28)	4 (4.30)	3.14 (0.88–11.2)	0.031

Multivariable analysis showed that diabetes mellitus was associated with higher odds of advanced pancreatic cancer (Stage III–IV) (adjusted OR 1.88, 95% CI 1.08–3.29, p = 0.025). Age ≥50 years (OR 2.41, p = 0.021), obesity (OR 1.69, p = 0.045), and chronic pancreatitis (OR 3.52, p = 0.034) were also significant predictors, while male sex and smoking were not (*Table V*).

Table V
Multivariable logistic regression analysis for advanced pancreatic cancer (Stage III–IV).

Variable	Adjusted OR	95% CI	p-value
Diabetes mellitus	1.88	1.08–3.29	0.025
Age ≥50 years	2.41	1.14–5.10	0.021
Male sex	1.12	0.60–2.10	0.72
Smoking	0.81	0.43–1.54	0.53
Obesity	1.69	1.01–2.98	0.045
Chronic pancreatitis	3.52	1.10–11.3	0.034

Among diabetic patients, longer diabetes duration was associated with more advanced disease. Patients with <1 year of diabetes had 61.11% with Stage III–IV cancer, 1–5 years had 75.00%, and >5 years had 89.47% (p = 0.039), suggesting a progressive increase in the risk of advanced pancreatic cancer with longer diabetes duration (*Table VI*).

Table VI
Association between Duration of Diabetes and Cancer Stage (*n* = 57).

Duration of DM	Stage I–II n (%)	Stage III–IV n (%)	p-value
<1 year	7 (38.89)	11 (61.11)	0.039
1–5 years	5 (25.00)	15 (75.00)	
>5 years	2 (10.53)	17 (89.47)	

DISCUSSION

Pancreatic cancer remains one of the most lethal malignancies worldwide, largely due to its insidious onset, aggressive biological behavior, and late-stage diagnosis [13]. Over recent decades, increasing attention has been directed toward the complex relationship between pancreatic cancer and diabetes mellitus, as epidemiological and mechanistic evidence suggests that diabetes may function both as a long-standing risk factor and as an early clinical manifestation of pancreatic malignancy [14]. In low- and middle-income countries such as Bangladesh, where the burden of diabetes is rapidly rising and cancer surveillance systems remain limited, understanding this association is particularly important for improving early detection strategies and clinical outcomes [14]. Within this context, the present study provides valuable insights into the demographic, clinical, and metabolic characteristics of pancreatic cancer patients with and without diabetes mellitus in a Bangladeshi population [15]. In the present study, patients with pancreatic cancer and concomitant diabetes mellitus were significantly older than their non-diabetic counterparts, with a higher proportion aged ≥50 years and a markedly greater mean age. The observed predominance of older age among pancreatic cancer patients with concomitant diabetes mellitus in the present study aligns closely with global epidemiological evidence indicating that pancreatic cancer incidence rises sharply after the fifth decade of life [16-17].Large population-based studies have consistently shown that advancing age is associated with prolonged exposure to metabolic dysregulation, chronic low-grade inflammation, and oxidative stress, which together contribute to pancreatic carcinogenesis [18]. Furthermore, aging is accompanied by progressive β-cell dysfunction and increasing insulin resistance, both of which may exacerbate hyperinsulinemia and activate insulin-like growth factor signaling pathways that promote tumor growth and survival within the pancreatic microenvironment [19]. Gender distribution and residential status did not differ significantly between diabetic and non-diabetic pancreatic cancer patients in the present study. These findings are consistent with previous studies examining the relationship between diabetes mellitus and pancreatic cancer. A retrospective study of pancreatic adenocarcinoma patients reported no significant differences in sex distribution between diabetic and non-diabetic individuals, suggesting that the presence of diabetes does not influence gender-related patterns in pancreatic cancer occurrence [20]. Similarly, a meta-analysis assessing the risk of pancreatic cancer in patients with diabetes found no significant sex-based differences in the relative risk of developing the disease, further supporting the observation that diabetes-associated pancreatic cancer does not vary significantly by sex [21]. While smoking is a well-established risk factor for pancreatic cancer, the inverse association observed in our study — with significantly lower smoking prevalence among PC patients with diabetes mellitus compared to those without (33.33% vs. 46.24%, $p = 0.028$) — is consistent with findings from other retrospective analyses showing that diabetic PC patients may have lower smoking rates than non-diabetic PC patients. For example, one study reported that tobacco smoking was significantly less frequent in PC patients with DM compared to non-DM patients (24.4% vs. 75.6%, $p = 0.03$), suggesting potential differences in risk profiles between these subgroups [20].In contrast, Hwang et al., in a large population-based study, reported that patients with type 2 diabetes mellitus were older, predominantly male, and exhibited higher rates of pancreatic resection, smoking history, comorbidity burden, and BMI [22].Although tumor location, stage, and metastasis were similar between pancreatic cancer patients with and without diabetes, DM independently increased the risk of advanced-stage disease (Stage III–IV; OR 1.88, 95% CI: 1.08–3.29, p = 0.025), with longer duration (>5 years) further promoting tumor progression. This aligns with a case-control study at MD Anderson Cancer Center, which reported that DM was associated with larger tumors, elevated CA19-9, and reduced overall survival, including an 11-month decrease among patients undergoing tumor resection [23]. Analysis of DM characteristics revealed that type 2 DM predominated (89.47%), with approximately half of the patients presenting with new-onset DM (<3 years). Poor glycemic control (HbA1c ≥7%) was observed in 63.16% of patients, and both oral hypoglycemic agents and insulin therapy were used for management. These findings are consistent with previously reported studies, which demonstrate that type 2 DM is the most common form associated with pancreatic cancer and that a significant proportion of patients exhibit new-onset diabetes shortly before diagnosis, often reflecting the metabolic effects of the tumor itself [17]. Furthermore, elevated HbA1c levels and suboptimal glycemic control have been identified as frequent features in pancreatic cancer patients with diabetes, highlighting the clinical relevance of monitoring glycemic status in this population [1]. Regarding risk factors, obesity (BMI ≥25 kg/m²) and chronic pancreatitis were significantly associated with PC in DM patients. In multivariable analysis, obesity conferred a 1.69-fold increased risk of advanced PC (p = 0.045), whereas chronic pancreatitis was associated with a 3.52-fold increased risk (p = 0.034). The present findings align with prior epidemiological and mechanistic studies, underscoring the role of lifestyle-related metabolic factors in the development of diabetes among patients with pancreatic cancer (PC). In a large prospective cohort of 29,133 Finnish men, Stolzenberg-Solomon et al. demonstrated that elevated fasting glucose, hyperinsulinemia, and increased insulin resistance were positively associated with pancreatic ductal adenocarcinoma (PDAC), supporting a potential causal role of obesity-related hyperinsulinemia in pancreatic carcinogenesis [24]. Given that obesity is strongly linked to insulin resistance, persistently elevated insulin levels may exert mitogenic effects within the pancreas. Mechanistically, high local insulin concentrations arising from obesity, prediabetes, or type 2 diabetes mellitus may induce proxicrine stimulation of adjacent acinar and ductal cells, enhancing cellular survival and proliferation. Sustained β-cell hyperactivity in response to insulin resistance may further amplify this effect. Conversely, diabetes mellitus may also arise as a consequence of PC. Previous studies report that approximately 57% of patients

with pancreatic cancer and new-onset diabetes mellitus (NODM) experience diabetes resolution following pancreaticoduodenectomy, suggesting a tumor-mediated pathogenesis [25]. Proposed mechanisms include tumor-derived factors inducing peripheral insulin resistance, along with PDAC-associated islet microvascular dysfunction, microthrombosis, and perivascular fibrosis, which collectively impair normal insulin secretion dynamics [26].

LIMITATIONS

This retrospective, single-center study is subject to selection bias and residual confounding, limiting causal inference and mechanistic interpretation. Temporal relationships between diabetes onset and pancreatic carcinogenesis could not be fully elucidated. Lack of molecular and genetic data restricted mechanistic insights, while the modest sample size may limit generalizability and translational applicability to broader populations or prospective risk-stratification strategies.

CONCLUSION & RECOMMENDATIONS

This study demonstrates a significant association between diabetes mellitus and advanced-stage pancreatic cancer among Bangladeshi patients, supporting the concept of a bidirectional biological link. Hyperinsulinemia, chronic inflammation, and metabolic dysregulation may promote tumor progression, while pancreatic malignancy itself can induce diabetogenic changes. The strong association with new-onset and longer-duration diabetes highlights its potential role as an early clinical indicator. Integrating targeted pancreatic evaluation into diabetes care may improve early detection and enable more effective, stage-adapted interventions.

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CONFLICT OF INTEREST

None declared.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Maternal and Perinatal Outcomes in Gestational Diabetes Mellitus with and without Concomitant Preeclampsia

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) and preeclampsia (PE) are common pregnancy complications associated with significant maternal and perinatal morbidity. The coexistence of these conditions may exacerbate adverse outcomes, yet data on their combined impact are limited, particularly in low-resource settings.Aim of the study: To compare maternal and perinatal outcomes in women with GDM with and without concomitant preeclampsia. **Methods & MAterials:** This hospital-based comparative observational study included 120 pregnant women with GDM, divided into two groups: Group A (GDM with PE, n=60) and Group B (GDM without PE, n=60). Maternal, perinatal, and neonatal outcomes were prospectively recorded and analyzed using SPSS v26. Continuous variables were compared using the Student's t-test and categorical variables using Chi-square or Fisher's exact test. A p-value <0.05 was considered significant. **Result:** Women with GDM and PE had significantly higher rates of labor induction (51.7% vs. 31.7%, p=0.01), preterm delivery (48.3% vs. 18.3%, p<0.001), postpartum hemorrhage (18.3% vs. 7.5%, p=0.02), eclampsia (6.7% vs. 0%, p=0.002), HELLP syndrome (6.7% vs. 0%, p=0.01), and ICU admission (21.7% vs. 3.3%, p<0.001). Neonatal outcomes were also worse, including low birth weight (35% vs. 11.7%, p<0.001), SGA (31.7% vs. 10%, p<0.001), APGAR <7 at 5 min (30% vs. 8.3%, p<0.001), NICU admission (51.7% vs. 15%, p<0.001), and higher rates of hypoglycemia, respiratory distress, birth asphyxia, and sepsis. **Conclusion:** The coexistence of preeclampsia in GDM pregnancies significantly increases maternal and perinatal morbidity. Early identification, close monitoring, and tailored management strategies are essential to mitigate these risks.

Keywords: *Gestational diabetes mellitus, Preeclampsia, Maternal outcomes, Perinatal outcomes, Neonatal complications*

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INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as glucose intolerance first recognized during pregnancy, resulting from insulin resistance and impaired pancreatic β-cell function [1]. Preeclampsia (PE) is a hypertensive disorder of pregnancy characterized by new-onset hypertension and proteinuria after 20 weeks' gestation, often accompanied by systemic manifestations such as endothelial dysfunction, multiorgan involvement, and impaired placental perfusion, which can significantly compromise both maternal and fetal health [2]. Globally, the prevalence of GDM has increased substantially, with recent estimates suggesting an overall frequency of approximately 14.7% among pregnant women based on standardized diagnostic criteria [3]. The global prevalence of preeclampsia is about 4.43% of all pregnancies, highlighting its significant contribution to maternal morbidity worldwide [2]. In Bangladesh, the prevalence of GDM among pregnant women has been variably reported, with nearly one-third of women potentially affected when using contemporary diagnostic criteria [4]. Preeclampsia in Bangladesh is comparatively high, affecting an estimated 10% of pregnancies and contributing substantially to adverse maternal outcomes [5]. Major causes of GDM include advanced maternal age, pre-pregnancy obesity, family history of type 2 diabetes, and metabolic syndrome, reflecting complex genetic and environmental interactions [6]. In addition, rapid urbanization, sedentary lifestyle, and nutritional transitions in low- and middle-income countries further exacerbate the burden of metabolic disorders during pregnancy. Risk factors for preeclampsia similarly encompass chronic hypertension, renal disease, obesity, and preexisting diabetes, indicating overlapping pathophysiological pathways with GDM [7]. Women with GDM are at increased risk of hypertensive disorders of pregnancy, including preeclampsia, due to shared etiologic mechanisms such as endothelial dysfunction, chronic inflammation, and placental vascular abnormalities [8]. The coexistence of gestational diabetes and preeclampsia has been associated with worsened maternal outcomes, including higher rates of cesarean delivery, gestational hypertension, postpartum complications, and overall maternal morbidity [9]. Adverse perinatal outcomes associated with GDM include macrosomia, neonatal hypoglycemia, respiratory distress, and increased rates of neonatal intensive care unit admissions [10]. Preeclampsia contributes significantly to perinatal risks such as preterm birth, intrauterine growth restriction, stillbirth, and neonatal mortality [11]. The combined effect of GDM and preeclampsia has been shown to amplify these risks, further increasing the likelihood of low birth weight, preterm delivery, and perinatal complications compared with either condition alone [1]. Despite advances in obstetric care, the burden of concurrent GDM and preeclampsia remains substantial, particularly in low-resource settings where screening, early diagnosis, and standardized management practices are often inconsistent [12]. Understanding the differential impact of concomitant preeclampsia on maternal and neonatal outcomes in women with GDM is crucial for optimizing antenatal care and resource allocation. The co-occurrence of gestational diabetes and preeclampsia represents a critical challenge in obstetric care due to synergistic effects on maternal and perinatal morbidity and mortality,

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particularly in regions with high metabolic disease burdens. To compare maternal and perinatal outcomes among women with gestational diabetes mellitus with and without concomitant preeclampsia.

METHODS & MATERIALS

This was a hospital-based comparative observational study conducted at the Department of Obstetrics and Gynaecology, Bangladesh Medical University, Dhaka, Bangladesh. The study was carried out for one year from January 2024 to December 2024 among pregnant women diagnosed with gestational diabetes mellitus (GDM). A total of 120 pregnant women with GDM were enrolled and divided into two groups:

Group A (n=60): GDM with concomitant preeclampsia
Group B (n=60): GDM without preeclampsia

Inclusion and Exclusion Criteria

Inclusion Criteria

Patients were eligible if they met all of the following criteria:

1. Age 25-40 years.
2. Singleton pregnancy
3. Diagnosis of gestational diabetes mellitus
4. Gestational age ≥28 weeks

Exclusion Criteria

Patients were excluded if they had:

1. Pre-existing diabetes mellitus
2. Known renal, cardiac, or autoimmune disease
3. Major fetal congenital anomalies diagnosed before enrollment

Diagnostic Criteria

Gestational Diabetes Mellitus: GDM was diagnosed using standard OGTT thresholds. Preeclampsia: Preeclampsia was defined as blood pressure ≥140/90 mmHg on two occasions at least 4 hours apart after 20 weeks of gestation with proteinuria (≥300 mg/24 h) or evidence of end-organ dysfunction.

Data Collection Procedure

After obtaining informed consent, data were collected using a structured questionnaire and review of medical records. Information on demographic characteristics including age, education level, occupation, and family income was recorded. Obstetric and menstrual history such as gravida and menstrual pattern were documented. Anthropometric measurements including body mass index (BMI) and gestational weight gain were assessed. Relevant laboratory parameters such as fasting blood glucose, HbA1c, and hemoglobin levels were obtained from hospital investigations. Sonographic findings, including fetal movements and fetal heart rate, were noted from ultrasonography reports. All participants were followed prospectively until delivery and during the early postpartum period.

Maternal outcomes evaluated included induction of labor, preterm delivery before 37 completed weeks of gestation, postpartum hemorrhage, occurrence of eclampsia and HELLP syndrome, requirement for intensive care unit admission, and maternal mortality. Perinatal and neonatal outcomes comprised birth weight with classification into small for gestational age (SGA), large for gestational age (LGA), and macrosomia, APGAR score at 5 minutes, need for neonatal intensive care unit (NICU) admission, stillbirth, and neonatal mortality. In addition, neonatal complications such as hypoglycemia, respiratory distress syndrome, hyperbilirubinemia, meconium aspiration, birth asphyxia, congenital anomalies, and neonatal sepsis were recorded systematically for analysis.

Statistical Analysis

Data were entered and analyzed using the Statistical Package for Social Sciences (SPSS) software version 26.0. Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were summarized as frequency and percentage. The Student's t-test was applied to compare continuous variables between groups, and the Chi-square test or Fisher's exact test was used for comparison of categorical variables as appropriate. All statistical tests were two-tailed, and a p-value less than 0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee of the study hospital. Written informed consent was taken from all participants. Confidentiality and anonymity were maintained throughout the study.

RESULT

Table I showed that most participants in both groups were <35 years (Group A: 75.00%, Group B: 83.33%), with mean ages of 29.65 ± 5.34 and 32.78 ± 3.89 years, respectively. SSC or lower education was higher in Group A (50.00% vs. 30.00%, p=0.018). Most were housewives, and family income distributions were similar (p>0.05).

Table I
Demographic characteristics of the study population (*n*=120).

Variable	Group A (n=60)		Group B (n=60)		p-value
	n	%	n	%	
Age (years)					
<35	45	75.00	50	83.33	0.24
≥35	15	25.00	10	16.67	
Mean ± SD	29.65 ± 5.34		32.78 ± 3.89		0.08
Education					
SSC and lower	30	50.00	18	30.00	0.018
HSC and above	30	50.00	42	70.00	
Occupation					
Housewife	45	75.00	51	85.00	0.19
Service	15	25.00	9	15.00	
Family Income					
Lower middle and below	46	76.67	49	81.67	0.49
Higher middle and above	14	23.33	11	18.33	

Table II indicated that most participants were obese (Group A: 55.00%, Group B: 56.67%) with mean BMI 30.45 ± 6.98 and 32.76 ± 3.91 kg/m². Excessive weight gain occurred in 55.00% vs. 63.33%. Anaemia was more common in Group A (33.33% vs. 13.33%, p=0.015). Fasting glucose (108.4 ± 12.9 vs. 97.8 ± 10.6 mg/dL) and HbA1c (6.9 ± 0.7 vs. 6.2 ± 0.6%) were significantly higher (p<0.001).

Table II
Baseline characteristics of the study population (*n*=120).

Variable	Group A (n=60)		Group B (n=60)		p-value
	n	%	n	%	
BMI (kg/m²)					
Normal (18.5–24.9)	5	8.33	7	11.67	0.79
Overweight (25–29.9)	22	36.67	19	31.67	
Obese (>30)	33	55.00	34	56.67	
Mean ± SD	30.45 ± 6.98		32.76 ± 3.91		0.08
Weight gain					
Excessive	33	55.00	38	63.33	0.36
Normal	27	45.00	22	36.67	
Anaemia					
Absent	40	66.67	52	86.67	0.015
Mild	19	31.67	7	11.67	
Moderate	1	1.67	1	1.67	
Fasting glucose (mg/dL)					
Mean ± SD	108.4 ± 12.9		97.8 ± 10.6		<0.001
HbA1c (%)					
Mean ± SD	6.9 ± 0.7		6.2 ± 0.6		<0.001
Menstrual cycle					
Regular	33	55.00	38	63.33	0.36
Irregular	27	45.00	22	36.67	
Gestational age (weeks)					
Mean ± SD	34.67 ± 2.51		35.73 ± 2.88		0.06
Gravida					
Primigravida	18	30.00	22	36.67	0.43
Multigravida	42	70.00	38	63.33	

Fetal movement was present in 95.00% of Group A and 100% of Group B (p<0.05). Mean fetal heart rate was 145.42 ± 14.98 bpm in Group A and 142.83 ± 28.66 bpm in Group B, with no statistically significant difference (p=0.51) (*Table III*).

Table III
Sonographic findings among patients (*n*=120).

Fetal movement	Group A (n=60)		Group B (n=60)		p-value
	n	%	n	%	
Present	57	95.00	60	100	<0.05
Absent	3	5.00	0	0	
Fetal heart sound (Mean ± SD)	145.42 ± 14.98		142.83 ± 28.66		0.51

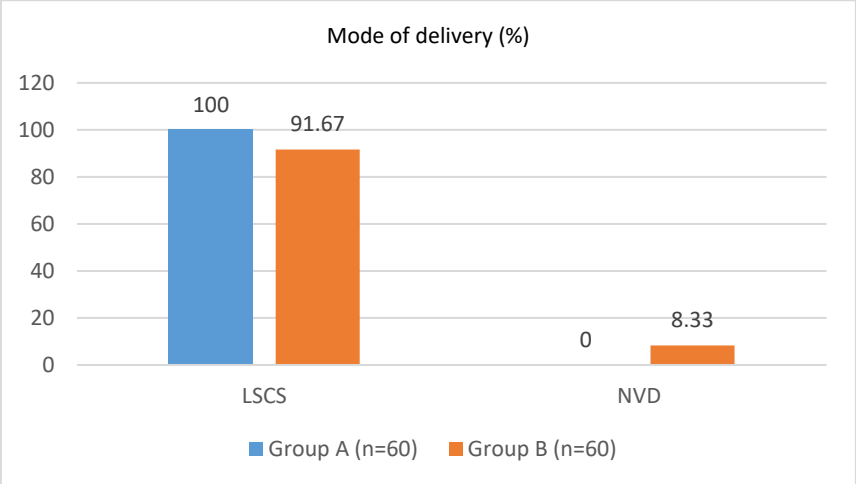

Figure 1 Mode of delivery among woman.

LSCS was the predominant delivery mode, occurring in 100% of Group A and 91.67% of Group B, while NVD was reported only in 8.33% of Group B (Figure 1). Table 4 showed higher rates of adverse maternal outcomes in Group A: induction of labor (51.67% vs. 31.7%, p=0.01), preterm delivery (48.33% vs. 18.3%, p<0.001), postpartum hemorrhage (18.33% vs. 7.5%, p=0.02), eclampsia and HELLP syndrome (6.67% vs. 0%, p≤0.01), and ICU admission (21.67% vs. 3.3%, p<0.001). Maternal mortality was 1.67% in Group A (p=0.16) (*Table IV*).

Table IV
Maternal outcomes (*n*=120).

Outcomes	Group A (n=60)		Group B (n=60)		p-value
	n	%	n	%	
Induction of labor	31	51.67	19	31.7	0.01
Preterm delivery (<37 wk)	29	48.33	11	18.3	<0.001
Postpartum hemorrhage	11	18.33	4	7.5	0.02
Eclampsia	4	6.67	0	0	0.002
HELLP syndrome	4	6.67	0	0	0.01
ICU admission	13	21.67	2	3.3	<0.001
Maternal mortality	1	1.67	0	0	0.16

Group A had lower mean birth weight than Group B (2875 ± 505 g vs. 3335 ± 425 g, p < 0.001). Low birth weight, SGA, APGAR <7 at 5 min, and NICU admissions were higher in Group A (35.00%, 31.67%, 30.00%, 51.67%; p < 0.001). Macrosomia (6.67% vs. 16.67%), stillbirth (6.67% vs. 1.67%), and neonatal mortality (6.67% vs. 1.67%) were also more frequent in Group A (*Table V*).

Table V
Perinatal outcomes (*n*=120).

Outcomes	Group A (n=60)		Group B (n=60)		p-value
	n	%	n	%	
Mean birth weight (g)	2875 ± 505		3335 ± 425		<0.001
Low birth weight (<2500 g)	21	35.00	7	11.67	<0.001
Macrosomia (>4000 g)	4	6.67	10	16.67	0.04
SGA	19	31.67	6	10.00	<0.001
LGA	6	10.00	13	21.67	0.03
APGAR <7 at 5 min	18	30.00	5	8.33	<0.001
NICU admission	31	51.67	9	15.00	<0.001
Stillbirth	4	6.67	1	1.67	0.04
Neonatal mortality	4	6.67	1	1.67	0.03

Respiratory distress syndrome (36.67% vs. 10.00%), hypoglycemia (31.67% vs. 16.67%), birth asphyxia (26.67% vs. 6.67%), hyperbilirubinemia (31.67% vs. 18.33%), meconium aspiration (16.67% vs. 5.00%), and neonatal sepsis (28.33% vs. 6.67%) were all higher in Group A (all p < 0.05), while congenital anomalies showed no significant difference (*Table VI*).

Table VI
Neonatal complications (*n*=120).

Complications	Group A (n=60)		Group B (n=60)		p-value
	n	%	n	%	
Neonatal hypoglycemia	19	31.67	10	16.67	0.01
Respiratory distress syndrome	22	36.67	6	10.00	<0.001
Hyperbilirubinemia	19	31.67	11	18.33	0.04
Meconium aspiration	10	16.67	3	5.00	0.01
Birth asphyxia	16	26.67	4	6.67	<0.001
Congenital anomalies	3	5.00	1	1.67	0.34
Neonatal sepsis	17	28.33	4	6.67	<0.001

DISCUSSION

Gestational diabetes mellitus (GDM), particularly when accompanied by preeclampsia, poses significant risks to both maternal and perinatal outcomes, warranting careful evaluation of their combined impact [13]. In this study of 120 women with gestational diabetes mellitus, we compared outcomes between those with concomitant preeclampsia (Group A, n=60) and those with GDM alone (Group B, n=60). The majority of participants in both groups were under 35 years of age (Group A: 75.00%; Group B: 83.33%, p=0.24). The mean age was slightly higher in Group B (32.78 ± 3.89 years) compared to Group A (29.65 ± 5.34 years, p=0.08). Educational status differed significantly; 30 women (50.00%) in Group A had SSC or lower education compared to 18 (30.00%) in Group B (p=0.018). Most participants were housewives (Group A: 75%; Group B: 85%; p=0.19), and family income did not differ significantly (p=0.49). These findings are consistent with prior studies showing that maternal age and education may influence access to prenatal care but are not the sole determinants of adverse outcomes [14,15]. Obesity was common in both groups (Group A: 55%; Group B: 56.67%), and mean BMI was slightly higher in Group B (32.76 ± 3.91 kg/m²) versus Group A (30.45 ± 6.98 kg/m², p=0.08). Excessive gestational weight gain was reported in 55% in Group A and 63.33% in Group B (p=0.36). Anemia was significantly more prevalent in Group A (33.34%) versus Group B (13.34%; p=0.015). Fasting glucose and HbA1c were significantly higher in Group A (108.4 ± 12.9 mg/dL and 6.9 ± 0.7%) compared to Group B (97.8 ± 10.6 mg/dL and 6.2 ± 0.6%, both p<0.001), confirming poorer glycemic control in women with concomitant preeclampsia [16]. Fetal movement was absent in 5% cases in Group A but present in all women in Group B (p<0.05). Fetal heart rate was comparable between groups (Group A: 145.42 ± 14.98 bpm; Group B:

142.83 ± 28.66 bpm, p=0.51). This also shows similarities with previous studies [17]. In the present study, cesarean section was the predominant mode of delivery, occurring in all women (100%) in Group A (GDM with concomitant preeclampsia) and in the majority of women in Group B (91.67%). Normal vaginal delivery was observed only in a small proportion of women (8.33%) in Group B. These findings are comparable to those reported by Umer et al., who demonstrated that the coexistence of preeclampsia and gestational diabetes mellitus was associated with the highest cesarean section rate, occurring in 82.7% of cases. The consistently high rate of cesarean delivery across studies underscores the increased obstetric risk and the preference for operative delivery in pregnancies complicated by GDM, particularly when associated with preeclampsia [18]. Adverse maternal outcomes were significantly higher in Group A. Induction of labor was performed in 51.67% women versus 31.7% women (p=0.01), preterm delivery in 48.33% versus 18.3%, (p<0.001), postpartum hemorrhage in 18.33% versus 7.5%, (p=0.02), eclampsia in 6.67% versus none (p=0.002), and HELLP syndrome in 6.67% versus none (p=0.01). ICU admission was necessary in 21.67% women versus 3.3%, (p<0.001), while maternal mortality occurred in 1.67% cases in Group A. These results confirm the synergistic effect of preeclampsia on maternal morbidity in GDM, consistent with prior studies [19]. Neonatal outcomes were significantly compromised in Group A. Mean birth weight was lower (2875 ± 505 g) compared to Group B (3335 ± 425 g, p<0.001). Low birth weight (<2500 g) occurred in 35% neonates versus 11.67%, (p<0.001), SGA in 31.67% versus 10%, (p<0.001), LGA in 10% versus 21.67%, (p=0.03), APGAR <7 at 5 minutes in 30% versus 8.33%, (p<0.001), NICU admission in 51.67% versus 15%, (p<0.001), stillbirth in 6.67% versus 1.67%, (p=0.04), and neonatal mortality in 6.67% versus 1.67%, (p=0.03). These findings are consistent with Karkia et al., demonstrating increased perinatal morbidity in GDM with superimposed preeclampsia [13]. Specific complications were also significantly higher in Group A: hypoglycemia in 31.67% versus 16.67%, (p=0.01), respiratory distress syndrome in 36.67% versus 10%, (p<0.001), hyperbilirubinemia in 31.67% versus 18.33%, (p=0.04), meconium aspiration in 16.67% versus 5%, (p=0.01), and birth asphyxia in 26.67% versus 6.67%, (p<0.001). Congenital anomalies and neonatal sepsis occurred in (5%) and (28.33%) neonates in Group A versus (1.67%) and (6.67%) in Group B (p=0.34 and p<0.001). These results align with the observations of Karkia et al., who found an elevated rate of neonatal complications in pregnancies affected by both gestational diabetes and hypertensive disorders, underscoring a consistent trend of heightened perinatal risk in these high-risk cases [13].

LIMITATIONS

This study was conducted in a single tertiary care hospital with a relatively small sample size, which may limit the generalizability of the findings to broader populations. Long-term maternal and neonatal outcomes were not assessed, restricting insights into postnatal complications. Potential confounding factors, such as variations in glycemic control, antihypertensive therapy, and socioeconomic determinants, were not fully controlled. Additionally, reliance on hospital records and patient-reported data may introduce information bias. Multicenter studies with larger cohorts are needed to validate these results.

CONCLUSION & RECOMMENDATIONS

The present study demonstrates that the coexistence of gestational diabetes mellitus and preeclampsia significantly exacerbates adverse maternal and perinatal outcomes compared with GDM alone. Women with both conditions exhibited higher rates of labor induction, preterm delivery, postpartum hemorrhage, eclampsia, HELLP syndrome, and ICU admission. Neonates born to this group were more likely to have low birth weight, small-for-gestational-age status, lower APGAR scores, NICU admission, and complications such as hypoglycemia, respiratory distress, birth asphyxia, and sepsis. These findings underscore the synergistic impact of preeclampsia on GDM pregnancies, highlighting the need for intensified antenatal surveillance, early detection, and tailored management strategies to mitigate maternal and neonatal morbidity and mortality in high-risk populations.

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CONFLICT OF INTEREST

None declared.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Comparison of Carbetocin, Oxytocin, and Misoprostol for the Prevention of Atonic Postpartum Hemorrhage in High-Risk Women Undergoing Cesarean Delivery in Bangladesh

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ABSTRACT

Background: Atonic postpartum hemorrhage (PPH) remains a leading cause of maternal morbidity and mortality worldwide, particularly in high-risk women undergoing cesarean delivery. Effective prophylactic uterotonics are critical to prevent excessive blood loss and reduce the need for additional interventions. Aim of the study: To compare the efficacy, safety, and clinical outcomes of carbetocin, oxytocin, and misoprostol in preventing atonic PPH among high-risk women undergoing cesarean delivery in Bangladesh. **Methods & Materials:** This prospective, randomized, comparative study included 135 high-risk pregnant women scheduled for cesarean section. Participants were assigned to receive carbetocin (100 µg IV), oxytocin (10 IU IV), or misoprostol (800 µg PR) immediately after delivery. Primary outcome was incidence of atonic PPH (≥1000 mL blood loss), with secondary outcomes including severity of PPH, need for additional uterotonics, surgical interventions, and maternal adverse effects. Data were analyzed using ANOVA, Chi-square tests, and relative risk calculation. **Results:** Carbetocin demonstrated the lowest incidence of PPH (6.67%) compared with oxytocin (13.33%) and misoprostol (11.11%). Carbetocin recipients achieved uterine tone more rapidly, required fewer additional uterotonics and surgical interventions, and experienced fewer adverse effects. Misoprostol was associated with higher rates of fever, shivering, and gastrointestinal symptoms. Relative risk analysis showed a trend favoring carbetocin, though not statistically significant. **Conclusion:** Carbetocin is the most effective and safe uterotonic for preventing atonic PPH in high-risk cesarean deliveries, offering rapid uterine stabilization and minimal adverse effects. Oxytocin provides moderate efficacy, whereas misoprostol, despite ease of administration, is less tolerable. These findings support preferential use of carbetocin in high-risk cesarean settings in Bangladesh.

Keywords: *Atonic postpartum hemorrhage, cesarean delivery, carbetocin, oxytocin, misoprostol, uterotonic prophylaxis, maternal outcomes.*

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INTRODUCTION

Atonic postpartum hemorrhage (PPH) refers to excessive bleeding of ≥ 500 mL following vaginal delivery or ≥ 1000 mL after cesarean delivery due to failure of the uterus to contract effectively, and it remains the most frequent obstetric emergency requiring uterotonic prophylaxis during cesarean delivery [1]. Uterotonic agents, for instance, oxytocin, carbetocin, and misoprostol, are administered after delivery of the fetus to promote sustained uterine contraction, decrease blood loss, prevent uterine atony, and thereby lessen the incidence of atonic PPH in high-risk women undergoing cesarean section [2]. In the Global perspective, postpartum hemorrhage impacts approximately 9.97% of women giving birth, meaning nearly 1 in 10 women experience significant bleeding (≥500 mL) after delivery, and about 4.5% develop severe PPH, making it a major contributor to maternal morbidity and mortality worldwide and underlining the critical need for effective preventive measures, such as uterotonic agents [3]. In the context of Bangladesh, obstetric hemorrhage has become the leading cause of maternal mortality, accounting for about 31% of all maternal deaths, with uterine atony from PPH being a major contributor, underscoring the need for effective prophylactic uterotonics such as carbetocin, oxytocin, and misoprostol in high-risk caesarean deliveries [4]. Atonic postpartum hemorrhage is primarily caused by failure of effective uterine contraction after delivery, with additional risk factors that include prolonged labor, multiple pregnancy, polyhydramnios, and cesarean section [5]. Atonic postpartum hemorrhage occurs due to the failure of effective uterine contraction after placental delivery, accounting for about 70–80% of all PPH cases worldwide, and is strongly associated with prolonged labor, over-distended uterus, multiple pregnancy, and cesarean section [6]. Prevention of atonic PPH during cesarean delivery includes prophylactic administration of uterotonic agents such as oxytocin, carbetocin, or misoprostol immediately after delivery of the baby, which significantly decreases blood loss ≥500 mL and lowers the risk of chronic hemorrhage [7]. Prophylactic administration of uterotonic agents, for instance, oxytocin, carbetocin, or misoprostol, immediately after delivery of the baby during cesarean section significantly decreases the incidence of blood loss ≥500 mL and severe PPH compared with no uterotonic use [8]. Carbetocin demonstrate significant reduction of the risk of postpartum hemorrhage ≥500 mL and the need for additional uterotonics compared with oxytocin, where misoprostol remains effective in low-resource settings due to its heat stability and ease of administration [9]. Carbetocin is comparatively expensive and

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not easily accessible in low-income settings, oxytocin requires cold-chain storage and skilled administration, and misoprostol is associated with higher rates of side effects like shivering and fever compared with oxytocin [10]. Misoprostol is associated with higher rates of shivering and pyrexia (30–40%) rather than oxytocin, which requires cold-chain storage and skilled administration, limiting its feasibility in some settings [11]. This study aimed to compare the efficacy, safety, security, and clinical outcomes of carbetocin, oxytocin, and misoprostol in preventing atonic postpartum hemorrhage among high-risk women undergoing cesarean delivery in Bangladesh, with special emphasis on reducing blood loss, need for additional uterotonics, and maternal morbidity.

METHODS & MATERIALS

This was a prospective, randomized, comparative study conducted at the Department of Obstetrics and Gynecology, Bnagladesh Medical University, Dhaka, Bangladesh over a period of 12 months from January 2024 to December 2024. The study aimed to compare the effectiveness and safety of carbetocin, oxytocin, and misoprostol in preventing atonic postpartum hemorrhage (PPH) among high-risk women undergoing cesarean delivery. A total of 135 pregnant women scheduled for cesarean section and identified as high risk for atonic PPH were enrolled in the study. High-risk status was defined by the presence of one or more of the following factors: previous cesarean section, multiparity (≥3), multiple pregnancy, anemia (hemoglobin <10 g/dL), prolonged labor, uterine overdistension, or history of PPH.

Group Allocation

Carbetocin group: Received 100 µg carbetocin intravenously as a single bolus immediately after delivery of the baby.

Oxytocin group: Received 10 IU oxytocin intravenously as a slow bolus followed by infusion as per hospital protocol.

Misoprostol group: Received 800 µg misoprostol per rectally immediately after delivery of the baby.

Spinal anesthesia was standardized for all participants. Cesarean sections were performed by experienced obstetricians following uniform surgical protocols.

Inclusion Criteria:

- Women aged 18–40 years.
- Singleton or multiple pregnancy.
- Gestational age ≥37 weeks.
- Undergoing elective or emergency cesarean delivery.
- Presence of at least one recognized risk factor for atonic PPH.

Exclusion Criteria:

- Known coagulation disorders.
- Placenta accreta spectrum, placenta previa with active bleeding, or uterine rupture.
- Severe preeclampsia/eclampsia.
- Cardiac disease or contraindications to uterotonic agents.
- Allergy or hypersensitivity to any of the study drugs.
- Renal or hepatic disease.

Ethical Considerations

The study protocol was approved by the Institutional Ethical Review Committee of the participating hospital. Written informed consent was obtained from all participants. Confidentiality of patient data was maintained.

Measurement of Blood Loss

Intraoperative blood loss was estimated by combining the volume collected in suction bottles (after subtracting amniotic fluid) and visual estimation from soaked surgical sponges and pads. Postoperative blood loss was assessed within the first 24 hours using pad counts and clinical evaluation.

Variable Definitions

Postpartum hemorrhage (PPH) was defined as an estimated blood loss of ≥1000 mL following cesarean section. The severity of PPH was further classified into two categories: minor PPH, which referred to an estimated blood loss of up to 1000 mL, and major PPH, which referred to blood loss exceeding 1000 mL and/or blood loss associated with clinical signs of hemodynamic instability.

Data Collection

Data were collected using a structured data collection sheet that recorded baseline demographic and obstetric characteristics, including age, body mass index (BMI), parity, gestational age, presence of anemia, history of previous cesarean section, and multiple pregnancy. Maternal outcomes and adverse events were prospectively monitored for the first 24 hours postpartum. The primary outcome measure was the incidence of atonic postpartum hemorrhage, defined as blood loss ≥1000 mL following cesarean section or any amount of blood loss associated with hemodynamic instability. Secondary outcome measures included the severity of PPH (classified as minor or major), requirement for additional uterotonic drugs such as ergometrine, need for surgical interventions (uterine artery ligation, compression sutures, or hysterectomy), blood transfusion requirement, maternal adverse effects (nausea, vomiting, fever, shivering, hypotension, diarrhea, and headache), time to achieve adequate uterine tone, need for intensive care unit (ICU) admission, and the relative risk of PPH among the study groups.

Statistical Analysis

Data were analyzed using SPSS software (version 26). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. Comparisons among groups were performed using one-way ANOVA for continuous variables and Chi-square or Fisher's exact test for categorical variables. Relative risk (RR) with 95% confidence intervals (CI) was calculated for the incidence of atonic PPH. A p-value <0.05 was considered statistically significant.

RESULT

A total of 135 women undergoing cesarean delivery were enrolled and equally allocated to the Carbetocin (n=45), Oxytocin (n=45), and Misoprostol (n=45) groups. The mean age was 26.56±5.87 years in the Carbetocin group, 29.34±3.65 years in the Oxytocin group, and 27.55±4.71 years in the Misoprostol group (p=0.14). Mean BMI was 27.46±2.92, 28.89±3.28, and 27.59±2.87 kg/m² (p=0.11). Primigravida women were 42.22%, 40.00%, and 44.44% respectively (p=0.91). Previous cesarean section was reported in 55.56%, 57.78%, and 53.33% (p=0.89), and anemia (Hb<10 g/dL) in 46.67%, 48.89%, and 46.67% (p=0.97) (*Table I*)

Table I
Baseline characteristics of study participants (*n*=135).

Variables	Carbetocin (n=45)	Oxytocin (n=45)	Misoprostol (n=45)	p-value
Age (years), Mean ± SD	26.56±5.87	29.34±3.65	27.55±4.71	0.14
BMI (kg/m2), Mean ± SD	27.46±2.92	28.89±3.28	27.59±2.87	0.11
Parity, Mean ± SD	3.76±0.74	3.32±0.74	3.17±0.48	0.06
Gestational age (weeks), Mean ± SD	37.73±1.92	37.39±1.65	37.51±1.66	0.74
Primigravida, n (%)	19 (42.22)	18 (40.0)	20 (44.44)	0.91
Previous CS, n (%)	25 (55.56)	26 (57.78)	24 (53.33)	0.89
Multiple pregnancy, n (%)	6 (13.33)	7 (15.56)	7 (15.56)	0.95
Anemia (Hb <10 g/dL), n (%)	21 (46.67)	22 (48.89)	21 (46.67)	0.97

The incidence of atonic postpartum hemorrhage (PPH) was lowest in the Carbetocin group at 6.67%, compared with 13.33% in the Oxytocin group and 11.11% in the Misoprostol group. Minor PPH occurred in 6.67%, 8.89%, and 6.67% women, while major PPH was observed only in the Oxytocin 4.44% and Misoprostol 6.67% groups (p=0.1) (*Table II*).

Table II
Incidence and severity of atonic postpartum hemorrhage among the study groups (*n*=135).

Variables	Carbetocin (n=45), n (%)	Oxytocin (n=45), n (%)	Misoprostol (n=45), n (%)	p-value
Incidence of PPH	3 (6.67)	6 (13.33)	5 (11.11)	0
Degree of PPH				
Minor	3 (6.67)	4 (8.89)	3 (6.67)	0.1
Major	0 (0.0)	2 (4.44)	3 (6.67)	0

Only 2.22% received additional ergometrine compared with 8.89% in Oxytocin and 11.11% in Misoprostol (p=0.03). Surgical measures included uterine artery ligation in 0, 2.22%, and 6.67% women; compression sutures in 0, 6.67%, and 8.89%; and hysterectomy in 0, 2.22%, and 0 women, respectively. Blood transfusions of one unit were required in 2.22%, 6.67%, and 6.67%, while transfusions of more than one unit were needed in 0, 4.44%, and 6.67% women (*Table III*).

Table III
Requirement for additional medical or surgical interventions to control bleeding among the study groups (*n*=135).

Additional lines	Type	Carbetocin (n=45), n (%)	Oxytocin (n=45), n (%)	Misoprostol (n=45), n (%)	p-value
Uterotonic drugs	Ergometrine	1 (2.22)	4 (8.89)	5 (11.11)	0.03
Surgical measures	Uterine artery ligation	0 (0.0)	1 (2.22)	3 (6.67)	0
	Compression sutures	0 (0.0)	3 (6.67)	4 (8.89)	
	Hysterectomy	0 (0.0)	1 (2.22)	0 (0.0)	
Blood transfusion	One unit	1 (2.22)	3 (6.67)	3 (6.67)	0
	More than 1 unit	0(0.0)	2 (4.44)	3 (6.67)	

Nausea/vomiting occurred in 28.89% compared with 6.67% in Carbetocin and 8.89% in Oxytocin (p<0.001). Fever/shivering was reported in 35.56% versus 2.22% and 4.44% (p<0.001). Diarrhea occurred in 13.33% compared with 2.22% in both Carbetocin and Oxytocin (p<0.001). Hypotension was reported in 8.89%, 15.56%, and 8.89% (p=0.14), and headache in 4.44%, 6.67%, and 11.11% (p=0.18) (*Table IV*).

Table IV
Maternal adverse effects (*n*=135).

Adverse Effect	Carbetocin (n=45), n (%)	Oxytocin (n=45), n (%)	Misoprostol (n=45), n (%)	p-value
Nausea/vomiting	3 (6.67)	4 (8.89)	13 (28.89)	<0.001
Fever/shivering	1 (2.22)	2 (4.44)	16 (35.56)	<0.001
Hypotension	4 (8.89)	7 (15.56)	4 (8.89)	0.14
Headache	2 (4.44)	3 (6.67)	5 (11.11)	0.18
Diarrhea	1 (2.22)	1 (2.22)	6 (13.33)	<0.001

Successful prevention of PPH was achieved in 93.33%, 82.22%, and 73.33% women (p<0.001). Uterine tone within 5 minutes was achieved in 86.67%, 64.44%, and 53.33% (p<0.001). Need for surgical intervention (B-Lynch / hysterectomy) occurred in 2.22%, 4.44%, and 6.67% (p=0.04), while ICU admissions were 2.22%, 4.44%, and 8.89% (p=0.06) (*Table V*).

Table V
Clinical effectiveness outcomes (*n*=135).

Outcome	Carbetocin (n=45), n (%)	Oxytocin (n=45), n (%)	Misoprostol (n=45), n (%)	p-value
Successful prevention of PPH	42 (93.33)	37 (82.22)	33 (73.33)	<0.001
Uterine tone achieved within 5 min	39 (86.67)	29 (64.44)	24 (53.33)	<0.001
Need for surgical intervention (B-Lynch / hysterectomy)	1 (2.22)	2 (4.44)	3 (6.67)	0.04
ICU admission	1 (2.22)	2 (4.44)	4 (8.89)	0.06

Relative risk of developing atonic PPH was higher in Oxytocin (RR=2; 95% CI: 0.54–7.39; p=0.29) and Misoprostol (RR=1.67; 95% CI: 0.43–6.46; p=0.45) compared with Carbetocin, although not statistically significant (*Table VI*).

Table VI
Relative risk of atonic PPH (*n*=135).

Comparison	Relative Risk (RR)	95% Confidence Interval	p-value
Oxytocin vs Carbetocin	2	0.54 – 7.39	0.29
Misoprostol vs Carbetocin	1.67	0.43 – 6.46	0.45

DISCUSSION

Postpartum hemorrhage (PPH) due to uterine atony remains the leading cause of maternal morbidity and mortality worldwide, particularly among high-risk women undergoing cesarean delivery [12]. The present study compared the effectiveness of Carbetocin, Oxytocin, and Misoprostol for the prevention of atonic PPH in a Bangladeshi high-risk obstetric population. In this study, baseline demographic characteristics including age (26.56±5.87 vs 29.34±3.65 vs 27.55±4.71 years), BMI (27.46±2.92 vs 28.89±3.28 vs 27.59±2.87 kg/m²), parity (3.76±0.74 vs 3.32±0.74 vs 3.17±0.48), gestational age (37.73±1.92 vs 37.39±1.65 vs 37.51±1.66 weeks), prevalence of primigravida (42.22% vs 40.0% vs 44.44%), previous cesarean section (55.56% vs 57.78% vs 53.33%), multiple pregnancy (13.33% vs 15.56% vs 15.56%), and anemia (46.67% vs 48.89% vs 46.67%) were statistically comparable among the three groups ($p>0.05$). These findings indicate that the observed clinical outcomes were unlikely to be influenced by baseline confounding variables and reflect true pharmacologic differences, consistent with randomized trials such as those by Abd El-Gaber et al., who also demonstrated comparable baseline obstetric characteristics across uterotonic groups in cesarean deliveries [2]. The incidence of atonic PPH was lowest in the carbetocin group (6.67%) compared to the oxytocin (13.33%) and misoprostol (11.11%) groups. Notably, no cases of major PPH were reported in the carbetocin group, whereas major hemorrhage occurred in 4.44% and 6.67% of women receiving oxytocin and misoprostol respectively. Similar reductions in blood loss and PPH incidence with carbetocin compared to oxytocin have been reported in previous studies, supporting the superior uterotonic efficacy of long-acting oxytocin analogues in cesarean sections [2,13,14]. Furthermore, the requirement for additional uterotonics such as ergometrine was significantly lower in the carbetocin group (2.22%) than in the oxytocin (8.89%) and misoprostol (11.11%) groups ($p=0.03$). Similarly, surgical interventions including uterine artery ligation and compression sutures were less frequently required following carbetocin administration. These observations align with previous findings, which demonstrated reduced need for supplementary uterotonics and invasive procedures in women receiving carbetocin during, cesarean delivery [15-17]. Adverse maternal effects were markedly more common in the misoprostol group, including nausea/vomiting (28.89%), fever/shivering (35.56%), and diarrhea (13.33%), all of which were statistically significant ($p<0.001$). In contrast, carbetocin exhibited a more favorable tolerability profile with minimal gastrointestinal and thermoregulatory side effects. These findings are consistent with previous reports which noted a higher incidence of pyrexia and shivering associated with misoprostol use in PPH prophylaxis [18-20]. Clinical effectiveness outcomes further reinforced the superiority of carbetocin. Successful prevention of PPH was achieved in 93.33% of patients receiving carbetocin compared to 82.22% in the oxytocin group and 73.33% in the misoprostol group ($p<0.001$). Rapid uterine tone within 5 minutes was also significantly higher in the carbetocin group (86.67%) than in oxytocin (64.44%) and misoprostol (53.33%) groups ($p<0.001$). Comparable results were observed in randomized controlled trial, which highlighted the sustained uterine contractility achieved with carbetocin following cesarean delivery [16]. Although the relative risk of developing atonic PPH was higher in the oxytocin (RR=2.0; 95% CI: 0.54–7.39) and misoprostol (RR=1.67; 95% CI: 0.43–6.46) groups compared to carbetocin, the differences did not reach statistical significance ($p>0.05$), possibly due to the modest sample size. Nonetheless, the overall clinical trend consistently favored carbetocin in reducing hemorrhagic complications and intervention requirements [2,16].

LIMITATIONS

This study was conducted at a single tertiary care center, limiting the generalizability of the findings to other settings in Bangladesh or globally. The sample size was relatively modest, reducing statistical power for rare outcomes. Blood loss estimation relied partly on visual assessment, which may introduce measurement bias. Long-term maternal outcomes beyond 24 hours postpartum were not assessed. Additionally, cost-effectiveness and feasibility aspects, particularly for carbetocin in low-resource settings, were not evaluated. Multicenter studies are warranted to validate these findings.

CONCLUSION

In high-risk women undergoing cesarean delivery, prophylactic administration of carbetocin demonstrated superior efficacy in preventing atonic postpartum hemorrhage compared with oxytocin and misoprostol. Carbetocin was associated with the lowest incidence of PPH, minimal need for additional uterotonics, rapid achievement of adequate uterine tone, and reduced requirement for surgical interventions. Oxytocin offered moderate protection, whereas misoprostol, while effective, was linked to higher rates of adverse maternal effects such as fever, shivering, and gastrointestinal symptoms. Despite comparable relative risks among groups, the clinical outcomes favor carbetocin as the most effective and safe uterotonic agent. These findings support its preferential use in high-risk cesarean deliveries in Bangladesh, balancing efficacy, safety, and rapid uterine stabilization.

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CONFLICT OF INTEREST

None declared.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Filarial Etiology in Vaginal Hydrocele – A Hospital-Based Observational Study from an Endemic Zone of Bangladesh

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ABSTRACT

Background: Lymphatic filariasis (LF) is a significant cause of long-term disability in endemic low- and middle-income countries, where filarial hydrocele represents the most common chronic manifestation in men, leading to substantial physical, social, and economic consequences. **Methods & Materials:** This prospective observational study was conducted in the Department of Surgery at Rangpur Medical College Hospital, northern Bangladesh, over 12 months (January–December 2014) among adult males with clinically diagnosed vaginal hydrocele who were admitted from the surgery outpatient department. Data were analyzed using SPSS 26.0, and $p < 0.05$ was considered statistically significant. **Results:** Among 100 adult males with vaginal hydrocele, 83% were classified as definite, highly likely, or suspected filarial cases. In contrast, 17% were non-filarial, indicating that most hydroceles in this setting are attributable to lymphatic filariasis. Filarial hydrocele was more frequent among rural residents, those living with poor sanitation, and men working in the biri industry, with significant differences compared to non-filarial cases. In multivariable analysis, rural residence (AOR 3.85; 95% CI 1.42–10.45), poor sanitation (AOR 2.67; 95% CI 1.01–7.08), and employment in the biri industry (AOR 4.28; 95% CI 1.36–13.46) remained independent predictors of filarial hydrocele. **Conclusion:** In this northern Bangladeshi endemic setting, most adult vaginal hydroceles were filarial and clustered among rural men with poor sanitation and biri-related occupations, indicating that filarial hydrocele is driven by socio-environmental disadvantage and should be addressed through targeted morbidity management, sanitation improvement, and focused preventive strategies for high-risk groups.

Keywords: *Filarial hydrocele, Lymphatic filariasis, and Socio-demographic correlates.*

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INTRODUCTION

Lymphatic filariasis (LF) is a mosquito-borne neglected tropical disease that remains a significant cause of long-term disability in many low- and middle-income countries. Globally, an estimated 120 million people are infected, and more than 1.2–1.3 billion are at risk, with approximately 40 million individuals living with chronic clinical manifestations such as lymphoedema and genital disease [1]. Although LF is rarely fatal, its chronic sequelae result in substantial years lived with disability and economic loss, justifying its designation as a significant public health and development problem [2]. Hydrocele is the most common chronic clinical manifestation of bancroftian filariasis in men; in some endemic communities, 40–60 % of adult males are affected [3]. The condition arises from lymphatic dysfunction and damage to scrotal lymphatics, with ultrasonographic and clinical studies suggesting that adult Wuchereria bancrofti worms preferentially lodge in these vessels, leading to dilatation, lymphangiectasia, and accumulation of transudative fluid in the tunica vaginalis [3,4]. Detailed work by Norões and Dreyer has further clarified the mechanisms of chronic filarial hydrocele and its implications for surgical repair [4]. Beyond the physical deformity, filarial hydrocele exerts a profound social and economic toll. Studies from Ghana and India show that men with hydrocele experience pain, difficulties with mobility and work, reduced productivity, and substantial treatment-related costs [5,6,7]. Qualitative and ethnographic research has documented stigma, marital strain, and sexual dysfunction associated with hydrocele, with effects on marriageability, conjugal life, and self-esteem [5,8,9]. These impacts are reflected in broader disability literature, indicating that LF-related disability affects work capacity, social roles, and psychological well-being, and that hydrocele contributes significantly to the overall disability burden of LF [4,10]. Surgical correction of a hydrocele has been shown to improve function and quality of life. Recent work has emphasized standardized hydrocele classifications and context-appropriate operative approaches to guide morbidity management in endemic areas [6,10,11]. South Asia bears a large share of the global LF burden, and India has been extensively studied with respect to epidemiology, transmission dynamics, and control strategies [12]. Bangladesh is also highly endemic, with LF reported from most regions, and approximately one-third of the districts are classified as endemic. Population-based surveys in northern districts have documented a moderate to high prevalence of LF, with hydrocele recognized as a common clinical manifestation among men and strongly associated with poverty, illiteracy, and limited access to preventive measures, including bed nets [13]. These areas are predominantly rural, and many affected individuals are engaged in low-income manual occupations, increasing the economic impact of disability. Despite this, there are relatively few analytic studies from Bangladesh that characterize the clinical and socio-demographic correlates of filarial hydrocele at the individual level. Existing work has primarily focused on community-based prevalence mapping or descriptions

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of overall LF morbidity, with limited attention to specific risk profiles for hydrocele among adult males presenting for surgical care [13]. Furthermore, while the international literature has identified associations between hydrocele and low socio-economic status, rural residence, certain occupations, and poor housing or sanitation conditions, there is a need to verify these relationships in different ecological and programmatic contexts [8-10]. Understanding which socio-demographic groups are most likely to present with filarial hydrocele in a high-endemic Bangladeshi setting is essential for planning targeted health education, vector control, MDA coverage improvement, and surgical morbidity management services. In this context, the present study was conducted in a tertiary-care surgical department in northern Bangladesh, an area recognized as highly endemic for LF. Therefore, this study aimed to determine the etiological spectrum of vaginal hydrocele and to identify clinical and socio-demographic correlates of filarial hydrocele among adult males in an endemic northern region of Bangladesh.

METHODS & MATERIALS

This prospective observational study was conducted in the Department of Surgery at Rangpur Medical College Hospital, Rangpur, a major tertiary care center in northern Bangladesh that serves a large population from both rural and urban areas. The study was carried out over 12 months, from January to December 2014. The study population comprised adult male patients diagnosed clinically with vaginal hydrocele who attended the surgery outpatient department and were admitted to the general surgery wards for treatment. Both new and recurrent cases were included, while patients with hydrocele secondary to trauma, tumors, tuberculosis, or systemic diseases such as nephrotic syndrome were excluded to ensure etiological specificity.

A total of 100 patients were enrolled as the study sample. Participants were selected through random sampling among eligible patients presenting during the study period to minimize selection bias. Data were collected prospectively using a structured questionnaire that covered socio-demographic variables, including age, residence, occupation, housing type, monthly income, and sanitation status, as well as detailed clinical findings. Each case was examined and categorized as definite, highly likely, suspected, or non-filarial hydrocele based on clinical features and, when indicated, parasitological or serological evidence.

All data were checked for completeness and consistency before entry and analyzed using Statistical Package for Social Sciences (SPSS) version 26.0. Descriptive statistics were computed to summarize baseline characteristics and etiological categories, and categorical variables were expressed as frequencies and percentages. The chi-square test was applied to determine associations between filarial and non-filarial cases across socio-demographic and clinical variables. Factors that showed significant associations in bivariate analysis were subsequently entered into a multivariable logistic regression model to identify independent predictors of filarial hydrocele while adjusting for potential confounders. Adjusted odds ratios (AORs) with 95% confidence intervals (CIs) were calculated, and a *p*-value of less than 0.05 was considered statistically significant.

RESULTS

Among the 100 adult male participants with hydrocele, the majority (53%) were diagnosed as definite filarial cases, while 10% were considered highly likely and 20% suspected to be of filarial origin. Non-filarial causes accounted for 17% of cases. These findings indicate that nearly four out of five hydrocele cases in this endemic area are attributable to lymphatic filariasis, underscoring the ongoing transmission and endemicity of the disease in northern Bangladesh (*Table I*).

Table I
Distribution of Study Participants by Etiological Category of Hydrocele.

Etiological category	Frequency (n)	Percentage (%)
Definite filariasis	53	53.00
Highly likely filariasis	10	10.00
Suspected filariasis	20	20.00
Non-filarial	17	17.00

Filarial hydrocele was more prevalent among rural residents (69.9%) compared with urban dwellers (30.1%), a difference that was statistically significant (p = 0.001). Poor sanitation was also significantly associated with filarial cases (81.9% vs. 58.8%; p = 0.03). Occupational exposure showed a strong relationship, with 57.8% of filarial cases working in the biri industry compared to only 17.6% of non-filarial cases (p = 0.002). Although not statistically significant, filarial hydrocele tended to occur more often among individuals aged 31–40 years, those from low-income households, and those with unilateral hydrocele. These associations suggest that environmental, occupational, and hygiene factors play critical roles in disease occurrence (*Table II*).

Table II
Comparison of Socio-Demographic and Clinical Characteristics between Filarial and Non-Filarial Hydrocele Cases.

Variable	Category	Filarial cases n (%)	Non-filarial cases n (%)	p-value
Age group (years)	18–30	25 (30.1)	3 (17.6)	0.49
	31–40	35 (42.2)	6 (35.3)	
	≥41	23 (27.7)	8 (47.1)	
Residence	Rural	58 (69.9)	5 (29.4)	0.001
	Urban	25 (30.1)	12 (70.6)	
Housing pattern	Kuncha	52 (62.7)	7 (41.2)	0.08
	Semi-pacca	22 (26.5)	7 (41.2)	
	Pacca	9 (10.8)	3 (17.6)	
Sanitation status	Poor	68 (81.9)	10 (58.8)	0.03
	Good/Very good	15 (18.1)	7 (41.2)	
Occupation	Biri industry	48 (57.8)	3 (17.6)	0.002
	Others	35 (42.2)	14 (82.4)	

Income level	Poor	66 (79.5)	11 (64.7)	0.18
	Middle/Upper	17 (20.5)	6 (35.3)	
Laterality	Unilateral	75 (90.4)	13 (76.5)	0.09
	Bilateral	8 (9.6)	4 (23.5)	

After adjusting for potential confounders, rural residence (AOR 3.85; 95% CI: 1.42–10.45; p = 0.008), poor sanitation (AOR 2.67; 95% CI: 1.01–7.08; p = 0.047), and occupation in the biri industry (AOR 4.28; 95% CI: 1.36–13.46; p = 0.013) remained significant independent predictors of filarial hydrocele. Although low income and unilateral hydrocele showed elevated odds, these associations were not statistically significant. The model demonstrates that exposure to unhygienic living conditions and certain occupations in rural settings substantially increases the risk of developing filarial hydrocele (*Table III*).

Table III
Multivariable Logistic Regression Identifying Independent Predictors of Filarial Hydrocele among Study Participants.

Predictor Variable	Adjusted Odds Ratio (AOR)	95% Confidence Interval	p-value
Rural residence	3.85	1.42 – 10.45	0.008
Poor sanitation	2.67	1.01 – 7.08	0.047
Works in biri industry	4.28	1.36 – 13.46	0.013
Low income	1.82	0.63 – 5.28	0.26
Unilateral hydrocele	2.12	0.68 – 6.56	0.19

DISCUSSION

The present study reveals that most adult vaginal hydroceles in this filariasis-endemic area of northern Bangladesh are of filarial origin and are strongly associated with socio-demographic disadvantages, particularly rural residence, poor sanitation, and work in the biri industry. The overall proportion of hydroceles attributable to filarial etiology in our series is high, with 83% of cases classified as definite, highly likely, or suspected filariasis. This pattern is consistent with community and hospital-based reports from other endemic regions, where hydrocele is described as the dominant chronic manifestation of lymphatic filariasis among adult men and contributes substantially to the burden of disability and stigma [5,14]. Njenga et al. in Kenya similarly documented hydrocele and limb lymphoedema as the principal chronic clinical outcomes in highly endemic communities, supporting the view that so-called idiopathic vaginal hydroceles in such settings frequently represent unrecognised filarial disease rather than primary non-filarial pathology [14]. The age distribution in our study, with a peak in the 31–40 year age group, is similar to that in previous studies, indicating that chronic scrotal pathology typically develops after years of cumulative infection and progressive lymphatic damage [4,14-17]. A study showed that adult worm death within scrotal lymphatics and the formation of intrascrotal nodules play a central role in the pathogenesis of filarial hydrocele [15]. Subsequent work from the same group demonstrated persistent lymphatic dilation and altered mechanics as key mechanisms underlying chronic, often recurrent, hydroceles [4]. More recent experimental and imaging studies have further clarified that lymphatic remodeling and contractile dysfunction, driven by inflammatory responses to adult worms and their Wolbachia endosymbionts, underpin the evolution from subclinical infection to established morbidity [16,17]. These pathophysiological insights provide a biological explanation for our finding that unilateral hydrocele predominates, yet bilateral disease also occurs; the specific pattern likely reflects the focal distribution of adult worms within the scrotal lymphatic network rather than a distinct etiological category. The strong, independent association between rural residence and filarial hydrocele in our data mirrors spatial analyses from India, where geo-environmental risk models consistently show higher transmission and morbidity in rural, low-lying, and poorly serviced areas compared with urban centers [18]. Sabesan et al. mapped filariasis risk across India and identified clusters of high endemicity linked to poor drainage, high vector densities, and disadvantaged housing environments, all of which are standard features of the rural communities served by our hospital [18]. The additional effect of poor sanitation in our multivariable model is also plausible. Although faeco-oral transmission is not involved, inadequate drainage and waste management encourage breeding of Culex vectors, which thrive in polluted water and peri-domestic habitats [18,19]. Our finding that occupation in the biri industry is a powerful predictor of filarial hydrocele suggests that occupational setting may concentrate risk: similar to the plantation and informal-sector labourers described in Ghana and Kenya, these workers often live in overcrowded housing, have prolonged evening exposure to mosquitoes, and limited access to preventive services [5,14,18]. The socio-economic implications of these associations are considerable. Economic studies have shown that chronic lymphatic filariasis, particularly hydrocele and lymphoedema, imposes substantial productivity losses, out-of-pocket costs, and long-term income erosion on affected households [20-22]. In our setting, the concentration of filarial hydrocele among low-income rural men and biri workers suggests a similar cycle: poverty increases exposure to infection; established morbidity then reinforces poverty through reduced work capacity and the costs of surgery and repeated care. Treatment-seeking studies also highlight diagnostic delays, inappropriate or prolonged use of antifilarial drugs, and fragmented care pathways for chronic filarial morbidity; these patterns likely apply in northern Bangladesh as well and help explain why many of our patients present with long-standing, large hydroceles [21,23]. At the same time, global programmatic narratives have tended to privilege interruption of transmission through mass drug administration, while morbidity management and disability prevention have received less sustained emphasis [1,2]. Our data reinforce the arguments from Wynd et al. and Zeldenryk et al. that the full burden of lymphatic filariasis cannot be captured by microfilariaemia prevalence alone, and that chronic manifestations, such as hydrocele, carry profound social, psychological, and economic consequences [2,19].

LIMITATIONS

This single-centre, hospital-based study, with a relatively small sample size, may not accurately reflect community-level patterns of hydrocele in the broader population. Etiological classification relied mainly on clinical criteria with limited laboratory confirmation, so some misclassification is possible. In addition, the cross-sectional design and lack of data on factors such as detailed mosquito exposure or prior antifilarial treatment limit causal inference regarding the observed associations.

CONCLUSION

In this endemic area of northern Bangladesh, most adult vaginal hydroceles were of filarial origin and were strongly associated with rural residence, poor

sanitation, and employment in the biri industry. These findings highlight that filarial hydrocele is closely linked to socio-environmental disadvantage and underscore the need for targeted morbidity management, improved sanitation and focused preventive interventions for high-risk rural and low-income male populations.

RECOMMENDATIONS

Routine evaluation of adult male hydrocele in endemic areas should include consideration of filarial etiology, with timely referral for appropriate antiparasitic treatment and hydrocelectomy. Targeted health education and morbidity management services should focus on high-risk groups, particularly rural residents and bidi workers. Public health programmes should integrate hydrocele care with lymphatic filariasis control activities, emphasizing improved sanitation, vector control, and poverty-oriented interventions in vulnerable communities.

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CONFLICT OF INTEREST

None declared.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Efficacy of bowel management program for improving quality of life in children with postoperative fecal incontinence

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ABSTRACT

Background: Fecal incontinence is still a severe consequence of surgical repair of anorectal abnormalities and Hirschsprung disease in young patients, significantly reducing quality of life. The purpose of this study was to assess the efficacy of a systematic bowel management program in enhancing the quality of life for children with postoperative fecal incontinence. **Methods & Material:** This quasi-experimental study was carried out at Mymensingh Medical College Hospital in Bangladesh from July 2023 to December 2024. A purposive sample was used to enroll 50 children aged 3 to 12 years old who had postoperative fecal incontinence after surgical repair of anorectal deformity or Hirschsprung disease. A seven-day bowel control treatment involving saline enemas with or without glycerin was implemented. At baseline and 12-week follow-up, quality of life was assessed using the Pediatric Quality of Life Inventory (PedsQL 4.0), which included domains such as physical, emotional, social, and school functioning. Data were entered and analyzed using SPSS version 26. **Results:** The bowel management treatment resulted in considerable improvements in all quality-of-life dimensions. Physical function ratings improved from 72.0±24.2 to 96.8±3.1 ($p<0.001$), emotional function from 68.2±28.2 to 88.3±9.7 ($p<0.001$), social function from 74.2±25.0 to 98.2±6.1 ($p<0.001$), and school function from 76.0±12.5 to 92.1±7.5 ($p<0.001$). 96% of patients had their stool consistency restored. Compliance was acceptable for 88% of individuals. Age and educational level were found to have a strong link with enema requirements. **Conclusion:** Structured bowel management programs increase quality of life in children with postoperative fecal incontinence by providing a non-invasive therapeutic strategy with high compliance and considerable functional improvements.

Keywords: *Bowel management program, Fecal incontinence, Hirschsprung disease, Quality of life.*

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INTRODUCTION

Faecal incontinence (FI) is an unfortunate chronic complication in children after surgery for congenital or acquired conditions involving congenital anorectal conditions, Hirschsprung's disease, or spinal dysraphisms. Despite improvements in current standard operating procedures for improving anorectal function, most patients remain with suboptimal bowel function, resulting in considerable pain, depression, or problematic perspectives affecting quality of life (QoL). In an article, it is stressed that FI following curative repair is most probably associated not only with anatomical factors but, more often, with complex interrelated issues involving neurologic function [1]. FI has been hard for many kids, causing embarrassment, absenteeism, worry, and low self-confidence. Based upon clinical assessment with specific tools, FI caused by diseases related to continence has a seriously negative influence upon kids' perspectives about their quality of life, related to emotional, social, or academic performance [2]. Traditional approaches to faecal incontinence, such as dietary modification, laxatives, stool softeners, and behaviour modifications, yield variable and often incomplete symptom control in pediatric patients. In response to these limitations, BMPs were developed as an intensive therapy aimed at predictable bowel emptying and social continence. BMPs were described as individualised regimens consisting of enemas, laxatives, transanal irrigation, and extensive education of the patient and their caregivers, tailored according to the child's anatomy and colonic motility [3]. A prospective cohort study reported significant reductions in soiling episodes and improved continence outcomes in children with ARM and Hirschsprung disease following participation in a structured BMP [4]. Another study reveals the effect of multidisciplinary bowel management in improving the rates of continence in children with complex colorectal problems [5]. Apart from the assessment of continence, the beneficial effects of BMPs in the improvement of quality of life have been established. There is documentation of marked improvements in the Pediatric Quality of Life Inventory (PedsQL), including the dimensions of physical, emotional, social, and school functioning, after bowel management programs [6]. The potential for the beneficial effects of effective bowel management in improving quality of life, both in the child and the parent, is pertinent in the already established psychosocial toll being suffered by the former. The above is further established in another study, showing the manifestation of increased psychosocial distress in the parents of children with anorectal malformations [7]. Based on a different study, personalised bowel care approaches influenced by anatomical factors, as well as the dynamics of the bowel, are related to good continence results in the long run [8]. Successful follow-through with BMP requires a multidisciplinary team-surgeons, gastroenterologists, nurses, and parents-and regular monitoring to maintain its effectiveness. Challenges still being faced, despite the effectiveness of the BMP, are related to long-term compliance and the availability of specialised care. A report underlines the importance of providing the patient with psychosocial support throughout, apart from regular follow-

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through, in preserving improvements in functionality over time [9]. This study aims to assess the effectiveness of a structured approach in improving the quality of life in terms of faecal incontinence in pediatric patients due to postoperative complications.

METHODS & MATERIALS

This quasi-experiment study took place at the Department of Paediatric Surgery, Mymensingh Medical College Hospital, Bangladesh, from July 2023 to December 2024. The study included patients with fecal incontinence among postoperative pediatric patients after the definitive surgical correction of anorectal malformation or Hirschsprung disease. Inclusion criteria include children aged 3-12 years with documented postoperative fecal incontinence persisting for more than six months after definitive surgical repair, with the ability to comply with follow-up care, and written informed consent from parents or authorized guardian. Exclusion criteria were active intestinal infection or inflammatory bowel disease, significant intellectual impairment precluding cooperation with bowel management plan, significant renal or hepatic failure making patients poor candidates for enema installation, prior entry in other bowel management programs, or anatomical complications requiring urgent surgical intervention. The baseline assessment consisted of a structured parental interview, a comprehensive clinical examination, and plain abdominal radiography in a standardized case record form. The bowel management program was initiated on the day of admission with a seven-day trial-and-error program with saline enemas, with or without glycerin, administered once daily. The initial volume of enema used was 10 ml/kg body weight, subsequently titrated based on the clinical response, radiographic distribution of stool, and Bristol Stool Chart. Parents were given standardized training regarding enema administration techniques. Treatment success was defined as no soiling with accompanying radiological clearing of the left colon and rectum. Quality of life was measured using the validated Pediatric Quality of Life Inventory (PedsQL 4.0) at admission and at 12-week follow-up. Data analysis was performed using SPSS version 26.0, using paired t-tests for continuous variables, chi-square testing for categorical data, and correlation analyses as needed. P-values < 0.05 were considered significant. Before participating, we received institutional review board approval and written informed consent.

RESULTS

Table I represents postoperative fecal incontinence in 28 men (56%) and 22 women (44%). Parental educational status varied significantly, with 40% having completed primary school, 16% completing SSC, 18% completing HSC, 12% holding graduate degrees or higher, and 14% having no formal schooling. The primary underlying diagnosis was predominantly anorectal malformation in 34 patients (68%), followed by Hirschsprung disease in 16 patients (32%).

Table I
Baseline demographic and clinical characteristics of the study participants (*n*=50).

Variable	Category	Frequency (n)	Percentage (%)
Gender	Male	28	56
	Female	22	44
Educational level	No formal education	7	14
	Completed primary education	20	40
	Completed SSC	8	16
	Completed HSC	9	18
	Graduate or above	6	12
Primary disease	ARM	34	68
	HD	16	32

According to *Table II*, the pre-intervention assessment revealed constipation in 76%, diarrhea in 24%, and no patients had normal stool consistency. Following the 12-week treatments, constipation decreased substantially to only one patient (2%), whereas 48 patients (96%) achieved normal stool consistency, and one patient (2%) continued to have diarrhea. The results showed significant improvements in bowel management, with 74% less constipation, 96% normal consistency, and 22% less diarrhea (p<0.001).

Table II
Effect of bowel management program on stool consistency (paired categorical analysis, *n* = 50).

Stool consistency	Pre-BMP n (%)	Post-BMP n (%)	Absolute change (%)	p-value
Constipation	38 (76.0)	1 (2.0)	−74.0	<0.001
Normal stool	0 (0.0)	48 (96.0)	+96.0	<0.001
Diarrhea	12 (24.0)	1 (2.0)	−22.0	<0.001

Table III showed statistically significant improvements in all four PedsQL domains. Physical functioning ratings significantly rose from 72.0±24.2 to 96.8±3.1 (p<0.001). Emotional functioning improved from 68.2±28.2 to 88.3±9.7 (p<0.001), indicating less anxiety and better psychological well-being. Social functioning significantly improved from 74.2±25.0 to 98.2±6.1 (p<0.001), indicating better peer relationships and social participation. School functioning improved from 76.0±12.5 to 92.1±7.5 (p<0.001), indicating more academic engagement and concentration.

Table III
Quality of life outcomes and procedural compliance following the Bowel Management Program.

Outcome measure	Pre-BMP, mean ± SD	Post-BMP, mean ± SD	p value*
Physical function	72.0 ± 24.2	96.8 ± 3.1	< 0.001
Emotional function	68.2 ± 28.2	88.3 ± 9.7	< 0.001
Social function	74.2 ± 25.0	98.2 ± 6.1	< 0.001
School function	76.0 ± 12.5	92.1 ± 7.5	< 0.001

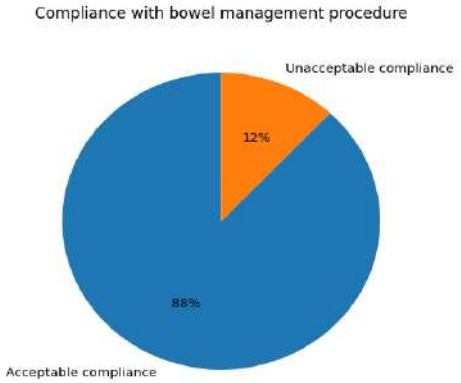

Figure 1 Compliance with the procedure among patients/guardians.

Figure 1 illustrates 88% participants adhered to the bowel management protocol, effectively completing the stipulated enema delivery schedules and follow-up obligations. Only 12% participants showed unsatisfactory compliance, which was explained by problems such as difficulty with enema delivery technique, scheduling conflicts, or psychosocial impediments.

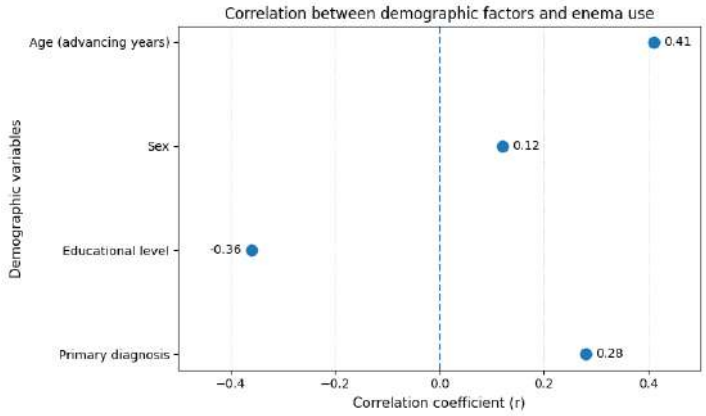

Figure 2 Correlation between demographic factors and enema use during bowel management.

Figure 2 depicts significant connections between demographic factors and enema requirements. Age showed a moderate positive connection (r=0.41), indicating that older children required larger or more frequent enema dosages. Parental educational level demonstrated a moderate negative correlation (r=-0.36), showing that higher parental education was related to fewer enema requirements. The primary diagnosis showed a weak positive connection (r=0.28), with anorectal malformation and Hirschsprung disease patients having differing enema needs. Gender had no significant link (r = 0.12, p = 0.39).

DISCUSSION

This study demonstrated that organized programs in bowel care can greatly affect the quality-of-life levels in pediatric patients in relation to fecal incontinence that occurred after surgeries performed to treat anorectal malformations and Hirschsprung disease. The great improvements that occurred in physical, emotional, social, and school functions advocate the importance of conservative bowel care approaches in treating patients with defects in the constitution and functions of the bowel. The marked improvement in stool texture, with 96% of patients exhibiting normal stooling patterns, is consistent with results from Pakarinen et al., who proved the effectiveness of structured bowel management programmes based on enemas [10]. Similar results were documented in children with anorectal malformations using structured bowel management programmes by Versteegh et al., who stressed the need for individualization of bowel management schemes and parental training [11]. The program's effectiveness in completely overcoming constipation and diarrhea, irrespective of the original functional disorder, underscores its potential for bowel homeostasis. These reported improvements in quality of life are in keeping with Witvliet et al., who highlight the massive effects experienced by fecal incontinence on affected well-being in pediatrics [12]. Social

functioning reported the largest increase in values from 74.2 to 98.2. This corresponds closely to the observations made by Pelizzo et al., that there was a considerable increase in social participation in affected individuals following successful intervention for their bowel management needs [13]. These values for emotional functioning noted in our observations highlight the psychological toll that fecal incontinence takes on affected individuals, in that affected pediatric patients become anxious and embarrassed about their condition and suffer from poor self-esteem that is effectively made better through incontinence management [14]. The compliance rate of 88% recorded in our study can be said to be quite good compared to the rate of adherence observed in other pediatric treatment programs, which generally varies between 70-85% [15]. On the other hand, the 12% rate of non-compliance points to certain challenges that need to be addressed. It has been found by Cairo et al. that factors such as time constraints, family problems, and psychosocial issues are some common causes for non-adherence [16]. The observation that an increase in age is associated with an increase in enema use is suggestive of a possible modification in functional or capacity changes in the colon, hence the need for adjustment in dosing. This could be related to physiological evidence, which shows an increase in colonic volume or characteristics with increasing age, among other factors [17]. On the other hand, a negative relationship between parental education levels and usage rates is an indicator that better chronic management practice could help decrease reliance solely on enema administration [18]. The preponderance of anorectal malformation cases (68%), observed in the population, represents the distribution of such defects, being a risk factor for persistent fecal incontinence greater than Hirschsprung disease [19]. The association observed between the primary diagnosis and the need for an enema relates primarily to the fact that the pathophysiology affects the management strategies, according to the defects being anatomical or neurosensory. Our findings lend strong support to the inclusion of structured Bowel Management Programs within standard postoperative care regimens for children with colorectal anomalies. The marked improvements attained within all measured endpoints, together with high levels of compliance, clearly establish both efficacy and feasibility [20]. The program's dependence on straightforward and easily accessible interventions renders it especially applicable within low-resource environments, having been successfully implemented within our institution to great effect [21]. The application of the validated PedsQL 4.0 measure allows us to enhance the reliability of our data on quality-of-life measurements, facilitating comparisons with other international studies on this topic [22]. This broad-based strategy for assessing change also acknowledges that effectively managing the disorder requires much more than just symptom control, but involves broad-based improvements in all aspects of the children's function.

LIMITATIONS

This study's limitations include the quasi-experimental design without a control group, which limits causal inference, and the relatively small sample size from a single center, which may affect generalizability. The 12-week follow-up period, while demonstrating short-term efficacy, does not assess long-term sustainability of improvements or potential need for ongoing intervention modifications.

CONCLUSION

This study concludes that systematic bowel management regimens greatly improve quality of life in children with postoperative fecal incontinence caused by anorectal abnormalities or Hirschsprung disease. The intervention normalized stool consistency in 96% of participants and resulted in statistically significant improvements across all quality-of-life dimensions, with especially substantial changes in social functioning. The 88% compliance rate implies that the program is very acceptable and feasible in ordinary clinical practice, establishing bowel control as a key component of complete postoperative care for these fragile children.

RECOMMENDATIONS

Future studies should incorporate randomized controlled trial designs with longer follow-up periods to establish sustained efficacy and optimal duration of bowel management interventions. Multicenter studies with larger, diverse populations are needed to enhance generalizability and identify predictors of treatment success that can guide personalized management protocols.

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CONFLICT OF INTEREST

None declared.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Frequency and Risk Factors of Postoperative Nausea and Vomiting in Patients Receiving General Anesthesia – A Cross-Sectional Study

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ABSTRACT

Introduction: Postoperative nausea and vomiting (PONV) are among the most frequent problems after general anesthesia that can negatively impact a patient's comfort and recovery. Several factors determine the occurrence of PONV, such as patient characteristics, nature and length of surgery, anesthetic method, and use of opioids around the time of surgery. **Methods and materials:** This cross-sectional study was conducted on 68 patients scheduled for elective surgery under general anesthesia at the Department of Anaesthesiology at Manipal AFC Hospital, from July 2021 to June, 2022. Adult patients aged 18 years and above were included in this study. Data were analyzed using SPSS version 26.0. **Result:** Thirty-eight patients (55.9%) were females, 50 (73.5%) were non-smokers, and 14 (20.6%) had a history of motion sickness or previous PONV, among the risk factors for PONV. Twenty, one patient (30.9%) had PONV within 24 hours; 12 (17.6%) had only nausea, and 9 (13.3%) had vomiting and nausea. The occurrence of PONV was more among females (16/38, 42.1%), patients who had surgery for >2 hours (9/16, 56.3%), and those who were given opioids postoperatively (16/40, 40.0%). The incidence also went up with increasing Apfel scores, 15.0% in low-risk, risk, 30.8% in moderate-risk, and 45.5% in high-risk patients. **Conclusion:** This cross-sectional study revealed that the rate of postoperative nausea and vomiting (PONV) was 30.9% for patients who underwent general anaesthesia. Major determiners of PONV were female gender, the length of the surgery, the use of opioids after the surgery, and a higher Apfel score.

Keywords: *Postoperative Nausea and Vomiting, General Anesthesia, Opioid.*

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INTRODUCTION

Postoperative nausea and vomiting (PONV) still constitute some of the most frequent and distressing complications experienced by patients who undergo surgery with general anesthesia. PONV is defined as nausea, retching, or vomiting experienced within the first 24 hours post-surgery. It is a leading cause of patient discomfort, delays in patient recovery, and unplanned hospital readmissions resulting from complications such as dehydration, electrolyte imbalance, wound dehiscence, and aspiration pneumonitis. On top of that, patients who experience uncontrolled PONV become dissatisfied, and hospital costs go up, which is why healthcare professionals must be able to identify the risk factors and provide the right approach to perioperative care that will focus on prophylaxis and target interventions [1,2]. Find more. Even though there have been significant developments in anesthetic techniques and antiemetic prophylaxis, PONV is still frequently experienced. Approximately 25 to 30 % of all patients who undergo general anesthesia for surgery are affected by PONV if it is not treated, but this figure may climb to 70 to 80 % in patients who are at a high risk of the disorder because they have several predisposing factors [1,3]. Recent observational studies have shown that the rate of PONV differs significantly among different populations and clinical settings; for instance, a cross-sectional study in Ethiopia documented a prevalence of 35.4 % among adult surgical patients, whereas a study in Bangladesh reported an incidence of 25.6 % in patients undergoing general anesthesia [4,5]. Other recent publications have recorded PONV incidences of approximately 29.9 % in large cohorts of same-day surgical patients and about 31.1 % following laparoscopic cholecystectomy, thus indicating that PONV remains a common problem in the modern era [6]. The pathophysiology of PONV is complex and involves multiple factors, with patient characteristics, anesthetic methods, and surgical elements playing an important role. Known patient, related risk factors are being female, younger age, nonsmoking, having a history of PONV or motion sickness, and higher body mass index (BMI) [1,6]. Anesthesia, related factors such as the use of volatile anesthetics (e.g., sevoflurane and isoflurane), nitrous oxide, and perioperative opioids have always been associated with higher PONV risk because of their emetogenic properties [7]. Longer duration of anesthesia and surgery also bring about higher risks, with studies showing that the chance of getting PONV increases with longer surgical times [6,8]. Besides patient and anesthesia factors, the nature of the surgery also has an effect on the risk of PONV; laparoscopic procedures, gynecologic surgeries, and surgeries with pneumoperitoneum are always associated with a higher number of PONV cases compared to other types of operations [6,7]. This difference emphasizes the necessity of taking into account the type and complexity of the surgery when assessing the risk of PONV and putting in place preventive measures. One of the ways to assess risk is through tools such as risk prediction charts. For example, the simplified scoring system proposed by a group led by Apfel, this score takes into consideration the four main risk factors: female gender, nonsmoker, positive history of PONV or motion sickness, and use of postoperative opioids, and helps to categorize patients into low, moderate, and high-risk groups for PONV [1,3]. There are numerous predictive tools of PONV that have been tested for their validity and accuracy; however, the global implementation of risk-adapted antiemetic prophylaxis is still quite different between healthcare institutions. This inconsistency is most evident in low-resource settings, where routine risk assessment for PONV and the use of a multimodal prophylaxis approach may not be part of the regular practice [5].

METHODS & MATERIALS

This cross-sectional study involved a total of 68 patients who were going to electively have general anesthesia at the Department of Anaesthesiology at Manipur AFC

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Hospital, Cumilla, Bangladesh, from July, 2021 to June, 2022. Adults of 18 years and above who gave their consent were included, while those with pre-existing nausea or vomiting, gastrointestinal problems, or incomplete records were excluded. Demographic data, surgical information such as the type and duration of the surgery, anesthetic technique (inhalational vs. total intravenous anesthesia), and the use of opioids during the perioperative period were documented. Known risk factors for postoperative nausea and vomiting (PONV), such as female sex, non-smoking status, and history of motion sickness or prior PONV, were recorded, and Apfel risk scores were determined for each patient. Postoperative surveillance lasted for 24 hours, during which time the instances of nausea and vomiting were noted. Data were processed with SPSS ver. 26.0, to find out the incidence of PONV and its relationship with demographic, surgical, and anesthetic variables, as well as the total Apfel scores. Statistical tests comprised descriptive statistics, chi-square tests for categorical variables, and p-values <0.05 were deemed significant. Ethical clearance was taken from Rokeya Specialised Hospital.

RESULTS

According to *Table I*, the largest group of patients was between 31 and 45 years of age, 24 (35.3%), next in numbers were patients between 18 and 30 years, 18 (26.5%), 17 (25.0%) were between 46 and 60 years, and 9 (13.2%) were >60 years. There were 38 female (55.9%) and 30 male (44.1%) patients in the study. The majority of patients had a normal weight (42, 61.8%), while 26 (38.2%) were either overweight or obes.

Table I
Socio-demographic characteristics of the study participants (*n*=68).

Variable	Frequency (n)	Percentage (%)
Age group (years)		
18–30	18	26.5
31–45	24	35.3
46–60	17	25.0
>60	9	13.2
Sex		
Male	30	44.1
Female	38	55.9
BMI		
Normal (<25 kg/m²)	42	61.8
Overweight/Obese (≥25 kg/m²)	26	38.2

Table II illustrates that 26 patients (38.2%) had general surgery, gynecological procedures (18, 26.5%) were the next biggest group, followed by orthopedic (14, 20.6%) and other surgeries (10, 14.7%). The majority of operations were 1- 2 hours long (32, 47.1%), 20 (29.4%) were under one hour, and 16 (23.5%) exceeded two hours. 52 patients (76.5%) received inhalational anesthesia, while 16 (23.5%) had TIVA. Forty (58.8%) patients were given postoperative opioid analgesics.

Table II
Surgical and anesthetic characteristics (*n*=68).

Variable	Frequency (n)	Percentage (%)
Type of surgery		
General surgery	26	38.2
Gynecological	18	26.5
Orthopedic	14	20.6
Others	10	14.7
Duration of surgery		
<1 hour	20	29.4
1–2 hours	32	47.1
>2 hours	16	23.5
Type of anesthesia		
Inhalational (volatile agents)	52	76.5
Total intravenous anesthesia (TIVA)	16	23.5
Postoperative opioid use		
Yes	40	58.8
No	28	41.2

From *Table III*, it can be seen that 38 patients (55.9%) were female and 50 (73.5%) did not smoke. A history of either motion sickness or PONV was noted in 14 patients (20.6%). Use of postoperative opioids, a further significant risk factor, was detected in 40 patients (58.8%).

Table III
Distribution of established PONV risk factors (*n*=68).

Risk factor	Present n (%)
Female sex	38 (55.9)
Non-smoker	50 (73.5)
History of motion sickness/PONV	14 (20.6)
Postoperative opioid use	40 (58.8)

According to *Table IV*, 47 patients (69.1%) were free of PONV. Twelve patients (17.6%) out of the affected ones reported only nausea, whereas 9 (13.3%) had vomiting either with or without nausea. In total, PONV was present in 21 patients (30.9%) during the first 24 hours following the operation.

Table IV
Incidence and pattern of PONV within 24 hours (*n*=68).

Outcome	Frequency (n)	Percentage (%)
No PONV	47	69.1
Nausea only	12	17.6
Vomiting (± nausea)	9	13.3
Total PONV	21	30.9

Table V suggests that females were more likely to have PONV than males. (16 of 38, 42.1% vs. 5 of 30, 16.7%). There were more patients with PONV in the group with a surgery duration of more than 2 hours (9 of 16, 56.3%) as compared to the group with a shorter duration (12 of 52, 23.1%). Likewise, postoperative nausea and vomiting (PONV) were more frequent in patients who received postoperative opioids (16 out of 40, 40.0%) as compared to patients who did not (5 of 28, 17.9%). These relationships were statistically significant.

Table V
Association between selected factors and PONV (*n*=68).

Variable	PONV n/N (%)	No PONV n/N (%)	p-value
Female	16/38 (42.1)	22/38 (57.9)	0.03
Male	5/30 (16.7)	25/30 (83.3)	
Duration >2 hrs	9/16 (56.3)	7/16 (43.7)	0.01
≤2 hrs	12/52 (23.1)	40/52 (76.9)	
Opioids (Yes)	16/40 (40.0)	24/40 (60.0)	0.02
Opioids (No)	5/28 (17.9)	23/28 (82.1)	

Table VI illustrates how PONV incidence gradually rises with the Apfel score. Only three out of twenty patients with a low risk (score 01) developed PONV. In the moderate risk category (score 2), 8 of 26 patients (30.8%) had PONV; therefore, the highest rate was in the high-risk group (score 34), where 10 of 22 patients (45.5%) were afflicted.

Table VI
Relationship between Apfel score and PONV (*n*=68).

Apfel score	Patients (n)	PONV n (%)
0–1 (Low risk)	20	3 (15.0)
2 (Moderate risk)	26	8 (30.8)
3–4 (High risk)	22	10 (45.5)

DISCUSSION

In this cross-sectional study of 68 patients undergoing surgery under general anesthesia, the overall incidence of postoperative nausea and vomiting (PONV) was 30.9%. This finding is consistent with contemporary literature reporting PONV rates between 20% and 40% in general surgical populations. Qiu et al. reported a 29.9% incidence among 7,759 ambulatory surgical patients, while Gan et al. noted that PONV occurs in approximately 30% of all surgical patients and may increase to 70–80% in high-risk individuals [3,9]. Teshome et al. also documented a 35.4% prevalence in a hospital-based study [10]. With regard to demographic factors, our study demonstrated a significantly higher incidence of PONV among females (42.1%) compared with males (16.7%). This pattern is well documented in previous research. In the study by Qiu et al., the incidence was 34.3% in females versus 19.0% in males [3]. Similarly, Apfel et al. identified female gender as one of the strongest independent predictors, with the risk being approximately two to three times higher than in males [11]. Surgical duration was another important determinant. Patients undergoing procedures lasting more than 2 hours experienced a PONV incidence of 56.3%, compared with 23.1% among those with shorter procedures. Previous studies have reported similar associations. Qiu et al. found that procedures exceeding one hour were associated with a PONV incidence of approximately 38–40%, compared with about 20–22% for shorter operations [3]. Jamtsho et al. reported 45.0% PONV following prolonged laparoscopic surgeries [2]. In our cohort, postoperative opioid use was associated with a PONV incidence of 40.0%, compared with 17.9% among patients who did not receive opioids. Similar observations have been reported previously. Teshome et al. documented 41.2% PONV in opioid users versus 21.5% in non-users [10]. Apfel et al. also demonstrated that postoperative opioid administration significantly increases the likelihood of PONV [11]. Regarding baseline risk factors, non-smokers constituted 73.5% of our study population, and 20.6% had a history of motion sickness or previous PONV. Prior studies have reported similar distributions. Veiga-Gil et al. noted that nonsmokers comprised approximately 70–80% of surgical cohorts and had a significantly higher risk of PONV [12]. Qiu et al. reported a history of motion sickness/PONV in 18.5% of patients, which was independently associated with postoperative symptoms [3]. The cumulative effect of risk factors was evident when assessed using the Apfel score. The incidence of PONV increased progressively from 15.0% in the low-risk group, to 30.8% in the moderate-risk group, and 45.5% in the high-risk group. The original Apfel model demonstrated a graded increase in risk, with PONV rates of approximately 10%, 20%, 40%, and up to 60–80% as the number of

risk factors increased from one to four [11]. A validation study by Eberhart et al. similarly confirmed a stepwise rise in incidence across risk categories [13].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

In this cross-sectional study, the incidence of postoperative nausea and vomiting (PONV) was 30.9% in patients who underwent general anesthesia. PONV occurrence was significantly associated with female gender, prolonged surgery, postoperative administration of opioids, and higher Apfel scores.

RECOMMENDATION

According to the data we have just discussed, a simple preoperative risk assessment tool such as an Apfel score should be a routine procedure for anyone going under general anesthesia. High-risk patients, for example, women, patients with long operation times, or those who may need postoperative opioids, should be specifically targeted for prophylactic antiemetic therapy and good postoperative surveillance.

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CONFLICT OF INTEREST

None declared.

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Clinical Profile and Etiological Pattern of Pathological Fractures in Patients Attending a Tertiary Care Hospital in Bangladesh

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ABSTRACT

Introduction: Pathological fractures, which are fractures that take place in bones that have been weakened by some kind of disease, constitute an important clinical problem that might lead to serious morbidity and loss of function. Such fractures can be caused by cancer, metabolic bone diseases, infections, or benign bone lesions, and usually happen after a very minor or no trauma at all. **Methods & Materials:** This cross-sectional observational study was carried out in the Department of Orthopaedics at 250-Bed Sadar Hospital, Cox's Bazar, Bangladesh, over the period from January 2025 to December 2025. 104 patients who came with pathological fractures were the subject of this study. Data were entered and analyzed using SPSS version 25. **Result:** The most common cause was metastatic malignancy (38, 36.5%), followed by osteoporosis/metabolic bone disease (28, 26.9%), primary bone tumors (16, 15.4%), infection (12, 11.5%), and benign lesions (10, 9.6%). Breast (10, 26.3%), lung (8, 21.1%), and prostate (7, 18.4%) were the top three cancers in the metastatic cases. The femur (42, 40.4%) was the bone most commonly involved, followed by the humerus (18, 17.3%), vertebrae (16, 15.4%), and tibia/fibula (14, 13.5%). Most patients (56, 53.8%) came after minor trauma. There were spontaneous fractures in 28 (26.9%), pain before fracture in 16 (15.4%), and incidental findings in 4 (3.9%). **Conclusion:** Pathological fractures in an advanced care hospital were mostly observed in middle-aged and elderly individuals with a predominant male ratio. The primary cause was metastatic malignancy, followed by osteoporosis and metabolic bone disease, and the femur was the most common site of involvement. Generally, most patients came after suffering from minor or no trauma.

Keywords: *Etiological Pattern, Pathological Fractures, Trivial Trauma.*

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INTRODUCTION

Pathological fractures are fractures that occur in bones weakened by some disease process and usually after little or no trauma. In contrast to traumatic fractures, which occur as a result of high-energy external forces, pathological fractures happen when bone strength is compromised by local or systemic pathology. These fractures constitute a major clinical issue as they are often a sign of serious underlying conditions like malignancy, metabolic bone disease, infection, or benign bone lesions, and they necessitate a different diagnostic and therapeutic approach than that used for traumatic fractures [1, 2]. The worldwide incidence of pathological fractures has been on the rise over the last few decades. The main reason for this increase has been population aging, better survival of patients with chronic diseases, and cancer treatments that not only extend life but also raise the risk of skeletal complications [2,3]. Among various causes, metastatic bone disease is the leading one for pathological fractures in adults. Breast, prostate, lung, thyroid, and kidney cancers are the most common primaries that metastasize to the bone. The resulting osteolytic or mixed lesions secondary to metastasis are responsible for weakening the skeletal framework and predisposing it to fractures even after minor stresses [3, 4]. Fractures due to pathological alterations in cancer patients contribute to the severity of the pain, a decrease in the patients' ability to move, a lower quality of life, and increased usage of healthcare services [4]. Besides, metabolic bone diseases make a significant contribution to the incidence of pathological fractures. Osteoporosis, the most common metabolic bone disorder, is clinically manifested by a decreased amount of bone as well as changes in the bone microstructure that result in higher bone fragility and predisposition to fractures [5]. Fragility fractures associated with osteoporosis have become a significant public health problem globally, especially for the elderly [5, 6]. The burden of osteoporosis and related fractures in the Asia-Pacific region, including South Asia, is still expected to increase significantly due to demographic changes and lack of preventive screening [6]. Besides cancer and metabolic disorders, the list of everyday conditions that can lead to pathological fractures is quite broad. Both benign and malignant primary bone tumors, tumor-like lesions such as bone cysts and fibrous dysplasia, chronic osteomyelitis, and systemic diseases that affect bone metabolism may weaken the bone structure enough to cause fractures [1, 7]. The younger population is mostly affected by benign lesions and primary bone tumors, whereas in the older population, metastatic disease and osteoporosis are the leading causes of fractures [2, 7]. It is, therefore, crucial to know the age and specific etiological patterns for early diagnosis and treatment. Accurately pinpointing the cause behind the pathological fracture is very important because the treatment of pathological fractures is very different from that of traumatic fractures. Management is frequently a complex decision that needs input from a team of orthopaedic surgeons, oncologists, radiologists, and pathologists. If a pathological fracture is not detected at the time of the first presentation, this may result in an inappropriate surgical procedure, the diagnosis of a malignancy being delayed, and altogether poor clinical results [1, 8]. Among the most important elements of the evaluation are a detailed clinical history, thorough physical examination, appropriate imaging, and histopathological examination if necessary [8]. Bangladesh, as a low- and middle-income country, may possibly have an epidemiological profile of pathological fractures that is different from that of high-income countries due to differences in disease prevalence, healthcare access, nutritional status, and diagnostic facilities. Although traumatic fractures have been

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massively studied in the region, there is very little information about the clinical features and the etiological distribution of pathological fractures [9,10].

METHODS & MATERIALS

This cross-sectional observational study took place in the Department of Orthopaedics at 250-Bed Sadar Hospital, Cox's Bazar, Bangladesh, from January 2025 to December 2025. In total, 104 patients with pathological fractures were consecutively recruited after their informed consent had been obtained. Patients of any age and either sex were eligible for the study, while those with fractures resulting from high-energy trauma and no underlying bone pathology were not considered. Demographic data, clinical history, and the way the injury had occurred were documented. All patients were subjected to radiological evaluation, including X-rays of the fractured area, and additional imaging (CT/MRI) if necessary. Laboratory tests were done to detect any metabolic or systemic disorders that might be the cause, such as serum levels of calcium, phosphate, alkaline phosphatase, vitamin D, and appropriate tumor markers. Fractures were divided into metastatic malignancy, primary bone tumor, osteoporosis/metabolic bone disease, chronic osteomyelitis/infection, and benign bone lesions according to clinical, radiological, and histopathological findings. When the case was metastatic, the primary tumor site was determined if possible. Location of fracture was noted, i.e., femur, humerus, tibia/fibula, vertebrae, pelvis, or other bones. Presentation mode was documented as fracture after trivial trauma, spontaneous fracture, pain before fracture, or incidental diagnosis. Data were input and analyzed with the support of SPSS version 25. Sex, etiology, fracture site, and mode of presentation as categorical variables were presented as frequencies and percentages.

RESULTS

Of the total 104 patients, there were 14 (13.5%) patients aged 20 years, 28 (26.9%) patients in the 21-40 years age group, 36 (34.6%) patients aged 41-60 years, and 26 (25.0%) patients aged more than 60 years. The largest proportion of pathological fractures was in the 41-60 years age group (*Table I*).

Table I
Age Distribution of the Study Patients (*n* = 104).

Age group (years)	Number	Percentage (%)
≤20	14	13.5
21–40	28	26.9
41–60	36	34.6
>60	26	25.0

Among the 104 patients, 62 (59.6%) were male, and 42 (40.4%) were female. There was a male predominance, and the male, to, female ratio was nearly 1.5:1 (*Table II*).

Table II
Gender Distribution of the Study Patients (n = 104).

Gender	Number	Percentage (%)
Male	62	59.6
Female	42	40.4

Metastatic malignancy was the leading cause among the etiologies; it accounted for 38 (36.5%) patients. Osteoporosis or metabolic bone disease was the diagnosis in 28 (26.9%) cases. Primary bone tumors were found in 16 (15.4%) patients, and chronic osteomyelitis or infection was recorded in 12 (11.5%) cases. Benign bone lesions such as cysts, fibrous dysplasia, etc., were seen in 10 (9.6%) patients (*Table III*).

Table III
Etiological Pattern of Pathological Fractures (*n* = 104).

Etiology	Number	Percentage (%)
Metastatic malignancy	38	36.5
Primary bone tumor	16	15.4
Osteoporosis/Metabolic bone disease	28	26.9
Chronic osteomyelitis/infection	12	11.5
Benign bone lesions	10	9.6

Among the 38 patients presenting with metastatic fractures, 10 (26.3%) had breast cancer, 8 (21.1%) were diagnosed with lung cancer, and 7 (18.4%) had prostate cancer. Thyroid carcinoma was the cause in 5 (13.2%) patients, whereas 4 (10.5%) patients each were due to kidney cancer and other primary malignancies (*Table IV*).

Table IV
Primary Sources of Metastasis (*n* = 38).

Primary tumor site	Number	Percentage (%)
Breast	10	26.3
Lung	8	21.1
Prostate	7	18.4
Thyroid	5	13.2
Kidney	4	10.5
Others	4	10.5

The femur was the bone most affected in these patients (n=42, 40.4%). Next came the cases involving the humerus 18 (17.3%), vertebrae 16 (15.4%), and tibia/fibula 14 (13.5%) . Pelvic fractures were observed in 8 (7.7%) patients, while 6 (5.7%) cases involved other bones (*Table V*).

Table V
Anatomical Distribution of Pathological Fractures (*n* = 104).

Bone involved	Number	Percentage (%)
Femur	42	40.4
Humerus	18	17.3
Tibia/Fibula	14	13.5
Vertebrae	16	15.4
Pelvis	8	7.7
Others	6	5.7

In terms of clinical presentation, 56 (53.8%) patients fractured after suffering minor injuries, while 28 (26.9%) had spontaneous fractures without any trauma. A prior history of continuous pain before fracture was given by 16 (15.4%) patients, and 4 (3.9%) cases were incidentally detected during workup for other diseases (*Table VI*).

Table VI
Mode of Presentation (*n* = 104).

Clinical presentation	Number	Percentage (%)
Fracture after trivial trauma	56	53.8
Spontaneous fracture	28	26.9
Pain preceding fracture	16	15.4
Incidental diagnosis	4	3.9

DISCUSSION

In the current study, most pathological fractures belonged to the age group 4160 years (36 cases, 34.6%), then to >60 years (26 cases, 25.0%), 2140 years (28 cases, 26.9%), and 20 years (14 cases, 13.5%). The data revealed that pathological fractures are more frequent among middle-aged and elderly people. A study has shown that 58% of pathological fractures were in patients more than 40 years of age, and the most frequent period of occurrence was the fifth and sixth decades [11]. In the present study, a male preponderance was noted with 62 males (59.6%) and 42 females (40.4%), the male-to-female ratio being around 1.5:1. Kumar et al. reported the presence of 64% male patients in their series. A slightly greater percentage of males compared to females in these studies, as well as in the current study, could be due to males having more exposure to risk factors for malignancy and the practice of delayed male patients' healthcare seeking that is common in developing regions [12]. Considering etiology, metastatic malignancy was the main reason in 38(36.5%) patients, followed by osteoporosis/metabolic bone disease in 28(26.9%) patients, primary bone tumors in 16(15.4%), infection in 12(11.5%), and benign lesions in 10(9.6%) patients. Errani et al. showed that about 6070% of pathological fractures in adults result from metastatic disease, which is a markedly higher percentage than found in the present study. Similarly, Coleman stated that the majority of pathological fractures that occur in cancer patients are due to skeletal metastases. Meanwhile, the percentage of osteoporotic fractures in the present study (26.9%) is significantly greater than that in some oncological series, which may be a reflection of the increasing problem and lack of diagnosis of osteoporosis in South Asian populations [3,8]. Among 38 metastatic cases, the main primary tumor that this study found to be the source of metastases was breast cancer (10 cases, 26.3%), followed by lung (8 cases, 21.1%), prostate (7 cases, 18.4%), thyroid (5 cases, 13.2%), and kidney and others (4 cases each, 10.5%). Kakhki et al.'s study has shown that breast cancer was responsible for 31% of bone metastases, followed by prostate (25%) and lung (16%). Similarly, Coleman stated that breast and prostate cancers are the most common causes of skeletal metastasis. The pattern of distribution of primary malignancies in the present study is in agreement with the well, known bone, seeking tumors [3, 4]. The anatomical distribution of the lesions revealed that the femur was the bone most frequently affected (42 cases, 40.4%), followed by the humerus (18 cases, 17.3%), vertebrae (16 cases, 15.4%), tibia/fibula (14 cases, 13.5%), pelvis (8 cases, 7.7%), and other bones (6 cases, 5.7%). Bickels et al. reported that approximately 50% of pathological fractures occur in the femur, while the humerus accounts for 10–20% of cases. Similarly, van der Linden et al. observed that long bones, particularly the femur and humerus, were involved in the majority of patients with skeletal metastases. The site distribution in the present study closely follows this biomechanical and disease-related pattern [13,14]. Concerning clinical presentation, 56 patients (53.8%) sustained fractures after trivial trauma, 28 (26.9%) had spontaneous

fractures without trauma, 16 (15.4%) reported pain preceding the fracture, and 4 (3.9%) were diagnosed incidentally. Kanis et al. reported that more than 50% of fragility fractures occur after low-energy trauma, while Rizzo noted that pathological fractures frequently occur spontaneously or following minimal injury and are often preceded by persistent localized pain. The clinical pattern observed in the present study, therefore, reflects the classical presentation of pathological and fragility fractures [1,5].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

Pathological fractures were found mostly in middle-aged and elderly patients, with males more frequently affected in this tertiary care center. Metastatic malignancy was the major cause, followed by osteoporosis and metabolic bone disease, with the femur being the most commonly involved site. More than half of the patients came for care after minor or no trauma at all.

RECOMMENDATION

Any patient with fractures caused by minor or no trauma should be checked thoroughly for any underlying pathology. This should include proper clinical, radiological, and laboratory investigations. Special emphasis on early cancer and osteoporosis screening is a must for middle-aged and elderly patients to allow timely diagnosis and treatment.

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CONFLICT OF INTEREST

None declared.

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A Comparative Study on the Efficacy of Mifepristone-Misoprostol Combination versus Misoprostol Alone and Intracervical Catheter (ICC) in the Management of IUFD at Rangpur Medical College Hospital

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ABSTRACT

Background: Intrauterine fetal death (IUFD) presents a profound obstetric challenge requiring safe and effective induction of labour. In Bangladesh, misoprostol alone and mechanical methods like an intracervical catheter (ICC) are commonly used, but evidence on the efficacy of the mifepristone-misoprostol combination in this setting is limited. Objective: To compare the induction-to-delivery interval and maternal outcomes of three methods for managing IUFD: mifepristone-misoprostol combination, misoprostol alone, and intracervical catheter (ICC). **Methods & Materials**: A prospective cohort study was conducted at Rangpur Medical College & Hospital, Rangpur, from January 2025 to December 2025. Using purposive sampling, 29 women with IUFD (≥24 weeks) were allocated to three groups: Group A (mifepristone 200mg orally followed by oral misoprostol, n=10), Group B (oral misoprostol alone, n=10), and Group C (ICC with oxytocin augmentation, n=9). The primary outcome was the induction-to-delivery interval. Data were analyzed using SPSS version 23.0. **Results**: The mean induction-to-delivery interval was significantly shortest with mifepristone-misoprostol (10.8±2.9 hours), followed by misoprostol alone (15.4±4.1 hours) and ICC (19.1±5.3 hours) ($p<0.001$). The 24-hour vaginal delivery success rate was highest in the combination group (90%), versus 70% with misoprostol and 55.6% with ICC. Maternal complication rates (e.g., PPH) were low and comparable across all three methods. **Conclusion**: The mifepristone-misoprostol regimen was the most efficacious method for labour induction in IUFD, achieving the shortest delivery time and highest success rate. Misoprostol alone was a viable alternative, while ICC was associated with the longest induction interval.

Keywords: *Intracervical catheter, intrauterine fetal death, labour induction, mifepristone, misoprostol, stillbirth*

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INTRODUCTION

Intrauterine fetal death (IUFD), defined as the demise of a fetus at or beyond 24 weeks of gestation, remains a devastating obstetric complication with profound psychological and social implications for the affected family [1]. Its global burden is disproportionately high in low- and middle-income countries (LMICs). In Bangladesh, the stillbirth rate is estimated at 22.1 per 1000 total births, translating to a significant public health challenge and highlighting an urgent need for improved antenatal and intrapartum care strategies [2]. The management of IUFD, therefore, is not only a clinical imperative to ensure maternal safety but also a critical step in the compassionate care for grieving parents. The cornerstone of IUFD management is the timely and safe induction of labour to achieve vaginal delivery, thereby avoiding the risks associated with prolonged retention of the fetus, such as coagulopathy and infection [3]. The ideal induction method should be highly effective, safe, accessible, and cost-effective, with minimal physical and emotional trauma to the mother. For decades, misoprostol, a synthetic prostaglandin E1 analogue, has been the mainstay of medical management in LMICs due to its low cost, thermal stability, and ease of administration [4]. However, its use as a single agent can be associated with a prolonged induction-to-delivery interval and an increased need for multiple doses, potentially extending the mother's distress. In recent years, the sequential use of mifepristone, an anti-progesterone, followed by a prostaglandin has emerged as a highly effective regimen for labour induction in both live and intrauterine fetal demise pregnancies [5]. Mifepristone induces cervical ripening by blocking progesterone receptors, thereby sensitizing the myometrium to the contractile effects of subsequent prostaglandins like misoprostol. Studies have demonstrated that this combination significantly reduces the induction-to-delivery interval compared to prostaglandins alone, potentially improving patient experience and reducing hospital stay [6,7]. Despite its proven efficacy, the adoption of this combination therapy, particularly for IUFD, remains inconsistent in resource-constrained settings like Bangladesh, often due to perceived cost and availability issues. Conversely, mechanical methods such as the intracervical catheter (ICC) or Foley catheter offer a non-pharmacological, low-cost alternative. These devices work by locally stimulating prostaglandin release and providing mechanical dilation. They are especially valuable in settings where specific uterotonic drugs are unavailable or contraindicated [8]. While effective, mechanical methods may be associated with discomfort, a slower induction process, and a higher risk of intrapartum fever or infection compared to pharmacological methods [9]. Recent systematic reviews underscore the variability in outcomes when comparing mechanical and pharmacological methods, indicating that context and protocol standardization are key. A significant gap exists in the direct comparative evidence of these three modalities-mifepristone-misoprostol

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combinations, misoprostol alone, and ICC-within the specific socio-cultural and clinical context of Bangladesh. Most existing studies originate from high-income countries or compare only two methods [10,11]. Furthermore, local data guiding clinicians at the tertiary hospitals of Rangpur Medical College Hospital, Rangpur, on the optimal, context-appropriate protocol is scarce. Understanding the comparative efficacy, safety profile, and practical outcomes of these methods is essential for developing standardized, effective, and patient-centered clinical guidelines [12,13]. Therefore, this prospective cohort study aimed to fill this evidence gap by directly comparing the efficacy, measured primarily by the induction-to-delivery interval, and maternal outcomes of the mifepristone-misoprostol combination regimen, misoprostol alone, and the intracervical catheter (with oxytocin augmentation) for the management of IUFD. The findings are intended to provide robust, locally relevant data to inform clinical decision-making and improve the standard of care for women facing this tragic obstetric event in Bangladesh.

METHODS & MATERIALS

This prospective cohort study enrolled 29 consecutive women diagnosed with IUFD (≥24 weeks of gestation) at Rangpur Medical College & Hospital, Rangpur, between January 2025 and December 2025. Participants were managed as per the hospital's existing protocols and allocated to one of three induction method groups based on clinician discretion and patient consent, reflecting real-world practice.

Inclusion and Exclusion Criteria

Inclusion Criteria

Inclusion required a confirmed diagnosis of IUFD by ultrasound (absent fetal cardiac activity), a gestational age of 24 weeks or more, a singleton pregnancy, and a willingness to participate by providing informed written consent. Women with no contraindications to vaginal delivery were eligible.

Exclusion Criteria

Women were excluded from the study if they had a known allergy to mifepristone or misoprostol, presented with clinical evidence of chorioamnionitis or coagulopathy, had a previous uterine scar (like a classical cesarean section), or had an obstetric condition mandating an immediate cesarean delivery.

Study Procedure

Participants were allocated to three groups: Group A received 200mg oral mifepristone, followed 24 hours later by oral misoprostol (50µg 4-hourly, max 200µg). Group B received oral misoprostol alone on the same regimen. Group C underwent insertion of a 16F Foley catheter as an intracervical catheter (ICC), with oxytocin infusion commenced if active labour did not ensue within 12 hours. Maternal demographics, induction-to-delivery interval, delivery mode, and complications were recorded on a structured datasheet.

Data Analysis

Data were analyzed using SPSS version 23.0. Continuous variables (e.g., induction-to-delivery interval) were compared using one-way ANOVA, and categorical variables (e.g., success rate) using the Chi-square test. A p-value of <0.05 was considered statistically significant.

RESULT

Table I presents the baseline demographic and obstetric characteristics distributed across Group A, Group B (Miso alone, n=10), and Group C (ICC, n=9). The overall mean maternal age was 25.6 ± 4.1 years, and the mean gestational age was 31.4 ± 3.8 weeks. Primigravida accounted for 24.1%, previous cesarean section for 13.8%, and gestational hypertension for 17.2% of cases. (p>0.05). (Table 1).

Table I
Baseline demographic and obstetric characteristics of the study participants.

Characteristic	Total	Group A	Group B	Group C	p-value
		Mife + Miso	Miso Alone	ICC	
	(n=29)	(n=10)	(n=10)	(n=9)	
Maternal age (years), Mean ±SD	25.6 ± 4.1	25.1 ± 3.9	26.0 ± 4.5	25.7 ± 4.0	0.887
Gestational age (weeks), Mean ±SD	31.4 ± 3.8	30.9 ± 3.5	32.0 ± 4.2	31.2 ± 3.8	0.786
Primigravida, n (%)	7 (24.1%)	2 (20.0%)	3 (30.0%)	2 (22.2%)	0.865
Previous C-section, n (%)	4 (13.8%)	1 (10.0%)	2 (20.0%)	1 (11.1%)	0.773
Gestational HTN, n (%)	5 (17.2%)	2 (20.0%)	1 (10.0%)	2 (22.2%)	0.732

Table II shows induction-to-delivery intervals where Group A had the shortest mean interval at 10.8 ± 2.9 hours (median 10.5, range 7–16), Group B averaged 15.4 ± 4.1 hours (median 15, range 10-23), and Group C, the longest at 19.1 ± 5.3 hours (median 18, range 13-29). (p < 0.001).

Table II
Primary outcome: Induction-to-delivery interval.

Group	n	Mean interval (hours) ±SD	Median (hours)	Range (hours)	p-value
A: Mife + Miso	10	10.8 ± 2.9	10.5	7 - 16	
B: Miso Alone	10	15.4 ± 4.1	15	10 - 23	<0.001
C: ICC	9	19.1 ± 5.3	18	13 - 29	

Analysis using One-way ANOVA.

Vaginal delivery ≤24 hours occurred in 90.0% of Group A, 70.0% of Group B, and 55.6% of Group C. Need for a second method or oxytocin was lowest in Group A (10.0%) and highest in Group C (44.4%). Cesarean rates were low (0% A, 10.0% B, 11.1% C). Chi-square analysis showed no statistically significant differences (p > 0.05) *Table III.*

Table III
Secondary outcomes: Success rate and need for additional intervention.

Outcome measure	Group A	Group B	Group C	p-value
Vaginal delivery ≤24 hours, n (%)	9 (90.0%)	7 (70.0%)	5 (55.6%)	0.186
Need for 2nd method/Oxytocin, n (%)	1 (10.0%)	3 (30.0%)	4 (44.4%)	0.230
Cesarean section, n (%)	0 (0.0%)	1 (10.0%)	1 (11.1%)	0.526

Analysis using the chi-square test.
Spontaneous vaginal delivery occurred in 8/10 (A), 7/10 (B), and 6/9 (C); assisted vaginal deliveries were two in each group, while cesarean sections were recorded only in Groups B and C (one each). Fetal condition showed macerated stillbirths of 8, 8, and 7, and fresh stillbirths of 2, 2, and 2. ($p > 0.05$) *Table IV*.

Table IV
Mode of delivery and fetal condition.

Characteristic	Group A	Group B	Group C	p-value
Mode of delivery				
Spontaneous vaginal, n	8	7	6	0.526
Assisted vaginal, n	2	2	2	
Cesarean section, n	0	1	1	
Fetal condition				
Macerated stillbirth, n	8	8	7	0.901
Fresh stillbirth, n	2	2	2	

Analysis using the Chi-square test.
A good maternal outcome was observed in all participants in Group A (100%), compared to 90.0% in Group B and 88.9% in Group C. Primary postpartum hemorrhage occurred in one case each in Groups B (10.0%) and C (11.1%), while no cases were reported in Group A. No instances of puerperal sepsis were recorded. Differences were not statistically significant ($p > 0.05$) *Table V*.

Table V
Maternal puerperium outcomes.

Maternal outcome	Group A	Group B	Group C	p-value
Good, n (%)	10 (100%)	9 (90.0%)	8 (88.9%)	0.526
Primary PPH, n (%)	0 (0.0%)	1 (10.0%)	1 (11.1%)	0.526
Puerperal sepsis, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

Analysis using the Chi-square test (excluding sepsis).
Presents complications and additional observations across the groups. Pyrexia (>38°C) was reported in none of Group A, one case in Group B, and two cases in Group C. Excessive vaginal bleeding (non-PPH) occurred once in each group. Severe pain was more frequently reported in Group C (n=5), compared to Group B (n=3) and Group A (n=2). Catheter dislodgement was observed only in Group C (n=1) *Table VI*.

Table IV
Complications and additional observations.

Complication / Observation	Group A	Group B	Group C
Pyrexia (>38°C), n	0	1	2
Excessive Vaginal Bleeding (non-PPH), n	1	1	1
Patient-reported Severe Pain, n	2	3	5
Catheter Dislodgement, n	N/A	N/A	1

DISCUSSION

This prospective cohort study provides a pragmatic comparison of three commonly employed methods for managing IUFD in a Bangladeshi tertiary care setting. The principal finding is that the sequential mifepristone-misoprostol regimen demonstrated superior efficacy, evidenced by a significantly shorter mean induction-to-delivery interval (10.8 hours) compared to both misoprostol alone (15.4 hours) and the intracervical catheter (19.1 hours). These results align robustly with the existing pharmacological rationale and prior research. Mifepristone, by antagonizing progesterone receptors, induces cervical ripening and upregulates myometrial gap junctions and oxytocin receptors, thereby creating a primed uterine environment that responds more rapidly and effectively to subsequent prostaglandin administration [5,14]. Studies from similar settings have consistently reported this synergistic effect, with combination therapy reducing the induction interval by approximately 30-40% compared to prostaglandin-only protocols [6,7]. Our findings reinforce this combination as the most time-efficient medical strategy, which is a critical consideration for minimizing the psychological distress associated with carrying a non-viable pregnancy. The performance of misoprostol alone as an intermediate option is also noteworthy. Its 70% 24-hour success rate, though lower than the combination regimen, confirms its established role as a reliable, accessible, and low-cost uterotonic, particularly vital in resource-constrained environments [4,15]. However, its longer induction interval and higher need for supplemental oxytocin (30%) highlight its limitations as a single

agent, potentially related to an unripe cervix at the time of induction. The intracervical catheter, while effective in achieving vaginal delivery, was associated with the longest induction process. This is mechanistically predictable, as mechanical methods primarily cause gradual cervical dilation through local pressure and endogenous prostaglandin release, a process inherently slower than the direct pharmacological stimulation of the myometrium [8,16]. The lower 24-hour success rate (55.6%) and higher rate of requiring a second method (44.4%) in our ICC group are consistent with previous comparative studies, including a meta-analysis (2019), which found Foley catheters to be less effective than misoprostol for achieving delivery within 24 hours [9]. Nevertheless, the ICC remains an indispensable tool in specific clinical scenarios, such as when uterotonics are contraindicated (e.g., in women with severe asthma or glaucoma) or unavailable, underscoring its value in a comprehensive obstetric toolkit [17]. An encouraging finding across all groups was the favorable maternal safety profile. The incidence of primary PPH was low (6.9% overall) and not significantly different between groups, and no cases of puerperal sepsis or uterine rupture occurred. This safety data is reassuring and consistent with other studies on IUFD management, which suggest that when managed with standardized protocols, induction of labour for fetal demise carries a low risk of serious maternal morbidity [18,19]. The absence of major complications, even with the mechanical method, which carries a theoretical infection risk, likely reflects the prophylactic antibiotic use and strict aseptic technique followed in our hospital setting. The strengths of this study include its prospective design within a real-world clinical context at a major Bangladeshi hospital, providing directly applicable local evidence. The comparative analysis of three distinct modalities adds practical value for clinicians. However, several limitations must be acknowledged. The modest sample size (n=29) limits the statistical power to detect differences in less common secondary outcomes, such as specific complication rates. The non-randomized allocation, based on clinician discretion, introduces potential selection bias, although the comparable baseline characteristics somewhat mitigate this concern. Furthermore, the single-center design may affect the generalizability of findings to primary care centers with differing resources and expertise. Despite these limitations, our findings carry important implications for clinical practice in Bangladesh and similar LMICs. They provide strong support for the adoption of the mifepristone-misoprostol combination as the first-line medical regimen for IUFD, where mifepristone is accessible and affordable, as it optimizes patient experience by shortening a profoundly difficult process [20,21]. For settings where mifepristone is not available, misoprostol alone remains a very effective alternative. The ICC should be retained as a vital backup or primary option for specific contraindications. Future research should focus on larger, multi-center randomized controlled trials to confirm these findings and perform robust cost-effectiveness analyses. Investigating patient-centered outcomes, such as psychological distress scores and overall satisfaction with the induction process, would also be highly valuable [22].

LIMITATIONS

The study's modest sample size, non-randomized design, and single-center setting may limit statistical power, introduce selection bias, and affect generalizability. Future multi-center randomized trials with larger cohorts are recommended to validate these findings.

CONCLUSION

This study demonstrates that for the management of IUFD at a tertiary hospital in Bangladesh, the mifepristone-misoprostol combination is the most efficacious method, yielding the shortest induction-to-delivery interval. Misoprostol alone is a reliable alternative, while the intracervical catheter, though effective, is associated with the longest induction process. All three methods were safe, with low maternal complication rates. These results can guide evidence-based protocol development to ensure timely, effective, and compassionate care for women experiencing this tragic obstetric event.

RECOMMENDATION

We recommend adopting the mifepristone-misoprostol combination as the first-line regimen for IUFD management where available. Misoprostol alone is a viable alternative. The intracervical catheter remains essential for specific contraindications. Institutional protocols should integrate these evidence-based options.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Functional Outcomes and Complications after Total Hip Arthroplasty in Adult Patients

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ABSTRACT

Background: Total hip arthroplasty is an established surgical intervention for advanced hip disorders, providing substantial pain relief and functional restoration. The global demand for this procedure continues to rise due to ageing populations and expanded surgical indications. Despite extensive international data, prospective outcome reports from resource-limited settings remain limited.**Objective:** This study aimed to evaluate functional outcomes and early postoperative complications following primary total hip arthroplasty in adult patients. **Methods & Materials:** This prospective observational study was conducted in the Department of Orthopedics, 250 Bed General Hospital, Pabna and City Health Aid Hospital, Pabna, Bangladesh, from December 2022 to December 2024. A total of 35 adult patients undergoing primary total hip arthroplasty were included. Functional assessment was performed using the Harris Hip Score, Oxford Hip Score and Visual Analogue Scale preoperatively and at 6 months postoperatively. Postoperative complications were documented during follow-up. **Results:** The mean Harris Hip Score improved from 41.8 ± 7.6 preoperatively to 88.6 ± 5.4 at 6 months ($p < 0.001$). The Oxford Hip Score increased from 19.6 ± 4.3 to 41.2 ± 3.8 ($p < 0.001$). Pain scores decreased significantly from 8.2 ± 0.9 to 1.6 ± 0.8 ($p < 0.001$). Excellent and good outcomes were achieved in 80.0% of patients. Overall, 14.3% experienced at least one complication, with superficial infection being the most common. **Conclusion:** Primary total hip arthroplasty demonstrated significant functional recovery and low early complication rates, supporting its effectiveness and safety in this clinical setting.

Keywords: *Total hip arthroplasty, Functional outcome, Postoperative complications.*

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INTRODUCTION

Total hip arthroplasty (THA) is recognized as a highly effective procedure for alleviating pain and restoring function in patients with advanced hip conditions, with demand rising due to ageing populations, broader indications and enhanced implant durability. Epidemiological data project continued growth in primary THA procedures globally. The main indications include osteoarthritis, avascular necrosis, rheumatoid arthritis and post-traumatic arthritis, with osteoarthritis as the predominant cause of disability among older adults worldwide [1,2].

Functional recovery after THA is often measured using validated tools such as the Harris Hip Score (HHS) and Oxford Hip Score (OHS), which assess pain relief, mobility and daily functioning [3,4]. Studies consistently demonstrate significant improvements in these scores postoperatively, though outcomes may vary depending on patient-specific factors including comorbidities and surgical variables [5,6]. Additionally, enhanced recovery protocols and pain management strategies have been shown to optimize postoperative function and reduce opioid requirements, contributing to improved rehabilitation after THA [7,8].

Comorbid conditions and baseline physical status have been shown to influence postoperative outcomes. Lan et al. reported that medical comorbidities may adversely affect pain relief and functional improvement after THA [9]. Similarly, Park et al. observed differences in functional outcomes and complication rates in patients undergoing THA in relation to underlying medical conditions [10]. Despite these observations, evidence from resource-limited settings remains comparatively scarce.

Although THA is generally associated with high success rates, postoperative complications such as surgical site infection, dislocation and deep vein thrombosis remain clinically relevant [11]. Data from international registries have provided valuable insights into complication profiles; however, local institutional data are essential for contextualizing outcomes and guiding quality improvement initiatives [11,12]. Moreover, the incidence and pattern of complications may differ according to patient demographics and perioperative protocols.

In South Asian settings, limited prospective data are evaluating short-term functional outcomes and complication rates after THA. Most available studies are retrospective or involve heterogeneous populations [13,14]. Furthermore, variations in healthcare infrastructure and postoperative rehabilitation practices may influence recovery trajectories. Generating institution-specific data is therefore important to assess the effectiveness of current clinical practices and to benchmark outcomes against international standards.

Given the increasing utilization of THA and the need for context-specific outcome evaluation, this prospective observational study was undertaken to assess functional outcomes and early postoperative complications in adult patients undergoing primary THA at two tertiary care centers in Pabna, Bangladesh. By systematically evaluating validated functional scores and documenting complication rates at 6 months, this study aims to provide clinically relevant evidence that may inform patient counseling, perioperative

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optimization and future research in similar healthcare settings.

OBJECTIVES

The objective of this study was to evaluate functional outcomes and early postoperative complications following primary total hip arthroplasty in adult patients.

METHODS & MATERIALS

This prospective observational study was conducted in the Department of Orthopedics, 250 Bed General Hospital, Pabna and City Health Aid Hospital, Pabna, Bangladesh. The study period extended from December 2022 to December 2024. A total of 35 adult patients undergoing primary total hip arthroplasty were included.

Selection Criteria

Inclusion criteria:

- Adult patients aged ≥30 years.
- Patients undergoing primary total hip arthroplasty.
- Diagnosis of primary osteoarthritis, avascular necrosis, rheumatoid arthritis, or post-traumatic arthritis.
- Patients are willing to participate and provide informed consent.
- Patients available for at least 6 months of follow-up.

Exclusion criteria:

- Revision total hip arthroplasty.
- Active local or systemic infection at the time of surgery.
- Pathological fractures due to malignancy.
- Severe neuromuscular disorders affecting ambulation.
- Patients were lost to follow-up for 6 months.

Data Collection Procedure

Eligible patients were identified in the orthopedic outpatient and inpatient departments. Baseline demographic and clinical data were recorded using a structured data collection form. Preoperative assessment included detailed history, physical examination, radiographic evaluation and routine laboratory investigations. Functional status was assessed using the Harris Hip Score and Oxford Hip Score, while pain severity was measured using the Visual Analogue Scale. All procedures were performed by experienced orthopedic surgeons using standard surgical techniques and perioperative protocols. Postoperative care included antibiotic prophylaxis, thromboprophylaxis, early mobilization and physiotherapy according to institutional guidelines. Functional outcomes were reassessed at 6 months postoperatively during scheduled follow-up visits. Data were collected by trained investigators to ensure uniformity and minimize observer bias. Standardized scoring systems were applied consistently to enhance reliability. All participants provided informed consent before inclusion. Confidentiality was maintained by anonymizing patient identifiers and restricting data access to the research team. Data were securely stored and periodically reviewed to ensure completeness and accuracy.

Statistical Analysis

Data were analyzed using SPSS version 25.0. Descriptive statistics were expressed as mean ± standard deviation for continuous variables and frequencies with percentages for categorical variables. Paired t-tests were used to compare preoperative and postoperative functional scores. A p-value <0.05 was considered statistically significant.

RESULT

Table I shows the baseline demographic and clinical characteristics of the study population. The mean age was 61.2 ± 8.4 years, with the majority of patients aged 60–69 years (37.1%). Males constituted 60.0% of the cohort. Primary osteoarthritis was the most common indication (51.4%), followed by avascular necrosis (25.7%). Most patients were classified as ASA II (57.1%). Regarding BMI, 42.9% had normal weight, 40.0% were overweight and 17.1% were obese.

Table I
Baseline Demographic and Clinical Characteristics (*n* = 35).

Variable		Frequency (n)	Percentage (%)
Age Group (years)	30–49	6	17.1
	50–59	11	31.4
	60–69	13	37.1
	≥70	5	14.3
	Mean ± SD	61.2 ± 8.4	
Sex	Male	21	60.0
	Female	14	40.0
Primary Diagnosis	Primary Osteoarthritis	18	51.4
	Avascular Necrosis	9	25.7
	Rheumatoid Arthritis	4	11.4
	Post-traumatic Arthritis	4	11.4
ASA Physical Status	ASA I	6	17.1
	ASA II	20	57.1
	ASA III	9	25.7
BMI Category	Normal (18.5–24.9)	15	42.9
	Overweight (25–29.9)	14	40.0
	Obese (≥30)	6	17.1

Table II presents the comparison of preoperative and 6-month postoperative functional scores. The mean Harris Hip Score improved from 41.8 ± 7.6 preoperatively to 88.6 ± 5.4 postoperatively, with a mean difference of 46.8 ($p < 0.001$). The Oxford Hip Score increased from 19.6 ± 4.3 to 41.2 ± 3.8, yielding a mean improvement of 21.6 ($p < 0.001$). Pain Visual Analogue Scale scores decreased significantly from 8.2 ± 0.9 to 1.6 ± 0.8, reflecting a mean reduction of 6.6 ($p < 0.001$).

Table II
Comparison of Preoperative and 6-Month Postoperative Functional Scores (n = 35).

Outcome Measure	Preoperative (Mean ± SD)	6-Month Postoperative (Mean ± SD)	Mean Difference	p-value
Harris Hip Score	41.8 ± 7.6	88.6 ± 5.4	46.8	<0.001
Oxford Hip Score	19.6 ± 4.3	41.2 ± 3.8	21.6	<0.001
Pain VAS (0–10)	8.2 ± 0.9	1.6 ± 0.8	−6.6	<0.001

Table III describes functional outcome categories at 6 months according to the Harris Hip Score classification. Excellent outcomes were observed in 51.4% of patients, while 28.6% achieved good results. Fair and poor outcomes were reported in 14.3% and 5.7% of patients, respectively.

Table III
Functional Outcome Categories at 6 Months (HHS Classification).

HHS Category	Frequency (n)	Percentage (%)
Excellent (90–100)	18	51.4
Good (80–89)	10	28.6
Fair (70–79)	5	14.3
Poor (<70)	2	5.7

Table IV outlines postoperative complications during the 6-month follow-up. Superficial surgical site infection occurred in 5.7% of patients. Deep infection, dislocation and deep vein thrombosis each occurred in 2.9% of cases. Overall, 14.3% of patients experienced at least one complication.

Table IV
Postoperative Complications (6-Month Follow-Up).

Complication	Frequency (n)	Percentage (%)
Superficial Surgical Site Infection	2	5.7
Deep Infection	1	2.9
Dislocation	1	2.9
Deep Vein Thrombosis	1	2.9
Total Patients with ≥1 Complication	5	14.3

Figure 1 Pre-operative Anteroposterior (AP) radiograph

Figure 2 Post-operative radiograph

Figure 1 shows the Pre-operative Anteroposterior (AP) radiograph of the pelvis in a 32-year-old male showing AVN of the right femoral head. *Figure 2* presents the X-ray showing a right hip (left of the image) that has been replaced, with the ball of this ball-and-socket joint replaced by a metal head that is set in the femur and the socket replaced by a cup.

DISCUSSION

This study demonstrated substantial improvement in functional outcomes and pain relief at 6 months following primary total hip arthroplasty, with a relatively low incidence of early postoperative complications. The mean Harris Hip Score increased from 41.8 preoperatively to 88.6 postoperatively, while the Oxford Hip Score improved markedly and pain scores declined significantly. More than half of the patients achieved an excellent functional outcome at 6 months.

These findings are consistent with the established role of THA in restoring hip function and alleviating pain. Ferguson et al. described THA as a highly effective intervention for end-stage hip disease, reporting predictable improvements in mobility and quality of life [15]. Similarly,

Wang et al. observed significant gains in physical function and reduction in pain among community-dwelling older adults following hip replacement [16]. The magnitude of improvement in our cohort aligns with these observations, indicating that comparable functional recovery can be achieved in a tertiary care setting in Bangladesh.

The marked increase in Harris Hip Score in this study parallels results from Vinjamuri et al., who reported significant postoperative improvements using HHS as a primary outcome measure [13]. Marahatta et al. also demonstrated substantial enhancement in functional scores after primary THA in arthritic hips [17]. The postoperative mean HHS in our study, approaching the excellent range, further supports the reliability of HHS as a sensitive tool for assessing early functional recovery, as emphasized by Kumar et al. in their validation study [18].

Pain reduction was one of the most prominent outcomes in this cohort, with the Visual Analogue Scale decreasing from 8.2 to 1.6 at 6 months. This substantial decline is comparable to the results reported by Lan et al., who found significant pain relief following THA, although outcomes were influenced by comorbid conditions [9]. The high proportion of patients categorized as ASA II in our study may have contributed to favorable early outcomes, as fewer severe systemic comorbidities are generally associated with better postoperative recovery.

Regarding outcome categories, 51.4% of patients achieved excellent results and 28.6% achieved good results. These proportions are comparable to those reported by Wod et al., who observed predominantly good-to-excellent outcomes following THA using modified HHS [14]. Fadlalla et al. similarly reported high rates of excellent functional recovery in younger adults undergoing ceramic-on-ceramic THA [19]. Although implant-specific factors were not the primary focus of the present study, the favorable functional distribution underscores the overall effectiveness of standardized surgical and rehabilitation protocols.

Complication rates in the current series were within acceptable limits compared to published literature. The overall complication rate was 14.3%, with superficial infection being the most frequent event. Healy et al. emphasized that early postoperative complications such as infection and dislocation remain clinically relevant despite advancements in surgical techniques [11]. Dale et al. reported a measurable risk of prosthetic joint infection after THA, highlighting the need for vigilant perioperative measures [12]. The low incidence of deep infection in our cohort may reflect adherence to antibiotic prophylaxis and infection control protocols.

The dislocation rate of 2.9% observed in this study is comparable to previously reported early dislocation rates in primary THA. Matharu et al. noted that the surgical approach can influence dislocation risk following THA [20]. Although approach-specific comparisons were not undertaken in the present study, the low dislocation frequency suggests satisfactory implant positioning and soft tissue handling.

Deep vein thrombosis occurred in one patient, representing 2.9% of the cohort. Belmont et al. documented thromboembolic events as recognized early complications following THA, particularly in patients with additional risk factors [21]. Routine thromboprophylaxis and early mobilization in our study likely contributed to the limited number of such events.

Primary osteoarthritis constituted the majority indication for surgery, consistent with global epidemiological trends described by Ferguson et al. [15]. Singh et al. reported that patients with osteonecrosis may experience comparatively different postoperative trajectories than those with osteoarthritis [22]. Although subgroup analysis was not performed, the overall improvement observed across the cohort suggests that satisfactory short-term outcomes can be achieved across varied diagnostic categories.

The demographic profile, with a mean age of 61.2 years and male predominance, is comparable to other regional studies. Dowsey et al. demonstrated that advancing age does not preclude favorable functional outcomes after THA, although recovery patterns may vary [14]. The predominance of ASA II status in this cohort may partly explain the high rate of excellent and good results, as comorbidity burden has been associated with functional variability in other studies [9].

Overall, the present findings corroborate existing literature demonstrating that primary THA results in significant functional recovery, substantial pain reduction and an acceptable short-term complication profile. The study adds prospective data from a Bangladeshi tertiary care context, reinforcing the global applicability of THA as an effective intervention for advanced hip pathology.

CONCLUSION

Primary total hip arthroplasty resulted in significant functional improvement and marked pain reduction at 6 months in adult patients. The majority achieved excellent or good outcomes and early postoperative complications were infrequent and manageable. These findings support the effectiveness and safety of THA in a tertiary care setting in Bangladesh, with outcomes comparable to published international data.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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THE PLANET

Original Article

Assessment of Nutritional Status and Exploration of Nutritional Concepts among Patients of Cirrhosis

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ABSTRACT

Background: Malnutrition is prevalent in patients with cirrhosis and has a substantial impact on morbidity and mortality. Lack of nutritional understanding, coupled with misconceptions and dietary myths about liver disease, exacerbates this issue. Owing to the scarcity of available data, this research aimed to evaluate the nutritional condition of hospitalized cirrhotic patients and to investigate their nutritional knowledge and perceptions. **Methods & Materials:** This descriptive cross-sectional study based in a hospital was carried out for six months within the inpatient Departments of Medicine and Gastroenterology at Rangpur Medical College Hospital following protocol approval. Cirrhotic patients who satisfied the inclusion and exclusion criteria were recruited following the acquisition of informed written consent. Data were obtained via clinical assessment, pertinent investigations, and a semi-structured questionnaire created by the researcher, then analyzed using SPSS version 23. **Results**: The average age was 47.25 ± 12.05 years, with a higher percentage of males (69%). The majority of patients came from lower middle-class backgrounds, with HBV being the primary cause (44.5%). Decompensated cirrhosis occurred in 77%, with Child–Pugh B being the most prevalent. Malnutrition impacted 52.8% as per RFH-SGA and was strongly correlated with disease severity, reduced education and socioeconomic status, and inadequate dietary knowledge ($p<0.05$). **Conclusion**: Nutritional status of one fourth to half of the patients of cirrhosis was not satisfactory as evidenced by rate of malnutrition detected by different assessment tools. It is related to both educational status, socio-economic condition as well as dietary knowledge of the patients.

Keywords: *Nutritional Status, Nutritional Concepts, Cirrhosis.*

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INTRODUCTION

Cirrhosis, a final pathway for a wide variety of chronic liver diseases, is a pathologic entity defined as diffuse hepatic fibrosis with the replacement of the normal liver architecture by nodules and can have varied clinical manifestations and complications [1]. Cirrhosis is a major cause of mortality and morbidity worldwide [2]. Decompensated cirrhosis is the 14th most common global cause of death in adults, the 4th in central Europe and 8th in North America [3,4].

The major complications of liver cirrhosis include esophageal varices, ascites, hepatic encephalopathy (HE), malnutrition, hepatopulmonary syndrome, hepatocellular carcinoma (HCC), hepatorenal syndrome (HRS), spontaneous bacterial peritonitis (SBP), and coagulation disorders [5]. Malnutrition is frequently a burden in patients with liver cirrhosis, occurring in 20-50% of patients [6].

The progression of malnutrition is associated with that of progression of liver failure. Malnutrition has been reported in 20% of patients with compensated cirrhosis and with 50% of patients with decompensated cirrhosis [7]. Malnutrition is associated with higher rate of cirrhotic complications, such as recurrent and treatment resistant ascites, susceptibility to infections, hepatic encephalopathy, as well as being independent predictors of lower survival in cirrhosis and in patients undergoing liver transplantation [8-11].

Accurate assessment of nutritional status is often difficult to obtain in patients with cirrhosis [12]. Multiple techniques have been proposed to detect malnutrition in patients with cirrhosis. Although there is no gold standard for the assessment of malnutrition in patients with cirrhosis, anthropometric measurements such as Body Mass Index (BMI), Mid Arm Muscle Circumference (MAMC), and Triceps Skin Fold (TSF) are currently recommended by many study results and anthropometry can be comparable in accuracy to more sophisticated major tools [13,14].

Besides anthropometric tools, different global assessment tool is widely practiced to assess nutritional status of cirrhotic patients. Currently two global assessment tools naming Subjective Global Assessment (SGA) and Royal Free Hospital- Subjective Global Assessment (RFH-SGA), are recommended by both European Association for the Study of the Liver Diseases (EASLD)and American Association for the Study of Liver Diseases (AASLD) nutritional guideline [6,15]. Both of the tools include subjective as well as objective parameter to assess nutritional status. Overall, SGA has fair to good inter-observer reproducibility and is associated with various clinical and prognostic variables of liver transplantation [16,17].

A number of cirrhotic patients avoid some foods in their diet due to their poor dietary knowledge. These unnecessary dietary restrictions also contribute in malnutrition in these patients, which highlight the utmost need to improve their nutritional knowledge for their better outcome. To the best of our knowledge there are few studies in our country to explore nutritional concepts of cirrhotic patients. For the above reason our study aimed to explore patient's concepts and knowledge regarding diet in cirrhosis in addition to assess their nutritional status.

METHODS & MATERIALS

Study settings: This study was a descriptive cross-sectional investigation carried out in the Departments of Gastroenterology and Medicine at Rangpur Medical College Hospital over a six-month from July 2018 to December 2018.

Study population: The study included patients suffering from chronic liver disease who were admitted to the appropriate departments of Rangpur Medical College Hospital, totaling 110 patients in the study.

Selection criteria: A purposive sampling method that is non-probability was employed. Adult patients (≥18 years) with

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chronic liver disease who were admitted to the appropriate departments and agreed to participate were included. Patients experiencing acute complications from cirrhosis, hepatocellular carcinoma, or other cancers, along with comorbid conditions or diseases that might notably impact nutritional status, were not included.

Study procedure: Following the approval from the Ethical Review Committee and acquiring written informed consent from all participants, sociodemographic and clinical data were gathered through in-person interviews utilizing a semi-structured questionnaire. The investigator conducted a nutritional assessment utilizing standard anthropometric measurements and RFH-SGA to eliminate interobserver variation, with data being recorded and analyzed through SPSS version 23.

Data analysis: The gathered data were checked for consistency and examined using SPSS v.23. Descriptive statistics (mean, frequency, percentage) encapsulated sociodemographic variables and dietary knowledge. Associations were evaluated using the chi-square test, with $p < 0.05$ regarded as statistically significant. Findings were displayed in tables, charts, and written format.

RESULTS

Table I shows that the study sample (n=110) was mainly middle-aged (41–60 years, 60%), male (69%), and largely from rural regions (61%). The majority of participants had low to moderate levels of education, with the largest segment holding an SSC (31.8%) and just 12.7% being graduates or above. The majority belonged to lower and lower-middle socioeconomic classes (81%), with predominant occupations being day laborers (24.5%) and housewives (18.3%), signifying a population primarily from rural, lower socioeconomic backgrounds with little education.

Table I
Sociodemographic Characteristics of Study Participants (*n*=110).

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–30	13	11.8
	31–40	18	16.4
	41–50	37	33.6
	51–60	29	26.4
	61–70	8	7.3
	>70	5	4.5
Sex	Male	76	69
	Female	34	31
Occupation	Government employee	12	10.9
	Private employee	15	13.6
	Businessman	19	17.3
	Housewife	20	18.3
	Day laborer	27	24.5
	Others	10	9.1
	Unemployed	7	6.4
Residence	Urban	43	39
	Rural	67	61
Educational qualification	Illiterate	21	19.10
	Primary	20	18.20
	SSC	35	31.80
	HSC	20	18.20
	Graduation and above	14	12.70
Socioeconomic status	Lower	42	38.20
	Lower middle	47	42.70
	Upper middle	13	11.80
	Upper	08	7.30

Table II presents most cirrhosis instances resulted from HBV (44.5%), followed by NASH (17.3%) and HCV (11.8%), with 13.6% of cases having an unknown cause. The majority of patients exhibited moderate to severe liver dysfunction (Child–Pugh B: 41%, C: 36%), with a large portion classified as decompensated (77%), suggesting the study group largely suffered from advanced liver disease.

Table II
Etiology, Severity, and Clinical Condition of Cirrhosis among Participants in the Study (*n*=110).

Variable	Category	Frequency (n)	Percentage (%)
Etiology of cirrhosis	HBV	49	44.5
	Unidentified	15	13.6
	NASH	19	17.3
	HCV	13	11.8
	Wilson's disease	6	5.5
	Others	5	4.5
	Alcoholic	3	2.7
Severity of cirrhosis (Child–Pugh)	A	25	23
	B	45	41
	C	40	36
Clinical Status of Cirrhosis	Compensated	25	23%
	Decompensated	85	77%

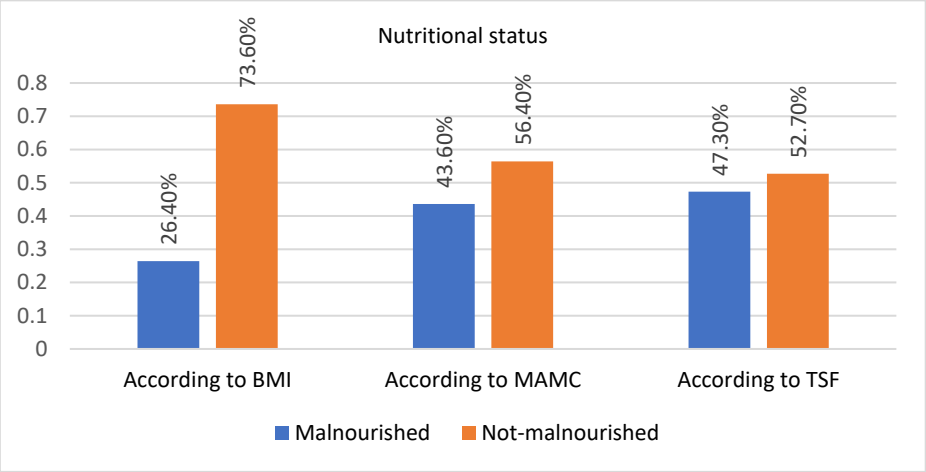

Figure 1 Nutritional Status of Patients Assessed by BMI, MAMC, and TSF

Figure 1 shows nutritional evaluation revealed 26.4% malnourished according to BMI, 43.6% by MAMC, and 47.3% by TSF, suggesting that MAMC and TSF identify more cases of malnutrition than BMI does.

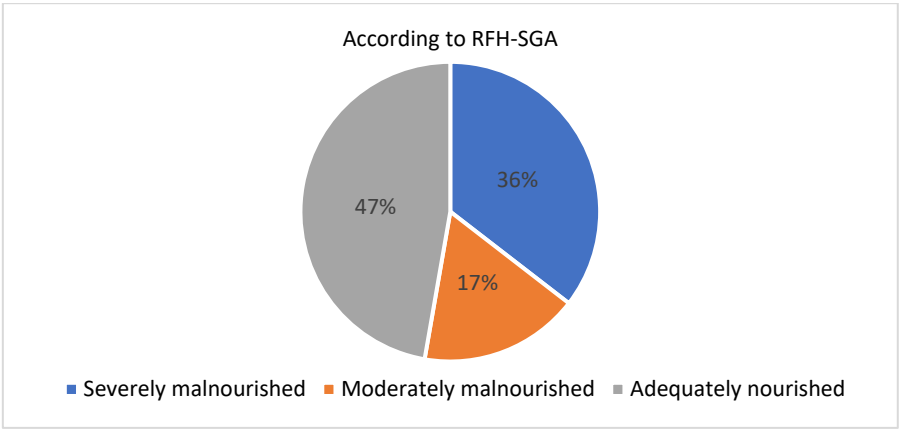

Figure 2 Nutritional Status of Patients According to RFH-SGA (*n*=110)

Figure 2 shows according to RFH-SGA, 35.5% of patients were severely malnourished, 17.3% were moderately malnourished, and 47.3% were adequately nourished, indicating that over half of the patients had some degree of malnutrition, highlighting the high prevalence of nutritional risk in this population.

Table III shows the connection between nutritional status and the severity of cirrhosis (Child–Pugh class) differed according to the assessment methods used. Utilizing RFH-SGA, malnutrition rose with disease severity: 24% in class A, 48.9% in B, and 60% in C (P=0.035). Likewise, MAMC and TSF demonstrated a notable increase in malnutrition as Child–Pugh class deteriorated (MAMC: 32% → 40% → 55%, P=0.025; TSF: 36% → 46.7% → 55%, P=0.042). On the other hand, BMI did not exhibit a notable correlation (P=0.512). The findings indicate that RFH-SGA, MAMC, and TSF are more effective than BMI in identifying malnutrition in advanced cirrhosis.

Table III
Association of Nutritional Status with Severity of Cirrhosis (Child–Pugh Class) Using Different Assessment Tools.

Tool	CP Group	Malnourished (n, %)	Not Malnourished / Adequately Nourished (n, %)	P value
RFH-SGA	A	6 (24)	19 (76)	0.035
	B	22 (48.89)	23 (51.11)	
	C	24 (60)	16 (40)	
MAMC	A	8 (32)	17 (68)	0.025
	B	18 (40)	27 (60)	
	C	22 (55)	18 (45)	
TSF	A	9 (36)	16 (64)	0.042
	B	21 (46.66)	24 (53.34)	
	C	22 (55)	18 (45)	
BMI	A	4 (16)	21 (84)	0.512
	B	11 (24.44)	34 (75.56)	
	C	4 (13.33)	26 (86.67)	

Table IV shows the patients' nutritional status was notably linked to both their educational qualification (P=0.031) and socioeconomic status (P=0.043). Malnutrition was more common in patients with less education, as 66.7% of illiterate individuals and 65% of those with a primary education experienced severe malnutrition, while only 14.3% of graduates or individuals with higher education faced the same issue. Likewise, individuals from lower socioeconomic backgrounds exhibited a greater incidence of severe malnutrition (64.3%) compared to those from higher socioeconomic backgrounds (12.5%). These results show that reduced education and lower socioeconomic status are significant risk factors for malnutrition in patients with cirrhosis.

Table IV
Association of Nutritional Status with Educational Qualification and Socioeconomic Status (*n*=110).

Variable	Category	Severely Malnourished n (%)	Moderately Malnourished n (%)	Adequately Nourished n (%)	P value
Educational qualification	Illiterate	14 (66.67)	2 (9.52)	5 (23.81)	0.031
	Primary	13 (65)	3 (15)	4 (20)	
	SSC	16 (45.71)	6 (17.14)	13 (37.14)	
	HSC	7 (35)	6 (30)	7 (35)	
	Graduation & above	2 (14.29)	2 (14.29)	10 (71.43)	
Socioeconomic status	Low	27 (64.29)	7 (16.67)	8 (19.05)	0.043
	Lower middle	19 (40.43)	9 (19.15)	19 (40.43)	
	Upper middle	5 (38.46)	2 (15.38)	6 (46.15)	
	Upper	1 (12.50)	1 (12.50)	6 (75)	

Table V shows only 40.9% received nutritional advice, mostly from doctors in hospitals; 73.3% got advice at each visit, and 62.2% followed it.

Table V
History and Compliance of Patients Regarding Nutritional Advice (n=110).

Variable	Category	Number	Frequency (%)	Total (n)
History of getting advice	Yes	45	40.90	110
	No	65	59.10	
From whom you get advice (among Yes, n=45)	Doctor	39	86.70	45
	Nurse	6	13.30	
From where you get advice (among Yes, n=45)	Hospital	33	73.30	45
	Private chamber	12	26.70	
Have you got dietary advice in each visit? (Among Yes, n=45)	Yes	33	73.30	45
	No	12	26.70	
Did you obey the advice? (Among Yes, n=45)	Yes	28	62.20	45
	No	17	37.80	

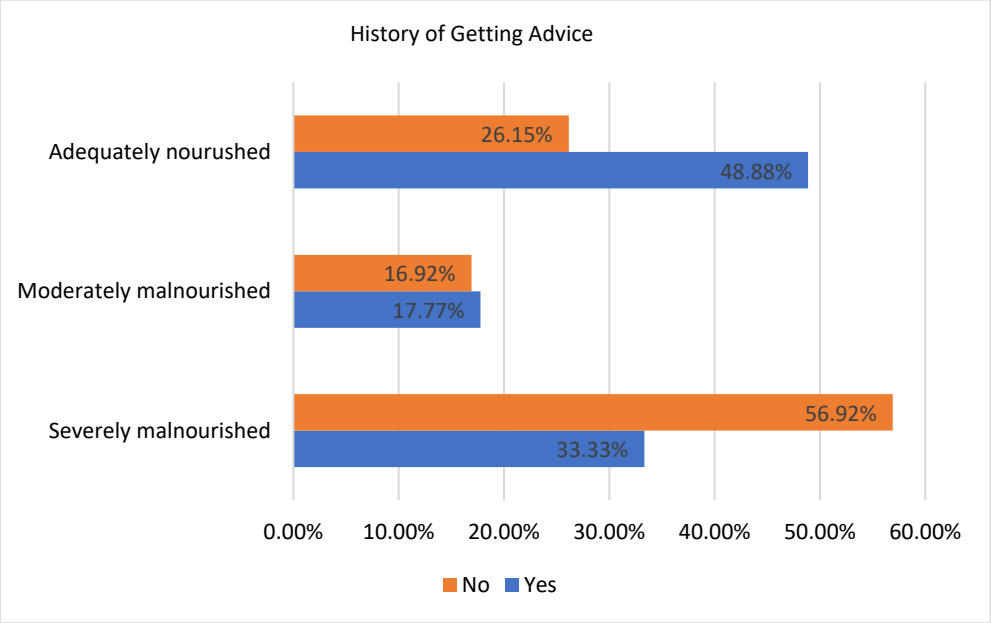

Figure 3 Association of Nutritional Status with History of Receiving Nutritional Advice (*n*=110)

Figure 3 shows patients who had previously received nutritional guidance demonstrated a notably lower incidence of severe malnutrition (33.3%) in contrast to those who had not received any advice (56.9%, P=0.030). This suggests that obtaining dietary advice is linked to improved nutritional health in the study group.

Table VI shows that enhanced dietary understanding correlated with better nutritional outcomes: for instance, among individuals aware of which foods to consume, 54.3% (19/35) were sufficiently nourished compared to 35.1% (20/57) in those lacking this knowledge (P=0.006). Consistently, sufficient dietary consumption significantly lowered severe malnutrition rates: 7.3% (3/41) compared to 61.4% (27/44) in the inadequate group and 88% (22/25) in the negligible intake group (P<0.001). This demonstrates that understanding and appropriate nutrition significantly enhance diet quality.

Table VI
Association of Dietary Knowledge and Dietary Intake with Nutritional Status of Patients (*n*=110).

Variable	Response	Adequately Nourished n (%)	Moderately Malnourished n (%)	Severely Malnourished n (%)	Total n (%)	P value
Dietary knowledge						
Do you avoid any food due to this disease?	Yes	23	6	10	39	<0.001
	No	16	13	42	71	
Do you know which foods you should take more?	Yes	19	7	9	35	0.006
	No	20	12	43	57	
Do you know how much kilo calories you need in each day?	Yes	22	6	12	40	0.004
	No	17	13	40	70	
Sufficient knowledge about salt intake	Yes	17	5	10	32	0.039
	No	22	14	42	78	
Sufficient knowledge about vitamin intake	Yes	19	8	11	38	0.018
	No	20	11	41	72	
Sufficient knowledge about diet frequency	Yes	26	6	12	44	<0.001
	No	13	13	40	66	
Sufficient knowledge about complementary food	Yes	22	6	9	37	<0.001
	No	17	13	43	73	
Dietary intake	Adequate	31	7	3	41	<0.001
	Inadequate	8	9	27	44	
	Negligible	0	3	22	25	

DISCUSSION

The present study included 110 patients with cirrhosis, with a mean age of 47.25 ± 12.05 years, consistent with previous studies by Sarin et al. (51.7 ± 9.2), Mukherjee et al. (47.7 ± 13.4), and Sajja et al. (52 ± 11) [18–20]. The majority of participants were male (69%) and female (31%), aligning with findings from Sharma et al. (69.7% male) and Trimukhe et al. (male: female 2.15:1) [21,22]. Occupational distribution revealed 10.9% government employees, 13.6% private employees, 17.3% businessmen, 18.3% housewives, 24.5%-day laborers, 9.1% other occupations, and 6.4% unemployed, comparable to Ahsan et al., who reported similar percentages across occupational categories [23]. Educational status showed that 19.1% were illiterate, 18.2% had primary education, 31.8% completed SSC, 18.2% HSC, and 12.7% had graduation or higher, reflecting trends reported by Ahsan et al. (2007) [23]. The majority of participants were from rural areas (61%), while 39% resided in urban regions, roughly consistent with Mendes et al., who reported 71.76% urban residency [24]. Socioeconomic distribution indicated that 38.2% belonged to the lower, 42.7% to the lower-middle, 11.8% to the upper-middle, and 7.3% to the upper class, closely aligning with previous reports [23].

Hepatitis B virus (HBV) was identified as the predominant cause of cirrhosis in this cohort (44.5%), followed by NASH (17.3%), HCV (11.8%), unidentified causes (13.6%), Wilson's disease (5.5%), other uncommon etiologies (4.5%), and alcoholic hepatitis (2.7%). This distribution is comparable to a large multicenter study of 770 cirrhotic patients, which reported HBV (49.2%), NASH (21.0%), HCV (14.7%), alcohol (4.0%), Wilson's disease (3.6%), autoimmune hepatitis (3.0%), and unknown causes (4.4%) [18,25]. In the present study, 77% of patients were decompensated and 23% compensated, with Child–Pugh class distribution of A (23%), B (41%), and C (36%), consistent with prior observations indicating predominance of advanced liver disease [13].

Assessment of nutritional status using RFH-SGA revealed 35.5% of patients were severely malnourished, 17.3% moderately malnourished, and 47.3% adequately nourished, yielding an overall malnutrition prevalence of 52.8%. Anthropometric measures identified malnutrition in 26.4% by BMI, 43.6% by MAMC, and 47.3% by TSF, indicating that MAMC and TSF were more sensitive than BMI in detecting malnutrition. These findings align with previous reports suggesting malnutrition prevalence ranging from 20% to 80% in cirrhotic populations and corroborate Sevastianos et al., who reported malnutrition in 54.2% of patients by RFH-SGA versus 18–44.6% by anthropometry [26].

Malnutrition prevalence increased with advancing disease severity. Using RFH-SGA, malnutrition was present in 24% of Child–Pugh A, 48.9% of B, and 60% of C patients (p = 0.035). Similar increasing trends were observed with MAMC (32%, 40%, 55%; p = 0.025) and TSF (36%, 46.7%, 55%; p = 0.042), whereas BMI showed no significant correlation with disease severity (p = 0.512), indicating the limited sensitivity of BMI in detecting malnutrition in advanced cirrhosis. These results are consistent with findings by Rana et al., who reported severe malnutrition in 27.8% of CP-A, 52.7% of CP-B, and 63% of CP-C patients [13].

Educational level and socioeconomic status significantly influenced nutritional outcomes. Severe malnutrition was most prevalent among illiterate patients (66.7%) and those with primary education (65%), decreasing progressively with higher educational attainment to 14.3% in graduates or higher (p = 0.031). Similarly, severe malnutrition was more frequent among individuals of lower socioeconomic status (64.3%) compared to those from upper-class backgrounds (12.5%) (p = 0.043). These trends are consistent with

Khan et al., who reported higher malnutrition rates in illiterate and low socioeconomic groups, with marked reductions among patients with higher education and socioeconomic status [27].

Nutritional counseling was provided to only 40.9% of participants, predominantly by doctors (86.7%) in hospital settings (73.3%), and adherence to advice was observed in 62.2% of cases. Patients who received nutritional guidance exhibited significantly lower rates of severe malnutrition (33.3% vs. 56.9%, p = 0.030), highlighting the beneficial impact of structured dietary counseling. El-Etreby et al. reported higher prevalence of dietary counseling (71.2%), mainly by physicians (93.3%), with differences in the setting of delivery [28].

Dietary knowledge and intake were strongly associated with nutritional status. Patients with awareness of foods to increase, caloric needs, and adequate salt, vitamin, and complementary food intake demonstrated significantly better nutritional outcomes ($p < 0.001$–0.006). Adequate dietary intake markedly reduced severe malnutrition (7.3% vs. 61.4% and 88% in inadequate and negligible intake groups, respectively, $p < 0.001$), indicating that both knowledge and implementation of appropriate nutrition are critical for maintaining nutritional health in cirrhotic patients [29–31].

CONCLUSION

Malnutrition is common among cirrhotic patients and increases with disease severity. RFH-SGA, MAMC, and TSF are more effective than BMI in detecting malnutrition. Lower education, socioeconomic status, poor dietary knowledge, and lack of nutritional counseling significantly worsen nutritional outcomes. Structured dietary guidance and adequate nutrition knowledge are associated with improved nutritional status, highlighting the need for routine assessment and targeted interventions in this population.

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Assessment of aetiological, clinical and electrophysiological profile of peripheral neuropathy and their correlation in a tertiary care center

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ABSTRACT

Background: Peripheral neuropathy is a prevalent neurological condition in clinical practice. Proper examination and management need a sequential approach because to its varying appearance and multiple causes. Neuropathies can be classified into subtypes and etiologies based on clinical observations, electro diagnostic testing, and laboratory studies customized to each patient. The study aims to investigate the clinical characteristics, etiology, and electrophysiological profile of peripheral neuropathy at a tertiary care hospital. **Methods & Materials:** The study examined 70 cases of chronic peripheral neuropathy treated at the Department of Neurology at Shaheed Ziaur Rahman Medical College & Hospital in Bogura, Bangladesh, over a 12-month period (June 2024 to May 2025). The study included a detailed examination of the presenting complaint, clinical examination, electrophysiological studies, and other relevant findings. Data were examined using the statistical software SPSS 20.0. **Results:** Patients were 18–75 years old, with male predominance (M: F = 2.4:1). Most had polyneuropathy (68.6%), predominantly affecting both upper and lower limbs (85.8%) with axonal (60%) or demyelinating (40%) patterns. Etiologies included immune-mediated causes, diabetes, CIDP, infections, hereditary, alcohol, and others. Sensory-motor involvement was most common (54.3%), while pure motor neuropathies were rare (1.2%). **Conclusion:** Peripheral neuropathy is more frequent in men aged 30-70. The majority have distal symmetrical motor sensory polyneuropathy. Diabetes is the leading cause of chronic peripheral neuropathy, followed by immune-mediated neuropathy. Hansen's neuropathy is a common infectious neuropathy.

Keywords: *Chronic peripheral neuropathy, electro diagnostic tests, diabetes mellites, immune mediated.*

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INTRODUCTION

Peripheral nerve disorders are neurological abnormalities caused by malfunction in the motor, sensory, or autonomic nerves. The etiology of neuropathies and their clinical manifestations are quite varied. Neuropathy can be caused by entrapment, systemic diseases, inflammation, autoimmune disorders, hereditary disorders, ischemia situations, paraneoplastic syndromes, deficiencies, infections, and toxins [1]. Peripheral neuropathy affects 2.4% of the population, but climbs to 8% among those over 55 years old. Neuropathy symptoms can be classified as acute (<4 weeks), subacute (4-12 weeks), or chronic (>12 weeks) [2]. Mononeuropathy refers to the involvement of a single nerve and indicates a localized process. The most prevalent causes are direct trauma, compression, vascular lesions, and neoplastic infiltration. Multiple mononeuropathy, also known as mononeuropathy multiplex, refers to the simultaneous or sequential destruction of multiple non-contiguous nerves. Electrophysiological investigations can pinpoint the location of the lesion more precisely than clinical examinations. Examination can distinguish between axonal loss and localized segmental demyelination. The purpose of this study is to look into the clinical characteristics, etiology, and electrophysiological profile of peripheral neuropathy in a tertiary care hospital.

METHODS & MATERIALS

A prospective observational study included 70 patients of chronic peripheral neuropathy from the Department of Neurology at Shaheed Ziaur Rahman Medical College & Hospital in Bogura, Bangladesh, from June 2024 to May 2025.

The study included patients presenting with symptoms and signs suggestive of persistent peripheral neuropathy, as well as any probable cases of ongoing peripheral neuropathy. Patients with acute or sub-acute neuropathy, myelopathy, traumatic neuropathy, or carpal tunnel syndrome were excluded from the study.

The patient provided a detailed history of their current problems, past medical history, family history, and comorbidities. A thorough neurological examination was conducted. We sent a complete blood hemogram, ESR, random blood glucose, renal function tests, liver function tests, serum thyroid and lipid profiles, and viral indicators. Specific tests include serum vitamin B12, HBA1C, serum electrophoresis, urine for Bence Jones proteins, and RA factor. ANA profile, vasculitis panel, Lymes serology, VDRL, and MRI spine with contrast were performed in selected cases. Electrodiagnostic tests are performed in all patients to determine the pattern of involvement. Demyelinating neuropathy is diagnosed when distal latency exceeds 115% of the upper limit of normal with normal CMAP or more than 150% of normal with low CMAP. Axonal neuropathy is characterized by reduced amplitude despite adequate distal delay and conduction velocity [3]. A split skin smear or nerve biopsy is performed, and genetic testing may be necessary. Data were analyzed using the statistical software SPSS 20.0.

RESULT

Table I shows the majority of patients were in the 31–50 years and 51–70 years age groups (41.43% each), indicating that neuropathy was most common in middle-aged and older adults. Fewer cases were observed in the 18–30 years (7.14%) and

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>71 years (10%) age groups. Among males, most cases occurred between 31–70 years (82%), while females showed a similar distribution, with 85% between 31–70 years. Overall, the findings suggest that neuropathy predominantly affects individuals in the middle and late adulthood period, with a male predominance across all age groups.

Table I
Age & Sex distribution of the participants (*n*=70).

Age (in years)	Male (50)n(%)	Female (20) n (%)	Total (70) n (%)
18 - 30	4 (8)	1 (5)	5 (7.14)
31 - 50	20 (40)	9 (45)	29 (41.43)
51 - 70	21 (42)	8 (40)	29 (41.43)
> 71	5 (10)	2 (10)	7 (10)

Table II presents Sensorimotor involvement was the most common presentation (54.29%), while pure sensory (18.57%) and pure motor (2.86%) symptoms were less frequent. The majority of patients had both upper and lower limb involvement (67.14%), whereas isolated lower limb involvement was uncommon (5.71%). Bladder involvement (4.29%) and cranial nerve involvement (2.86%) were rare. Skeletal deformities (2.86%), peripheral nerve thickening (1.42%), dysautonomia (1.42%), and gastrointestinal symptoms (1.42%) were infrequent, indicating that autonomic and structural complications were relatively uncommon.

Table II
Distribution of Clinical Symptoms and Neurological Involvement Among Study Participants (*n* = 70).

Symptom	N (%)
Sensorimotor	38 (54.29)
Pure sensory	13 (18.57)
Pure motor	2 (2.86)
Both upper & lower limbs involvement	47 (67.14)
Only lower limbs	4 (5.71)
Bladder involvement	3 (4.29)
Cranial nerve involvement	2 (2.86)
Skeletal deformities	2 (2.86)
Peripheral nerve thickening	1 (1.42)
Dysautonomia	1 (1.42)
GIT symptoms	1 (1.42)

Table III shows polyneuropathy was the most common pattern (68.57%), predominantly axonal (39/48), with fewer demyelinating cases (10/48), indicating that axonal neuropathy was the leading electrophysiological subtype. Mononeuritis multiplex accounted for 14.29% of cases and was mainly axonal in nature. Polyradiculoneuropathy represented 11.43% of cases and was largely demyelinating, reflecting conditions such as CIDP and related immune-mediated neuropathies. Mononeuropathy was least common (5.71%), with a mixed axonal and demyelinating distribution. Overall, axonal neuropathy predominated in polyneuropathy and mononeuritis multiplex, while demyelination was more characteristic of polyradiculoneuropathy cases.

Table III
Distribution of Neuropathy Patterns and Their Electrophysiological Types (Axonal vs. Demyelinating) Among Patients (*n* = 70).

Pattern	N=70, n (%)	Demyelination (20)	Axonal (50)
Poly neuropathy	48 (68. 57)	10	39
Mono neuritis multiplex	10 (14.29)		
Hansens	5		
Sjogren	1		
Vasculitis	1		
Para neoplastic	1		
No cause found	2	1	8
Poly radiculo neuropathy	8 (11.43)	7	2
CIDP			
Rheumatoid arthritis, with GM1,GD1a ab			
Recurrent CIDP			
Childhood CIDP			
MADASM			
MMNCB			
Lymes			
Diabetes			
Mono neuropathy	4 (5.71)		
Bilateral femoral	3		
Radial nerve	1	2	1

Table IV presents Endocrine causes were the most common etiology, accounting for 48.57% of cases, predominantly due to diabetes (41.43%), highlighting diabetes as the leading cause of neuropathy in this cohort. Immune-mediated neuropathies constituted 30%, with CIDP and its variants forming a significant proportion, indicating a substantial burden of treatable inflammatory neuropathies. Infectious causes were identified in 14.11% of cases, mainly leprosy, while hereditary neuropathies accounted for 7.05%. Alcohol-related (8.23%), paraneoplastic (3.52%), drug-induced (2.35%), and chronic kidney disease–related neuropathies were less frequent. No identifiable cause was found in 6 cases. Overall, metabolic and immune-mediated factors were the predominant contributors to neuropathy in this population.

Table IV
Etiological Distribution of Peripheral Neuropathy Cases (*n* = 70).

Aetiology	Number of Cases	Percentage (%)
Endocrine causes	34	48.57
– Diabetes	29	41.43
– Impaired glucose tolerance	5	7.14
Immune mediated	21	30.00
– CIDP	12	17.14
– Pure motor variant	1	1.43
– Sensory variant	2	2.86
– Recurrent CIDP	1	1.43
– Childhood CIDP	1	1.43
– Pure motor variant (second case)	1	1.43
– MADSAM	1	1.43
– MMNCB	1	1.43
– GM1/GD1a antibody	1	1.43
– Multiple myeloma	1	1.43
– Connective tissue diseases	9	12.86
—— Rheumatoid arthritis	2	2.86
—— Sjogren syndrome	1	1.43
—— Systemic sclerosis	2	2.86
—— Vasculitis	2	2.86
—— Panel negative	2	2.86
Medical disorders	1	1.43
– Chronic kidney disease	1	1.43
Hereditary neuropathy	6	8.57
– CMT 1	2	2.86
– CMT 2	2	2.86
– SPG11	2	2.86
Infectious neuropathy	12	17.14
– Leprosy	8	11.43
– Lyme	1	1.43
– Brucellosis	1	1.43
– HIV	1	1.43
– Others	1	1.43
Alcohol-related neuropathy	7	10.00
Paraneoplastic	3	4.29
– NHL	1	1.43
– Ovarian carcinoma	1	1.43
– Anti-Hu antibody	1	1.43
Drug induced	2	2.86
– Bortezomib	1	1.43
– Leflunomide	1	1.43
No cause found	6	8.57

Table V shows Among the 31 cases, axonal neuropathy was predominant, accounting for 24 cases (77.4%), while demyelinating neuropathy comprised 7 cases (22.6%). Diabetes mellitus and entrapment neuropathy together contributed 12 cases (38.7%), mainly with an axonal pattern. Hansen's disease accounted for 5 cases (16.1%), all predominantly axonal. Impaired glucose intolerance was seen in 4 cases (12.9%), also largely axonal. Alcohol-related neuropathy (2 cases, 6.5%), rheumatoid arthritis (2 cases, 6.5%), and single cases (3.2% each) of HIV, leflunomide exposure, celiac disease, chronic kidney disease, sensory variant CIDP, and idiopathic causes were noted. Demyelination was relatively limited and mainly associated with immune-mediated and idiopathic cases. Overall, metabolic and systemic causes were the major contributors, with a clear predominance of axonal pathology (77.4%) over demyelination (22.6%).

Table V
Etiological Distribution and Electrophysiological Pattern (Axonal vs. Demyelinating) of Neuropathy Cases (*n* = 31).

Cause	N=31	Demyelination (7)	Axonal (24)
DM Entrapment	9	5	11
Sensory variant CIDP	31	-	2
Hansens	5	-	1
Leflunomide	1	-	1
Celiac disease	1	-	1
Impaired glucose intolerance	4	-	1
HIV neuropathy	1	-	-
Alcohol	2	-	1
Metabolic (CKD)	1	-	1
Rheumatoid arthritis	2	1	1
idiopathic	1	1	2

Table IV presents among the three cases, hereditary neuropathy was the most common cause (2/3, 66.7%) and demonstrated a purely axonal pattern. Motor CIDP accounted for one case (33.3%) and showed a demyelinating pattern. Overall, axonal neuropathy predominated (66.7%), while demyelination was limited to the immune-mediated case (33.3%).

Table- IV
Pure Motor Neuropathy.

Cause	N=3	Axonal	Demyelination
Hereditary neuropathy	2	2	-
Motor CIDP	1	-	1

DISCUSSION

Peripheral neuropathy is a frequent neurological condition with varied symptoms and causes. In our study, the age of presentation ranged from 18 to 75 years, with the bulk of cases falling between 51 and 70 years old, followed by 31 and 50 years old. There is a male majority of 67%, which is in conformity with the study done by Sase and coworkers [4] (62%), and Goel and coworkers (61%) [5]. Diabetes and dietary deficits are the leading causes of neuropathy [6, 7]. Other causes include entrapment neuropathy and idiopathic. The prevalence of diabetic neuropathy in our study was consistent with that of Bansal et al [8]. Diabetes is the leading cause of slowly progressing neuropathy. It has varying manifestations. The most prevalent observation is distal symmetrical polyneuropathy, with a length-dependent pattern. In two diabetes cases, one exhibited unilateral meralgia paresthetica, while the other had asymmetrical progressive entrapment neuropathy of the femoral nerve with poor glycemic control. Imaging was used to rule out plexopathy. A middle-aged diabetic with poor glycemic control came with increasing quadriparesis. Workups for genetic, autoimmune, and paraneoplastic panels were negative, and nerve biopsy revealed conflicting results. She was administered rituximab to treat immune-mediated neuropathy. In research by Sase and coworkers [4], GBS was the second most common cause. Mygland and coworkers [9] found that alcoholic and toxic neuropathy were the next most common causes. Immune-mediated neuropathy was the second most common cause in our investigation. Lubec et al. [10] reported CIDP at 6.2%, which is lower than our findings. Entrapment neuropathy was found in 9% of cases in a study by Sase and colleagues [4] and 17% in a study by Vishali et al [7], followed by infective neuropathy. Immune-mediated neuropathy is the second most common cause in our study. The majority of CIDP patients were associated with diabetes, with one case confirming MADSAM through nerve biopsy. The cases included DADS variant, bone marrow biopsy-proven multiple myeloma, pure motor variant, sensory variant, remitting and relapsing type, childhood CIDP, GM1, GM2 antibody positive MMNCB, and GM1, GD1a antibody positive. Two cases of connective tissue disorders with mononeuritis multiplex pattern were diagnosed with rheumatoid arthritis and positive for SSA and SSB antibodies. One patient presented with increasing quadriparesis, dysphagia, oesophageal spasm, functional gut motility dysfunction, and hearing loss. A systemic sclerosis work-up revealed a positive result. In one example, a patient arrived with gradually worsening sensory ataxia and severe dysautonomia. An autoimmune and paraneoplastic panel was negative. The patient reacted to steroids rather than IV immunoglobulins. Two cases were clinically suspected of vasculitis with mononeuritis multiplex presentation, but the panel was negative. The patients responded to drugs. Eight occurrences of Hansen's neuropathy were caused by infections. They appeared with mononeuritis multiplex neuropathy. Five instances had MDT treatment, with one completing the course, one defaulting, and one newly diagnosed with split skin smear. One patient remained with a hypasthetic patch, while another had deformities and peripheral nerve thickening. Two cases had significant fiber involvement. Electrodiagnostic investigations indicated motor involvement in three cases. It highlights the importance of taking drug resistance into account while treating Hansen's illness. Two instances presented with gradual quadriparesis, considerable weight loss, and wasting. Spine MRI revealed root enlargement at the conus, indicating Lymes serology. Treatment with doxycycline improved the condition. One instance with bladder involvement tested positive for brucella antibodies, comparable to others. Six occurrences of alcohol-related neuropathy were reported, with the majority being painful. Thiamine supplementation treated a case of small and large fiber neuropathy significantly. One example of pure sensory neuropathy presented with GIT symptoms for three years. Constraints prevented the use of antigliadin antibodies. A duodenal biopsy revealed lymphocytic infiltration but was negative for periodic acid Schiff base stain. But she replied with doxycycline. Smith et al. [11] discovered that only 31% of chronic idiopathic neuropathy cases were idiopathic, whereas the rest were caused by reduced glucose tolerance. Hughes et al. [12]

did not identify glucose intolerance as a significant risk factor. We recommend considering immune-mediated neuropathy in idiopathic patients, even if the panel was negative, as research for novel antibodies continues.

LIMITATION

This was a single-centered study with a modest sample size. As a result, the study's conclusions may not accurately reflect the situation throughout the country.

CONCLUSION

Diabetes, the most prevalent cause, highlights the importance of glycemic control and lifestyle changes. The rise in immune-mediated neuropathy could be attributed to environmental, lifestyle, genetic, and epigenetic factors. Infectious causes should be recognized as avoidable. More large-scale investigations are needed to have a better knowledge of illness profiles.

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Comparison between Subtarsal and Infraorbital Approaches for The Management of Infraorbital Rim and Orbital Floor Fracture

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ABSTRACT

Background: Subtarsal or infraorbital incisions can be utilized for managing orbital fractures. The subtarsal technique typically offers superior cosmetic and functional results, while the infraorbital technique is quicker but can lead to more noticeable scars. This study evaluates the two methods regarding aesthetic outcomes, functional restoration, and surgical complications. **Methods & Materials:** This prospective study at Dhaka Medical College involved 30 patients with infraorbital fractures, categorized into subtarsal and infraorbital groups. All received CT evaluations and surgical correction using mini-plates. A follow-up at 1 week, 1, 3, and 6 months assessed complications, surgical duration, and cosmetic results. Data were examined to compare outcomes between the two methods. **Results:** In this study involving 30 individuals with infraorbital fractures, the majority were young men. Unilateral fractures occurred most frequently, with the primary cause being road traffic collisions. Complications occurring early and late were more prevalent in the infraorbital group. The operative duration was less for infraorbital access (45 ± 6 min compared to 52 ± 7 min), whereas the subtarsal method experienced fewer complications (26.7% versus 46.7%) and produced superior aesthetic results (good–excellent: 80% versus 53.3%). **Conclusion:** The subtarsal method for infraorbital fractures resulted in fewer early and late complications and better aesthetic results compared to the infraorbital method. Even though it was a bit longer, it delivered improved cosmetic outcomes, rendering it a safer and more aesthetically pleasing choice, particularly when appearance is a key concern.

Keywords: *Subtarsal Approaches, Infraorbital Approaches, Infraorbital Rim, Orbital Floor Fracture.*

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INTRODUCTION

The management of maxillofacial trauma follows established trauma care principles, with particular emphasis on the preservation of vision and ocular motility. The presence of an oculocardiac reflex, manifested by bradycardia, nausea, or syncope, necessitates prompt intervention, as it may precipitate potentially fatal cardiac arrhythmias if left untreated [1]. Orbital fractures are common in facial trauma, accounting for approximately 30%–40% of cases [2]. The orbital floor is formed by the maxilla, zygomatic, and palatine bones and contains the infraorbital groove, which transmits the infraorbital nerve and vessels, rendering this region particularly susceptible to injury during both trauma and surgical intervention [3].

Surgical access to the infraorbital rim and orbital floor can be achieved through transcutaneous or transconjunctival approaches, with postoperative cosmetic outcome being a major determinant in the choice of incision. Common external lower eyelid approaches include subciliary, subtarsal, and infraorbital incisions [4]. The subtarsal incision is placed just inferior to the tarsal plate, whereas the infraorbital incision is made within a natural skin crease near the infraorbital rim. Variations in eyelid anatomy, incision placement, and dissection planes can influence both functional and aesthetic outcomes, and each approach is associated with specific complications [5]. International literature comparing subtarsal and infraorbital approaches for infraorbital rim and orbital floor fractures suggests that both techniques provide adequate surgical exposure. However, the subtarsal approach is often favored due to its direct access, preservation of lower eyelid support structures, and lower incidence of complications such as eyelid malposition when compared with subciliary incisions [6].

Infraorbital incisions allow rapid and straightforward access to the fracture site but are more likely to result in visible scarring, although scar prominence generally diminishes over time [7]. Retrospective analyses of subtarsal incisions have demonstrated favorable long-term outcomes, with minimal complications, rare occurrences of ectropion, and scars that are largely inconspicuous by 12 months postoperatively [8]. In contrast, comparative studies involving infraorbital incisions have reported increased scar visibility and more prolonged postoperative edema compared with subtarsal and subciliary techniques [9].

In Bangladesh, a study by Hasan MZ et al. showed that the transconjunctival approach for infraorbital fractures resulted in superior cosmetic outcomes with no visible scarring, whereas the subciliary approach was associated with noticeable scars and transient lower eyelid malposition [10]. However, local evidence comparing subtarsal and infraorbital approaches remains limited. Most available studies focus on transconjunctival versus

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subciliary incisions, with little data addressing long-term outcomes, patient satisfaction, or pediatric cases. Given these gaps in the literature, the present study aimed to compare the subtarsal and infraorbital approaches in the management of infraorbital rim and orbital floor fractures, with particular emphasis on cosmetic outcomes, functional recovery, and postoperative complication rates, in order to inform and improve surgical decision-making in the local context.

METHODS & MATERIALS

This prospective comparative study was conducted at Dhaka Medical College (DMC) over a 12-month period from January 2024 to December 2024. The study included 30 patients diagnosed with infraorbital rim and/or orbital floor fractures, who were equally divided into two groups: 15 patients underwent the subtarsal approach and 15 underwent the infraorbital approach.

Patient Selection: Patients of any age or gender presenting with unilateral or bilateral infraorbital fractures requiring surgical repair were eligible. Exclusion criteria included prior orbital or eyelid surgery, severe ocular trauma, uncontrolled systemic illnesses, or contraindications to anesthesia. Informed consent was obtained from all participants before enrollment.

Preoperative Assessment: All patients underwent detailed history-taking, physical examination, and radiological evaluation, including computed tomography (CT) scans of the orbit to assess fracture patterns and plan surgical intervention. Comorbidities such as diabetes mellitus, hypertension, cardiovascular disease, and asthma were recorded. The cause of injury—road traffic accident, fall, sports injury, assault, or other causes—was documented.

Surgical Procedure: Surgeries were performed by experienced maxillofacial surgeons under standard sterile conditions. The subtarsal incision was placed approximately 5–7 mm below the lower eyelid margin, while the infraorbital incision was made along the natural skin crease of the infraorbital region. Fracture reduction and fixation were performed using mini-plates and screws as indicated.

Postoperative Evaluation: Patients were monitored for early complications including bleeding, hematoma, edema, ecchymosis, and vision disturbances. Late complications, such as scarring, infraorbital nerve dysfunction, eyelid malposition, and persistent diplopia, were assessed during follow-up visits at 1 week, 1 month, 3 months, and 6 months post-surgery. Operative time was recorded, and aesthetic outcomes were evaluated based on patient satisfaction and surgeon assessment, classified as good–excellent or fair.

Data Analysis: Data were entered into statistical software and analyzed using descriptive statistics. Frequencies, percentages, and means with standard deviations were calculated to compare the outcomes between the subtarsal and infraorbital approach groups. Differences in complication rates, operative times, and aesthetic results were evaluated to determine the relative safety and efficacy of each surgical approach.

RESULTS

A total of 30 patients with infraorbital rim and/or orbital floor fractures were included in the study. Patients were equally allocated into two groups: the subtarsal approach and the infraorbital approach group.

Socio-demographic and Clinical Characteristics

Table I shows the majority of the participants were young adults. Thirteen patients (43.3%) belonged to the 18–35 years age group, followed by those aged >18 years (26.7%), 35–50 years (23.3%), and >50 years (6.7%). Male patients predominated, accounting for 18 cases (60%), while females comprised 12 cases (40%).

Table I
Socio-demographic characteristics of the study participants (n = 30).

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	≤18	8	26.7
	18–35	13	43.3
	35–50	7	23.3
	>50	2	6.7
Gender	Male	18	60.0
	Female	12	40.0

Table II presents regarding comorbid conditions, diabetes mellitus was present in 12 patients (40%), hypertension in 10 patients (33.3%), cardiovascular disease in 5 patients (16.7%), asthma in 3 patients (10%), and other comorbidities in 2 patients (6.7%). Some patients had more than one comorbidity.

Table II
Distribution of comorbidities among participants (multiple responses).

Comorbidity	Frequency (n)	Percentage (%)
Diabetes mellitus	12	40.0
Hypertension	10	33.3
Cardiovascular disease	5	16.7
Asthma	3	10.0
Others	2	6.7

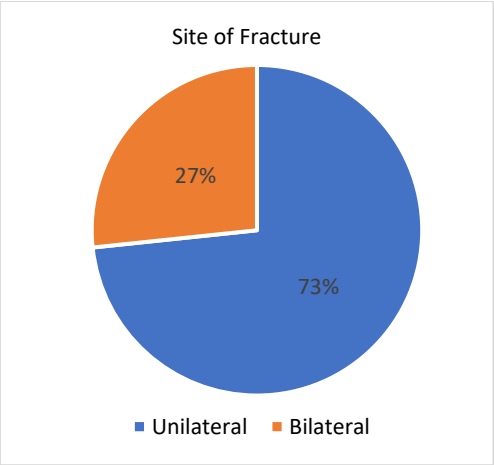

Figure 1 Laterality of infraorbital rim and orbital floor fractures

Figure 1 shows Unilateral fractures were more common, observed in 22 patients (73.3%), whereas bilateral fractures were identified in 8 patients (26.7%).

Etiology of Injury

Table III shows road traffic accidents were the most frequent cause of injury, accounting for 11 cases (36.7%). Falls were reported in 7 patients (23.3%), sports-related injuries in 5 patients (16.7%), assaults in 4 patients (13.3%), and other causes in 3 patients (10%).

Table III
Etiology of injury (*n*=30).

Cause of injury	Frequency (n)	Percentage (%)
Road traffic accident	11	36.7
Falls	7	23.3
Sports injury	5	16.7
Assault	4	13.3
Others	3	10.0

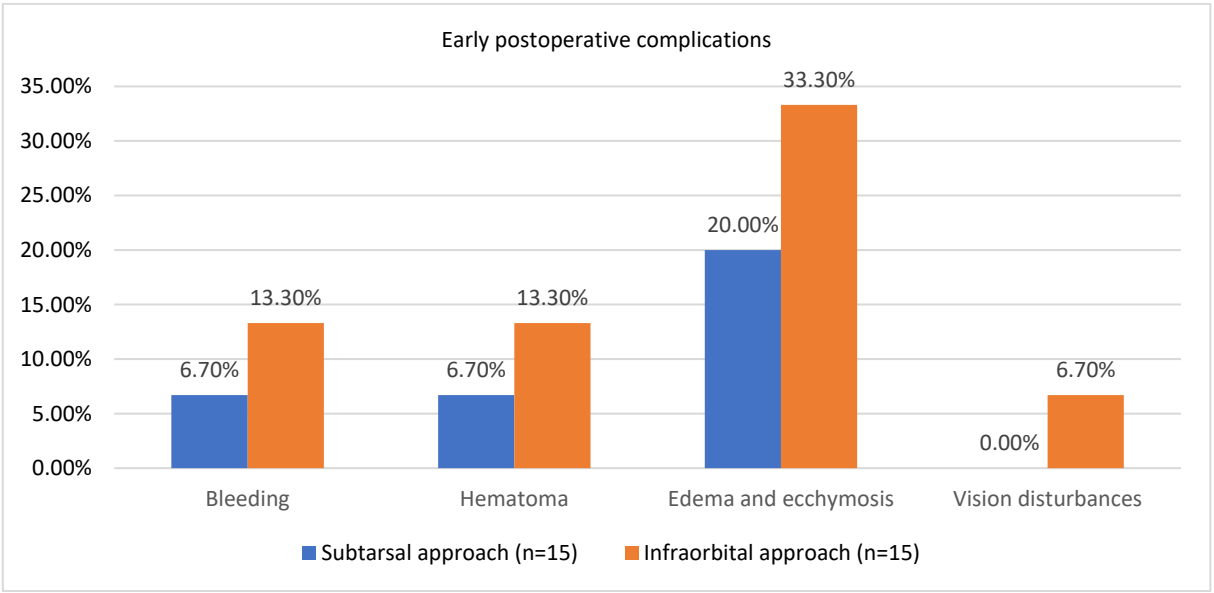

Figure 2 Early postoperative complications by surgical approach

Early Postoperative Complications

In *Figure 2*, early complications were observed in both groups, with a higher frequency in the infraorbital approach group. In the subtarsal group, mild postoperative bleeding occurred in 1 patient (6.7%), hematoma in 1 patient (6.7%), and edema with ecchymosis in 3 patients (20%). No cases of postoperative vision disturbance were recorded in this group.

In contrast, the infraorbital group showed postoperative bleeding in 2 patients (13.3%), hematoma in 2 patients (13.3%), and edema with ecchymosis in 5 patients (33.3%). Transient vision disturbance was observed in 1 patient (6.7%), which resolved within the early postoperative period.

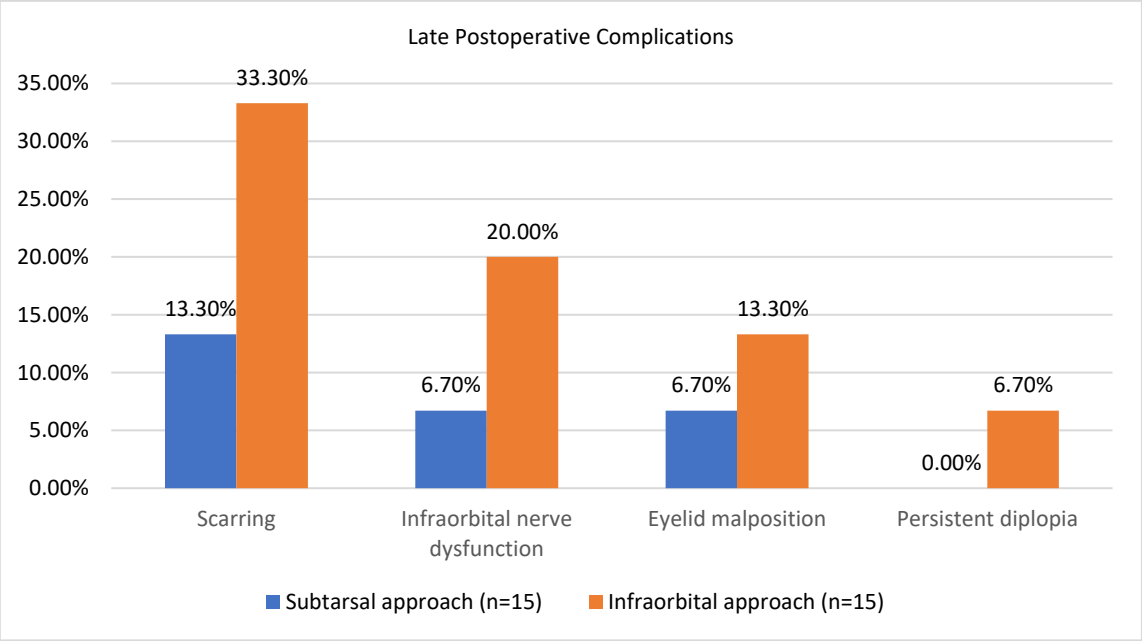

Figure 3 Late postoperative complications by surgical approach

Late Postoperative Complications

Figure 3 shows Late complications were less frequent in the subtarsal approach group shown in Figure 3 . Minimal scarring was noted in 2 patients (13.3%), infraorbital nerve dysfunction in 1 patient (6.7%), and eyelid malposition in 1 patient (6.7%). No cases of persistent diplopia were observed in this group.

In the infraorbital approach group, visible scarring was reported in 5 patients (33.3%). Infraorbital nerve dysfunction occurred in 3 patients (20%), eyelid malposition in 2 patients (13.3%), and persistent diplopia in 1 patient (6.7%).

Operative Outcomes and Aesthetic Evaluation

Table IV shows the mean operating time was shorter in the infraorbital approach group (mean ± SD: 45 ± 6 minutes) compared to the subtarsal approach group (52 ± 7 minutes). The overall complication rate was lower in the subtarsal group (26.7%) than in the infraorbital group (46.7%). Aesthetic outcomes, assessed clinically at follow-up, were rated as good to excellent in 12 patients (80%) in the subtarsal group, compared with 8 patients (53.3%) in the infraorbital group. Fair cosmetic outcomes were observed in 3 patients (20%) in the subtarsal group and 7 patients (46.7%) in the infraorbital group.

Table IV
Comparison of operative and aesthetic outcomes.

Outcome variable	Subtarsal approach,n(%)	Infraorbital approach, n (%)
Mean operating time (Minutes, Mean ± SD)	52 ± 7	45 ± 6
Overall complication rate	26.7%	46.7%
Good–excellent aesthetic outcome	12 (80.0)	8 (53.3)
Fair aesthetic outcome	3 (20.0)	7 (46.7)

Overall, the subtarsal approach demonstrated fewer complications and superior aesthetic outcomes, whereas the infraorbital approach offered shorter operating time but was associated with a higher incidence of visible scarring and late complications.

DISCUSSION

In this study, the majority of orbital fractures occurred in younger individuals, with 43.3% of patients aged between 18 and 35 years and nearly 70% aged 35 years or younger. This observation is consistent with a reference study of 504 cases, which also reported a predominance of fractures in younger age groups, with a mean age of 39.3 years [11]. Male predominance (60%) observed in our cohort aligns with previous findings, where males accounted for up to 77% of orbital fracture cases, with a male-to-female ratio of approximately 3.3:1, reflecting increased exposure to high-risk trauma [12].

Regarding comorbidities, patients in this study with infraorbital rim and orbital floor fractures presented with diabetes (40%), hypertension (33.3%), cardiovascular disorders (16.7%), and asthma (10%). In contrast, a large-scale review of 16,671 hospitalized patients indicated that most had no comorbid conditions (78.7%), with lower incidences of diabetes (9.85%), diabetes with complications (1.89%), chronic pulmonary disease (3.56%), cerebrovascular disease (3.18%), myocardial infarction (0.38%), heart failure (1.0%), and peripheral vascular disease (0.33%) [13]. These findings underscore the importance of considering systemic comorbidities in surgical planning and perioperative management.

Unilateral fractures of the infraorbital rim and orbital floor were more prevalent (73.3%) than bilateral fractures (26.7%), which is in agreement with a comprehensive review reporting 77.5% unilateral and 22.5% bilateral fractures, confirming the typical predominance of one-sided orbital injuries [12].

Mechanisms of injury in this study were led by road traffic accidents (36.7%), followed by falls (23.3%), sports-related trauma (16.7%), assaults (13.3%), and other causes (10%). These results are in line with broader trauma literature, which identifies road traffic accidents (54.7%),

falls (28.8%), assaults (3.8%), and other mechanisms (12.7%) as common contributors to orbital fractures [14].

Early postoperative complications were more frequent in the infraorbital approach, including bleeding (13.3%), hematoma (13.3%), edema/ecchymosis (33.3%), and transient visual disturbances (6.7%), compared to the subtarsal approach (bleeding 6.7%, hematoma 6.7%, edema/ecchymosis 20%, no visual disturbances). Late complications also favored the subtarsal approach, with the infraorbital group showing higher rates of noticeable scarring (33.3% vs. 13.3%), infraorbital nerve dysfunction (20% vs. 6.7%), eyelid malposition (13.3% vs. 6.7%), and persistent diplopia (6.7% vs. 0%). These findings are consistent with existing literature: subciliary approaches have reported diplopia (12–15%), corneal injury (7%), ptosis (1–5%), entropion/ectropion (3–9%), and visual impairment (1%), while transconjunctival approaches showed diplopia (10–11%), enophthalmos (7%), ptosis (5%), and subtarsal approaches generally demonstrated lower rates of scarring (8–16.7%), scleral exposure (8–10%), and eyelid swelling (1.4–8%) [8,15-17].

The mean operating time was slightly longer for the subtarsal approach (52 ± 7 min) compared to the infraorbital approach (45 ± 6 min), reflecting the meticulous dissection required for cosmetically favorable incisions. All approaches provided adequate exposure of the fractures, with the transconjunctival approach requiring the longest exposure time (~22 min) [9]. Overall complication rates were lower with the subtarsal approach (26.7%) compared to the infraorbital approach (46.7%), while rates for transconjunctival (36.19%) and subciliary (21.4%) approaches showed significant differences ($P < 0.0001$) [1]. Aesthetic outcomes were superior with subtarsal incisions, achieving good–excellent results in 80% of cases compared to 53.3% for infraorbital incisions, while fair outcomes were more common with infraorbital access (46.7% vs. 20%). Subtarsal incisions placed along natural lower eyelid creases demonstrated significant scar improvement over time, with POSAS scores decreasing from 7.33 ± 1.01 to 3.33 ± 0.64 ($p = 0.001$), supporting their superior cosmetic performance [18].

CONCLUSION

In this study, the subtarsal approach for infraorbital rim and orbital floor fractures was associated with fewer early and late complications, including lower rates of scarring, infraorbital nerve dysfunction, and eyelid malposition, compared to the infraorbital approach. Although the operative time was slightly longer with the subtarsal technique, it resulted in superior aesthetic outcomes, with most patients achieving good to excellent cosmetic results. Overall, the subtarsal approach appears to be a safer and more cosmetically favorable option for managing infraorbital fractures, making it preferable, especially in cases where aesthetic considerations are important.

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Beyond the Fever – A Prospective Analysis of Acute Neuropsychiatric Morbidity and Sleep Disturbances During Epidemic Dengue Outbreaks

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ABSTRACT

Background: Dengue outbreaks are intensifying globally, yet the focus remains largely on hematological parameters. This study sought to explore the "hidden" neuropsychiatric morbidity and sleep disturbances during a historic epidemic in Bangladesh. **Methods & Materials:** A prospective observational analysis was conducted on 292 laboratory-confirmed cases at BIRDEM General Hospital, Dhaka. Data on classic clinical symptoms, diagnostic markers (NS1/IgM/IgG), and acute mental health status were evaluated. **Results:** Beyond the hallmark febrile symptoms, significant psychiatric morbidity was observed: 7.9% of patients experienced acute irritability, and 7.9% suffered from insomnia. Despite the absence of prior psychiatric history, low mood (3.8%) and lack of interest (4.1%) were documented during the acute phase. **Conclusion:** Acute dengue infection exerts a measurable neuropsychiatric toll. Identifying these symptoms is crucial for holistic patient care and understanding the expanded clinical spectrum of the virus.

Keywords: *Bangladesh, Dengue fever, Neuropsychiatric morbidity.*

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INTRODUCTION

Dengue is a paramount tropical infection orchestrated by an arbovirus belonging to the *Flaviviridae* family, comprising four distinct serotypes (DENV-1–4). Transmitted primarily through the bite of infected female *Aedes aegypti* and *Aedes albopictus* mosquitoes, the virus exploits urbanized landscapes and climate-driven variables such as rainfall and humidity to sustain its transmission cycles [1,2]. While the global burden of dengue is staggering—with approximately 390 million infections annually—the clinical focus has traditionally remained tethered to the "fever-pain-bleed" triad of classic Dengue Hemorrhagic Fever (DHF) and Dengue Shock Syndrome (DSS) [3].

However, the catastrophic 2023 outbreaks in Bangladesh have highlighted an increasingly complex diagnostic landscape. Beyond the standard febrile and critical phases, there is an emerging recognition of Expanded Dengue Syndrome (EDS), where the virus exhibits significant neurotropic potential [4]. While hematological complications often dominate the clinical foreground, a "hidden" epidemic of neuropsychiatric morbidity frequently unfolds in the shadows. Recent evidence suggests that the acute phase of dengue is not merely a systemic inflammatory event but a neuro-inflammatory one, capable of inducing profound changes in mood, behavior, and sleep architecture [5,6].

Recent international studies have begun to quantify this psychological toll. Research found that hospitalized dengue patients exhibited acute psychiatric manifestations, including anxiety and depressive episodes, often independent of the severity of the systemic illness [7]. Furthermore, studies highlighted that sleep-wake disturbances, particularly insomnia, are prevalent during the viremic phase, yet they remain largely under-reported in tropical medicine literature [8]. These symptoms—ranging from acute irritability to suicidal ideation—often emerge in patients with no prior psychiatric or neurological history, suggesting a direct viral impact on the blood-brain barrier or a cytokine-mediated neuro-inflammatory response [9].

In Bangladesh, despite decades of experience in managing dengue, the neuropsychiatric dimension remains critically under-explored. The intersection of this viral threat with a high metabolic burden, such as diabetes mellitus, further complicates the neurological prognosis. This study, titled **"**Beyond the Fever**,"** seeks to bridge this significant gap in the literature. By prospectively analyzing the prevalence of acute neuropsychiatric morbidity and sleep disturbances during a major epidemic surge, we aim to refine the clinical understanding of the "hidden" mental health burden of dengue and advocate for a more holistic approach to management in the hyper-endemic regions of the world.

METHODS & MATERIALS

An observational study was carried out on 292 laboratory-confirmed dengue patients who were admitted to BIRDEM General Hospital in Dhaka from January 2023 to December 2024. Data on sociodemographic, such as age, gender, and residence, were gathered, along with initial clinical characteristics and existing chronic comorbid conditions. The group mainly included adults with an average age of 35.6 ± 15.2 years, showing a slight lean towards males. Patients experiencing simultaneous acute illnesses were meticulously recorded, guaranteeing that noted neuropsychiatric symptoms were probably linked to the acute dengue infection instead of prior health issues.

Primary diagnostic confirmation was obtained via NS1 antigen testing, complemented by serological evaluation for IgM and IgG antibodies. Laboratory measurements, such as C-reactive protein (CRP) and serum glutamic pyruvic transaminase (SGPT), were assessed to determine systemic inflammation and liver involvement. Typical dengue symptoms, including fever, body pain, and headaches, were documented to provide context for

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clinical presentation and to contrast with new neuropsychiatric results.

Data were examined to establish the frequency of symptoms, their association with laboratory and clinical results, and the effect of the acute viral exposure on mental and behavioral well-being. This method offered a thorough description of both traditional dengue characteristics and the rarer neuropsychiatric issues observed in the study group throughout the 24-month study period.

RESULTS

Table I shows total of 292 laboratory-confirmed dengue patients were enrolled, with a mean age of 35.63 ± 15.22 years (range: 11–85 years). A slight male predominance was observed (54.8%), and the vast majority of participants resided in urban areas (83.9%). Notably, 89.4% of the cohort had no concurrent acute illness, and 65.1% had no prior chronic comorbidities, ensuring that the observed neuropsychiatric symptoms were predominantly associated with the acute viral insult rather than pre-existing conditions.

Table I
Sociodemographic and Baseline Clinical Profile (*n*=292).

Variable	Frequency(n)	Percentage (%)
Age Group (Years)		
< 40	190	65.1
≥ 40	102	34.9
Gender		
Male	160	54.8
Female	132	45.2
Residence		
Urban	245	83.9
Rural	47	16.1
Comorbidities		
None	190	65.1
Diabetes Mellitus	75	25.7
Hypertension	42	14.4

Table II shows Most cases were confirmed by NS1 antigen (82.3%), with fewer showing IgM (13%) or IgG (9.2%) positivity. Elevated CRP (80.1%) and raised SGPT (50.3%) indicate that systemic inflammation and hepatic involvement were common.

Table II
Diagnostic and Inflammatory Profile of the Study Population (*n* = 292).

Parameter	Number of Cases(n)	Percentage (%)
NS1 antigen positivity	240	82.3
IgM seropositivity	38	13.0
IgG seropositivity	27	9.2
Elevated C-reactive protein (CRP)	234	80.1
Raised SGPT levels (hepatic involvement)	147	50.3

Table III presents acute irritability was the most prominent behavioral change, documented in 7.9% (n=23) of the cohort. Sleep architecture was significantly compromised, with insomnia reported by 7.9% of patients. Although the cohort was largely psychologically resilient prior to infection, acute-phase affective symptoms emerged, including a lack of interest (4.1%) and low mood (3.8%). Hypersomnia and excessive talking were rare, occurring in 1.0% and 0.3% of cases, respectively.

Table III
Acute Neuropsychiatric and Behavioral Manifestations.

Variables	Present n (%)	Absent n (%)
Irritability	23 (7.9)	269 (92.1)
Insomnia	23 (7.9)	269 (92.1)
Lack of Interest	12 (4.1)	280 (95.9)
Low Mood	11 (3.8)	281 (96.2)
Decreased Food Intake	20 (6.8)	272 (93.2)
Hypersomnia	3 (1.0)	289 (99.0)

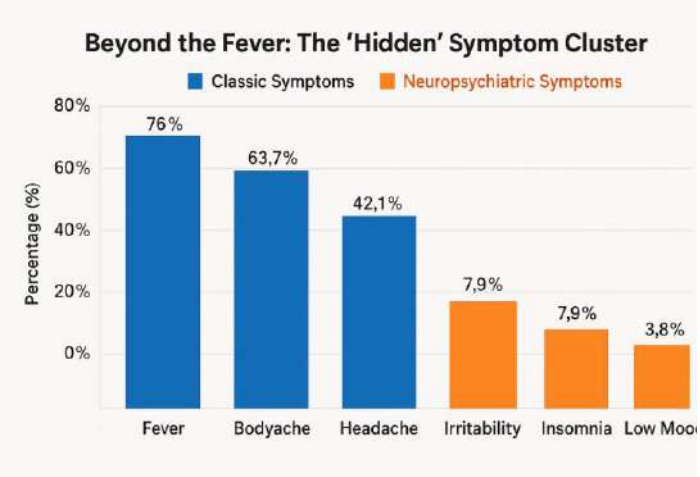

Figure 1 Symptom cluster

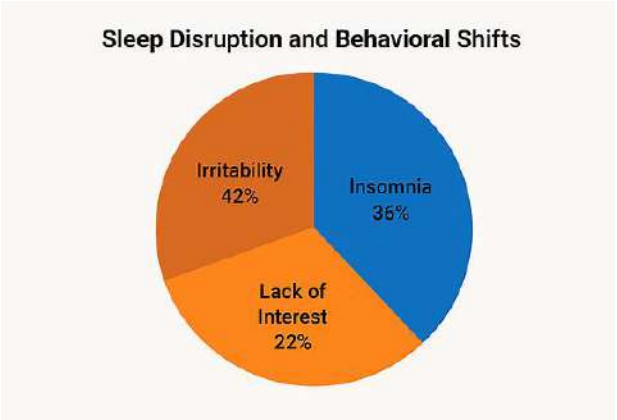

Figure 2 Sleep Disruption and Behavioral Shifts – a visual breakdown of behavioral changes among symptomatic patients

Figure 1 shows the traditional "dengue triad" of fever (76%), body ache (63.7%), and headache (42.1%), the study identified a significant cluster of neuropsychiatric and behavioral disturbances. *Figure 2* shows that irritability (42%, orange) and insomnia (36%, blue) are the dominant neuropsychiatric features, while lack of interest (22%, burnt orange) is less common.

DISCUSSION

This study offers a granular exploration of the clinico-behavioral landscape of dengue during the catastrophic 2023–2024 outbreak in Bangladesh. While the systemic morbidity of Dengue Virus (DENV) is well-documented, our findings illuminate a neglected dimension of the illness: the acute neuropsychiatric and sleep-wake disruptions that occur during the viremic phase. By identifying a significant prevalence of irritability and insomnia even in patients without prior neurological vulnerabilities, this research underscores the necessity of expanding the clinical definition of dengue to include acute mental health disturbances.

The demographic profile of our study—characterized by a mean age of 35.63 years and a 65.1% concentration of patients under 40—reflects a distinct epidemiological shift in South Asia. This aligns with findings by Prattay et al. (2022), who noted a similar adult predominance (73.33%) during the 2019 Dhaka surge [10]. Historically a pediatric disease, the transition toward an adult-centric epidemic may be attributed to the re-emergence of DENV-3 and DENV-4 serotypes, against which the young adult population lacks sufficient herd immunity. The male preponderance (54.8%) observed in our study mirrors regional trends described by Karunakaran et al. (2014), likely driven by gendered patterns of outdoor labor and mobility that increase exposure to the peak-daylight feeding activity of *Aedes aegypti* [11].

A primary contribution of this study is the documentation of acute neuropsychiatric morbidity, a facet often overshadowed by hematological markers. We observed a 7.9% prevalence of acute irritability and an approximately 4% incidence of low mood and anhedonia (lack of interest). These findings are consistent with recent international data; for instance, reported that dengue patients in Sri Lanka exhibited depressive or anxiety symptoms during hospital stay [7].

Unlike classic delirium, the irritability noted in our cohort occurred in a clear conscious state, suggesting that DENV-induced pro-inflammatory cytokines—such as IL-6 and TNF-alpha—may cause transient limbic system dysfunction [9]. This "behavioral viremia" supports the classification of such symptoms under Expanded Dengue Syndrome (EDS), where the virus exerts direct or indirect effects on the central nervous system [5].

The disruption of sleep was another critical finding, with 7.9% of patients suffering from acute-onset insomnia. While physical discomfort from high-grade fever (76%) and severe musculoskeletal pain (63.7%) undoubtedly contributes to sleep fragmentation, recent studies suggest a more complex mechanism. Hypothesized that DENV may interfere with the circadian regulatory pathways or the blood-brain barrier's integrity, leading to significant sleep-wake disturbances [8]. The presence of insomnia in our study, documented even during the recovery phase for some, indicates that the viral impact on sleep architecture may persist beyond the febrile period, necessitating closer psychological follow-up.

The diagnostic landscape of our study was dominated by NS1 antigen sensitivity (82.3%), reinforcing its role as the premier sentinel marker during early outbreak cascades [12]. The significant prevalence of thrombocytopenia (70.9%) and hepatic distress (raised SGPT in 50.3%) aligns with the systemic inflammatory profile described by Muller, Depelsenaire and Young (2017) [13].

Furthermore, the intersection of dengue with diabetes mellitus (25.7%) in our study proved clinically significant. Uncontrolled glycemic status (HbA1C >6.5%) was a potent predictor of complications, doubling the risk of severe manifestations (26.2% vs 12.4%). This synergy between metabolic phenotypes and viral pathogenesis suggests that glucose dysregulation may enhance viral replication or exacerbate the vascular leak syndrome characteristic of severe dengue.

CONCLUSION

The "Beyond the Fever" paradigm reveals that DENV is as much a neuropsychiatric challenge as it is a systemic one. While the majority of patients achieve clinical recovery, the acute toll on mental health—specifically irritability and insomnia—remains an under-recognized morbidity. Our study advocates for a holistic diagnostic approach that integrates psychological screening and sleep assessment into standard dengue protocols. As Bangladesh continues to face intensifying arboviral cycles, recognizing these "hidden" symptoms is essential for mitigating the long-term psychological sequelae of the disease and refining national health strategies for the most vulnerable populations.

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Diagnostic Accuracy of Prostate Cancer in TRUS-Guided Prostatic Biopsy in Patients with PSA Levels of 4–10 ng/mL

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ABSTRACT

Background: Prostate carcinoma (CoP) remains a major health concern worldwide, with high incidence and mortality rates, particularly in developed countries, and early detection is critical to improving patient outcomes. The purpose of the study is to evaluate the diagnostic accuracy of TRUS-guided prostatic biopsy for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL. **Methods & Materials:** This prospective observational study at the Department of Urology, Bangladesh Medical University (BMU), Dhaka, Bangladesh (April 2024–March 2025) included 120 men with PSA 4–10 ng/mL. All underwent DRE and systematic TRUS-guided prostate biopsy, with histopathology classified by ISUP Grade Group and TRUS findings correlated to assess diagnostic accuracy. Mean PSA was compared between cancer and benign groups ($p < 0.05$). **Results:** Among 120 men with PSA 4–10 ng/mL, the mean age was 64.5 ± 6.8 years, and mean PSA was 6.8 ± 1.7 ng/mL. Prostate cancer was detected in 58 patients (48.3%), including clinically significant disease in 38 (31.7%), while 62 (51.7%) had benign pathology. Suspicious TRUS findings correctly identified cancer in 45 cases, with 10 false positives and 13 false negatives, giving a sensitivity of 77.6%, specificity of 83.9%, PPV of 81.8%, NPV of 80.0%, and overall accuracy of 80.8%. Mean PSA was significantly higher in cancer patients than in those with benign disease (7.6 ± 1.9 vs. 6.3 ± 1.4 ng/mL; $p < 0.0001$). **Conclusion:** TRUS-guided prostatic biopsy is an effective and reliable method for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL.

Keywords: *Prostate Cancer, TRUS-Guided Biopsy, PSA Gray-Zone.*

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INTRODUCTION

Prostate carcinoma (CoP) is recognized as a significant health concern among men. In Europe, its annual incidence reaches 214 cases per 1000 men, making it the most common solid tumor in the male population [1]. The prevalence of CoP varies worldwide, with higher rates observed in developed countries. In the United States, it ranks as the second leading cause of cancer-related mortality in men and is the sixth most common cause of cancer-related deaths globally [2,3]. While CoP generally progresses slowly, certain tumors can exhibit aggressive behavior. Many patients remain symptom-free in the early stages, whereas others may present with symptoms that typically reflect advanced disease. Early detection, especially at a localized stage, is critical to achieving a successful cure. Globally, prostate cancer is the second most frequently diagnosed malignancy and the fifth leading cause of cancer-related deaths among men.

Traditionally, a "normal" prostate-specific antigen (PSA) level has been considered ≤4 ng/mL; however, no PSA threshold guarantees the absence of prostate cancer [4]. Clinical guidelines from the European Association of Urology (EAU) recommend that the decision to perform a prostate biopsy should consider both PSA levels and digital rectal examination (DRE) findings [5]. Differentiating between prostate adenocarcinoma and benign prostatic hyperplasia (BPH) is particularly challenging in patients whose PSA falls within the "gray-zone" range of 4–10 ng/mL [6]. The presence of an elevated PSA or an abnormal DRE is associated with a higher likelihood of detecting prostate cancer.

For early diagnosis and monitoring, DRE in combination with PSA testing is widely employed. When PSA is elevated or DRE reveals abnormalities, transrectal ultrasound-guided (TRUS-guided) prostate biopsy is generally performed [7]. This technique has become routine in urology and can be safely carried out on an outpatient basis without anesthesia. The use of Trucut needles with spring-loaded biopsy guns ensures the procedure is straightforward and well-tolerated. Despite its widespread use, TRUS detection of prostate malignancy remains challenging due to the variable ultrasonographic appearance of tumors. This has led to the development of the sextant TRUS-guided biopsy technique, initially described by Hodge et al. [8] In cases where ultrasound images show suspicious lesions, targeted biopsies are often performed alongside the sextant approach [9]. However, even with these improvements, the overall sensitivity and specificity of detecting prostate cancer remain suboptimal, with false-negative rates reported between 30% and 45% for a single biopsy session [10,11]. Consequently, modifications in biopsy protocols, including taking more than six systematic cores, have been suggested to improve coverage of the prostate and enhance detection rates [12,13].

Despite the widespread use of PSA testing, DRE, and TRUS-guided biopsy, there remains considerable variability in prostate cancer detection rates, particularly in patients with PSA levels in the gray-zone of 4–10 ng/mL. Previous studies have reported differing sensitivities and false-negative rates, and there is limited data from Bangladesh and similar populations

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regarding the diagnostic performance of TRUS-guided biopsies in this PSA range. Furthermore, questions remain about the optimal biopsy strategy and the correlation between TRUS findings and histopathology in these patients. Addressing these gaps is essential to improve early detection and guide clinical decision-making. The purpose of the study is to evaluate the diagnostic accuracy of TRUS-guided prostatic biopsy for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL. The aim of the study to evaluate the diagnostic accuracy of TRUS-guided prostatic biopsy for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL.

METHODS & MATERIALS

This prospective observational study was conducted at the Department of Urology, Bangladesh Medical University (BMU), Dhaka, Bangladesh, from April 2024 to March 2025. A total of 120 male patients with serum PSA levels of 4–10 ng/mL were enrolled based on predefined inclusion and exclusion criteria. Data were collected on demographic characteristics, digital rectal examination (DRE) findings, and TRUS-guided prostate biopsy results to evaluate the diagnostic accuracy of TRUS in detecting prostate cancer.

Inclusion Criteria:

- Male patients aged ≥50 years.
- Serum PSA level between 4 and 10 ng/mL.
- Patients referred for TRUS-guided prostate biopsy.
- Provided informed consent for participation.

Exclusion Criteria:

- History of prostate cancer or prior prostate surgery.
- Active urinary tract infection or prostatitis at the time of biopsy.
- Use of 5-alpha-reductase inhibitors or other medications affecting PSA levels.
- Incomplete clinical or histopathological data.

Demographic data, including age, were recorded for all participants. DRE was performed by experienced urologists to identify abnormal or suspicious findings. Serum PSA levels were measured within one month prior to biopsy. All patients underwent systematic TRUS-guided prostate biopsy, with suspicious lesions such as hypoechoic nodules or asymmetry specifically targeted. A minimum of 12 cores were obtained from each patient to ensure adequate sampling.

Biopsy specimens were examined by experienced pathologists and classified according to the International Society of Urological Pathology (ISUP) Grade Group system, distinguishing clinically significant cancer (ISUP Grade Group ≥2) from clinically insignificant cancer (ISUP Grade Group 1). Benign tissue, prostatitis, high-grade prostatic intraepithelial neoplasia (PIN), and atypical lesions were also recorded.

TRUS findings were correlated with histopathology to determine true positive, false positive, true negative, and false negative results. Diagnostic performance was calculated in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy. Mean PSA levels were compared between patients with prostate cancer and those with benign pathology using appropriate statistical tests, with $p < 0.05$ considered statistically significant. Written informed consent was obtained from all participants prior to inclusion in the study.

RESULTS

Table I shows the mean age of the study participants was 64.5 ± 6.8 years (range: 50–82 years). Most patients were aged 60–69 years (64 patients, 53.3%), followed by those aged 50–59 years (28 patients, 23.3%) and those aged ≥70 years (28 patients, 23.3%). The mean PSA level was 6.8 ± 1.7 ng/mL. Regarding PSA categories, 45 patients (37.5%) had PSA 4.0–6.0 ng/mL, 43 patients (35.8%) had PSA 6.1–8.0 ng/mL, and 32 patients (26.7%) had PSA 8.1–10.0 ng/mL. On digital rectal examination (DRE), 89 patients (74.2%) were normal, whereas 31 patients (25.8%) had abnormal or suspicious findings.

Table I
Demographic and Clinical Characteristics of the Study Population (n = 120).

Variable		Frequency (n)	Percentage (%)
Age group (years)	50–59	28	23.3
	60–69	64	53.3
	≥70	28	23.3
	Mean ± SD	64.5 ± 6.8	
	Range	50–82	
PSA level (ng/mL)	Mean ± SD	6.8 ± 1.7	
PSA category (ng/mL)	4.0–6.0	45	37.5
	6.1–8.0	43	35.8
	8.1–10.0	32	26.7
Digital Rectal Examination (DRE)	Normal	89	74.2
	Abnormal/Suspicious	31	25.8

Table II presents TRUS-guided biopsy detected prostate cancer in 58 patients (48.3%), with clinically significant cancer (ISUP Grade Group ≥2) in 38 patients (31.7%) and clinically insignificant cancer (ISUP Grade Group 1) in 20 patients (16.7%). Benign pathology was observed in 62 patients (51.7%), including 55 cases of benign prostatic tissue (45.8%), 5 cases of prostatitis (4.2%), and 2 cases of high-grade PIN or atypical lesions (1.7%).

Table II
Histopathological Diagnosis on TRUS-Guided Prostatic Biopsy (*n* = 120).

Histopathological Finding	Number (n)	Percentage (%)
Any Prostate Cancer	58	48.3
- Clinically Significant (ISUP Grade Group ≥2)	38	31.7
- Clinically Insignificant (ISUP Grade Group 1)	20	16.7
Benign Pathology	62	51.7
- Benign Prostatic Tissue	55	45.8
- Prostatitis	5	4.2
- High-grade PIN / Atypical	2	1.7
Total	120	100.0

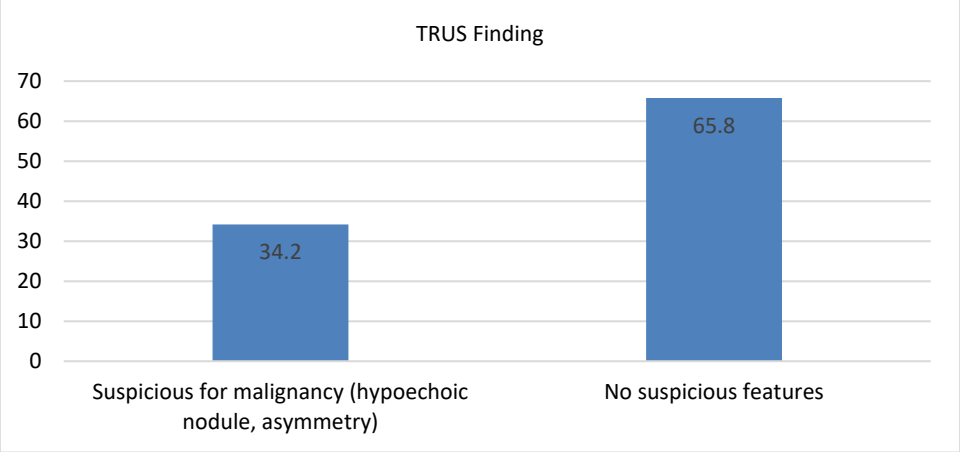

Figure 1 TRUS Findings in the Study Population (n = 120).

Figure 1 presents Suspicious findings on TRUS, including hypoechoic nodules and asymmetry, were identified in 41 patients (34.2%). The remaining 79 patients (65.8%) had no suspicious features on TRUS examination.

Table III shows Among the 55 patients with suspicious TRUS findings, 45 (81.8%) were confirmed to have prostate cancer (true positives), while 10 (18.2%) had benign histology (false positives). Of the 65 patients with non-suspicious TRUS findings, 52 (80.0%) had benign histology (true negatives), whereas 13 (20.0%) were diagnosed with prostate cancer (false negatives).

Table III
Correlation of TRUS Findings with Histopathology (*n* = 120).

TRUS Finding	Prostate Cancer Present (n)	Prostate Cancer Absent (n)	Total (n)
Suspicious on TRUS	45 (TP)	10 (FP)	55
Not Suspicious on TRUS	13 (FN)	52 (TN)	65
Total	58	62	120

Table IV presents the diagnostic performance of TRUS-guided biopsy in this study showed a sensitivity of 77.6%, specificity of 83.9%, positive predictive value (PPV) of 81.8%, negative predictive value (NPV) of 80.0%, and an overall diagnostic accuracy of 80.8%.

Table IV
Diagnostic Performance of Suspicious TRUS Findings (*n* = 120).

Diagnostic Parameter	Value (%)
Sensitivity	77.6
Specificity	83.9
Positive Predictive Value (PPV)	81.8
Negative Predictive Value (NPV)	80.0
Overall Diagnostic Accuracy	80.8

Table V shows the mean PSA level was significantly higher in patients diagnosed with prostate cancer (7.6 ± 1.9 ng/mL) compared to those with benign pathology (6.3 ± 1.4 ng/mL) (p = < 0.0001).

Table V
PSA Levels According to Histopathological Diagnosis (*n* = 120).

Diagnosis	Frequency (n)	Mean PSA (ng/mL) ± SD	p-value
Prostate Cancer	58	7.6 ± 1.9	< 0.0001
Benign Pathology	62	6.3 ± 1.4	

DISCUSSION

Prostate cancer is a significant urological malignancy that poses a considerable health burden among men, particularly when detected late. Serum prostate-specific antigen (PSA) levels and digital rectal examination (DRE) serve as initial screening tools, but their diagnostic accuracy is limited, especially in patients with PSA levels in the gray-zone of 4–10 ng/mL. The findings of this study demonstrate that TRUS-guided prostate biopsy provides a reliable method for detecting prostate cancer in this population, with appreciable sensitivity, specificity, and overall diagnostic accuracy. These results highlight the clinical importance of employing TRUS-guided biopsy in patients with gray-zone PSA to improve early detection and facilitate timely management of clinically significant prostate cancer.

In the present study, the majority of patients were aged 60–69 years (53.3%), with a mean age of 64.5 ± 6.8 years, a finding that is consistent with previously reported biopsy cohorts. Similar age distributions have been described by Seo et al., who evaluated men aged ≥40 years and reported a predominance of patients in the sixth and seventh decades of life [14]. The mean PSA level in our cohort was 6.8 ± 1.7 ng/mL, with 37.5% of patients in the 4.0–6.0 ng/mL range, 35.8% in the 6.1–8.0 ng/mL range, and 26.7% in the 8.1–10.0 ng/mL range. This distribution closely reflects the PSA "gray zone" population analyzed by Seo et al., who reported a prostate cancer detection rate of 19.6% among men with PSA levels between 4.0 and 9.9 ng/mL [14]. In our study, abnormal or suspicious findings on digital rectal examination (DRE) were observed in 25.8% of patients, supporting earlier observations by Sheikh et al., who demonstrated that although DRE has limited sensitivity when used alone, it significantly improves cancer detection when combined with PSA testing, particularly in patients with lower or intermediate PSA values [15]. Taken together, these findings suggest that our study population is representative of a typical biopsy cohort within the intermediate PSA range, and they reaffirm the ongoing clinical relevance of DRE as an adjunctive diagnostic tool.

Histopathological examination of TRUS-guided prostate biopsies in the present study revealed prostate cancer in 58 patients (48.3%), of whom 38 patients (31.7%) had clinically significant disease (ISUP Grade Group ≥2) and 20 patients (16.7%) had clinically insignificant cancer (ISUP Grade Group 1). Benign pathology was identified in 62 patients (51.7%), including benign prostatic tissue in 55 cases (45.8%), prostatitis in 5 cases (4.2%), and high-grade PIN or atypical lesions in 2 cases (1.7%). These findings are broadly consistent with those reported by Gupta et al., who identified prostate adenocarcinoma in 24% of men undergoing systematic TRUS-guided biopsy, with high-grade PIN and cellular atypia reported in 2.1% and 4.9% of cases, respectively, and benign tissue or prostatitis accounting for the majority of negative biopsies [16]. The higher proportion of prostate cancer and clinically significant disease observed in our cohort may be attributable to differences in patient selection and the restriction of our study population to individuals with PSA levels between 4 and 10 ng/mL. Overall, our results confirm that systematic TRUS-guided biopsy captures a wide spectrum of disease severity, while emphasizing that benign histology remains the most frequent outcome in patients presenting with intermediate PSA levels.

With respect to TRUS findings, suspicious sonographic features such as hypoechoic nodules and glandular asymmetry were identified in 41 patients (34.2%), while the remaining 79 patients (65.8%) showed no suspicious features on ultrasound. These findings are in agreement with previous studies underscoring the diagnostic value of hypoechoic lesions in prostate cancer detection. Noh et al. demonstrated that in a cohort of 970 men undergoing TRUS-guided biopsy, cancer detection was significantly higher in patients with hypoechoic lesions (43.9%) compared with those without visible abnormalities (21.4%) [17]. Similarly, Onur et al., in a large cohort of 3,912 patients, reported that hypoechoic areas were commonly observed during TRUS examinations, reinforcing their frequent occurrence in routine clinical practice [18]. Collectively, these studies support our observation that hypoechoic lesions on TRUS are meaningful indicators of potential malignancy, although a substantial proportion of cancers may still be missed due to the absence of visible sonographic abnormalities.

Correlation analysis between TRUS findings and histopathology demonstrated that among 55 patients with suspicious lesions on TRUS, 45 (81.8%) were confirmed to have prostate cancer (true positives), while 10 (18.2%) had benign histology (false positives). Conversely, of the 65 patients with non-suspicious TRUS findings, 13 (20.0%) were diagnosed with prostate cancer (false negatives), and 52 (80.0%) were confirmed as true negatives. These results are comparable to those reported by Kuligowska et al., who found that gray-scale TRUS abnormalities were present in more than half of cancers among patients with PSA levels between 4 and 9.9 ng/mL and reported favorable predictive metrics, including specificity of approximately 89% and a positive predictive value of 76% [19]. Both studies highlight that although suspicious TRUS findings are strongly associated with malignancy, a notable proportion of cancers may remain undetected in the absence of ultrasound abnormalities, reinforcing the importance of systematic TRUS-guided biopsy in patients with intermediate PSA levels.

The diagnostic performance of suspicious TRUS findings in our study demonstrated a sensitivity of 77.6%, specificity of 83.9%, positive predictive value of 81.8%, negative predictive value of 80.0%, and an overall diagnostic accuracy of 80.8%. These results are broadly comparable to earlier reports. Maricic et al., in their long-term evaluation of TRUS-guided prostate biopsy before and after the implementation of PSA testing, reported similar PPV values (~80.5%) and slightly higher overall accuracy (~86.2%), as well as higher specificity and NPV [20]. Differences in patient characteristics, cancer prevalence, and diagnostic thresholds may account for these variations. Likewise, Tamsel et al. evaluated the performance of TRUS across different PSA strata and observed an overall diagnostic accuracy of approximately 80% in patients with PSA levels of 4–9.9 ng/mL, with specificity close to 89% and PPV near 76% [21]. Taken together, these findings confirm that TRUS provides reproducible and clinically useful diagnostic accuracy in patients with intermediate PSA levels, while underscoring the need for systematic biopsy to identify cancers that are not apparent on ultrasound imaging.

Finally, the present study demonstrated a statistically significant difference in mean PSA levels between patients diagnosed with prostate cancer (7.6 ± 1.9 ng/mL) and those with benign pathology (6.3 ± 1.4 ng/mL), with a p-value < 0.0001. This

observation is consistent with the findings of Zheng et al., who reported that PSA levels and PSA-derived parameters differed significantly between malignant and benign groups among men with PSA values in the 4–10 ng/mL range, aiding in diagnostic discrimination [22]. Despite the significant difference, the overlap in PSA values between cancer and benign groups observed in both studies highlights the inherent limitation of relying on total PSA alone within this intermediate range. Nonetheless, our findings support the continued role of PSA as an important risk stratification tool when interpreted in conjunction with TRUS-guided biopsy and other clinical parameters to optimize prostate cancer detection and minimize unnecessary biopsies.

LIMITATIONS

The study had a few limitations:

- The study was conducted at a single center, which may limit the generalizability of the findings to other populations.
- The sample size was relatively small, which could affect the precision of diagnostic accuracy estimates.

CONCLUSION

Prostate cancer remains a significant health concern, and accurate early detection is essential for appropriate management. In this study, TRUS-guided prostatic biopsy proved to be a reliable diagnostic tool for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL. Among the study population, nearly half were diagnosed with prostate cancer, with a substantial proportion exhibiting clinically significant disease, while the remainder had benign pathology. Suspicious TRUS findings demonstrated a strong correlation with histopathology, with good sensitivity, specificity, and overall diagnostic accuracy. Furthermore, patients with prostate cancer had significantly higher mean PSA levels compared to those with benign conditions. These findings highlight that TRUS-guided biopsy, combined with PSA assessment and careful evaluation of sonographic abnormalities, remains a valuable and effective approach for prostate cancer detection in patients within the intermediate PSA range.

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Evaluation of treatment modalities of cesarean scar pregnancy

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ABSTRACT

Background: Cesarean scar pregnancy (CSP) occurs when a gestational sac implants within the myometrium or fibrous tissue of a previous cesarean section scar. Management of CSP is challenging as there are no specific guidelines and management should be individualized. Aim of the study: This study aimed to evaluate different treatment modalities for diagnosed CSP cases. **Methods & Materials:** This retrospective observational study was done at the Obstetrics & Gynecology Department, Bangladesh Medical University (BMU), and Central Hospital, Dhaka, Bangladesh from June 2023 June 2025. Patients were grouped by gestational age, <7.5 weeks (n=10) and >7.5 weeks (n=7), managed according to unit protocol, and treatment modality was recorded. Serum β-hCG was measured pre-treatment and on day 7 to assess percentage decline, with ultrasound follow-up at 15 days and clinical follow-up up to 6 weeks. **Results**: Among 17 cesarean scar pregnancy cases, 10 were <7.5 weeks and 7 were >7.5 weeks. Mean age, symptoms, number of prior cesarean deliveries, and abortion history were similar between groups, with nearly half asymptomatic and bleeding the commonest symptom, and all comparisons were non-significant (p=0.93). Methotrexate plus folinic acid was used in 47.1% overall, while laparotomy with excision of the gestational sac was the most frequent procedure (35.3%), and other modalities were used in small proportions without significant group differences (p=0.42). Pre-treatment β-hCG was comparable between groups, and it declined by day 7 in both; the mean percentage fall was higher in the <7.5-week group (88.87% vs 82.56%), but remained non-significant (p>0.05). **Conclusion**: Early diagnosis is very important to reducing complication and also in successful management. Medical management may be considered first for hemodynamically stable patients, whereas invasive procedures should be reserved for active bleeding, suspected rupture, high-risk features, or failed conservative therapy.

Keywords: *Cesarean scar pregnancy, Methotrexate, and Previous caesarean scar, β-hCG.*

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INTRODUCTION

Cesarean scar pregnancy (CSP) is a distinct form of ectopic implantation in which the gestational sac embeds within the myometrial defect, or "niche", of a previous lower-segment cesarean incision, most often diagnosed in the first trimester by transvaginal ultrasonography (TVS) with supportive Doppler features [1,2]. Although rare, CSP is being encountered more frequently as cesarean delivery rates rise globally and regionally [1,3]. Contemporary series estimate an overall incidence around 1 in 2,000 pregnancies, and the burden is expected to increase in populations with high cesarean prevalence [1,2]. In South Asia, the rapid expansion of facility births and cesarean delivery, including Bangladesh, enlarges the pool at risk, with population studies showing steep upward trends over recent decades [3,4]. In this context, early recognition and timely, fertility-preserving management are increasingly relevant to routine gynecologic and obstetric practice.

CSP carries disproportionate clinical importance because it can progress while remaining unstable, with risks of major hemorrhage, uterine rupture, need for hysterectomy, and downstream placenta accreta spectrum if a pregnancy continues or is managed late [1,2,5]. Management is therefore usually directed toward early termination and scar site control while minimizing morbidity and preserving future fertility when desired. However, an internationally accepted "best" strategy has not been established, and practice varies by gestational age, viability, myometrial thickness, vascularity, β-human chorionic gonadotropin (β-hCG) level, clinician expertise, and availability of interventional radiology, hysteroscopy, and minimally invasive surgery [2,6]. Ultrasound-based grading and classification systems have been proposed to link implantation depth and vascularity with treatment selection, but cutoff thresholds remain inconsistent across studies [6]. Reported approaches include systemic or local methotrexate (MTX) regimens, suction curettage with adjunct tamponade, hysteroscopic resection, uterine artery embolization (UAE) with or without subsequent evacuation, laparoscopic or transvaginal scar excision and repair, laparotomy, and, in selected unstable cases, hysterectomy [7-10]. Large multicenter series suggest higher primary success with hysteroscopy-assisted evacuation than curettage alone, and limited added value of MTX pre-treatment in selected endogenic CSP, yet most comparative data remain heterogeneous with variable definitions of success and inconsistent reporting of bleeding and re-intervention [7,9,11].

Bangladesh-specific data describing real-world treatment patterns and short-term response metrics for CSP are limited, despite increasing cesarean exposure and resource variability [3]. An observational evaluation within a tertiary referral center can help contextualize the performance, safety signals, and follow-up needs of commonly used modalities under routine care. Therefore, this study aimed to evaluate different treatment modalities for diagnosed CSP cases.

METHODS & MATERIALS

This retrospective observational study was conducted in the Department of Obstetrics and Gynecology, Bangladesh Medical University (BMU) and Central Hospital,

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Dhaka, Bangladesh. All consecutive patients diagnosed with cesarean scar pregnancy (CSP) during the study period June 2023 June 2025, were evaluated and treated. Diagnosis was established by transvaginal ultrasonography (TVS) and also β-hCG in patients with a prior lower segment cesarean section, supported by clinical assessment and imaging features consistent with CSP. Gestational age was calculated from last menstrual period and/or early ultrasonography, and participants were stratified into two groups for analysis: Group A (n=10), gestational age <7.5 weeks, and Group B (n=7), gestational age >7.5 weeks. Baseline variables included age, presenting symptoms, number of previous cesarean deliveries, and abortion history. Treatment modality was documented as medical management with methotrexate plus folinic acid rescue, surgical approaches (dilatation and curettage with or without adjunct procedures, hysteroscopic resection, laparotomy with excision of gestational sac, hysterectomy), or conservative management without surgery. Serum β-human chorionic gonadotropin (β-HCG) was measured pre-treatment and post-treatment, with the post-treatment mean β-HCG specifically recorded on day 7; percentage decline was calculated to assess biochemical response. Follow-up included repeat TVS at 15 days to assess resolution, and patients were monitored for up to 6 weeks to document clinical outcome and any further interventions. Data were collected from the hospital records and analyzed using descriptive statistics in SPSS (v-26.0). Group comparisons used chi-square or Fisher's exact test for categorical variables and Student's t-test for continuous variables, with $p<0.05$ considered statistically significant.

RESULTS

Among 17 cesarean scar pregnancy cases, 10 were in Group A (<7.5 weeks) and 7 in Group B (>7.5 weeks). Mean age was similar between groups, 28.8 years in Group A versus 30.5 years in Group B (overall mean 29.5 years), with no statistically significant difference (p=0.51). Nearly half were asymptomatic (47.1%), while bleeding was the most common symptom (29.4%), followed by pain alone (11.8%), and pain with bleeding (11.8%), with comparable distributions across gestational age groups (p=0.93). Most had one previous lower segment cesarean section (70.6%) overall, and 29.4% had two cesarean sections, again without group difference (p=1.00). Prior abortion history was absent in 52.9%, one abortion occurred in 35.3%, and two abortions in 11.8%, with no significant group association (p=0.28). Medical management with MTX plus folinic acid was used in 47.1% overall, more frequently in Group A (60.0%) than Group B (28.6%), but the difference was not significant (p=0.34) *Table I.*

Table I
Baseline demographic, clinical, and obstetric characteristics of cesarean scar pregnancy cases by gestational age group (*n* = 17).

Variables	Category	Total (n = 17), n (%)	Gestational age		p-value
			Group-A (<7.5 w), n = 10, n (%)	Group-B (>7.5 w), n = 7, n (%)	
Age (year)	Mean ± SD	29.5 ± 6.1	28.8 ± 5.25	30.5 ± 4.8	0.51
Symptoms	Asymptomatic	8 (47.1)	5 (50.0)	3 (42.9)	0.93
	Bleeding	5 (29.4)	3 (30.0)	2 (28.6)	
	Pain	2 (11.8)	1 (10.0)	1 (14.3)	
	Pain with bleeding	2 (11.8)	1 (10.0)	1 (14.3)	
Previous LSCS	1	12 (70.6)	7 (70.0)	5 (71.4)	1.00
	2	5 (29.4)	3 (30.0)	2 (28.6)	
Abortion	0	9 (52.9)	6 (60.0)	3 (42.9)	0.28
	1	6 (35.3)	4 (40.0)	2 (28.6)	
	2	2 (11.8)	0 (0.0)	2 (28.6)	
MTX + folinic acid	Yes	8 (47.1)	6 (60.0)	2 (28.6)	0.34
	No	9 (52.9)	4 (40.0)	5 (71.4)	

Treatment approaches varied across the 17 patients, with laparotomy plus excision of the gestational sac being the most frequent modality, used in 35.3% on cases, 30.0% in Group A and 42.9% in Group B. Simple D and C was performed in 17.6% overall, and no surgery was also reported in 17.6%, occurring only in Group A (30.0% in Group A, 0.0% in Group B), with overall comparisons remaining non-significant. Hysterectomy was performed in 11.8% overall, while D and C with ligation of the descending cervical artery, D and C followed by hysterectomy, and hysteroscopic resection were each used in 5.9% of cases, each showing small numbers and no statistically significant difference between gestational age groups (p=0.424) *Table II.*

Table II
Distribution of treatment modalities for cesarean scar pregnancy by gestational age group.

Treatment	Total (n = 17), n (%)	Gestational age		p-value
		Group-A (<7.5 w), n = 10, n (%)	Group-B (>7.5 w), n = 7, n (%)	
D and C (simple)	3 (17.6)	2 (20.0)	1 (14.3)	0.42
D and C and ligation of descending cervical artery	1 (5.9)	1 (10.0)	0 (0.0)	
D and C followed by hysterectomy	1 (5.9)	0 (0.0)	1 (14.3)	
Laparotomy followed by excision of scar pregnancy	6 (35.3)	3 (30.0)	3 (42.9)	
Hysterectomy	2 (11.8)	1 (10.0)	1 (14.3)	
Hysteroscopic resection of scar pregnancy	1 (5.9)	0 (0.0)	1 (14.3)	
No surgery	3 (17.6)	3 (30.0)	0 (0.0)	

Mean pre-treatment β-hCG was comparable between groups, 22,130.5 in Group A versus 21,608.78 in Group B (p>0.05). After treatment, mean β-hCG declined to 2,405.05 in Group A and 3,859.56 in Group B. The mean percentage fall in β-hCG was higher in Group A (88.87%) than Group B (82.56%), with no statistically significant difference reported (p>0.05) *Table III*.

Table III
Serum β-hCG response before and after treatment in cesarean scar pregnancy by gestational age group.

Variables	Gestational age		p-value
	Group-A (<7.5 w), n=10	Group-B (>7.5 w), n=7	
Pre-treatment β-HCG (Mean)	21608.78	22130.5	>0.05
Post-treatment β-HCG (Mean)	2405.05	3859.56	
% Fall in β-HCG	88.87	82.56	

DISCUSSION

Cesarean scar pregnancy (CSP) remains an uncommon but potentially catastrophic form of ectopic implantation, and its clinical importance is increasing in parallel with rising cesarean delivery rates. In this study of 17 CSP cases, the age ranging from 23 to 34 years (mean age 29.5 years), aligning with the reproductive age profile reported across contemporary CSP series and reviews [12-14]. Gestational age range was ranged from 4 week 5 days to 14 weeks. Vaginal bleeding is frequently described as the most common presenting symptom in CSP, ranging from light spotting to profuse bleeding with hemodynamic compromise if not treated promptly. In contrast, the most frequent presentation in our series was absence of symptoms, observed in 47.1% of women, suggesting that a substantial proportion were detected through early imaging rather than symptom-driven presentation. This pattern is comparable to prior reports by Maymon et al. and Lorena et al., where 36.5% and 30.4% of cases, respectively, were asymptomatic [12,15,16]. Per-vaginal bleeding was the second most common presentation in our study (29.4%), consistent with Lorena et al., who also highlighted bleeding as a dominant presenting feature in their case series [15]. Clinically, this reinforces two simultaneous realities: CSP should remain high on the differential when bleeding occurs in early pregnancy after cesarean delivery, and equally, a "well" patient may still harbor a high-risk implantation, emphasizing the value of early transvaginal assessment in women with prior cesarean section.

All women in our study had a history of lower-segment cesarean section (LSCS), most commonly one previous cesarean (70.6%), with the remainder having two prior cesareans (29.4%), broadly similar to patterns described by Kaliamoorthi et al. [12]. Importantly, our distribution illustrates that CSP can occur even after a single cesarean delivery, and while prior uterine surgery is the key risk substrate, the "low cesarean count" does not equate to "low CSP risk" in an individual patient. For diagnosis, transvaginal ultrasonography remains the principal, cost-effective modality, with reported sensitivity around 84% [17]. When sonographic criteria are equivocal, MRI can be used as a secondary tool, and diagnostic confidence can be further strengthened by color and power Doppler to characterize peri trophoblastic vascularity and associated indices. In our study, transvaginal ultrasonography confirmed CSP in 16 of 17 cases (94.1%), exceeding the sensitivity reported by Kaliamoorthi et al. and Rotas et al. (85% and 84.6%, respectively) [12,18], a difference that may reflect earlier gestational presentation, operator expertise, and systematic use of transvaginal techniques in a high-suspicion population. Cesarean scar pregnancy is often misdiagnosed either as cervical pregnancy or spontaneous abortion in progress [19,20]. Previous studies of 45 patients with scar pregnancies were reported; 21 were initially wrongly diagnosed as spontaneous abortion or cervicocisthmic pregnancy. In our study, we found 3 out of 17 cases were initially misdiagnosed as an incomplete abortion but finally, they were diagnosed as scar ectopic pregnancy using TVS. Management in our series was intentionally individualized and therefore heterogeneous, with laparotomy plus excision of the scar pregnancy as the most frequent modality overall (35.3%), followed by D&C (17.6%), and hysterectomy required in 4 cases (23.5%) due to uterine rupture and torrential bleeding, with blood transfusion needed in these unstable presentations. This plurality of practice mirrors the wider literature, where systematic reviews consistently demonstrate that no single approach is universally optimal, and treatment selection depends on gestational age, CSP type, vascularity, residual myometrial thickness, hemodynamic status, local expertise, and fertility intent [21-24]. Aggregate evidence suggests high primary success with minimally invasive operative strategies and image-guided uterine evacuation approaches, whereas systemic methotrexate (MTX) alone is associated with lower primary success and more frequent need for additional interventions. In the 2024 meta-analysis by Alameddine et al., successful resolution after primary treatment was reported around 86% with ultrasound-guided suction curettage, 90% with hysteroscopy, 96% with laparoscopy, versus about 72% with systemic MTX [11]. In line with this, contemporary expert recommendations caution against sharp curettage alone, and generally favor ultrasound-guided vacuum aspiration or operative resection when feasible, with intragestational MTX preferred over systemic MTX when medical therapy is selected [25,26].

Gestational age stratification in our study demonstrated clinically meaningful, although statistically non-significant, trends that were directionally consistent with published experience. MTX plus folinic acid was used more often in earlier gestations (<7.5 weeks, 60.0%) than later gestations (28.6%), while more invasive approaches, including laparotomy and hysterectomy, were proportionally higher beyond 7.5 weeks. This aligns with broader datasets indicating that later gestational age at diagnosis increases procedural complexity and hemorrhage risk, and reduces the feasibility of simple evacuation-only pathways [27]. Our β-hCG kinetics also supported this trajectory, with a greater proportional decline in earlier gestations (88.87% vs 82.56%), consistent with the concept that lower trophoblastic burden and earlier intervention shorten biochemical resolution [12,23-25]. Evidence on MTX further underscores the need for careful candidate selection, since systemic MTX performs better at earlier gestations and lower β-hCG thresholds, while higher β-hCG and larger sac dimensions are associated with reduced success and higher rates of adjunctive procedures [28-30].

LIMITATION

The primary limitation of this study is that vascularity and cesarean scar pregnancy (CSP) subtype were not assessed during the ultrasound examination. Additionally, the small sample size, which reflects the low incidence of CSP, may limit the generalizability of the findings.

CONCLUSION

Early diagnosis is feasible with transvaginal ultrasonography, ideally complemented by color, or power Doppler to assess implantation site vascularity and guide risk stratification. Although no single treatment is universally established, we

suggest medical management as the initial approach for carefully selected, hemodynamically stable patients, with close clinical and sonographic monitoring. Invasive interventions, including, laparotomy with excision of scar pregnancy, uterine artery embolization, or hysterectomy or ligation of the descending cervical artery, should be reserved for patients with active heavy bleeding, suspected rupture, failed conservative therapy, or high-risk anatomical features. In our experience, β-hCG trends are useful for follow-up but should not be the sole determinant of treatment selection. Standardized diagnostic criteria, coupled with a structured management and follow-up protocol, can improve uterine preservation, reduce hemorrhagic complications, and support safer, timely care for this challenging form of ectopic pregnancy.

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Different Pattern of Presentation of Acute Stroke and Their Relation with Neuroimaging

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ABSTRACT

Background: Stroke is a leading cause of mortality and disability worldwide, with a high burden in low- and middle-income countries. Early differentiation between ischemic and hemorrhagic strokes is crucial because management strategies differ. Understanding the relationship between clinical presentation and CT findings is essential in stroke care. **Objective:** To evaluate the clinical presentation patterns in patients with acute stroke and assess their relationship with CT-confirmed neuroimaging findings. **Methods & Materials:** This cross-sectional observational study was conducted at the Department of Medicine, Sir Salimullah Medical College and Mitford Hospital, Dhaka, from October 2015 to March 2016. A total of 100 patients with stroke were included in the study. Clinical evaluation was performed, followed by non-contrast CT of the brain. The associations between clinical features and stroke subtypes were analyzed using chi-square tests. **Results:** Most patients were aged 51–70 years, with a male predominance. Hemiplegia was the most common presenting feature in both ischemic and hemorrhagic stroke. Headache, vomiting and neck rigidity were significantly more frequent in hemorrhagic stroke. Severe impairment of consciousness was also more common in hemorrhagic cases. Clinical diagnosis showed high accuracy compared to CT findings. CT localization revealed basal ganglia and thalamic predominance in hemorrhagic stroke, whereas cortical involvement was more frequent in ischemic stroke. **Conclusion:** Although the clinical features overlap between stroke subtypes, certain symptoms and consciousness levels suggest hemorrhagic stroke. CT imaging remains indispensable for definitive diagnosis and should be prioritized in acute stroke management.

Keywords: *Acute stroke, clinical presentation, computed tomography, ischemic stroke, hemorrhagic stroke.*

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INTRODUCTION

Stroke remains one of the leading causes of death and long-term disability worldwide, accounting for substantial morbidity in both developed and developing countries [1]. The burden of stroke is particularly high in low- and middle-income countries, where limited access to advanced diagnostic and therapeutic facilities often delays accurate diagnosis and timely intervention [2]. Clinically, stroke is defined as the sudden onset of focal neurological deficits of presumed vascular origin lasting more than 24 hours or resulting in death [3]. Based on underlying pathology, stroke is broadly classified into ischemic and hemorrhagic types, each differing significantly in management strategies, prognosis and outcomes.

Neuroimaging plays a pivotal role in differentiating ischemic stroke from intracerebral or subarachnoid hemorrhage. Non-contrast computed tomography (CT) of the brain remains the first-line imaging modality in the acute setting because of its wide availability, rapid acquisition and high sensitivity for detecting hemorrhage [4]. Accurate early differentiation between ischemic and hemorrhagic stroke is essential, as therapeutic approaches such as antiplatelet therapy or thrombolysis are beneficial in ischemic stroke but potentially harmful in hemorrhagic stroke [5]. In many resource-limited settings, however, immediate access to CT scanning is not universally available, compelling clinicians to rely heavily on clinical features for provisional diagnosis.

Several studies have demonstrated that certain clinical presentations—such as sudden headache, vomiting, neck rigidity and altered level of consciousness—are more frequently associated with hemorrhagic stroke, whereas ischemic stroke commonly presents with focal neurological deficits without prominent meningeal signs [6]. Nonetheless, considerable overlap exists between the clinical manifestations of the two stroke subtypes, making purely clinical differentiation challenging. The accuracy of clinical diagnosis varies widely across studies and healthcare settings, underscoring the need to systematically evaluate how reliably clinical features correlate with neuroimaging findings.

In Bangladesh and similar settings, stroke constitutes a major cause of hospital admission, yet local data correlating clinical presentation with neuroimaging-confirmed diagnosis remain limited. Understanding the pattern of clinical presentation and its relationship with CT findings is particularly important in environments where delayed imaging is common or imaging facilities are scarce. Such evidence can assist clinicians in risk stratification, early decision-making and prioritization of imaging resources.

The present study focuses specifically on the patterns of clinical presentation in acute stroke and examines their relationship with CT-confirmed neuroimaging findings. By

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analyzing the frequency of neurological deficits, associated symptoms, level of consciousness, temporal onset patterns and lesion localization on CT, this study aims to assess the reliability of clinical features in differentiating ischemic and hemorrhagic stroke. The findings are expected to contribute to improved clinical judgment in acute stroke care, particularly in settings where immediate neuroimaging may not be feasible.

OBJECTIVES

The objective of this study was to evaluate the clinical presentation patterns in patients with acute stroke and assess their relationship with CT-confirmed neuroimaging findings.

METHODS & MATERIALS

This was a hospital-based cross-sectional observational study conducted in the Department of Medicine, Sir Salimullah Medical College and Mitford Hospital, Dhaka, Bangladesh. The study was carried out over a six-month period from October 2015 to March 2016. A total of 100 patients with acute stroke were included in the study. The study population comprised adult patients of both sexes who were clinically diagnosed with acute stroke and subsequently underwent CT scanning of the brain for confirmation.

Inclusion criteria

- Patients admitted with acute stroke of sudden onset
- Patients of all ages and both sexes
- Patients who underwent CT scan of the brain during hospital stay
- Patients or attendants who provided informed consent

Exclusion criteria

- History of previous stroke
- History of head injury
- Presence of intracranial space-occupying lesions
- Known bleeding disorders
- Patients who did not consent to participate

Data Collection Procedure

Data were collected using a predesigned and pretested structured data collection sheet. After admission, detailed history was obtained either from the patient or accompanying attendants, focusing on the mode and time of onset, presenting symptoms and associated features. A thorough neurological examination was performed to document motor deficits, speech abnormalities, level of consciousness, cranial nerve involvement and meningeal signs. Particular emphasis was placed on identifying clinical features traditionally associated with different stroke subtypes, such as headache, vomiting, neck rigidity and impaired consciousness.

All patients included in the study underwent non-contrast CT scanning of the brain. CT findings were recorded regarding stroke type, lesion location and extent. Clinical diagnoses were made prior to reviewing CT results to avoid bias. Completed data collection sheets were checked daily for completeness and consistency. Data accuracy was ensured through cross-verification of clinical records, imaging reports and direct patient assessment, thereby maintaining reliability and internal consistency throughout the data collection process.

Ethical Considerations

Ethical approval was obtained from the Ethical Review Committee of Sir Salimullah Medical College and Mitford Hospital. Verbal informed consent was taken from patients or their legal guardians prior to enrollment. Confidentiality of patient information was strictly maintained and data were used solely for research purposes.

Statistical Analysis

Data were coded, entered and analyzed using Statistical Package for Social Sciences (SPSS) version 22. Descriptive statistics were used to summarize demographic variables and clinical features. Categorical variables were expressed as frequencies and percentages. Associations between clinical features and stroke subtype were assessed using the chi-square test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table I showed the age distribution of the study patients. The maximum number of patients 47.0% in age group 51-60 years followed by 23.0% between ages 60-70 years. Mean age 53.2±12.4 years.

Table I
Age distribution of the patients (*n*=100).

Age in year	Frequency (N)	Percentage (%)
21-30	2	2.0
31-40	6	6.0
41-50	12	12.0
51-60	47	47.0
61-70	23	23.0
>70	10	10.0
Total	100	100.0

Table II showed the gender distribution of the study patients. 71.0% patients were male and 29.0% patients were female. Male was predominance. Male: Female ratio was 2.44: 1.

Table II
Sex ratio of the studied patients (*n*=100).

Sex	Number of patients	Percentage (%)
Male	71	71.0
Female	29	29.0
Total	100	100.0
M:F ratio	2.44:1	

Table III gives impression that hemiplegia is the commonest presentation in both hemorrhagic (77.8%) and ischaemic stroke (87.8). Impaired consciousness (61.1% and 58.5%), sphincter disturbances (55.6% and 52.8%), speech abnormality (61.1% and 58.5%) are the most common presentation in haemorrhagic and ischemic stroke respectively. Analysis of different clinical feature shows that headache (p value <0.05), vomiting (p value <0.05) and neck rigidity (p value <0.01) has significant association with haemorrhage.

Table III
Various clinical presentation of stroke (*n*=100).

Presentation	Haemorrahage (n=18)		Infarction (n=82)		P-value
	No.	%	No.	%	
Hemiplegia	14	77.8	72	87.8	0.27
Dyarthria	9	50.0	42	51.2	0.49
Dysphagia	11	61.1	48	58.5	0.84
Impaired conscious	12	66.7	48	58.5	0.52
Sphincter disturbance	10	55.6	43	52.4	0.80
Headache	13	72.2	37	45.1	S0.03
Vomiting	13	72.2	32	39.0	0.01
Cranial Nerve Palsy (7^{th})	3	16.7	6	7.3	0.20
Convulsion	6	33.3	10	12.2	0.02
Neck rigidity	14	77.8	5	6.1	<0.001
Hiccup	8	44.4	17	20.7	0.03

Chi-square test was done; Ns= not significant, s= significant

Table IV shows most of the patients with right sided hemiplegia 55.6% and 63.4% in case of haemorrhage and infarction respectively.

Table IV
Presentation with hemiplegia.

Side affected	Haemorrhage	Infarction
Right	10(55.6%)	52(63.4%)
Left	8(44.4%)	30(36.6%)
Total	18(100.0%)	82(100.0%)

Headache was present in 16 out of 18 patients with hemorrhagic stroke, compared with 35 out of 82 patients with ischemic stroke. Vomiting was observed in 15 patients with hemorrhagic stroke and in 30 patients with ischemic stroke. Both headache and vomiting showed a statistically significant association with hemorrhagic stroke ($p < 0.001$), indicating that these symptoms were more frequently associated with hemorrhagic pathology at presentation (*Table V*).

Table V
Association of headache and vomiting with stroke subtype (*n* = 100).

	Clinical feature	Hemorrhagic stroke (n = 18)	Ischemic stroke (n = 82)	p-value
Headache	Present	16	35	< 0.001
	Absent	2	47	
Vomiting	Present	15	30	< 0.001
	Absent	3	52	

Table VI shows that most of the infarction occurred during sleep (47.6%) and early morning (36.6%), whereas in case of haemorrhage most of the incidence occurred in the morning (22.22%) and other part of the day (50%) i.e. when the patient is awake.

Table VI
Variation of time of onset of stroke.

Type of stroke	Onset while asleep	Onset while awaken	
		Early morning	Other time
Infarction (n=82)	39(47.6%)	30 (36.6%)	13(15.9%)
Haemorrhage (n=18)	03(16.7%)	04(22.22%)	9(50%)
Sub-arachnoid haemorrhage	0(0.0%)	1(5.6%)	1(5.6%)

Table VII shows impaired consciousness in many of the cases. In cases of infarction 51.2% is grade II. Whereas in case of haemorrhage stroke majority 50% were in grade III on presentation. Grading was done on the basis of response of the patients to external stimuli e.g. Grade I fully conscious; Grade II response to vocal command; Grade III response to painful stimuli and Grade IV unresponsiveness. Arbitrarily grade I corresponds to GCS 13-14, grade II to GCS 9-12, grade III to GCS =<8 and grade IV to GCS 3.

Table VII
Level of consciousness at presentation.

Type of stroke	Grade I GCS 13-14	Grade II GCS 9-12	Grade III GCS=<8	Grade IV GCS 3
Infraction	34(41.5%)	42(51.2%)	05(6. 1%)	01(1.2%)
Haemorrhage	01(5.6%)	02(11.11%)	9(50%)	02(11.11%)
Sub-arachnoid haemorrhage	00	02(11.11%)	00	02(11.11%)

Table VIII shows that clinical diagnosis of infarction in done in 82 cases and is 86.5% accurate, whereas clinical diagnosis of haemorrhagic stroke is done in 18 cases which is 83.3% accurate.

Table VIII
Correlation between clinical and CT diagnosis of stroke.

	Clinical diagnosis	Matched with CT scan diagnosis	Not matched with CT scan diagnosis	Total diagnosis	Percentage of accuracy
Infarction	82	71	11	77	86.5%
Haemorrhgage	18	15	3	23	83.3%

Table IX shows that haemorrhagic stroke involved Basal ganglia (33.33%) and Thalamus (27.77%) in most cases. Whereas infarction affected largely (52.43%) the cortical area.

Table IX
Site of lesion detected by CT scan of brain.

Site	Haemorrhage	Infarction
Cerebral		
Cortial	01(5.55%)	43(52.43%)
Internal capsule	01(5.55%)	17(20.73%)
Basal ganglia	06(33.33%)	05(6.4%)
Thalamus	05(27.77%)	04(5.12%)
Pons	02(11.11%)	06(7.69%)
External capsule	00	05(6.4%)
Subarachnoid	02(11.11%)	00
Cerebellum	01(5.55%)	02(2.56%)

DISCUSSION

The clinical presentation of acute stroke closely correlates with CT-imaging findings, reinforcing the combined diagnostic value of neurological assessment and neuroimaging. The majority of stroke patients present between their 51st and 70th years, reflecting epidemiological data from diverse regions that identify the sixth and seventh decades as peak periods for stroke incidence due to cumulative vascular risk exposure with advancing age [7]. Male predominance in stroke incidence, as noted with a male-to-female ratio of approximately 2.44:1, aligns with studies from South Asia and other populations where increased exposure to modifiable risk factors, including hypertension and lifestyle behaviors, accounts for higher male susceptibility [8].

Hemiplegia remains the most frequent presenting symptom in both ischemic and hemorrhagic strokes, consistent with its recognition as the hallmark unilateral motor deficit characterizing stroke onset across subtypes [9]. However, the absence of statistically significant differences in hemiplegia incidence between stroke types highlights the limited ability of motor deficits alone to discriminate ischemic from hemorrhagic events, echoing prior observations emphasizing the overlap in basic neurological presentations [10].

Other neurological features such as dysarthria, dysphagia, sphincter disturbances and impaired consciousness are commonly observed across both ischemic and hemorrhagic strokes, signaling the challenge in relying exclusively on clinical features for stroke subtype differentiation [11]. Conversely, symptoms including headache, vomiting and neck rigidity have demonstrated significant associations with hemorrhagic pathology. Over 70% of hemorrhagic stroke patients present with these symptoms compared to less than half in ischemic cases, likely reflecting the pathophysiological effects of raised intracranial pressure and meningeal irritation specific to hemorrhagic injury [12]. Neck rigidity, in particular, is markedly more indicative of hemorrhagic strokes, facilitating clinical differentiation from ischemic infarcts [13].

Temporal patterns of stroke onset further differ by subtype. Ischemic strokes predominantly initiate during sleep or early morning hours aligning with circadian fluctuations influencing blood pressure, platelet activity and fibrinolysis, consistent with circadian variation data in cerebrovascular events [14]. In contrast, hemorrhagic strokes show a higher incidence during daytime, correlating to episodic blood pressure surges induced by physical or emotional stress [15].

Level of consciousness at presentation notably varies between stroke types; severe impairment is significantly more frequent in hemorrhagic cases, with approximately 50% presenting in coma Grade III or worse due to abrupt intracranial pressure increases and mass effect [16]. Ischemic stroke patients often present with mild to moderate consciousness changes, consistent with infarctions lacking significant mass effect, such as lacunar or cortical strokes [9].

Clinical diagnosis correlates well with CT-confirmed diagnosis, with diagnostic accuracy exceeding 80% for both ischemic and hemorrhagic stroke, aligning with prior reports of clinical diagnostic accuracy ranging from 75 to 85% in acute stroke cohorts [7]. Despite this, discordance between clinical impressions and neuroimaging findings underscores the indispensability of CT imaging to

definitively classify stroke subtype and guide prompt therapeutic decisions [8].

Neuroanatomical localization on CT reveals distinct stroke subtype patterns. Hemorrhagic lesions predominantly involve deep brain structures such as the basal ganglia and thalamus, consistent with hypertensive hemorrhage distributions reported extensively in the literature [12]. In comparison, ischemic infarcts are mainly cortical, reflecting thromboembolic occlusion of large cerebral vessels, well-characterized by CT angiography and perfusion studies [7]. In ischemic stroke, advanced CT modalities including CT perfusion (CTP) enable detailed assessment of cerebral blood volume and flow, enhancing the evaluation of infarct core and penumbra and enabling prediction of neurological deterioration [8,14]. Radiomics approaches extracting quantitative features from CT imaging also offer predictive power for hemorrhagic transformation after ischemic stroke, directly linking imaging phenotype with clinical severity and prognosis [12].

Overall, this evidence highlights that while clinical assessments remain foundational for initial acute stroke evaluation, reliance solely on clinical features lacks sufficient specificity for definitive stroke classification. The integration of clinical presentation data with rapid, accessible neuroimaging—particularly non-contrast CT supplemented by CT angiography and perfusion—is critical to accurately diagnose stroke subtype, assess severity and guide management interventions [7,8]. Emerging applications of artificial intelligence and machine learning in imaging analysis and clinical prediction models promise to enhance early stroke detection and individualized care [9,15].

In summary, the integration of detailed clinical assessment with advanced CT neuroimaging establishes the cornerstone of precise acute stroke diagnosis and subtype differentiation, enabling optimized therapeutic strategies and improved patient outcomes in cerebrovascular emergencies.

CONCLUSION

The study demonstrated that although many clinical features overlap between ischemic and hemorrhagic stroke, symptoms such as headache, vomiting, neck rigidity, altered consciousness, and lesion localization on CT showed significant associations with hemorrhagic stroke. Although informative, clinical assessment alone cannot reliably distinguish stroke subtypes in all cases. Prompt CT imaging remains essential for accurate diagnosis and appropriate management, particularly in resource-limited settings, where early clinical judgment influences treatment decisions.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Comparison of Hematological Parameters Between Splenectomized and Non-Splenectomized Transfusion-Dependent Thalassemia Patients

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ABSTRACT

Background: Thalassemia is a common inherited blood disorder caused by mutations in the hemoglobin gene clusters, leading to defective globin chain synthesis and, in severe cases, transfusion-dependent anemia. The purpose of the study is to evaluate the impact of splenectomy on iron overload by comparing serum ferritin levels between splenectomized and non-splenectomized transfusion-dependent thalassemia patients. **Methods & Materials:** This cross-sectional comparative study at the Department of Transfusion Medicine, Bangabandhu Sheikh Mujib Medical University, Dhaka, included 60 transfusion-dependent thalassemia patients (30 splenectomized, 30 non-splenectomized) to compare hematological parameters, transfusion interval, and serum ferritin. Blood samples were analyzed for complete blood count and peripheral blood film (Sysmex XN-2000) and serum ferritin (Chemiluminescent Immunoassay, Liaison XL). Data were compared using Student's t-test and chi-square test ($p<0.05$). **Results:** Among 60 transfusion-dependent thalassemia patients, most were 11–20 years old (mean 17.78 ± 6.57 vs 18.87 ± 10.95 years; $p = 0.644$) and male (61.7%; $p = 0.184$). Splenectomized patients had longer transfusion intervals (>4 weeks: 60.0% vs 16.7%; $p = 0.001$), higher MCV, WBC, platelet counts, and serum ferritin (all $p < 0.05$), while peripheral blood film patterns were similar ($p = 0.117$), with severe anemia more common in splenectomized patients. **Conclusion:** Splenectomy in transfusion-dependent thalassemia reduces transfusion frequency and alters hematological parameters but increases iron overload, highlighting the need for careful iron monitoring.

Keywords: *Hematology, Splenectomy, Thalassemia.*

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INTRODUCTION

Thalassemias represent the most common monogenic disorders worldwide and comprise a group of inherited anemias resulting from mutations within the hemoglobin (Hb) gene clusters. These genetic defects lead to impaired or absent synthesis of one or more globin chain components of the hemoglobin tetramer[1]. Among inherited disorders characterized by reduced or defective hemoglobin chain production, thalassemia accounts for the highest prevalence[2]. Although thalassemias occur across nearly all ethnic groups and geographic regions, their highest distribution is observed within a wide geographic belt extending from sub-Saharan Africa through the Mediterranean region, the Middle East, and the Arabian Peninsula to the Indian subcontinent and Southeast Asia[3]. It is estimated that approximately 270 million individuals worldwide are carriers of hemoglobinopathies, of whom nearly one-third are carriers of β-thalassemia[4].

The clinical presentation of thalassemia ranges from relatively mild, nontransfusion-dependent thalassemia (NTDT) to severe transfusion-dependent thalassemia (TDT)[5]. In patients with TDT, regular red blood cell transfusion remains the cornerstone of management, while iron chelation therapy using desferrioxamine (DFO), deferiprone (DFP), or deferasirox (DFX) is essential to prevent complications related to iron overload[6]. Children with β-thalassemia major accumulate excess iron soon after becoming transfusion dependent, placing them at increased risk of iron deposition in multiple organs. This progressive iron excess may ultimately lead to significant organ dysfunction if inadequately managed.

Splenomegaly in thalassemia patients develops primarily as a consequence of excessive red blood cell destruction and compensatory extramedullary hematopoiesis. A key physiological role of the spleen is the clearance of abnormal or damaged red blood cells from the circulation[7]. Enlargement of the spleen results in sequestration and destruction of red blood cells, white blood cells (WBCs), and platelets, and may be associated with abdominal discomfort and pain. In patients with transfusion-dependent thalassemia, the primary indication for splenectomy is hypersplenism, which is characterized by a marked increase in red blood cell transfusion requirements exceeding 200–220 mL/kg/year, clinically significant splenomegaly, and the presence of severe pancytopenia[8].

The spleen plays a critical role in eliminating abnormal red blood cells from the peripheral circulation. Surgical removal of the spleen may enhance red blood cell survival by reducing splenic destruction, thereby potentially lowering transfusion requirements. However, splenectomy is also associated with alterations in hematological parameters, including thrombocytosis and an increased number of nucleated red blood cells, which may contribute to post-splenectomy complications[9,10]. In

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thalassemic red blood cells, oxidation of globin subunits results in the formation of hemichrome, which binds to the red blood cell membrane. Subsequent degradation of heme leads to the release of toxic non–transferrin-bound iron species, contributing further to cellular damage[11-13].

Although splenectomy is commonly performed to reduce transfusion requirements in transfusion-dependent thalassemia patients, its impact on iron overload remains unclear. Previous studies have reported inconsistent effects of splenectomy on serum ferritin levels and transfusion burden, and direct comparisons between splenectomized and non-splenectomized patients are limited. This lack of consistent evidence highlights the need for further evaluation. The purpose of the study is to evaluate the impact of splenectomy on iron overload by comparing serum ferritin levels between splenectomized and non-splenectomized transfusion-dependent thalassemia patients.

OBJECTIVE

- To evaluate the impact of splenectomy on iron overload by comparing serum ferritin levels between splenectomized and non-splenectomized transfusion-dependent thalassemia patients.

METHODS & MATERIALS

This cross-sectional, comparative study was conducted at the Department of Transfusion Medicine, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from December 2021 to October 2022. A total of 60 transfusion-dependent thalassemia patients were included, comprising 30 splenectomized and 30 non-splenectomized individuals, who were selected based on specific inclusion and exclusion criteria for the comparison of hematological parameters between splenectomized and non-splenectomized transfusion-dependent thalassemia patients.

Inclusion criteria:

- Transfusion-dependent thalassemic patients aged above 5 years
- Both male and female patients
- Splenectomized thalassemic patients who were dependent on regular transfusions and had received at least 10 transfusions prior to surgery
- Non-splenectomized thalassemic patients (with hypersplenism or splenomegaly) receiving regular blood transfusions for at least 2 years

Exclusion criteria:

- Thalassemic patients aged below 5 years
- Thalassemic patients not dependent on regular blood transfusions
- Thalassemic patients without splenectomy, hypersplenism, or splenomegaly
- Patients with bleeding disorders due to causes other than thalassemia
- Thalassemic patients or their guardians unwilling to provide informed consent

The study focused on demographic variables (age and sex), clinical data (transfusion interval), and laboratory parameters including hemoglobin, hematological indices (MCV, MCH, MCHC, RDW, HCT, WBC, platelet count), serum ferritin, and peripheral blood film findings. After obtaining ethical approval from the Institutional Review Board (IRB) of BSMMU, demographic and clinical information was collected using a semi-structured questionnaire and review of medical records.

For laboratory evaluation, 5 mL of venous blood was collected under aseptic conditions from each participant. Serum ferritin levels were measured by Chemiluminescent Immunoassay (CLIA) using the automated analyzer Liaison XL at the Department of Biochemistry and Molecular Biology, BSMMU. Complete blood count and peripheral blood film analyses were performed using Fluorescence Flow Cytometry (FFC) on the Sysmex XN-2000 autoanalyzer at the Department of Laboratory Medicine, BSMMU. All collected data were recorded in case record forms and compiled into a master chart for analysis.

Continuous variables were expressed as mean ± standard deviation, and categorical variables were presented as frequency and percentage. Comparisons between splenectomized and non-splenectomized groups were made using Student's t-test for continuous variables and chi-square test for categorical variables. A p-value less than 0.05 was considered statistically significant. Ethical approval was obtained from the IRB of BSMMU. Informed written consent was obtained from all participants or their guardians after explaining the purpose of the study, procedures, confidentiality, voluntary participation, and the right to withdraw at any time. The study was conducted under direct supervision, and all laboratory analyses were performed in accredited departments following standard protocols. The results of this study are intended for publication in peer-reviewed journals and may guide clinicians in optimizing the management of transfusion-dependent thalassemia patients.

RESULTS

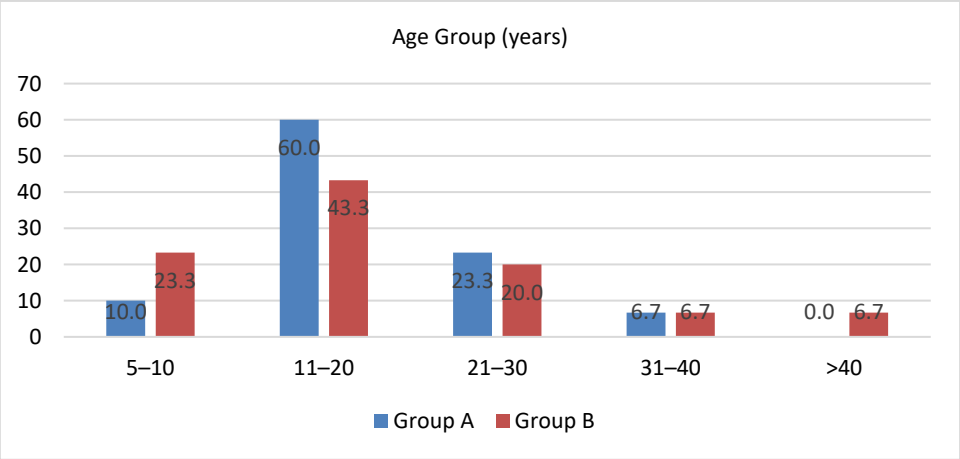

Figure 1 Age Distribution of the Study Population (n = 60).

The majority of patients were aged 11–20 years, with 18 (60.0%) in the splenectomized group and 13 (43.3%) in the non-splenectomized group. Patients aged 21–30 years comprised 7 (23.3%) and 6 (20.0%) of the splenectomized and non-splenectomized groups, respectively. Fewer patients were aged 5–10 years (10.0% vs 23.3%), 31–40 years (6.7% in both groups), and >40 years (0% vs 6.7%). Mean age was 17.78 ± 6.57 years in the splenectomized group and 18.87 ± 10.95 years in the non-splenectomized group, with no statistically significant difference (p = 0.644) *Figure 1*.

Males predominated in both groups, comprising 21 (70.0%) in the splenectomized group and 16 (53.3%) in the non-splenectomized group. Females accounted for 9 (30.0%) and 14 (46.7%) of the splenectomized and non-splenectomized groups, respectively. The difference in sex distribution was not statistically significant (p = 0.184) *Table I*.

Table I
Sex Distribution of the Study Population (*n* = 60).

Sex	Group A (n = 30)	Group B (n = 30)	Total (n = 60)	p-value
Male	21 (70.0)	16 (53.3)	37 (61.7)	0.184
Female	9 (30.0)	14 (46.7)	23 (38.3)	

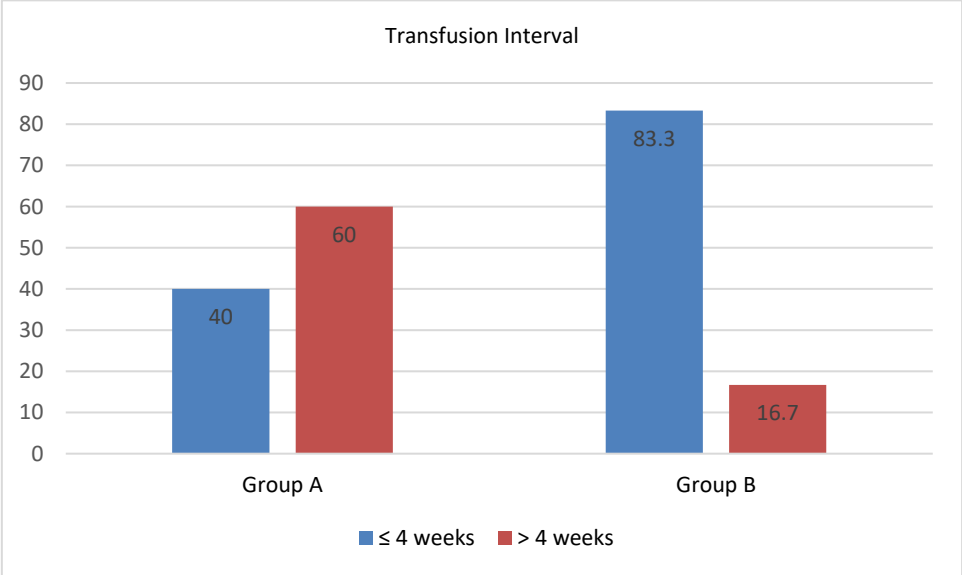

Figure 2 Transfusion Interval Distribution of the Study Population (*n* = 60).

Among the study population, 60.0% of splenectomized patients received transfusions at intervals greater than 4 weeks, compared to only 16.7% of non-splenectomized patients. Conversely, 40.0% of splenectomized patients and 83.3% of non-splenectomized patients received transfusions at intervals of 4 weeks or less. The difference was statistically significant (p = 0.001) *Figure 2*.

There was no significant difference in hemoglobin, MCH, MCHC, RDW, or hematocrit between the groups. Splenectomized patients had significantly higher MCV (75.64 ± 6.93 vs 69.99 ± 8.89 fL; p = 0.008), WBC count (12.24 ± 5.35 vs 9.31 ± 3.88 ×10³/µL; p = 0.019), and platelet count (556.0 ± 255.91 vs 210.34 ± 116.15 ×10³/µL; p < 0.001) compared to non-splenectomized patients (*Table II*).

Table II
Hematological Parameters in Splenectomized and Non-Splenectomized Transfusion-Dependent Thalassemia Patients (*n* = 60).

Hematological Variable	Group A (n = 30)	Group B (n = 30)	p-value
Hb (g/dL)	7.26 ± 1.57	6.78 ± 1.83	0.285
MCV (fL)	75.64 ± 6.93	69.99 ± 8.89	0.008
MCH (pg)	23.31 ± 2.94	25.21 ± 12.99	0.441
MCHC (g/dL)	30.83 ± 2.83	30.93 ± 2.15	0.874
RDW	26.13 ± 6.07	27.93 ± 5.87	0.248
HCT	25.21 ± 9.95	26.79 ± 24.45	0.744
WBC (10³/L)	12.24 ± 5.35	9.31 ± 3.88	0.019
Platelet (10³/L)	556.0 ± 255.91	210.34 ± 116.15	<0.001

Splenectomized patients had significantly higher serum ferritin levels than non-splenectomized patients. Half of the splenectomized patients (50.0%) had ferritin levels >5000 ng/mL, compared to 13.3% in non-splenectomized patients. Mean ferritin was 5843.98 ± 4162.00 ng/mL in splenectomized patients and 3253.32 ± 2247.28 ng/mL in non-splenectomized patients (p = 0.004) *Table III*.

Table III
Comparison of Serum Ferritin Levels Between Splenectomized and Non-Splenectomized Patients (*n* = 60).

Serum Ferritin (ng/mL)	Group A (n = 30)	Group B (n = 30)	Total (n = 60)	p-value
<1000	1 (3.3)	4 (13.3)	5 (8.3)	0.004
1000–2500	6 (20)	8 (13.3)	14 (23.3)	
2500–5000	8 (26.7)	15 (50)	23 (38.3)	
>5000	15 (50)	4 (13.3)	19 (31.7)	
Mean ± SD (ng/mL)	5843.98 ± 4162.00	3253.32 ± 2247.28	—	0.004

Peripheral blood film findings were comparable between the groups, with no statistically significant difference (p = 0.117). Moderate anemia predominated in non-splenectomized patients, while severe anemia was more frequent among splenectomized patients (*Table IV*).

Table IV
Peripheral Blood Film Patterns in Splenectomized and Non-Splenectomized Patients (*n* = 60).

Peripheral Blood Film (PBF) Result	Group A (n = 30)	Group B (n = 30)	Total (n = 60)	p-value
Mild microcytic hypochromic anaemia with target cells and nucleated cells	3 (10.0)	2 (6.7)	5 (8.3)	0.117
Moderate microcytic hypochromic anaemia, anisopoikilocytosis, target cells	16 (53.3)	9 (30.0)	25 (41.7)	
Severe microcytic hypochromic anaemia, anisopoikilocytosis, target cells, fragmented cells, teardrop cells	11 (36.7)	19 (63.3)	30 (50.0)	

DISCUSSION

Transfusion-dependent thalassemia (TDT) is a severe inherited anemia that often necessitates regular red blood cell transfusions to maintain adequate hemoglobin levels and prevent complications. Splenectomy is frequently performed in these patients to reduce transfusion requirements and manage hypersplenism, but its impact on hematological parameters and iron overload remains incompletely understood. The findings of this study demonstrate that splenectomized patients have higher mean corpuscular volume, white blood cell and platelet counts, as well as significantly elevated serum ferritin levels compared to non-splenectomized patients. These results highlight the dual impact of splenectomy—altering hematological indices while potentially exacerbating iron overload—underscoring the need for careful post-splenectomy monitoring and optimized chelation therapy in TDT patients.

In the present study, the majority of patients were aged 11–20 years, with mean ages of 17.78 ± 6.57 years in the splenectomized group and 18.87 ± 10.95 years in the non-splenectomized group, and no statistically significant difference was observed between groups (p = 0.644). This age distribution indicates that transfusion-dependent thalassemia predominantly affects children and adolescents, which is consistent with previous literature. Bhattacharjee et al. reported a median age at splenectomy of 12 years (range 5–34) in a retrospective cohort of TDT patients, noting that most procedures occurred during childhood or adolescence, reflecting the early onset of complications necessitating splenectomy[14]. Similarly, Caocci et al. found a median age at splenectomy of 12 years (range 1–32) in adult TDT patients[15], confirming that splenectomy is commonly performed at a relatively young age in thalassemia populations. These findings collectively support the observation that the bulk of TDT patients, regardless of splenectomy status, are relatively young, which aligns with the age distribution reported in our study.

In the present study, males predominated in both groups, comprising 21 (70.0%) in the splenectomized group and 16 (53.3%) in the non-splenectomized group, while females accounted for 9 (30.0%) and 14 (46.7%), respectively. The difference in sex distribution between the two groups was not statistically significant (p = 0.184), indicating a comparable gender pattern among splenectomized and non-splenectomized transfusion-dependent thalassemia patients. This finding aligns with the results reported by Azeez et al., who observed that among 60 thalassemia major patients, 33 (55%) were male and 27 (45%) were female, with no significant sex-related differences between splenectomized and non-splenectomized groups[16]. These observations suggest that sex does not appear to influence the likelihood of undergoing splenectomy in transfusion-dependent thalassemia populations and that male predominance in these cohorts may reflect general demographic patterns rather than disease- or treatment-specific factors.

In the present study, splenectomized patients demonstrated significantly longer transfusion intervals compared with non-splenectomized patients, with 60.0% of splenectomized individuals receiving transfusions at intervals greater than 4 weeks versus only 16.7% of non-splenectomized patients (p = 0.001). Conversely, the majority of non-splenectomized patients (83.3%) required transfusions at intervals of 4 weeks or less. These findings indicate that splenectomy is associated with reduced transfusion dependence, reflecting improved red blood cell survival and decreased peripheral destruction. Similar observations have been reported by Osataphan et al., who found that splenectomy in transfusion-dependent thalassemia patients significantly reduced the need for transfusions and, in many cases, enabled conversion from transfusion-dependent to non-transfusion-dependent status[5]. Likewise, Bhosale et al. noted a reduction in both transfusion requirement and frequency following splenectomy in β-thalassemia patients[17], supporting the finding of a greater proportion of longer transfusion intervals among splenectomized patients in the current study. These concordant results underscore the clinical benefit of splenectomy in prolonging transfusion intervals and reducing transfusional burden in thalassemia populations.

In this study, splenectomized transfusion-dependent thalassemia patients exhibited significantly higher mean corpuscular volume (MCV: 75.64 ± 6.93 vs 69.99 ± 8.89 fL; p = 0.008), white blood cell count (12.24 ± 5.35 vs 9.31 ± 3.88 $\times 10^3/\mu L$; p = 0.019), and platelet count (556.0 ± 255.91 vs 210.34 ± 116.15 $\times 10^3/\mu L$; p < 0.001) compared with non-splenectomized patients, while hemoglobin, MCH, MCHC, RDW, and hematocrit showed no statistically significant differences. These findings are consistent with previous studies demonstrating the hematologic impact of splenectomy in thalassemia. Tripodi et al. reported significantly elevated leukocyte and platelet counts in splenectomized patients relative to non-splenectomized counterparts[18], reflecting reduced peripheral destruction and sequestration of blood cells after splenectomy, which

parallels the higher WBC and platelet counts observed in our study. Similarly, Mohamed AAF et al. documented a significant increase in both platelet and total leukocyte counts following splenectomy, supporting our observation of elevated counts in the splenectomized cohort[19]. The increase in MCV observed in our study may also reflect improved red blood cell survival and altered erythropoiesis post-splenectomy, further highlighting the physiological hematologic changes associated with spleen removal in transfusion-dependent thalassemia patients.

In the present study, splenectomized transfusion-dependent thalassemia patients exhibited significantly higher serum ferritin levels compared to non-splenectomized patients, with half of the splenectomized individuals (50.0%) exceeding 5000 ng/mL and a mean ferritin of 5843.98 ± 4162.00 ng/mL versus 3253.32 ± 2247.28 ng/mL in the non-splenectomized group ($p = 0.004$). These findings are consistent with previous reports highlighting increased iron overload in splenectomized thalassemia patients. Pootrakul et al. observed significantly higher serum ferritin levels in splenectomized β-thalassemia/Hb E patients compared with non-splenectomized patients[20], reflecting enhanced iron accumulation following splenectomy. Similarly, Casale et al., in a retrospective analysis of transfusion-dependent thalassemia major patients, reported that ferritin concentrations were markedly elevated in the splenectomized group during the presplenectomy period[10], emphasizing the association between spleen removal and higher iron burden, even though levels may decline over the long term. These studies support our results, indicating that splenectomy contributes to greater iron accumulation and underscores the importance of careful iron monitoring and chelation management in this patient population.

In this study, peripheral blood film examination revealed that microcytic hypochromic anemia with varying degrees of anisopoikilocytosis and target cells was prevalent among both splenectomized and non-splenectomized transfusion-dependent thalassemia patients. Moderate anemia predominated in non-splenectomized patients (30.0%), whereas severe anemia with features such as fragmented cells and teardrop cells was more frequent among splenectomized patients (36.7%), although the difference was not statistically significant ($p = 0.117$). These findings are in line with previous observations by Shehata et al., who reported that splenectomized thalassemia patients often exhibit increased circulating nucleated red blood cells (NRBCs) and reticulocytes[21], reflecting more pronounced ineffective erythropoiesis and abnormal red cell morphology post-splenectomy. The higher proportion of severe anemia features in the splenectomized group in our cohort may be attributed to the loss of splenic filtration, which normally removes abnormal and fragmented erythrocytes, thereby allowing these cells to persist in peripheral circulation. Overall, our results support the notion that splenectomy influences peripheral blood film patterns by increasing the prevalence of severe morphologic abnormalities in transfusion-dependent thalassemia patients.

LIMITATIONS

The study had several limitations:

- The study was conducted at a single tertiary care center, which may limit the generalizability of the findings.
- Participants were selected using non-random, convenience sampling, introducing the possibility of selection bias.
- Long-term outcomes following splenectomy could not be evaluated due to the cross-sectional study design.
- Advanced modalities for assessing iron overload, such as magnetic resonance imaging or liver biopsy, were not employed; instead, serum ferritin was used as a cost-effective surrogate marker, which may not fully reflect total body iron stores.

CONCLUSION

Splenectomy is commonly performed in transfusion-dependent thalassemia patients to reduce red blood cell destruction and transfusion requirements. In this study, splenectomized patients showed longer transfusion intervals and higher white blood cell and platelet counts compared to non-splenectomized patients, reflecting improved hematologic stability post-splenectomy. However, they also exhibited significantly higher serum ferritin levels, indicating increased iron overload. Peripheral blood film findings were largely similar between groups, although more severe anemia features were observed in splenectomized patients. These results suggest that while splenectomy can reduce transfusion burden and modify hematological parameters, careful monitoring and management of iron accumulation remain crucial.

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The severity of illness of ICU patients – A Single Center Study

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ABSTRACT

Background: The Intensive Care Unit (ICU) is an essential subset of the hospital treatment providing specialized care to patients with most complex diseases, where illness is often life-threatening. Knowledge of illness severity in ICU patients is important to enhance their care and outcomes. The present study intended to investigate the demographic profile, pattern of morbidities and mortality in ICU population of Ad-din Sakina Medical College Hospital, Bangladesh. **Methods & Materials:** This was a prospective descriptive study carried out from January 2023 to December 2023 among 144 patients of the ICU. Patients' demographics (age, sex) and diagnosis, ICU stay and outcome (improved, referred to a higher center, or death) were recorded. Microsoft Excel was used to enter data and analysis was done using Statistical Package for the Social Sciences (SPSS) version 26.0. **Results:** Most ICU patients were more than 60 years of age (41.92 %) and had a slight male preference (50.95%). Common reasons for ICU admission were respiratory, neurological and cardiovascular diseases. Medical diseases were responsible for 90.78% of ICU admissions, and the total mortality was 36%. The lowest survival rate was found in patients with respiratory and cardiovascular comorbidities. Most of deaths fell within the first 3 days after ICU admission thus emphasizing the importance of early ICU management. **Conclusion:** Respiratory and cardiovascular disorders were determined to be the main cause of death in the ICU. The results highlight the significance of early diagnosis, prompt treatment and adequate ICU care, especially in low-income countries, for favorable patient outcome. More investigation is necessary to improve the management of ICU and lower mortality in the critically ill.

Keywords: *ICU, mortality rate, Morbidity rate, Single Center Study, Bangladesh.*

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INTRODUCTION

ICU (Intensive Care Unit) is a specialised ward for patients who need intensive monitoring, treatment and nursing care. It provides advanced life-support systems such as pulmonary and hemodynamic support and is intended for continuous monitoring and intensive care. These units, variously named, Intensive Therapy Units (ITU)/Intensive Treatment Units (ITU)/Critical Care Units (ITU), undertake the control of those patients whose condition is potentially reversible with a view to increasing the chances of survival [1, 2].

ICU admissions are often made up of patients with varying degrees of illness, including respiratory failure, cardiac arrest, and neurologic emergencies. In particular, in the ICU setting the severity of illness plays an important role in the treatment outcome since critically ill patients have challenging medical conditions and are in need of prompt and specialized care [3,4]. ICU outcomes are unpredictable, with mortality rate serving as a key metric for gauging performance in critical care after excluding outliers and adjusting for baseline variables, the mortality rate between 6.4% - 40%, annually fluctuates according to patient population and illness severity [5].

In many high-income countries, ICU beds have become specialized, with ICUs devoted to specific subspecialties (e.g., cardiology, neurology, and trauma). However, in most of the developing country, like Bangladesh, the model of general ICU is prevailing due to resource constraints [6]. ICU in Bangladesh has been growing following the country's first ICU that opened in 1980 with over 78% of ICUs situated in private settings [7]. Mortality in such organizations has been reported to correlate with the patient's age, comorbidity, the time to treatment, and quality of care [8].

The miserable of illness of ICU patients is an important parameter for assessing treatment of the critically ill. ICU admission is a marker of severe morbidity, and the determinants of mortality and morbidity outcomes are important for quality-of-care evaluation [9]. The objective of this study is to find out severity of ill patients admitted in ICU at a tertiary center in Bangladesh. In particular, we will explore mortality rate, morbidity pattern, patient biases, and length of stay in the ICU at the time of death. These characteristics are crucial for understanding the issues of monitoring severely ill patients with limited resources and to implement interventions for a better ICU outcome.

METHODS & MATERIALS

Study Settings and Population

This prospective descriptive study was carried out in Ad-din Sakina Medical College Hospital, Bangladesh, during January 2023 to December 2023. Patients who were admitted to an ICU in this time period. The ICU of the hospital is a modern and well-resourced facility, consisting of 10 beds accommodating critically-ill patients from diverse medical and surgical subspecialties. The ICU was launched on 14th February 2018 and is manned by a dedicated anesthetic team that offers high dependency care to patients requiring high end medical and surgical management.

Study Procedure

This study is based on prospective data of patients who were admitted to the ICU during the study period. Details of age, gender, diagnosis, length of stay in the ICU, and outcome were recorded. Specialists from different subspecialities were involved in the diagnosis, aided by appropriate laboratory work-up. The results were categorized as the discharge of patients and recovered, referred to higher hospital and died away. The information was retrieved from admission and discharge records of ICUs which was a guarantee regarding the accuracy and completeness of patient data.

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Data Analysis

Microsoft Excel 2007 was used for primary analysis of data. The statistical analysis was done using the Statistical Package for the Social Sciences (SPSS), software version 26.0. Demographic and clinical characteristics were reported as descriptive statistics, and differences in frequencies were compared using the Chi-square test.

Ethical Considerations

This study received ethical approval from the Ethics Committee of Ad-din Sakina Medical College Hospital (Ad-din Sakina Medical College Hospital). Ethical considerations and confidentiality of information and data Responsible conduct of research pertaining to the ethics involved in the use of this database required that all patients' confidentiality and data be upheld. Written consent was taken from all patients before enrollment.

RESULTS

Table I Demographic data on ICU patients according to age and sex is shown in table 1. Regarding the age, most of the patients are 60 or older (41.92%) with 60 patients. The next largest group is 40 to 59 years, making up 29.74% of the studied group with 43 patients. The 20- to 39-year age group is the largest accounted for (22.95%) in the ICU, 33 patients, meanwhile the patients younger than 20 years is the smallest (5.39%), 8 patients. As for sex ratio, the sex ratio-varied slightly, with 73 male patients (50.95%) and 71 female patients (49.05%) in the ICU, indicating a nearly equal ratio of male-to-female patients in the sample. The findings demonstrate that among ICU admissions, the eldest can be seen, in particular in those aged 60 and over and that ICU population is more or less equally distributed among males and females.

Table I
Demographic Distribution of ICU Patients.

Age (years)	Frequency (n)	Percentage (%)
<20 years	8	5.39
20-39 years	33	22.95
40-59 years	43	29.74
≥60 years	60	41.92
Sex		
Male	73	50.95
Female	71	49.05

Table II outlines the mortality rates based on the primary cause of admission for ICU patients. Among the 144 ICU patients, the majority were admitted due to medical causes, with 130 patients in this category. The mortality rate for medical causes was 36.92%, with 48 patients dying as a result of medical conditions. In contrast, 14 patients were admitted for surgical causes, and the mortality rate in this group was 28.57%, with 4 deaths. Overall, the total mortality rate across all causes of admission was 36.11%, with 52 deaths out of the 144 patients.

Table II
Mortality Rates Based on Primary Cause of Admission in ICU Patients.

Primary Cause	Number of Patient	Number of Death	Mortality Rate
Medical Cause	130	48	36.92
Surgical Cause	14	4	28.57
Total	144	52	36.11

Table III presents the distribution of ICU patients based on their morbidity patterns. The largest group of patients (20.00%) was admitted due to respiratory diseases, with 29 patients. Neurological diseases were the second most common cause, accounting for 16.17% of the total ICU admissions, with 23 patients. Cardiovascular diseases were responsible for 11.13% of ICU admissions, with 16 patients. Renal diseases contributed to 10.43% of the ICU population, with 15 patients. Post-operative complications from surgical causes were observed in 9.22% of patients, totaling 13. Cancer and endocrine diseases each accounted for 6.95% and 6.78% of admissions, respectively, with 10 patients each. Hepatic diseases were responsible for 6.62% of ICU admissions (9 patients), followed by dengue fever at 5.56% (8 patients). GIT problems were noted in 4.18% of cases, with 6 patients. Organophosphorous poisoning and unknown poisoning accounted for smaller proportions, with 3 (1.74%) and 1 (0.87%) patient, respectively. Lastly, a single case of hanging was recorded, representing just 0.35% of ICU admissions.

Table III
Distribution of ICU Patients According to Morbidity Pattern.

Morbidity Pattern	Frequency (n)	Percentage (%)
Respiratory Disease	29	20.00
Neurological Disease	23	16.17
Cardiovascular Disease	16	11.13
Renal Disease	15	10.43
Post operative complication (Surgical Cause)	13	9.22
Cancer	10	6.95
Endocrine Disease	10	6.78
Hepatic Disease	9	6.62
Dengue Fever	8	5.56
GIT Problem	6	4.18
Organophosphorous (OPC) Poisoning	3	1.74
Unknown Poisoning	1	0.87
Hanging	1	0.35
Total	144	100

Table IV presents the mortality rates of ICU patients based on their disease patterns, with a total of 52 patients. Respiratory diseases accounted for the highest mortality rate at 26.90%, with a total of 14 patients in this category, including 8 males and 6 females. Neurological diseases followed with a mortality rate of 21.15%, involving 11 patients, with 6 males and 5 females. Renal diseases had a mortality rate of 17.30%, with 9 patients in total (5 males and 4 females). Cardiovascular diseases showed a mortality rate of 13.4%, with 7 patients (4 males and 3 females). Hepatic diseases contributed to a mortality rate of 11.53%, with 6 patients (4 males and 2 females). Lastly, cancer had the lowest mortality rate at 9.6%, with 5 patients (4 males and 1 female).

Table IV
Mortality of the patients according to disease pattern of ICU admission (*n*=52)

Disease Pattern	Frequency			Mortality Rate
	Male	female	Total	
Respiratory Disease	8	6	14	26.90
Neurological Disease	6	5	11	21.15
Renal Disease	5	4	9	17.30
Cardiovascular Disease	4	3	7	13.4
Hepatic Disease	4	2	6	11.53
Cancer	4	1	5	9.6
Total	31	21	52	

Table V provides the distribution of ICU patients' length of stay before death, with a total of 52 deaths recorded. The majority of deaths occurred within the first 3 days of ICU admission, with 22 patients (42.31%) passing away within 1 to 3 days. A significant portion, 11 patients (21.15%), died within the first 24 hours of their ICU stay. Additionally, 10 patients (19.23%) each passed away after staying between 4 days and 1 week, and another 10 patients (19.23%) died after staying more than 1 week in the ICU.

Table V
Length of stay in ICU before death (*n*=52)

Length of stay	Number of Deaths (n)	Percentage (%)
< 24 hours	11	21.15
1-3 days	22	42.31
4 days to 1 week	10	19.23
> 1 week	10	19.23

Table VI presents the outcomes of ICU patients, with a total of 144 admissions. The majority of patients, 86 (60%), died during their stay in the ICU, highlighting the critical nature of the conditions for which patients are admitted. A smaller proportion of patients, 6 (4%), were referred to other facilities, suggesting that their conditions required specialized care elsewhere. The remaining 52 patients (36%) showed improvement, indicating that a significant number of patients were able to recover or stabilize during their ICU treatment.

Table VI
Outcome of admitted patients in ICU (*n*=144).

Outcome	Number of Deaths (n)	Percentage (%)
Death	86	60
Referred	6	4
Improved	52	36

DISCUSSION

The illness severity and mortality in patients in the Intensive Care Unit (ICU) are determined by several patient-related and ICU-related factors. These are age, sex, disease severity, comorbidities, time to medical treatment, goodness of ICU nurses, and ICU quality. ICU admissions generally consist of critically unwell patients who are deemed 'rescueable' with organ support, including mechanical ventilation and invasive monitoring. There was a slight male preponderance in ICU admissions in the present cohort (73 males (50.95%) and 71 females (49.05%), nearly equal sex ratio). This male predominance could be due to cultural reasons in male-dominated societies, where male members of the family are given preference for health-related issues [10].

The age of the patients in this cohort study ranged from 18 to 85 years of age, implying that there is no age group that is spared from severe or life-threatening disease requiring ICU admission. Patients 60 years and older formed the majority of ICU admissions, accounting for 41.92% of the study population. This contrasts with the previous studies in which younger and middle-aged men were frequently represented in the ICU admissions [11]. Findings of this study showed that older population especially people aged 60 years and older were the most common ICU admissions, which confirms greater susceptibly of the elderly to more severe illness.

The most frequent reason for ICU admission was for medical cases compared to surgical cases, with 130 (90.78%) medical and 14 (9.22%) surgical patients. But medical patients' death rate was significantly higher 36.92% as compared to 28.57% in surgical patients. This is in line with others showing that medical patients are more severely ill and more comorbid, and have higher death rates overall [12]. Respiratory, neurology, and cardiovascular diseases were the predominant reasons for which ICU patients

were admitted, and respiratory diseases especially were highly prevalent considering the high air pollution and smoking rates. Respiratory and cardiovascular diseases were also the leading cause of mortality in our study as well as in other literature [13].

In this series, the general ICU mortality was 36%, and it is analogous to other series we obtained from underdeveloped countries. For instance, research done in large public hospital of Bangladesh has declared 57.23% mortality rate [11]. African ICU studies have reported ICU mortality rates from 34%-43% [14, 15] whereas developed countries, including France and the USA, have reported mean ICU mortality rates ranging between 8%-18% [16, 17]. The higher mortalities in low-resource countries are often attributed to patients presenting late, lack of trained staff, and lack of life-support equipment, characteristics which are echoed in many low-resource settings around the world.

The analysis also showed higher mortality rates in males and elderly patients which were similar to the other studies by Dongre et al. (2016) and Alam et al. (2017) [4, 5]. Mortality was greatest in the first 1-3 days of ICU stay, demonstrating the sensors perform best in the ICU as the first 72 hours are essential for patient outcomes [18]. A short mean duration of admission for non-survivors is indicative of the pattern that patient with a grave condition dies rather quickly and survivors are stabilized over a longer period before being referred to ward for further management.

Comparing the aforementioned clinical parameter with the mortality rate in ICU of this study, the patients with severe medical conditions, older ages and male sex have the mortality higher, fact also supported by a previous study showing a mortality rate closely associated with these characteristics. This emphasises the need for early detection of clinical predictors for timely medical therapies as well as for ameliorating ICU-level care with a goal of reduction of mortality rates, especially in resource-poor region.

CONCLUSION

This work underscores the outcome of ICU patients, which are older adults (age 60+ yrs) and often affected by respiratory and heart diseases. There was a lower mortality among males than females, being medical cases more lethal than surgical ones. More than half the deaths occurred within 72 hours of admission highlighting the importance of early diagnosis and improved ICU care, particularly in resource-poor regions. Enhanced ICU management and guidelines are essential in the reduction of mortality" especially in vulnerable populations and in the developing world.

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Prevalence of Hepatitis B virus infection among the multi-transfused thalassemic and hemophilic patients receiving RCC & FFP

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ABSTRACT

Background: Patients with thalassemia and hemophilia require frequent blood transfusions, which increase their risk of hepatitis B virus (HBV) infection. As a major global health problem, HBV can lead to chronic liver disease and hepatocellular carcinoma, making multi-transfused patients particularly vulnerable. **Objective:** To assess the prevalence of Hepatitis B virus infection among the multi- transfused thalassemic and hemophilic patients receiving red cell concentrate (RCC) & fresh frozen plasma (FFP). **Methods & Materials:** A cross-sectional study was conducted in the Departments of Transfusion Medicine and Virology at BSMMU, Dhaka, over one year following IRB approval. Fifty multi-transfused patients (25 hemophilia and 25 thalassemia) receiving RCC or FFP were enrolled. Data were collected using a structured questionnaire after informed consent, and blood samples were tested for HBsAg and Anti-HBc (Total). Data were analyzed using SPSS version 22. **Results:** Among the participants, 22.0% were Anti-HBc (total) positive, while all were HBsAg negative. Anti-HBc positivity was significantly associated with a history of receiving blood transfusions from multiple centers other than BSMMU ($p<0.05$), whereas no significant association was found with hepatitis B immunization history ($p>0.05$). **Conclusion:** Anti-HBc positivity was found in 22.0% of multi-transfused thalassemic and hemophilic patients, and was significantly associated with a history of receiving blood transfusions from multiple centers other than BSMMU.

Keywords: *Thalassemia, Hemophilia, HBV, Anti-HBc, TTI*

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INTRODUCTION

Transfusion-transmitted infections (TTIs) remain a major public health problem worldwide, particularly among multi-transfused patients such as those with thalassemia and hemophilia [1,2]. Thalassemia is a hereditary blood disorder common in the "thalassemia belt," which includes Mediterranean countries, the Middle East, and South Asian nations such as Bangladesh, India, and Sri Lanka [3]. Patients with transfusion-dependent β-thalassemia major (BTM) and HbE-β-thalassemia (EBT) require regular blood transfusions and are therefore at high risk of transfusion-associated viral infections. Among TTIs, hepatitis B virus (HBV) and hepatitis C virus (HCV) are the most common causes of chronic viral hepatitis and hepatocellular carcinoma in multi-transfused patients [4]. Although strict screening procedures have greatly reduced TTIs in developed countries [5], developing countries still face significant challenges in ensuring blood safety due to limited resources and inadequate screening systems [6]. Bangladesh lies within the global thalassemia belt, with approximately 9176 new cases each year [7]. These patients require frequent transfusions, often every 7–120 days, which increases the risk of acquiring TTIs when proper donor screening is not consistently implemented [8,9].

Regular transfusion therapy has improved survival and quality of life in hereditary hemolytic anemia, but it carries the risk of blood-borne viral infections, particularly hepatitis B [10]. HBV infection remains a major global health problem, affecting more than 2 billion people, with about 400 million chronic carriers [11]. Studies have reported high rates of HBsAg and anti-HBc positivity among multi-transfused children in countries such as Egypt [12].

Hemophilia patients are classified as having mild, moderate, or severe disease depending on clotting factor deficiency [13]. Management often involves replacement therapy using fresh frozen plasma (FFP), cryoprecipitate, or clotting factor concentrates. However, repeated transfusions significantly increase the risk of TTIs, including HBV, HCV, HIV, and syphilis [14,15]. In many developing countries, including China, high costs limit access to recombinant clotting factors, making transfusion of FFP or cryoprecipitate the primary treatment option [16]. As the risk of viral infection increases with repeated transfusions, this study aims to determine the prevalence of hepatitis B virus infection among multi-transfused thalassemic and hemophilic patients receiving RCC and FFP.

OBJECTIVES

The objective of this study was to assess the prevalence of Hepatitis B virus infection among multi- transfused thalassemic and hemophilic patients receiving Red Cell Concentrate (RCC) & Fresh Frozen Plasma (FFP).

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METHODS & MATERIALS

This was a hospital-based cross-sectional study conducted in the Department of Transfusion Medicine, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh. The study was carried out over a twelve-months period from March 2021 to August 2023.

Sample Selection

Inclusion criteria

- Patients with thalassemia who received transfusions by RCC >10 times.
- Patients with hemophilia received transfusion of FFP >10 times.
- Thalassemic and hemophilic patients of aged 5-40 years

Exclusion criteria

- Age group <5 years or >40 years.
- Thalassemic patients who received transfusions other than RCC.
- Hemophilic patients who received a transfusion other than FFP.
- Patients known to be hepatitis B virus positive before starting blood transfusion.
- Patients who did not give consent.

Data Collection Procedure

A total of 50 multi-transfused patients receiving RCC and FFP were included in this study according to the inclusion and exclusion criteria. After explaining the purpose of the study, written informed consent was obtained from each participant or their authorized guardian. During the one-year study period at the Department of Transfusion Medicine, BSMMU, Dhaka, 3 ml of venous blood was collected from each participant under aseptic conditions. The samples were sent to the Virology Department, aliquoted, and stored at −20°C until analysis. Serum samples were tested for hepatitis B surface antigen (HBsAg) and total anti-HBc using enzyme-linked immunosorbent assay (ELISA) with a fully automated analyzer (Abbott Laboratories, USA). Demographic and clinical data, including age, sex, and transfusion history, were recorded using a predesigned questionnaire and hospital records.

Ethical Considerations:

Ethical approval was obtained from the Ethical Review Committee of Bangabandhu Sheikh Mujib Medical University (BSMMU). Written informed consent was obtained from all participants or their legal guardians, and confidentiality of patient information was strictly maintained.

Statistical Analysis

Data were analyzed using SPSS version 22. Categorical variables were presented as frequency and percentage, and associations were assessed using the chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

Table I shows the distribution of participants by demographic characteristics showed that out of the total 50, the majority were in the age groups of ≤10 years 19(38.0%) and 11-15 years 9(18.0%). The mean age of the participants was 16.64 years. Most of the participants were male 40(80.0%) and from rural areas 29(58.0%). In terms of economic condition, the poor class had the highest representation 38(76.0%).

Table I
Distribution of participants by demographic characteristics (*n*=50).

Characteristics		Frequency (N)	Percentage (%)
Age in year	10	19	38.0
	11-15	9	18.0
	16-20	8	16.0
	21-25	5	10.0
	26-30	3	6.0
	31-35	2	4.0
	>35	4	8.0
	Mean ± SD	16.64±9.8	
	Range (min-max)	(6-40)	
Gender	Male	40	80.0
	Female	10	20.0
Socio Economic Condition	Middle	12	24.0
	Poor	38	76.0
Residence	Urban	21	42.0
	Rural	29	58.0

Table II shows distribution of the study patients by hepatitis seropositivity. All Hemophilia patients (100.0%) and Thalassaemia patients (100.0%) tested negative for HBsAg Titre. Among Hemophilia patients, 6(24.0%) tested positive for Anti HBc (Total) Among Thalassaemia patients, 5 (20.0%) tested positive.

Table II
Distribution of the participant by hepatitis seropositivity (*n*=50).

Hepatitis seropositivity		Hemophilic patients (n=25)		Thalassaemia patients (n=25)	
		n	%	n	
HBsAg Titre	Positive	0	0.0	0	0.0
	Negative	25	100.0	25	100.0
Anti HBc Total	Positive	6	24.0	5	20.0
	Negative	19	76.0	20	80.0

Table III shows association between demographic characteristics with Anti HBc (total) category. The mean age was younger in positive group with compared to negative group but there was no statistically significant (p>0.05) difference in age between the positive and negative groups. Most of the participants were male but no statistically significant (p>0.05) difference in gender between the positive and negative groups. The differences of socio-economic condition and residence in the frequencies and percentages between the groups were not statistically significant (p>0.05).

Table III
Association between demographic characteristics with Anti HBc (total) category (*n*=50).

Characteristics		Anti HBc-Positive (n=11)		Anti HBc-Negative (n=39)		P-value
		n	%	n	%	
Age in year	10	3	27.3	16	41.0	[a]0.631[ns]
	11-15	3	27.3	6	15.4	
	16-20	2	18.2	6	15.4	
	21-25	3	27.3	2	5.1	
	26-30	0	0.0	3	7.7	
	31-35	0	0.0	2	5.1	
	>35	0	0.0	4	10.3	
	Mean ± SD	15.4±5.3		17.0±10.8		
	Range (min-max)	(9-22)		(6-40)		
Gender	Male	9	81.8	31	79.5	[b]0.618[ns]
	Female	2	18.2	8	20.5	
Socio Economic Condition	Middle	2	18.2	10	25.6	[b]0.472[ns]
	Poor	9	81.8	29	74.4	
Residence	Urban	3	27.3	18	46.2	[b]0.221[ns]
	Rural	8	72.7	21	53.8	

ns =not significant; [a]p value reached from Unpaired t-test; [b]p value reached from Fisher's exact test

Table IV presents the association between the type of hemophilia with Anti HBc (total) category. The associations between the type of hemophilia with Anti HBc (total) category were not statistically significant (p>0.05), indicating that there was no strong evidence of an association between the type of hemophilia with Anti HBc (total) category.

Table IV
Association between the type of hemophilia with Anti HBc (total) category (*n*=25).

Type of hemophilia	Anti HBc-Positive (n=6)		Anti HBc-Negative (n=19)		P-value
	n	%	n	%	
A	4	66.7	18	94.7	0.132 [ns]
B	2	33.3	1	5.3	

ns =not significant; p value reached from Fisher's exact test

Table V presents the association between the type of Thalassemia with Anti HBc (total) category. The associations between the type of Thalassemia with Anti HBc (total) category was not statistically significant (p>0.05), indicating that there was no strong evidence of an association between the type of Thalassemia with Anti HBc (total) category.

Table V
Association between the type of Thalassemia with Anti HBc (total) category (*n*=25).

Type of thalassemia	Anti HBc-Positive (n=5)		Anti HBc-Negative (n=20)		P-value
	n	%	n	%	
BTM	4	80.0	10	50.0	0.244[ns]
Eβ	1	20.0	10	50.0	

ns =not significant; p value reached from Fisher's exact test

Table VI shows that there was no statistically significant association between transfusion-related variables and Anti-HBc (Total) status. Although Anti-HBc–positive patients had a lower mean age at first transfusion and a higher mean number of transfused units compared to Anti-HBc–negative patients, these differences were not significant (p>0.05). The usual interval between transfusions was also not associated with Anti-HBc (Total) positivity.

Table VI
Association Between Transfusion-Related Variables and Anti-HBc (Total) Status (*n* = 50).

Variable		Anti HBc-Positive (n=11)		Anti HBc-Negative (n=39)		P-value
		N	%	n	%	
Age at first transfusion (years)		1.67 ± 1.80		2.82 ± 2.94		0.225[ns]
Total units transfused		27.36 ± 19.12		23.82 ± 18.77		0.584[ns]
Usual transfusion interval	0.5 month	2	18.2	5	12.8	0.965[ns]
	1 month	7	63.6	24	61.5	
	2 months	1	9.1	5	12.8	
	3 months	1	9.1	4	10.3	
	6 months	0	0.0	1	2.6	

ns =not significant; p value reached from Fisher's exact test

Table VII shows the association between H/O transfusions other than BSMMU (Bangabandhu Sheikh Mujib Medical University), with Anti HBc (total) category. There was a statistically significant (p<0.005) association between H/O blood transfusion other than BSMMU with Anti HBc (total) category.

Table VII
Association between H/O receiving transfusions from multiple centers with Anti HBc (total) category (*n*=50).

H/O receiving Blood Transfusion from multiple center	Anti HBc-Positive (n=11)		Anti HBc-Negative (n=39)		P-value
	n	%	n	%	
Yes	11	100.0	10	25.6	0.001[s]
No	0	0.0	29	74.4	

s = significant; p value reached from Fisher's exact test

Table VIII shows the association between history of hepatitis B immunization with Anti HBc (total) category. There was no statistically significant (p>0.05) association between history of hepatitis B immunization with Anti HBc (total) category.

Table VIII
Association between history of hepatitis B immunization with Anti HBc (total) category (*n*=50).

H/O hepatitis B Immunization	Anti HBc-Positive (n=11)		Anti HBc-Negative (n=39)		P-value
	n	%	n	%	
Yes (n=35)	6	17.1	29	82.9	0.205[ns]
No (n=15)	5	33.3	10	66.7	

ns =not significant; p value reached from Fisher's exact test

DISCUSSION

Despite the implementation of rigorous infection screening protocols at Bangabandhu Sheikh Mujib Medical University (BSMMU) before every blood transfusion, some multi-transfused patients were still found infected with transfusion-transmitted infections such as hepatitis B virus (HBV) and hepatitis C virus (HCV). This situation raises concerns regarding the limitations of conventional screening methods. One possible explanation is the presence of asymptomatic donors in the window period, during which hepatitis B surface antigen (HBsAg) cannot be detected by routine immunological tests. Another possibility is occult HBV infection, characterized by the absence of detectable HBsAg despite the presence of HBV DNA in the liver or serum [17]. In addition, rapid immunochromatographic (ICT) screening methods used in some settings may have limited sensitivity in detecting certain HBV serotypes, which could result in missed infections [6]. To minimize these risks, nucleic acid testing (NAT) has been recommended because it detects HBV DNA and significantly reduces the window period, thereby improving the safety of blood transfusion [18].

This cross-sectional study aimed to determine the prevalence of HBsAg and Anti-HBc antibodies among multi-transfused thalassemic patients receiving red cell concentrate (RCC) and hemophilic patients receiving fresh frozen plasma (FFP). A total of 50 multi-transfused patients (25 thalassemia and 25 hemophilia) attending the Department of Transfusion Medicine, BSMMU, Dhaka, between July 2022 and June 2023 were included. All patients had received more than ten transfusions and were aged between 5 and 40 years.

In this study, the overall prevalence of Anti-HBc positivity was 22.0% among the study participants. Similar studies have reported varying prevalence rates of HBV infection among multi-transfused patients. Bhuyan et al. (2021) reported a prevalence of 3.37% HBV infection among thalassemia patients in Bangladesh [19]. Tognon et al. (2020) screened 29,713 donors and found an overall HBV infection prevalence of 10.8% [20]. Mishra et al. (2020) reported 1.5% HBsAg positivity among multi-transfused β-thalassemia major patients [21], while Al-Moshary et al. (2019) detected HBV infection in 4.87% of β-thalassemia major patients [22]. In Bangladesh, Chakrabarty et al. (2014) reported 6.5% HBsAg positivity among multi-transfused thalassemia patients [23]. However, some studies reported no HBsAg positivity, which is consistent with the findings of the present study [24].

In the current study, all participants were negative for HBsAg, although a considerable proportion showed Anti-HBc positivity, suggesting previous exposure to HBV infection. The mean age of the participants was slightly lower in the Anti-HBc positive group compared with the negative group; however, the difference was not statistically significant (p>0.05). Tognon et al. (2020) also reported that HBV infection was associated with younger age in transfused patients [20]. Most participants in this study were male, which is expected because hemophilia is an X-linked genetic disorder affecting males.

Socioeconomic status and place of residence did not show any statistically significant association with Anti-HBc positivity in this study. However, previous research in Bangladesh has suggested that lower socioeconomic status and overcrowded living conditions may contribute to higher HBV prevalence [25,26].

No significant association was observed between Anti-HBc positivity and factors such as type of hemophilia, type of thalassemia, age at first transfusion, total units of transfusion, or interval between transfusions (p>0.05). Similar findings were reported by Bhuyan et al. (2021) [19]. However, receiving blood transfusions from multiple centers outside BSMMU showed a statistically significant association with Anti-HBc positivity (p<0.005). This finding indicates that transfusions from different sources may increase the risk of exposure to inadequately screened blood [20,27].

Vaccination history also appeared to influence HBV exposure. A higher proportion of Anti-HBc negative participants had received hepatitis B vaccination, which supports the protective effect of immunization. Previous studies have also demonstrated that vaccination significantly reduces the risk of HBV infection among transfusion-dependent patients [28,29].

Overall, the findings of this study emphasize the importance of strict donor screening, improved blood safety practices, HBV vaccination, and the implementation of NAT-based screening methods to minimize the risk of transfusion-transmitted infections among multi-transfused patients [30].

CONCLUSION

This hospital-based cross-sectional study demonstrates that, although no active Hepatitis B virus infection was detected among multi-transfused thalassemic and hemophilic patients receiving RCC and FFP (as evidenced by 100% HBsAg negativity), a considerable proportion (22.0%) showed Anti-HBc (total) positivity, indicating previous exposure to HBV. This finding highlights the presence of occult or past HBV infection despite routine donor screening practices.

Most demographic factors, disease type (thalassemia or hemophilia), transfusion-related variables (age at first transfusion, total units transfused, and transfusion interval), type of blood component, and hepatitis B vaccination history were not significantly associated with Anti-HBc positivity. However, a history of receiving blood transfusions from multiple centers other than BSMMU emerged as a significant risk factor, underscoring the variability in transfusion safety standards across different facilities.

These results emphasize that standard HBsAg-based screening alone may be insufficient to fully prevent transfusion-transmitted HBV infection in multi-transfused patients. Incorporation of Anti-HBc testing and nucleic acid testing (NAT) into routine donor screening, along with strengthening centralized transfusion services and ensuring complete hepatitis B vaccination coverage, is crucial to further reduce residual HBV transmission risk. Continuous surveillance and improved transfusion safety measures are essential to protect this vulnerable patient population.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Radiographic Detection of Postmenopausal Osteoporosis Using Dental Panoramic Imaging among Bangladeshi Women

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ABSTRACT

Background: Osteoporosis is a major public health concern among postmenopausal women, particularly in low-resource settings where access to bone densitometry is limited. Dental panoramic radiography may offer a simple, cost-effective alternative for early identification of women at risk of low bone mass. **Objective:** To assess mandibular cortical morphology and radio morphometric indices on panoramic radiographs for detecting radiographic features of osteoporosis among postmenopausal Bangladeshi women. **Methods & Materials:** This cross-sectional descriptive study was conducted at the Department of Oral and Maxillofacial Radiology, Dhaka Dental College Hospital from July, 2022 to June, 2023. Panoramic radiographs of 50 randomly selected postmenopausal women aged 50–80 years were evaluated. The Mandibular Cortical Index (MCI), Mental Index (MI), and Panoramic Mandibular Index (PMI) were measured using standard methods. **Results:** Normal mandibular cortices (C1) were observed in 32.0% of participants, while 28.0% had moderately eroded cortices (C2) and 40.0% exhibited severely eroded cortices (C3). Nearly half (46.0%) had MI values below 3 mm, and 62.0% had PMI values below 0.30. Based on combined indices, 38.0% of the women were categorized as having radiographic features suggestive of osteoporosis. **Conclusion:** A substantial proportion of postmenopausal Bangladeshi women demonstrated radiographic indicators of osteoporosis. Panoramic imaging offers potential as an adjunctive, low-cost tool for early detection of osteoporosis, particularly in regions where advanced diagnostic facilities are unavailable.

Keywords: *Postmenopausal osteoporosis, Dental panoramic radiography, Mandibular cortical index, Mental index*

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INTRODUCTION

Osteoporosis is a skeletal, systemic chronic condition which is marked by loss of bone mass and bone microarchitecture resulting in loss of bone fragility and predisposition to fracture [1,2]. According to the World Health Organization (WHO), osteoporosis is quantitatively defined as bone mineral density (BMD) 2.5 standard deviations or less when compared to the norm of the young adult age, which is measured by dual-energy X-ray absorptiometry (DEXA) [1]. Even though the disease is silent, it ends in fracture of bones which is the first and most devastating clinical manifestation of the disease. These fractures have significant personal and social effects, such as chronic pain, loss of mobility, and dependence in their daily functioning [3]. The fact that osteoporosis presents silently and is often not diagnosed early enough and has not been screened sufficiently has made it to become a leading public health issue in both low and high-income countries. Osteoporosis and associated with low bone mineral density (LBMD) have increased in burden worldwide, as demographic ageing has increased. The Global Burden of Disease Study estimated that LBMD has over 438,000 deaths and over 16 million disability-adjusted life-years (DALYs) in 2019, nearly doubling the burden in 1990 [2]. Osteoporosis is a condition that is currently estimated to impact 200 million individuals across the globe, with one out of every three females and one out of every five males over the age of 50 years having a good chance of having an osteoporosis related fracture at some point in their lives [1,3]. Hip fractures are considered the most damaging of the consequences and nowadays one-year mortality rates vary between 20% and 30% of the population regardless of modern orthopedic and rehabilitative treatment [4]. These fractures are extending significant socioeconomic pressure due to the long hospitalization, institutionalization, and productivity loss [5]. Preventive measures and early detection of people at risk although there has been a breakthrough in pharmacological management is paramount in minimizing the fracture load in the world. The issue in South and South-East Asia is augmented by ageing of population, lack of nutritional adequacy and lack of screening opportunities [6]. Women of South Asian ancestry are particularly susceptible because of reduced skeletal structure, reduced peak bone mass and widespread vitamin D deficiency, which in combination with each other makes them vulnerable to premature bone loss and fragility fractures [6]. The country, Bangladesh, which is a lower-middle-income country with a fast-growing ageing population of women, represents this emerging crisis. It has been estimated that the number of women above 50 years of age will grow significantly in the next few decades and recent statistics have shown that osteoporosis and osteopenia is very common among the Bangladeshi women [7,9]. According to Begum and others, 50% of all over 50-year-old women living in Bangladesh exhibited low bone mass through the use of the DEXA scanner, and the same data were also found in rural and urban regions, indicating that socioeconomic disparities have played a limited protective role [8]. Ali et al. confirmed these results by heel quantitative ultrasound and they discovered that 45% of women aged above 50 years had suboptimal bone quality especially women who had a low body mass index (BMI), who consumed insufficient calcium in their diets and did not engage in physical activity [7]. According to the results of recent local and regional studies, the epidemiological processes related to osteoporosis in Bangladesh are similar to those in neighbouring South Asia countries

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like India and Nepal where prevalence rates and lack of awareness remain high [6,9]. The Kha et al. study in Bangladesh indicated that 63% of postmenopausal women had osteopenia or osteoporosis and that there were significant correlations between age and parity as well as the nutritional status and physical inactivity [9]. However, in contrast to most of the developed environments, there is practically no population-based screening initiatives, and the access to the diagnostic gold standard, DEXA, in Bangladesh is restricted to the tertiary centres in urban areas. As a result, most women are yet to be diagnosed until they have fractures. Estrogen deficiency after menopause is the leading pathophysiologic process involved in postmenopausal osteoporosis that initiates an increase of bone resorption as compared to bone formation leading to a rapid loss of trabecular bone volume and structural integrity [10]. Nonetheless, in the Bangladeshi setting, hormonal deterioration is not merely one of a number of convergent factors that increase bone loss. Deficiencies in nutrients are widespread and national dietary surveys have continued to record unacceptable calcium consumption and prevalence of vitamin D deficiency in women [11,13]. A survey by Ahmed et al. found that 78% of the postmenopausal women in tertiary care hospitals in Dhaka were deficient in vitamin D and this was strongly linked with reduced lumbar and femur neck BMD [12]. Similarly, Islam et al. (2010) showed that supplementation with calcium and vitamin D increased levels of serum 25(OH)D and bone density in Bangladeshi women which confirms the fact that these nutritional risk factors can be modified [11]. To worsen these shortcomings are the lifestyle factors including low amount of sun exposure, the customary mode of dressing, reduced levels of physical activity, and multiparity, which all lead to cumulative bone demineralization [9]. All this makes postmenopausal Bangladeshi women especially vulnerable to undiagnosed low bone mass and fragility fracture [7,14]. Nevertheless, osteoporosis is undiagnosed and underreported in Bangladesh with no cost-effective diagnostic methods and poor knowledge of the community [6]. There is growing interest in the use of more convenient modalities of identifying the precursors of bone loss as DEXA facilities are only available in specialised centres. A potential adjunctive tool in identifying postmenopausal women potentially at risk of osteoporosis has been suggested to be dental panoramic radiography, as one of the routine imaging modalities in dental and maxillofacial practice [7]. The radiomorphmetric indices of the mandibular cortex including the mandibular cortical index (MCI), mental index (MI), and panoramic mandibular index (PMI) have demonstrated strong correlations with systemic BMD in various groups of people. Since panoramic imaging is highly available, and relatively cheap particularly in the urban dental set ups in Bangladesh, an assessment of its diagnostic utility in the detection of osteoporosis can offer a pragmatic and generalizable intervention in the early detection of risk. Thus, the current research will evaluate the radiographic appearance of the mandibular cortex using dental panoramic records in postmenopausal Bangladeshi women and establish the percentages of women who show radiographic signs of osteoporosis. Through this, this work aims at adding to the accumulating evidence that dental panoramic radiography has the potential to be a low-cost adjunct to early detection of osteoporosis in resource-constrained environments.

METHODS & MATERIALS

The study is a cross-sectional descriptive study that was done in the Department of Oral and Maxillofacial Radiology, Dhaka Dental College Hospital, Dhaka, Bangladesh from July, 2022 to June, 2023. The radiology department provided a random sample of 50 postmenopausal women between the age of 50 and 80 years to obtain panoramic radiographs. Women were chosen as postmenopausal when their menstrual period was gone or at least a few months and they were clinically deemed to be at the postmenopausal phase. The radiographs of sufficient quality, with clearly visualised mandibular inferior cortices and mental foramina on both sides were included. All the images were obtained with the help of the Gendex Orthoralix 9200 panoramic X-ray unit according to the standard exposure procedure of the department and analyzed and measured through VixWin Platinum software to evaluate the morphology and thickness of the mandibular inferior cortex. In every radiograph, the bilateral visual inspection of mandibular cortical shape was assessed based on the Mandibular Cortical Index (MCI, Klemetti index) and classified into C1, C2, or C3. With category C1, the endosteal margin of the mandibular cortex is flat and sharp, indicating a normal cortex; category C2 indicates semilunar defects or endosteal cortical residues, indicating mild to moderate erosion; and category C3 indicates erosion of the cortical layer which is gross and with noticeable porous characteristics, indicative of osteopenia. The mental index (MI) which is a measure of mandibular cortical width in the area of the mental foramen was determined by first locating the mental foramen, then drawing a tangent along the anterior border of the mandible, and subsequently a line perpendicular to this tangent which passed through the centre of the mental foramen; the cortical width was measured at this point of the line crossing the inferior cortex. Panoramic mandibular index (PMI) was obtained as the ratio of cortical width at the area of mental foramen (MI) to the distance between the lower end of the mandible and the lower end of the mental foramen (MI/h). To describe it, MI values lower than 3 mm and PMI values lower than 0.3 were regarded as indicative of decreased mandibular cortical thickness; and values above it were regarded as within the normal range. The MCI group of each of the participants, MI, and PMI were noted and a combined radiographic evaluation was conducted to categorize the women into having or not having features that indicated osteoporosis. Measurement on digital images on a calibrated monitor was done at a standardised magnification by a trained dental radiology observer. The summary of the data was done using descriptive statistics and the findings are displayed in form of frequencies and percentages.

RESULTS

The distribution of mandibular cortical morphology showed that 32.0% of women demonstrated a normal cortex (C1), while 28.0% exhibited mild to moderate endosteal erosion (C2). The largest proportion, 40.0%, presented with severely eroded and porous cortices (C3), indicating that nearly half of the study population showed cortical features commonly associated with low bone mass (*Table I*).

Table I
Distribution of Mandibular Cortical Shape (Mandibular Cortical Index, MCI).

Cortical shape category	n	%
C1: Sharp and even endosteal margin (normal)	16	32.0
C2: Mild to moderately eroded cortex	14	28.0
C3: Severely eroded, porous cortex	20	40.0
Total	50	100.0

The mental index assessment revealed that 54.0% of participants had a cortical width of 3 mm or greater, whereas 46.0% had MI values below 3 mm. Nearly half the sample demonstrated reduced cortical width at the mental foramen region, a radiographic feature suggestive of diminished mandibular bone mass (*Table II*).

Table II
Mental Index (MI) Categories Among Postmenopausal Women (*n* = 50).

Mental index category	n	%
MI ≥ 3 mm	27	54.0
MI < 3 mm	23	46.0
Total	50	100.0

Panoramic mandibular index values showed that only 38.0% of women had PMI measurements of 0.30 or greater. The majority, 62.0%, had PMI values below 0.30, indicating a high proportion of participants with reduced mandibular cortical thickness relative to mandibular height—an additional marker consistent with low bone density (*Table III*).

Table III
Panoramic Mandibular Index (PMI) Categories Among Postmenopausal Women (*n* = 50).

Panoramic mandibular index category	n	%
PMI ≥ 0.30	19	38.0
PMI < 0.30	31	62.0
Total	50	100.0

The combined radiographic assessment categorized 62.0% of women as non-osteoporotic based on cortical morphology and mandibular indices, while 38.0% were classified as osteoporotic (*Table IV*).

Table IV
Overall Radiographic Classification Based on Mandibular Indices (*n* = 50).

Radiographic classification*	n	%
Non-osteoporotic	31	62.0
Osteoporotic	19	38.0
Total	50	100.0

*Note. *"Osteoporotic" defined as presence of C3 cortical category and, or MI < 3 mm and, or PMI < 0.30 on panoramic radiography.*

DISCUSSION

The current research estimated the usefulness of dental panoramic radiography in screening postmenopausal osteoporosis in Bangladeshi women using three mandibular indices, including Mandibular Cortical Index (MCI), Mental Index (MI) and Panoramic Mandibular Index (PMI). The results showed that 40.0% of the respondents had a severely eroded porous cortical margin (C3), 28.0% had mild to moderate cortical erosion (C2), and only 32.0% had normal cortical outline (C1). This implies that almost two-thirds of the study population had radiographic signs of cortical atrophy, which is an indication of poor mandibular bone quality. Similar distributions have been seen in other international studies which supports the validity of cortical morphology as a proxy measure of systemic bone loss. As an example, Popic et al. found out that C3 pattern was demonstrated by 57.4% of osteoporotic women, and the C2 and C3 categories were also very high in the postmenopausal women (Munhoz et al., Grocholewicz et al.) [15-17]. Likewise, Nemati et al. discovered that the level of cortical erosion above age and duration of menopause was increasing in a progressive manner which suggests that mandibular cortical alterations are closely related to the systemic skeletal demineralization [18]. This trend was also supported by the Mental Index (MI) and Panoramic Mandibular Index (PMI). The current analysis found that 46.0% of women had a MI value of less than 3 mm and 62.0% had a PMI value of less than 0.30, which are typical values of lowered cortical bone mass. This data is consistent with the results of Mudda et al., who have mentioned much lower MI and PMI scores in postmenopausal women than in those before menopause in Indian women [19]. Grocholewicz et al. have obtained the same mean MI and PMI values (3.31 mm and 0.33, respectively), which confirms that a low percentage of mandibular cortical width and mandibular height are also expected radiographic findings of low bone mineral density [17]. In a number of other studies, such as Popica and Balto and others, statistically significant correlations were reported between MI, PMI and the scores of bone mineral density by DEXA [15,20]. It is worth noting that Balto et al. reported that PMI cutoff of 0.41 would have high sensitivity and specificity to osteoporosis, whereas Carmo and Medeiros were able to confirm that MI below 3 mm would be highly predictive of low lumbar and femoral BMD [20,21]. The fact that these results are comparable with the results of the current Bangladeshi cohort highlights the relevance of mandibular indices as stable radiographic variables in ethnic and geographic backgrounds. A combination of the three indices showed that 38.0% of women were in the radiographic features of osteoporosis, and 62.0% were between the non-osteoporotic. This percentage of radiographic osteoporosis is in agreement with other findings made in other countries. According to Gaur et al., a concomitant measure of MCI, MI, and PMI was found to have a sensitivity and specificity of 100 and 88.8%, respectively, with respect to the use of DEXA [22]. On the same note, Valerio et al. also presented a significant inter-group variation in all the three indices ($p < 0.05$) and indicated that the combined panoramic indices could better identify low bone density cases at the early stages [23]. Balto et al. also validated the usefulness of multi-index analysis in a larger Saudi cohort, and multi-

index analysis demonstrated significantly better diagnostic performance than the indices used individually [20]. Kolte et al. and Abdinian and Milaei also found statistically significant correlations between MCI, MI, and PMI, which is why it is beneficial to use multi-parameter assessment to correctly classify osteoporotic risk [24,25]. The incidence of cortical erosion (C2 and C3), low MI and PMI values, and a combined 38% rate of radiographic osteoporosis, all of which are evident in this case, all indicate the presence of a significant undetected low bone mass in postmenopausal Bangladeshi women. This observation is especially applicable in an environment where there is a lack of DEXA facilities, and more affordable screening methods are urgently required. Likewise, other studies done in Europe, the Middle East, South Asia have also made similar conclusions that dental panoramic imaging has a promising role to play in screening osteoporosis [26-28]. The consistency of these results in the various populations favors the possibility of using panoramic radiography as a screening tool beforehand in a dental or radiology department, particularly in resource-deprived areas. Hence, the present study adds more insights to the existing body of research that regular dental panoramic imaging, by evaluating mandibular cortical morphology and radiomorphmetric indices, can be a useful low-cost supplemental procedure used in the timely detection of postmenopausal females who have a potential risk of osteoporosis.

LIMITATIONS

The current research had the following weaknesses because the sample size used was very small, and no confirmatory bone mineral density (BMD) test had been done with DEXA thus limiting the scope of diagnostic sensitivity and specificity. Furthermore, it was also descriptive and single-centered, which did not allow generalizing the results to the whole population of the country.

CONCLUSION

In this study, the proportion of postmenopausal Bangladeshi women whose radiographic features are indicative of osteoporosis when assessed by dental panoramic radiography was found to be significant. The large proportions of severely eroded mandibular cortices (C3), low mental index (MI < 3 mm), and low panoramic mandibular index (PMI < 0.30) suggest that the weight of undetected low bone mass is high in this group. The fact that these findings have been similar to those of other researchers worldwide also indicates that dental panoramic radiograph, which is regularly taken in clinical practices, can be used as a beneficial ailment to diagnose osteoporosis at an early stage in resource-strained conditions.

RECOMMENDATION

More multicentric, large-scale research, that is using DEXA validation, is necessary to establish the diagnostic validity of mandibular indices in screening osteoporosis. Education of dental practitioners on how to detect cortical erosion and low mandibular indices on panoramic views might help improve the detection of cases at an early stage. It is possible that a cost-effective public health measure involving the screening of postmenopausal women in Bangladesh with opportunistic radiographic osteoporosis through routine dental and radiology practice.

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The study was approved by the Institutional Ethics Committee

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THE PLANET

Original Article

Antimicrobial Resistance Patterns and Phenotypic Profiles of Pseudomonas aeruginosa Isolated from Clinical Samples

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ABSTRACT

Background: Pseudomonas aeruginosa is a significant concern among hospital-acquired pathogens, due to the growing resistance to antibiotics, particularly colistin and carbapenems. The goal of this study was to determine the resistances and phenotypes of P. aeruginosa strains obtained from clinical samples. **Methods & Materials:** This cross-sectional study, conducted at the Department of Microbiology, Dhaka Medical College in 2019, analyzed 350 clinical samples using standard microbiological and molecular techniques to identify Pseudomonas aeruginosa and assess antimicrobial resistance. Susceptibility testing was performed via disc diffusion and MIC methods, with PCR used to detect resistance genes. In vivo efficacy of various antibiotic regimens was evaluated in mice models. Data were analyzed using SPSS version 26. **Results:** Among 236 bacterial isolates, P. aeruginosa was found to constitute 26.69% (n=63), mostly from wound swabs (66.67%). High levels of resistance were found to ceftriaxone (82.54%), ceftazidime (74.60%), and amikacin (74.60%). The incidence of multi-drug resistance was found to be 61.90%, of which 19.05% had extensive drug resistance, while 6.35% had pan-resistance. The overall colistin resistance was found to be 19.05%, while the detection of both pmrC and phoP genes was found to occur in 50% of colistin-resistant strains. Carbapenemase was detected in 85.71% of imipenem-resistant strains. **Conclusion:** High levels of multidrug, extensive, and pan-resistance in P. aeruginosa isolates were alarming. The colistin-imipenem combination appeared to possess encouraging effectiveness against resistant isolates, justifying assessment for therapeutic use.

Keywords: *Pseudomonas aeruginosa, Antimicrobial resistance, Colistin resistance, Carbapenemase.*

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INTRODUCTION

Pseudomonas aeruginosa is a Gram-negative opportunistic pathogen that results in morbidity and fatality in nosocomial related infections, particularly in immunocompromised patients, and at intensive care units [1]. The Pseudomonas species that is widely distributed possess a high level of adaptability and intrinsic resistance to a large range of drugs. Pseudomonas has a capability of forming biofilms, which helps it to survive in hospital conditions [2]. The adaptability of this versatile pathogen to survive in the low nutrient environment makes it stand out and be a significant cause of nosocomial infections in many countries across the world [3]. The world has been experiencing a significant problem in treatment, the development of multi-drug resistant (MDR), extensively drug-resistant (XDR), and pan-drug-resistant (PDR) strains of P. aeruginosa, which in turn have been increasing the cost of healthcare as managing the infection of such bacteria is becoming more difficult [4]. The resistance to carbapenems as the last-resort antibiotics in the infection caused by Pseudomonadales has been increasing due to the evolution of carbapenemase-producing bacteria through gene transfer and chromosomal mutations that altered the susceptibility of carbapenems in the targeted bacteria because of the changes that occurred in the cell wall permeability of the bacteria [5]. Also rediscovered in response to the increased cases of resistance, colistin, a polymyxin antibiotic, has been named as a prime drug against MDR/Xenodrug-resistant (XDR) Gram-negative pathogens [6,7]. Despite this, there has been increase in resistance to colistin in P. aeruginosa, which is due to the mutations in two-component regulatory systems as pmrAB and phoPQ, resulting in lipopolysaccharides changes, which inhibits the binding of antibiotics [8]. Even more importantly, the discovery of plasmid-mediated colistin resistance genes (mcr-1 through mcr-5) in Enterobacteriaceae has been a cause of concern, whereas in Pseudomonas, their functions are ill-defined [9]. Antimicrobial resistance is also a very high issue in resource limited settings such as the South Asian region because of numerous factors including the inappropriate use of antimicrobials, poor infection control practices, and the lack of competence in diagnosis [10]. It is known that Bangladesh is experiencing dramatic issues in terms of hospital-acquired infections as well as antimicrobial resistance, yet the information about the resistance profile and the mechanism of P. aeruginosa is horrendously scarce and untapped [11]. There is increasing resistance to the use of the available antimicrobials, and the inability to respond to treatment is accumulating. Combination antimicrobial therapy has taken a fresh significance in terms of its suitability in combating any resistant strain and its suitability to prevent the development of resistance. The objective of the research is to determine the patterns of antimicrobial resistance of P. aeruginosa of clinical origin, resistance phenotyping, including MDR, XDR, and PDR, genes involved in colistin resistance, and combined antibiotics against MDR.

METHODS & MATERIALS

The current cross-sectional research was conducted in the Department of Microbiology, Dhaka Medical College, between January and December 2019 on 236 samples of culture-positive bacterial samples to detect P. aeruginosa. The samples taken included wound swabs, urine, endotracheal aspirates (ETA) and blood samples of adult inpatients and ICU patients, which were taken aseptically. The data gathered such as the demographics was captured on a pre-designed sheet and the data was processed and analysed using Microsoft Excel. The culture and sensitivity tests were done under the standard protocols

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of microbiological tests using media like blood agar, MacConkey agar and Mueller-Hinton agar. The identification of P. aeruginosa and other Gram-negative organisms was performed based on the study of the colony features, Gram staining, and biochemical analysis. The susceptibility tests were done by modified Kirby- Bauer disk diffusion for antimicrobial susceptibility tests, and through agar dilution minimum inhibitory concentration of colistin resistance was determined. Validation was done by using control strains (E. coli ATCC 25922). Producers of extended-spectrum beta-lactamase, carbapenemase and Metallo beta-lactamase were identified using the double-disk synergy, combined disk and modified Hodge tests. Combination studies of antibiotic combinations such as imipenem, colistin and amikacin were evaluated using agar dilution and FICI values were read. Detection of resistance genes mcr-1 through mcr-5, pmrAB, C, phoPQ was done using Polymerase chain reaction where DNA was extracted using E. coli pellets, amplified using thermal cyclers and investigated using agarose gel electrophoresis. To determine homology in the sequenced E. coli strains, the sequenced strains were validated and subsequently confirmed through the use of BLAST analysis. In vivo experiments were carried out to investigate the in vivo emergence resistances in which Swiss Albino mice were exposed to resistant strains. Survivability was also monitored, and microbicidal clearance after the therapy was done by the blood culture. DMC provided ethical clearance, and the patients were kept confidential. Data analysis and processing were performed using SPSS software v 26.

RESULTS

Table I shows that *P. aeruginosa* was the most prevalent, constituting 26.69% (n=63). *Escherichia coli* was the next, making up 19.07% isolates, while *Klebsiella pneumoniae* was the third most prevalent, constituting 14.41%. Gram-positive bacteria, *Staphylococcus aureus* being the most preponderant, constituting 10.59% isolates, while other gram-negative organisms included *Enterobacter cloacae* (7.63%) and *Acinetobacter baumannii* (6.36%), respectively (*Table I*).

Table I
Distribution of organisms isolated from different samples (*n*=236).

Isolated Bacteria	n (%)
P. aeruginosa	63 (26.69)
Non-aeruginosa pseudomonas	4 (1.69)
E. coli	45 (19.07)
K. pneumoniae	34 (14.41)
K. oxytoca	2 (0.85)
P. mirabilis	11 (4.66)
P. vulgaris	3 (1.27)
Acinetobacter baumannii	15 (6.36)
C. freundii	4 (1.69)
C. koseri	2 (0.85)
E. cloacae	18 (7.63)
E. aerogenes	6 (2.54)
S. typhimurium	2 (0.85)
S. aureus	25 (10.59)
Coagulase-negative staphylococci	2 (0.85)

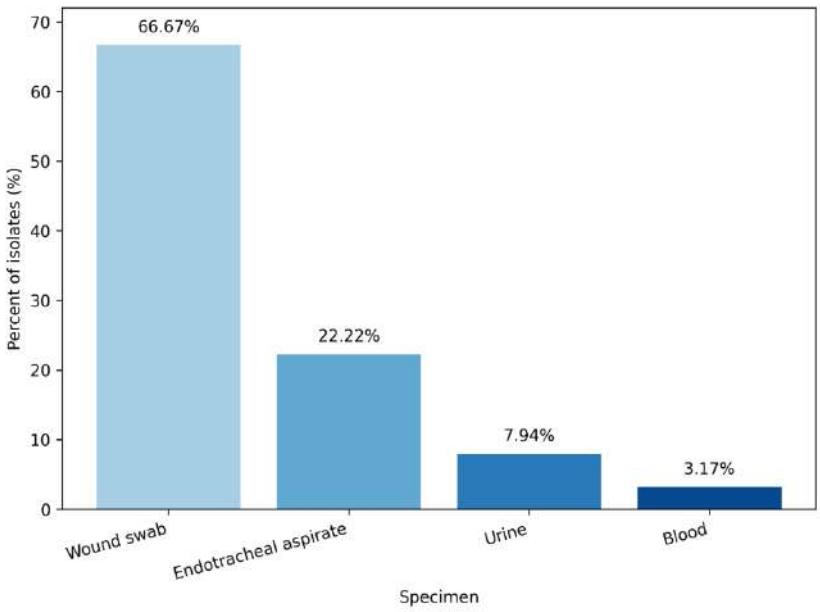

Figure 1 Distribution of *P. aeruginosa* isolates by specimen (*n*=63).

Figure 1 reveals that the isolates of *P. aeruginosa* were based on the type of samples, which gave dominance in wound swab samples, accounting for 66.67% of the isolates. The isolates from endotracheal aspirates comprised 22.22%, which is quite high, showing its prevalence in the respiratory tract, especially within ICUs. Urinary tract infection isolates comprised 7.94%, while blood isolates comprised the least, which is 3.17%.

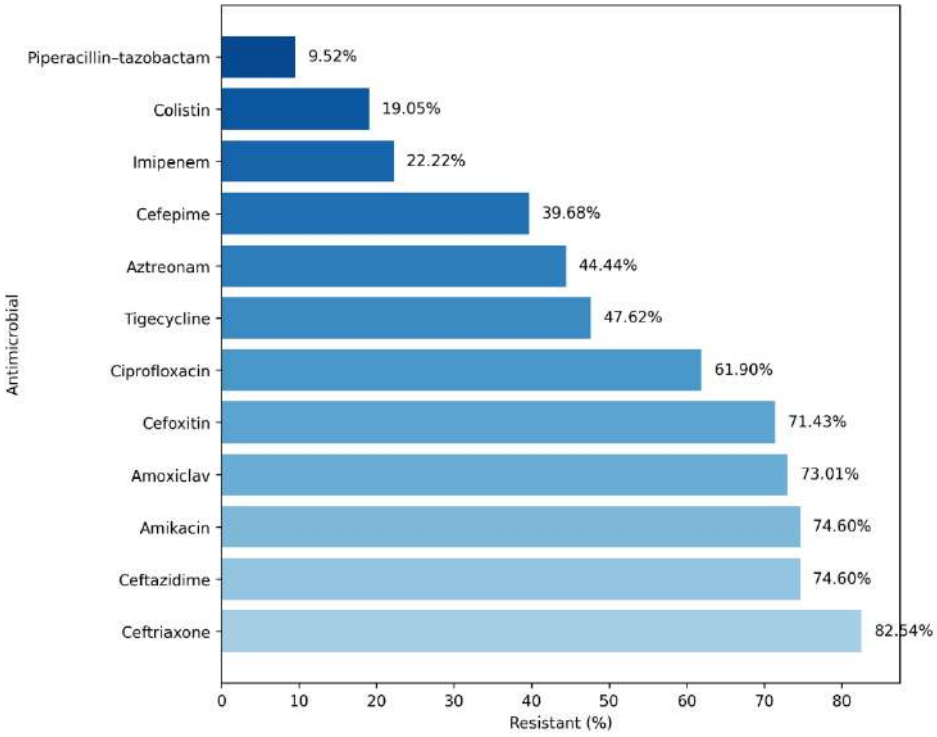

Figure 2 Antimicrobial resistance pattern in *P. aeruginosa* (*n*=63).

Figure 2 exhibits very high levels of antimicrobial resistance among the isolates of *P. aeruginosa*. Resistance to ceftriaxone showed a high frequency of 82.54% among isolates, followed by ceftazidime and amikacin, exhibiting resistances of both 74.60% respectively. Carbapenems, specifically imipenem, showed resistance among 22.22% isolates, and colistin among 19.05% isolates. It is notable that the lowest level of resistance was shown by piperacillin and tazobactam among all agents tested, with a value of 9.52%.

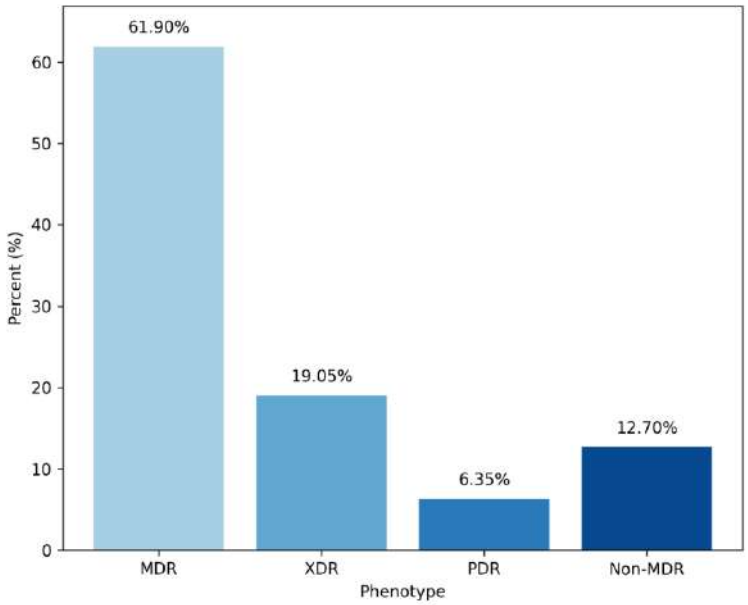

Figure 3 Resistance phenotype categories in *P. aeruginosa* (*n*=63).

Figure 3 illustrates that 61.90% of the isolates belonged to the MDR category, showing non-susceptibility to at least one drug in three or more classes of antimicrobials. The ExDR isolates contributed 19.05%. The pan-drug-resistant isolates showed resistance to all the tested drugs and contributed 6.35%. Only 12.70% belonged to the non-MDR category.

Table II indicates that among the 12 colistin-resistant *P. aeruginosa* isolates, wound swabs accounted for the highest proportion (58.33%), followed by endotracheal aspirates (25%) and urine (16.67%). All colistin-resistant isolates exhibited 100% co-resistance to ceftriaxone and ceftazidime, while resistance to amoxiclav was 91.67%. High levels of co-resistance were also observed with ciprofloxacin (83.33%), amikacin and cefoxitin (75%), and imipenem (58.33%). Moderate resistance was noted for cefepime and aztreonam (50% each), with lower rates for tigecycline (41.67%) and piperacillin–tazobactam (25%), reflecting a concerning multi-drug resistance pattern.

Table II
Colistin resistance in *P. aeruginosa*, distribution and co-resistance (*n*=12).

A. Distribution by specimen, plus specimen-level prevalence	
Specimen	**Colistin-resistant isolates, n (%)**
Wound swab	7 (58.33)
Endotracheal aspirate	3 (25.00)
Urine	2 (16.67)
Blood	0 (0.00)
B. Co-resistance pattern among colistin-resistant isolates (*n*=12)	
Antimicrobial	**Resistant, n (%)**
Ceftriaxone	12 (100.00)
Ceftazidime	12 (100.00)
Amoxiclav	11 (91.67)
Ciprofloxacin	10 (83.33)
Amikacin	9 (75.00)
Cefoxitin	9 (75.00)
Imipenem	7 (58.33)
Cefepime	6 (50.00)
Aztreonam	6 (50.00)
Tigecycline	5 (41.67)
Piperacillin–tazobactam	3 (25.00)

Table III depicts that the production of Extended-spectrum β-lactamases (ESBLs) was observed in 13 isolates of *P. aeruginosa* (20.63%). The highest proportion of ESBL-producing isolates was isolated from the samples of patient wound swabs (19%), and one from the endotracheal aspirates (1.5%).

Table III
ESBL phenotype in *P. aeruginosa* (*n*=63).

Specimen	ESBL-positive isolates, n (%)
Wound swab	12 (19)
Endotracheal aspirate	1 (1.5)
Urine	0 (0)
Blood	0 (0)

Table IV demonstrates that the total of 14 imipenem-resistant isolates of *P. aeruginosa*, the highest percentage of specimens was from the swabs of the wounds (78.57%), and the second highest was from the endotracheal aspirates (14.29%). Results from the carbapenemase test using the phenotypic technique showed that the highest positivity was seen in the combined disc test (85.71%), followed by the double-disc synergy test (64.29%), and then the modified Hodge test (28.57%). According to the imipenem MIC distribution, half of the isolates (50%) had a MIC of 32 µg/ml, while a significant portion showed high-level resistance with MIC values ≥128 µg/ml in 28.6% of cases, indicating significantly lower susceptibility among the isolates under study.

Table IV
Imipenem resistance and carbapenemase phenotype in *P. aeruginosa* (*n*=14).

A. Distribution of imipenem-resistant isolates	
Specimen	**Imipenem-resistant isolates, n (%)**
Wound swab	11 (78.57)
Endotracheal aspirate	2 (14.29)
Urine	1 (7.14)
Blood	0 (0.00)
B. Phenotypic carbapenemase detection among imipenem-resistant isolates (*n*=14)	
Method	**Positive, n (%)**
Combined disc assay	12 (85.71)
Double disc synergy test	9 (64.29)
Modified Hodge test	4 (28.57)
C. Imipenem MIC distribution (*n*=14)	
Imipenem MIC (µg/ml)	**n (%)**
≥256	2 (14.29)
128	2 (14.29)
64	1 (7.14)
32	7 (50.00)
16	1 (7.14)
8	1 (7.14)

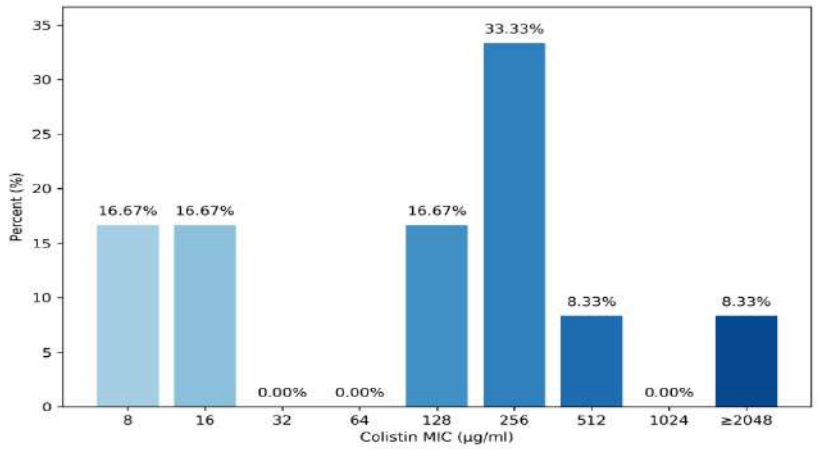

Figure 4 (A) Colistin MIC distribution (*n*=12).

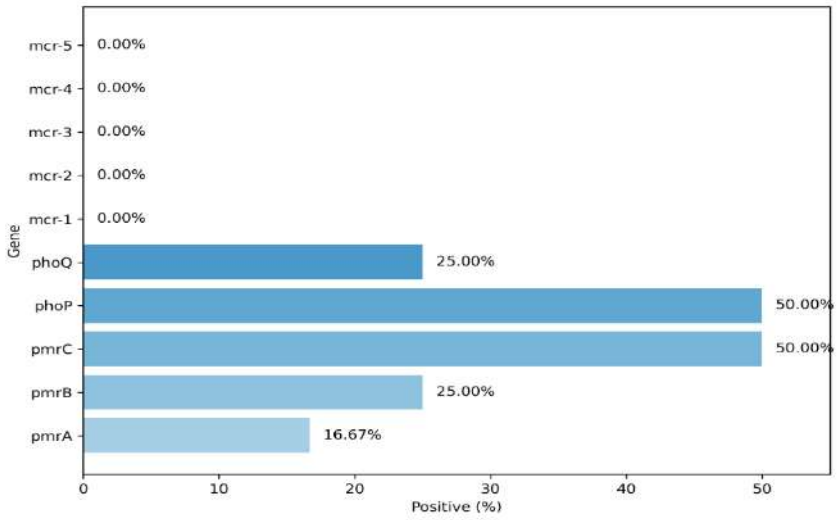

Figure 4 (B) PCR detection of resistance-associated genes among colistin-resistant isolates (*n*=12).

Figure 4 depicts the distribution of colistin MIC among the resistant isolates showed that there is heterogeneity, with 33.33% having an MIC of 256 µg/ml. There is one isolate that showed high resistance, with an MIC of >2048 µg/ml. Characterization of the resistant isolates showed that the genes pmrC and phoP were present in 50%, while the pmrB and phoQ genes were present in 25%, and the pmrA gene was present in 16.67% of the isolates that showed resistance to colistin.

Table V shows that colistin-imipenem displayed 100% synergy in vitro with a median FICI of 0.38, as well as complete in vivo microbial eradication. The imipenem-amikacin pair indicated 75% synergy (median FICI = 0.50) with complete in vivo efficacy. On the contrary, the results of colistin-amikacin indicated mostly indifferent interactions (75%) with a median FICI of 2.00 and a lack of in vivo efficacy. These results show that the imipenem/colistin pair has considerably higher therapeutic value against resistant strains of *P. aeruginosa*.

Table V
Combination efficacy against resistant *P. aeruginosa*, in vitro and in vivo summary.

Combination	Agar dilution MIC reduction, n (%) (n=4)	Checkerboard outcome, n (%) (n=4)	FICI median (range)	In vivo synergy (%)	In vivo blood culture negative, n=5, n (%)
Colistin + Imipenem	8-fold: 2 (50.00), 4-fold: 2 (50.00)	Synergy: 4 (100.00)	0.38 (0.25-0.50)	100	5 (100)
Imipenem + Amikacin	4-fold: 3 (75.00), 2-fold: 1 (25.00)	Synergy: 3 (75.00), Additive: 1 (25.00)	0.50 (0.50-1.00)	100	5 (100)
Colistin + Amikacin	2-fold: 1 (25.00), none: 3 (75.00)	Additive: 1 (25.00), Indifferent: 3 (75.00)	2.00 (1.00-2.00)	0	0 (0)

DISCUSSION

This paper presented thorough information about the pattern of antibiotic resistance and the phenotypic features of P. aeruginosa in Bangladesh. P. aeruginosa (26.69) was second in the list of clinical isolates because it is commonly known to be among the most common nosocomial infections found in healthcare facilities globally [12]. The high rate of isolates due to wound infections (66.67) goes hand in hand with its inherent virulence factor of colonization of injured epithelial surfaces, especially in surgical patients and persons with persistent wounds [13]. The resistance rates against the first-line antibiotics were surprisingly high with 82.54% resistant to ceftriaxone and 74.60% to ceftazidine. These levels of resistance are way higher in a report by Ranjar et al. [14]. But this should be the case, as the antimicrobial stewardship programs are not yet optimal in the majority of South Asian clinical facilities [15]. This trend is supported by the prevalence of healthcare settings that promote MDR, XDR and PDR phenotypes. It is also important to note that carbapenem resistance, which is also identified in the study as present in 22.22% of isolates is of particular concern in terms of therapeutic implications, since carbapenems were traditionally viewed as the last-line agents in the treatment of complicated Pseudomonas infections [16]. The phenotypic carbapenemase test yielded the expected results that only 85.71% of imipenem-resistant strains had enzyme production that is a strong indication that enzymatic mechanisms rather than impermeability/efflux mechanisms are the dominant mechanisms of resistance [6]. The variation in the ranges of distribution (16≥256 µg/ml) could either be due to fluctuating expression levels of the carbapenemase-producing gene or could also be due to the fact that the level of colistin resistance of 19.05% is a cause of concern due to the significance of the drug being a last resort drug in the presence of MDR and XDR gram negatives [17]. These are bigger than the results of Biswas et al., which is in line with the increasing figures of the countries where colistin is a leading consumer [18]. Genus level was characterized by chromosomal mutations in two-component systems of regulation, particularly in the genes that encode pmrC and PhoP (50% of the isolates positive) that mediate the alteration of lipopolysaccharides and thus reduces the affinity of colistin binding [19]. It is clear that the isolates tested negative in the mcr gene and this could mean that the colistin resistance in this area could be chromosome-based and that the possibility of horizontal transmission could be reduced compared to the mcr gene-carrying Enterobacteriaceae [20]. The co-resistance between the colistin-resistant isolates, e.g. 100% resistance to cephalosporins, and 58.33% resistance to carbapenems is very high, which is a dramatic decrease in the available chemotherapeutic options [21]. Instead, the fact that the piperacillin-tazobactam that remained 75 per cent susceptible in colistin-resistant isolates, points to efficacy, which has to be confirmed by the clinical outcomes studies and then definitive guidance can be provided [22]. Combination therapy with antibiotics was also a productive field, with colistin-imipenem being very synergistic (100% in vitro combination with 50% median FICI of 0.38) and full microbiologic regeneration of mice models. The explanation of this is probably due to the fact that colistin generates the degradation of outer membrane integrity since now imipenem can get in and inhibit cell wall synthesis as a mechanism of action [23]. It is remarkable that their profile of stronger combination is in comparison with colistin-amikacin (which is largely non-selective) creating rationale in methodologically-based combination therapy strategies. It is important to note that, on such data, such colistin-carbapenem combination therapy regimens must be investigated in clinical practice in infections caused by the susceptible or provisionally resistant strains, etc. [24].

LIMITATIONS

The study could be limited in terms of generalization because only one center was studied and the study is based on identification of carbapenemase using the phenotypic technique and does not involve the molecular examination of the beta-lactamase genes. The information in animal models would also need confirmation.

CONCLUSION

P. aeruginosa isolates were found to have exceptionally high proportions in relation to multidrug resistance, extensively drug-resistance, pan-drug resistance, high colistin resistance, and carbapenem resistance, effected mostly because of chromosome mutation and not plasmid-located genes. Colistin/imipenem combination exhibited synergistic interactions in vitro and was completely effective in vivo, and this would be useful in designing an effective treatment regimen in case of resistant isolates. These findings highlight the importance of proper antimicrobial use/utilization, strict infection and conscientiousness in selection of combination regimens in the management of severe cases of P. aeruginosa infection in resource- constrained settings.

RECOMMENDATIONS

Multi-center surveillance studies based on whole-genome sequencing should be employed in future studies that attempt to understand how resistance spreads. Conversely, the prospective studies will play an imperative role in the establishment of the most suitable treatment modalities in P. aeruginosa-resistant patients.

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CONFLICT OF INTEREST

None declared

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Fine Needle Aspiration Cytology in the Diagnosis of Neck Swelling

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ABSTRACT

Background: In otolaryngology practice, neck swellings are a common clinical presentation that can have a variety of causes, from benign inflammatory conditions to malignant neoplasms. For the preoperative assessment of neck masses, fine needle aspiration cytology (FNAC) has become a popular and reasonably priced diagnostic technique. This study sought to assess the diagnostic precision, sensitivity, and specificity of FNAC in identifying neck swellings. **Methods & Materials:** This descriptive cross-sectional study was conducted at the Department of Otolaryngology and Head and Neck Surgery, Dhaka Medical College Hospital from January 2024 to December 2024. Under aseptic conditions, FNAC was performed on 100 consecutive patients with neck swelling who satisfied the inclusion criteria using a 23-gauge needle. Histopathological analysis of surgically removed specimens was then used as the reference standard to correlate cytological diagnoses. Sensitivity, specificity, positive and negative predictive values, and overall accuracy were among the diagnostic performance metrics that were computed. **Results:** The mean age of the 53 male and 47 female participants in the study ranged primarily from 15 to 45 years. Thyroid lesions accounted for the largest proportion of neck masses (42%), followed by lymph node pathologies (35%), was made up of thyroid lesions. Malignant lesions made up 27% of cases, whereas benign and inflammatory lesions made up 73%. With an overall diagnostic accuracy of 87%, FNAC showed a sensitivity of 85.2%, specificity of 87.7%, positive predictive value of 71.9%, and negative predictive value of 94.1%. False-positive and false-negative results were found in 9% and 4% of cases, respectively. **Conclusion:** For assessing neck swellings, FNAC is a dependable, secure, and reasonably priced first-line diagnostic method with good specificity and tolerable sensitivity. Discordant cases require histopathological confirmation for a conclusive diagnosis and suitable therapeutic management, even though it greatly facilitates preoperative decision-making and minimizes needless surgical procedures.

Keywords: *FNAC, Neck Swelling, Neoplasm.*

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INTRODUCTION

Neck swellings are part of the clinical presentation of otolaryngology and head-neck surgery and they are considered to be one of the most common occurrence in both fields [1]. Among many disorders that may cause them, there are congenital defects, inflammatory lesions, benign neoplasma, and malignant tumor; all of them require a different approach to diagnosis and treatment [2]. The neck is anatomically a complex part of the body that is composed of lymphoid tissue, thyroid, salivary glands, and soft tissue structures and it is difficult to differentiate between the two entities [3]. Early and correct classification of benign and malignant pathology is important in order to treat with proper management; here unnecessary surgery in benign cases is prevented and immediate treatment with a malignancy is done. FNAC is an important diagnostic method used in the evaluation of palpable neck masses over the last four decades [4]. In this minimum invasive procedure, a fine-gauge needle is used to remove cellular material which is subject to cytological assessment. FNAC has several advantages over open biopsy, such as being simple to operate, fast, reproducible, cheap, and associated with minimal side effects such as nerve damage or tumor seeding [5]. It is possible to perform in outpatient conditions without general anesthesia, and this is particularly beneficial in high-risk and pediatric patients. Real-time evaluation of specimen sufficiency and possibility of repeat aspiration, also increases its clinical usefulness [6]. The diagnostic result of FNAC on the neck swellings has been widely reported with a sensitivity of 76 to 98 and a specificity of 89 to 100 at different locations and in different pathologies [7]. In most of the instances, specific cytomorphological features of soft tissue tumors, mass salivary glands, thyroid nodules and lesions of lymph nodes make possible accurate characterization of the preoperative settings. FNAC is especially applicable in high-burden situations where it can be applied to detect metastatic carcinoma in lymph nodes and diagnose tuberculous lymphadenitis [8]. In the case of thyroid nodules, it is the first-line test, which it is backed by the Bethesda System for Reporting Thyroid Cytopathology, standardizing the categories and management [9]. FNAC has been used to distinguish between pleomorphic adenoma and malignant neoplasma in the pathology of salivary glands, which is supplemented by Milan System of Reporting Salivary Gland Cytopathology. FNAC does have major limitations, however. It is operator-dependent and requires competent cytopathologists to interpret it and technical expertise in sampling [10]. Cystic or heterogeneous lesions have more of a likelihood of sampling errors and some, including follicular thyroid neoplasma and some types of lymphoma, are not definitively diagnosable by cytology. False negative can occur due to poor sampling, low grade malignancies or subtle cytological atypia, on the other hand, false positive can be due to reactive changes simulating malignancy or interpretation error [11]. To ensure quality control, the results of cytology have to be correlated with subsequent histopathology. Discordant cases help to enhance diagnostic criteria by pointing out errors in sampling or interpretation. FNAC performance validation on a local scale is particularly important to the efficient utilization of limited healthcare resources in resource-limited areas with a high TB rate such as Bangladesh. With this in mind, this study was aimed at evaluating the efficacy of FNAC as a method of diagnosing neck swellings. The study was conducted to evaluate the sensitivity, specificity, predictive values, overall accuracy, characterize the spectrum of pathologies, find common patterns of diagnostic discordance and evaluate the role of FNAC

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as a first-line diagnostic method to reference to regarding this issue.

METHODS & MATERIALS

The study was a descriptive, cross-sectional study that was done in the Department of Otolaryngology and Head and Neck Surgery, Dhaka Medical College Hospital within the period of January 2024 to December 2024. Swollen-neck patients who fulfilled the inclusion criteria and provided informed, written consent were enrolled and otherwise not. Sociodemographic data, history of clinical, and examination outcomes were collected with the help of a pretested structured questionnaire. Fine needle aspiration cytology was done by use of a 23-gauge needle and a 10-ml disposable syringe and was done as an outpatient procedure under aseptic conditions in all patients. The smears were prepared and analyzed by cytopathology. The removal of the tissue was considered the reference standard, which was examined histopathologically, and in case of the necessity, open biopsy of the neck mass was performed. Next, the histopathology and cytological diagnoses were compared; discordant cases were given special consideration. The cytological test was calculated in terms of diagnostic sensitivity, specificity, the overall accuracy, discordance rate, and the positive and negative predictive values. The SPSS version 26 was used to input and analyze the data.

RESULTS

The demographic profile of the study population is shown in *Table I*. The majority of patients (37%) were in the 15-30 age range, followed by those in the 31-45 age range (28%). With 53% of the population being male and 47% being female, the gender distribution was comparatively balanced. Socioeconomic assessment showed that 44% of patients were from the poor economic strata, 38% were from the middle class, and only 18% were from the upper socioeconomic class. There was a wide range in educational attainment, with 30% having secondary education and 26% being illiterate. 66% of the study population lived in cities, which suggests that they seek healthcare more frequently than those who live in rural areas (34%). According to the occupational distribution, housewives made up 12% of the study population, while workers (30%) and businessmen (22%), respectively, were the largest groups.

Table I
Socio-demographic characteristics of the study population (n = 100)

Characteristic	Category	(n)	(%)
Age group (years)	<15	9	9%
	15-30	37	37%
	31-45	28	28%
	46-60	19	19%
	>60	7	7%
Sex	Male	53	53%
	Female	47	47%
Socioeconomic status	Poor	44	44%
	Middle	38	38%
	Upper	18	18%
Education level	Illiterate	26	26%
	Can sign only	6	6%
	Primary	14	14%
	Secondary	30	30%
	Higher secondary	24	24%
Place of residence	Urban	66	66%
	Rural	34	34%
Occupation	Business	22	22%
	Service holder	16	16%
	Worker	30	30%
	Farmer	14	14%
	Housewife	12	12%
	Retired	6	6%

The clinical symptomatology of the patients is represented in *Table II*. Neck swelling was the main complaint for all patients (100%) when they first arrived. 84% of patients reported pain and tenderness. With 78% reporting an elevated temperature and 76% reporting anorexia and nausea. In 60% of patients, lymphadenopathy was clinically identified, suggesting either metastatic disease or reactive enlargement. Swallowing difficulties (54%) and respiratory discomfort (12%) were examples of local compressive symptoms. 44% of patients reported having a headache, which may have been caused by a systemic illness or referred pain from neck lesions.

Table II
Clinical presentation of the study population (n = 100).

Symptom/sign	(n)	(%)
Swelling in the neck	100	100%
Pain and tenderness	84	84%
Elevated temperature	78	78%
Anorexia, nausea	76	76%
Lymphadenopathy	60	60%
Difficulty swallowing	54	54%
Headache	44	44%
Respiratory discomfort	12	12%

There were multiple responses

Neck masses are categorized in *Table III* according to their anatomical site. Thyroid gland lesions were the most common site of involvement (42%). The second most prevalent category (35%), which included both inflammatory and malignant disorders, was lymph node pathologies. 13% of cases involved salivary gland lesions, primarily affecting the parotid gland. Lipomas, cysts, and abscesses were among the 10% of soft tissue masses that made up the study population.

Table III
Distribution of neck masses by anatomical site (n = 100).

Site of neck mass	(n)	(%)
Thyroid	42	42%
Lymph node	35	35%
Salivary gland	13	13%
Soft tissue	10	10%
Others	0	0%

The cytological diagnoses are listed in *Table IV* according to anatomical site. Hashimoto's thyroiditis (35.7%) and nodular goiter (52.4%) were the most prevalent thyroid lesions. Papillary carcinoma (9.5%) and medullary carcinoma (2.4%) were examples of malignant thyroid neoplasms. The most common diagnosis in lymph node pathology was reactive lymphoid hyperplasia (40%). 22.8% of cases of lymph nodes were granulomatous lymphadenitis. Malignant conditions included lymphoma (17.1%) and metastatic lymphadenitis (20%). 30.7% of the salivary gland lesions had mucoepidermoid carcinoma, while the majority (69.2%) had pleomorphic adenoma. The majority of the soft tissue lesions were benign, consisting of abscesses (20%), benign cystic lesions (20%), and lipomas 60%.

Table IV
Fine-needle aspiration cytology (FNAC) diagnosis of neck masses by site (n = 100).

Sites of Neck masses	Cytological diagnosis	(n)	(%)
Thyroid (n = 42)	Nodular goiter	22	52.4%
	Hashimoto's thyroiditis	15	35.7%
	Papillary carcinoma	4	9.5%
	Medullary carcinoma	1	2.4%
Lymph node (n = 35)	Reactive lymphoid hyperplasia	14	40%
	Granulomatous lymphadenitis	8	22.8%
	Metastatic lymphadenitis	7	20%
	Lymphoma	6	17.1%
Salivary gland (n = 13)	Pleomorphic adenoma	9	69.2%
	Mucoepidermoid carcinoma	4	30.7%
Soft tissue (n = 10)	Lipoma	6	60%
	Benign cystic lesion	2	20%
	Abscess	2	20%

The final histopathological diagnoses that serve as the benchmark are shown in *Table V*. Hashimoto's thyroiditis (23.3%) and colloid goiter (20.5%) were the most common benign and inflammatory lesions. Reactive lymphadenitis (13.7%), granulomatous lymphadenitis (12.32%), pleomorphic adenoma (10.9%), lipoma (6.8%), thyroglossal cyst (4.1%), fungal lymphadenitis (4.1%), branchial cleft cyst (2.7%), and dermoid cyst (1.4%) were among the other benign conditions. Among the malignant lesions, metastatic carcinoma (25.9%), non-Hodgkin lymphoma (18.5%), mucoepidermoid carcinoma (18.5%), papillary carcinoma (14.8%), Hodgkin lymphoma (11.1%), medullary carcinoma (7.4%), and follicular adenoma (3.7%).

Table V
Histopathological diagnosis of neck masses (n = 100).

Groups	Histopathological diagnosis	(n)	(%)
Benign and inflammatory lesions (n = 73)	Hashimoto's thyroiditis	17	23.30%
	Thyroglossal cyst	3	4.10%
	Colloid goiter	15	20.50%
	Reactive lymphadenitis	10	13.70%
	Fungal lymphadenitis	3	4.10%
	Granulomatous lymphadenitis	9	12.32%
	Pleomorphic adenoma	8	10.90%
	Branchial cleft cyst	2	2.70%
	Lipoma	5	6.80%
	Dermoid cyst	1	1.40%
Malignant lesions (n = 27)	Papillary carcinoma	4	14.80%
	Follicular adenoma	1	3.70%
	Medullary carcinoma	2	7.40%
	Hodgkin lymphoma	3	11.10%
	Non-Hodgkin lymphoma	5	18.50%
	Metastatic carcinoma	7	25.90%
	Mucoepidermoid carcinoma	5	18.50%

Table VI demonstrates the correlation between Cytodiagnosis and subsequent histology. There were 64% of true positive cases, which denotes those benign lesions were correctly identified. There were 23% of true negative cases, demonstrating accurate malignancy identification. The most clinically significant error category, false-negative results, which can postpone cancer treatment, happened in 4% of cases. 9% had false-positive results, meaning that histology revealed benign conditions but cytology indicated malignancy, which could have resulted in needless aggressive interventions.

Table VI
Correlation between Cytodiagnosis and Subsequent histology (*n*=100).

Category	Benign cytology (n) (%)	Malignant cytology (n) (%)
Benign histology	64 (64%) (true positive)	4 (4%) (false negative)
Malignant histology	9 (9%) (false positive)	23 (23%) (true negative)

Table VII depicts the Diagnostic performance of FNAC for detecting malignant neck lesions. FNAC demonstrated a sensitivity of 85.2%, specificity of 87.7%, positive predictive value of 71.9%, negative predictive value of 94.1%, and overall diagnostic accuracy of 87% when using histopathology as the gold standard and classifying malignancy as the positive condition.

Table VII
Diagnostic performance of FNAC for detecting malignant neck lesions (positive = malignant).

Parameter	Value (%)
Sensitivity	85.2
Specificity	87.7
Positive predictive value	71.9
Negative predictive value	94.1
Overall diagnostic accuracy	87.0

DISCUSSION

This research tested the diagnostic importance of the fine needle aspiration cytology. The international reports also indicate that neck masses accuracy is between 82% and 96% and FNAC had an overall accuracy of 87% with a sensitivity of 85.2% and a specificity of 87.7% [12,13]. FNAC positive result is particularly reliable in proving malignancy as demonstrated by high specificity. This in most cases can aid in the early treatment decision without having to wait and confirm the situation through histopathology. Thyroid lesions (42%), then soft tissue lesions (10%), salivary gland masses (13%), and lymph node enlargements (35%), were the most frequent pathology of the neck. This trend aligns with that of Kohale et al., who also report autoimmune conditions and endemic deficiency of iodine to be the leading causes of thyroid conditions [14]. High percentage of lymph node pathology (especially granulomatous lymphadenitis possible pathologic sign of tuberculosis, 22.8% of lymph node cases) is also a clear indication of high prevalence of extrapulmonary tuberculosis in Bangladesh, which is also observed in other developing countries [15,16]. Rajbhandari et al., who demonstrated that 27-45% of lymph node FNAC samples reacted, indicated that reactive lymphoid hyperplasia was the most frequent diagnosis of lymph nodes (40) [17]. Most patients were younger adults (15-45 years old) and most of them were males with a slight prevalence (53%). Conversely, the older age groups have higher chances of having a neck mass particularly thyroid nodules and metastatic nodes as demonstrated by Iacob et al. [18]. Although it is probable that many were inflammatory or infectious, not indolent neoplasma by virtue of high rates of pain, tenderness, and fever, the fact that the proportion of the patients of lower socioeconomic status and urban dwellers was larger is more likely to be indicative of health service usage patterns. In relation to thyroid pathology FNAC has proven to be very concordant when it comes to benign diseases of the thyroid gland like the Hashimoto thyroiditis and the nodular goiter. The familiar limitation that cytology can not distinguish between follicular adenoma and carcinoma without assessing the presence of capsular or vascular invasion was also proved by a false-negative case in which a cytological diagnosis of follicular neoplasm proved to be follicular carcinoma [19,20]. We achieve a specificity of 87.7% which is equivalent to reported thyroid FNAC sensitivity and specificity (70-92% and 88-100%, respectively) particularly with the Bethesda system, which confirms FNAC as a viable technique in the assessment of thyroid nodules [21,22]. FNAC was particularly effective in the metastatic lymph node disease case, with an overall diagnostic accuracy rate of 87% and comparable sensitivity of 91% to 98% reported [23]. Errors in reactive background interpretation or sampling issues in necrotic lesions were the major reasons of missing cases of metastatic squamous cell carcinoma [24]. Conversely, caseous necrosis and classic granulomatous cytology were generally readily diagnostic of tuberculous lymphadenitis, and Ziehl-Neelsen staining was performed when there was need to do so. This lymphoma diagnosis was still a challenging one as half of the cases were initially diagnosed as reactive hyperplasia, which echoes the known shortcoming of FNAC in lymphoblastic disorders [25]. The findings are in line with existing recommendations that support core or excisional biopsy as a preferred method of diagnosing suspected lymphoma. Salivary gland FNAC, following a system of work with the risks that is provided within the Milan system, did incredibly well as it correctly identified mucoepidermoid carcinoma in most of the cases and pleomorphic adenoma in all [26]. False negatives (4%) were due to sampling error, interpretive issues and inherent cytological limitations whereas false positives (9) were due to reactive atypia in Hashimoto thyroiditis, granulomatous inflammation or cystic degeneration. In order to minimize these errors, standardized reporting systems, high frequency cytology-histology correlation, and quality assurance processes are important.

LIMITATIONS

Among limitations in the study are the single center, relatively small sample size, the absence of a routine ultrasound guidance that may have enhanced the sampling error, and partial histological validation of benign cytology. However, the findings confirm the use of FNAC as a rapidly and least invasive and cost-effective initial test of neck masses, especially where resources are scarce.

CONCLUSION

Our investigation confirmed that the fine needle aspiration cytology is an extremely convenient, cost effective and less invasive method of diagnosing neck swellings and that its overall accuracy is 87%, specificity (87.7%) is high and sensitivity (85.2%) is high. It is effective in most instances to distinguish benign and malignant lesions to be able to plan the surgery more appropriately and avoid unnecessary surgeries in most cases. But, in cases where the cytological findings prove ambiguous or inconsistent with clinical suspicion, histopathological verification is needed because FNAC is limited in nature, particularly in the diagnosis of lymphomas and follicular thyroid neoplasms. FNAC is used when the clinical assessment and radiological imaging are done to the maximum in order to maximize diagnostic accuracy.

RECOMMENDATION

In order to reduce sampling errors and obtain better diagnostic accuracy, future researches must incorporate ultrasound-guided FNAC and larger and multicenter cohorts. More rigid reporting systems and regular cytology-histology correlation would be introduced to minimize conflict of interpretations.

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CONFLICT OF INTEREST

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Complications in The Laparoscopic Management of Benign Cystic Lesions of The Liver

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ABSTRACT

Background: Benign cystic liver lesions, including hydatid cysts, simple cysts, and abscesses, are increasingly detected through routine imaging. While laparoscopic surgery offers a minimally invasive alternative to open procedures, sparse data exist on its safety profile and complications. This study aimed to evaluate the adverse events of laparoscopic management for these lesions. **Methods & Materials:** This prospective observational study was conducted from July to December 2014 at five centres in Dhaka- Bangabandhu Sheikh Mujib Medical University, Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders, Dhaka Medical College Hospital, Shaheed Suhrawardy Medical College, and selected private hospitals. The study included 30 patients with BCLL (HC n=18, SC n=8, LA n=4) undergoing LS. Inclusion criteria comprised symptomatic cysts, cysts >5cm, and failed medical management for LA. Data were analysed using SPSS version 22.0. **Results:** Mean operative times (MOT) ranged from 55-95 minutes. Complications occurred in 10% of cases, including port-site infections (PSI) (6.67%), bile leakage (BL) (3.33%), and peritonitis (3.33%). Conversion rate (CR) was 3.33% with no mortality. **Conclusion:** While laparoscopic management of BCLL demonstrates acceptable safety with a 10% complication rate, careful patient selection and meticulous surgical technique remain essential to minimise adverse events and optimise outcomes.

Keywords: *Laparoscopic Surgery, Hydatid Cyst, Simple Liver Cyst, Liver Abscess, Complications*

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INTRODUCTION

Though uncommon, benign hepatic cystic lesions (hydatid cysts, simple cysts, and abscesses) are becoming more common in the diagnosis in situations of regular screening using advanced imaging techniques (ultrasound, CT). Although laparoscopic surgery is a minimally invasive form of surgery as compared to the open ones, laparoscopy has distinct complications that must be carefully handled both intraoperative and postoperative. Echinococcus granulosus causes hepatic hydatid disease and it is still endemic in some areas like the Mediterranean, North Africa and Middle East and the Indian subcontinent. The case of sporadic is on the increase as a result of global traveling [1]. Fifty to ninety-three percent of cysts occur in the liver, the cysts being formed by the migration of larvae via the portal system and where multilayered structures are developed that contain a germinal endocyst which is likely to give rise to daughter cysts. The asymptomatic cases are frequent; nevertheless, the symptomatic manifestations comprise the abdominal pain, jaundice, or risk of rupture. Peritonitis or biliary fistulas may result because of rupture. Diagnosis includes serology (e.g., ELISA), eosinophilia as well as imaging. Septa and hydatid sand are detected by ultrasound, and calcifications are detected by CT. Muqim et al. and Koea. have pointed out the feasibility of laparoscopic cystectomy with associated complications of 5-15% such as rupture of the cyst, anaphylaxis due to spillage or biliary leakage. [1,2]. These risks should be minimized by scrupulous aspiration and the use of scolicidal agents [2]. Simple liver cysts are either solitary, multiple or polycystic types, which frequently occur sporadically or as a result of autosomal dominant inherited conditions. Polycystic liver disease is often accompanied by renal or pancreatic involvement. These cysts are usually asymptomatic and non-liver-functionality disabling, but when large they can be painful, haemolytic or mass effecting. Unilocular and thin-walled features can be confirmed with the help of ultrasound and CT. The asymptomatic cysts only need observation but the symptomatic ones respond to laparoscopic deroofing. Choi et al. report that giant cysts can be successfully managed, although this may be accompanied by intra-abdominal bleeding, infection and recurrence (maximally 20%), which are mostly the result of poor excision or haemorrhage of the capsule [3]. Accurate fenestration methods are also highlighted to curb recurrence [3]. Liver abscess may be pyogenic or amoebic, where they are predominant in the tropical areas and are common in diabetics or immunocompromised patients. Pyogenic abscesses are polymicrobial (E. coli or Streptococcus milleri), whereas amoebic forms are derived out of Entamoeba histolytica. The clinical symptoms are fever, malaise, and pain in the right upper quadrant. Small lesions require medical therapy, whereas large lesions and multiloculated abscesses are subject to drainage. Laparoscopic drainage has been promoted instead of percutaneous because it enhances failure rates related to viscous pus (1025) [4-6]. However, laparoscopic drainage can lead to bowel injury, pus relapse (1025), or sepsis because of poor evacuation. Extensive access and extensive irrigation is critical [5,8]. Laparoscopic surgery of these lesions reduces morbidity, hospital stay and recovery and is better than laparotomy, but there remains a problem of visualisation of deep lesions, spillage due to hydatid cases and adhesion-related injuries. The intraoperative complications like vascular trauma or biliary trauma are present in 2-8% instances. The problems postoperative are wound infection, long ileus or cyst recurrence. As highlighted by Alkhyatt et al., preoperative planning is essential in order to reduce these risks. Well trained surgical teams show reduced overall complication rates. Although these advantages are present, the information about laparoscopic results in the cases of benign cystic liver lesions is sparse. This paper will test the profile of adverse events associated with laparoscopic treatment of

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benign liver cystic lesions (hydatid cysts, simple cysts, and abscesses) and establish the instances of the clinical settings where the laparoscopic treatment presents a clear benefit over open surgery.

METHODS & MATERIALS

The study was a prospective observational study that was carried out within a 6-month period, between July 2014 and December 2014 in the Department of Surgery in Bangabandhu Sheikh Mujib Medical University (BSMMU), Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM), Dhaka Medical College Hospital (DMCH), Shaheed Suhrawardy Medical College (ShSMC) and various local hospitals in the city of Dhaka. The study involved 30 male and female patients diagnosed to have benign cystic lesions of the liver. A purposive sampling method was used to select the patients who were selected by sampling the patients that were admitted to the participating hospitals so long as they met the inclusion and exclusion criteria. The inclusion criteria included patients having hydatid cyst of the liver, single or multiple large cysts, large or multiloculated liver abscess, and failed medical therapy against hydatid cyst or liver abscess. The exclusion criteria were the presence of deep-seated hydatid cysts, a number of small simple liver cysts, and the refusal of patients to laparoscopic surgery. The laparoscopic management and surgical outcome of benign cystic lesions of the liver was the main outcome variable. All the participants had their informed written consent prior to being included in the study after clarifying the nature of the study, its purpose, and the possible risks involved in the study. The study received ethical approval of the Institutional Review Board (IRB) of the relevant institutions.

Statistical Analysis

The data collection was based on the clinical examination, operative results, and postoperative outcomes, such as the operative time, and complications. The obtained data were tabulated and analysed in the Statistical Package of Social Sciences (SPSS) version 22.0 and summarised using the descriptive statistical techniques to summarise the patient data in terms of demographics, cyst characteristics, surgical procedures, complications, and outcomes of follow-ups.

RESULTS

The mean age was 43.6 years (range 17–63) in the hydatid cyst group, 46.7 years (range 43–65) in the simple liver cyst group, and 59.6 years (range 52–69) in the liver abscess group. The youngest patient was 17 years old, and the oldest was 69 years old in the overall study population (*Table I*).

Table I
Age Distribution of 30 Patients Operated by Laparoscopic Approach (*n*=30).

Type of Lesion	Total (n)	Youngest Patient (years)	Oldest Patient (years)	Mean Age (years)
Hydatid cysts	18	17	63	43.6
Simple liver cysts	8	43	65	46.7
Liver abscess	4	52	69	59.6

Males predominated in the hydatid cyst (55%) and liver abscess (75%) groups, whereas females (63%) were more common in the simple liver cyst group (*Table II*).

Table II
Sex Distribution of 30 Patients Operated by Laparoscopic Approach (*n*=30).

Type of Lesion	Total (n)	Male n (%)	Female n (%)
Hydatid cysts	18	10 (55)	8 (45)
Simple liver cysts	8	3 (37)	5 (63)
Liver abscess	4	3 (75)	1 (25)

Pain was the predominant symptom in all groups. Fever was frequent in liver abscess patients, while abdominal swelling was seen only in hydatid cyst cases (*Table III*).

Table III
Clinical Presentations of Patients Undergoing Laparoscopic Surgery for Benign Cystic Lesions of the Liver (*n*=30).

Presentation	Hydatid Cysts (n=18) n (%)	Simple Liver Cysts (n=8) n (%)	Liver Abscess (n=4) n (%)
Abdominal pain	13 (72.22)	5 (62.5)	4 (100)
Nausea/Dyspepsia	8 (44.44)	3 (37.5)	2 (50)
Abdominal swelling/Mass	5 (27.78)	0 (0.0)	0 (0.0)
Fever	1 (5.55)	0 (0.0)	4 (100)

Most lesions were single and predominantly located in the right hepatic lobe across all groups, with no bilateral involvement observed (*Table IV*).

Table IV
Number and Location of Benign Cystic Lesions of the Liver (*n*=30).

Type of Lesion	Total (n)	Single Cyst n (%)	Multiple Cysts n (%)	Right Lobe n (%)	Left Lobe n (%)	Bilateral n (%)
Hydatid cysts	18	16 (88.89)	2 (11.11)	15 (83.33)	3 (16.67)	0 (0.0)
Simple liver cysts	8	7 (87.5)	1 (12.5)	7 (87.5)	1 (12.5)	0 (0.0)
Liver abscess	4	4 (100)	0 (0.0)	4 (100)	0 (0.0)	0 (0.0)

Unroofing and omentoplasty were the mainstay procedures for hydatid cysts, while all simple liver cysts underwent unroofing and all liver abscesses required drainage (*Table V*).

Table V
Types of Laparoscopic Procedures Performed (*n*=30).

Type of Lesion	Total (n)	Procedure Type	No. of Patients n (%)
Hydatid cysts	18	Unroofing and omentoplasty	17 (94)
		Partial pericystectomy	1 (6)
Simple liver cysts	8	Unroofing of the cyst	8 (100)
Liver abscess	4	Drainage of the abscess cavity	4 (100)

The mean operative time was longest for hydatid cyst surgeries (95 minutes) and shortest for simple liver cysts (55 minutes), reflecting procedural complexity differences (*Table VI*).

Table VI
Operative Time for Laparoscopic Procedures (*n*=30).

Indication	Number of Cases (n)	Operative Time (minutes) (Range)
Hydatid cysts	18	95 (80–120)
Simple liver cysts	8	55 (45–65)
Liver abscess	4	65 (55–75)

Minor complications included port site infection (6.67%), bile leakage (3.33%), and peritonitis (3.33%). One procedure required conversion to open surgery, and no mortality was reported (*Table VII*).

Table VII
Postoperative Complications of Laparoscopic Surgery (*n*=30).

Complication	No. of Patients	Percentage (%)
Anaphylactic shock	0	0
Port site infection	2	6.67
Bile leakage	1	3.33
Peritonitis	1	3.33
Conversion to open surgery	1	3.33
Mortality	0	0

DISCUSSION

The laparoscopic revolution of the hepatobiliary surgery has revolutionized the treatment of benign cystic hepatic masses which has been seen to be better than the old open methods. The present study proves the flexibility of minimally invasive procedures in a wide variety of pathologies such as hepatic hydatid cysts (n = 18), simple liver cysts (n = 8), and liver abscesses (n = 4). Demographic analysis showed age specific distribution- hydatid cysts was observed in men at 43.6 years of age, simple cysts in 46.7 years, and liver abscesses at 59.6 years of age- consistent with Palanivelu et al. and Muqim et al. [1,9,10]. Gender distribution was different based on pathology- males had been predominant in hydatid disease (55%), and simple cysts (63%) and liver abscesses (75%), with only fever in liver ab The right hepatic lobe contained 83-100% of the lesions, mainly in the form of solitary cysts (87.5-100%) which agrees with the findings of Ali and Alaswad and Shetty [11,12]. Diagnostic workup involved the use of ultrasonography and CT images in all cases, and ELISA in case of hydatid disease. In their study, Soares et al. pointed out that radiological characteristics that characterise simple cysts are the thin walls, unilocularity and lack of tissue response [13]. The MRI was also useful in the diagnosis of biliary communication, which is important in the treatment of hydatid, according to Li et al. [14,15]. Hydatid cysts were unroofed with omentoplasty (94%) or partial pericystectomy (6%) with the inclusion of scolicidal irrigation using hypertonic saline. Similar methods are proposed by Alkhyatt et al. and Osemek et al. though more advanced equipment like the Palanivelu Hydatid System was not available in our place, so simple cysts took only 55 minutes of operation [16,4]. The complexity of the procedure was reflected in the duration of operation: 95 minutes in case of hydatid cysts, and 55 minutes in case of simple cysts. Our 3.33% conversion rate is much better than 425% that is reported by Rihani et al and the one conversion was due to haemorrhage during surgery on the hydatids. There was also little postoperative morbidity as port site infection (6.67%), bile leakage (3.33%), and mild peritonitis (3.33%) were treated conservatively. The lack of anaphylaxis goes against the issues that were raised in history, which prove that correct precautions are a guarantee of safety as stated by Baskaran and Patnaik [17,18]. Zero mortality is equivalent to Palanivelu et al. and Ekwunife et al. [19,7]. Perioperative praziquantel administration of hydatid cases probably avoided consequences, but due to its limited follow-up (13/30 patients), it does not provide a comprehensive evaluation of the long term. This experience proves laparoscopic management as the gold standard of benign hepatic cystic lesions, which offers less morbidity.

LIMITATIONS

The weaknesses of the study are that the sample size is small, the duration is limited to six months, the study is limited to one centre and therefore could not be generalized, no long-term follow-up to determine the recurrence and no comparison with open surgical outcomes.

CONCLUSION

The weaknesses of the study are that the sample size is small, the duration is limited to six months, the study is limited to one centre and therefore could not be generalized, no long-term follow-up to determine the recurrence and no comparison with open surgical outcomes.

RECOMMENDATION

The weaknesses of the study are that the sample size is small, the duration is limited to six months, the study is limited to one centre and therefore could not be generalized, no long-term follow-up to determine the recurrence and no comparison with open surgical outcomes.

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CONFLICT OF INTEREST

None declared

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Oxidative Stress and Antioxidant Response in Gentamicin-Treated Rats – Role of Green Tea Extract on Renal Malondialdehyde (MDA) Levels

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ABSTRACT

Background: Gentamicin is an effective aminoglycoside antibiotic, but its use is limited by nephrotoxicity caused by oxidative stress. Malondialdehyde (MDA) reflects oxidative damage, while enzymes like SOD, CAT, GPx, and GSH indicate antioxidant status. Green tea extract (GTE), rich in epigallocatechin-3-gallate (EGCG), possesses potent antioxidant properties that may protect against such injury. This study evaluates the protective effect of GTE on renal oxidative stress by measuring MDA and antioxidant enzyme activity in gentamicin-treated rats. **Methods & Materials:** This experimental study was conducted in the Department of Physiology, Sir Salimullah Medical College, Dhaka (July 2019–June 2020) on 30 healthy male Long Evans rats (90–120 days old, 150–200 g). Renal oxidative stress markers (MDA) and antioxidant enzymes (SOD, CAT, GPx, GSH) were measured by spectrophotometric methods, while serum creatinine, urea, and BUN were assessed using enzymatic colorimetric assays. Kidney tissues were examined histologically after H&E staining. Data were analyzed using SPSS v26, with $p \leq 0.05$ considered statistically significant. **Results:** Most rats showed elevated oxidative stress, with over two-thirds having high MDA levels and reduced antioxidant enzyme activity. Strong negative correlations between MDA and antioxidants confirmed oxidative–antioxidant imbalance. Histological analysis revealed frequent tubular damage and congestion, indicating significant renal injury and oxidative dominance in gentamicin-treated rats. **Conclusion:** Gentamicin caused significant oxidative stress and kidney damage in rats, while green tea extract effectively reduced lipid peroxidation and restored antioxidant defenses. These results highlight the protective role of green tea polyphenols against drug-induced nephrotoxicity and suggest their potential as a safe, natural adjunct to minimize kidney injury during gentamicin therapy.

Keywords: *Gentamicin-induced nephrotoxicity, Oxidative stress, Green tea extract (Camellia sinensis), Antioxidant enzymes, and Malondialdehyde (MDA)*

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INTRODUCTION

Gentamicin is a potent aminoglycoside antibiotic widely used for the treatment of life-threatening Gram-negative bacterial infections. Despite its efficacy, gentamicin's clinical use is often limited by its nephrotoxic effects, which remain a significant cause of acute kidney injury (AKI) in hospitalized patients [1]. Drug-induced nephrotoxicity contributes to approximately 60% of AKI cases globally, with aminoglycosides accounting for a substantial proportion [2]. In developing regions, where aminoglycosides are frequently prescribed due to their low cost and broad antibacterial activity, the burden of gentamicin-associated renal injury is even higher [3]. Understanding the mechanisms of this toxicity and identifying protective strategies are crucial for minimizing renal complications while preserving therapeutic efficacy. A hallmark of gentamicin nephrotoxicity is lipid peroxidation, which compromises membrane integrity and cellular homeostasis. The byproduct malondialdehyde (MDA), formed during this process, serves as a reliable biomarker of oxidative stress [4]. Elevated renal MDA levels have been consistently observed in gentamicin-treated animals, confirming the role of oxidative damage in renal pathology [5]. The accumulation of ROS also activates inflammatory signaling pathways, including NF-κB, amplifying cytokine release and tissue injury [6]. Collectively, these events culminate in tubular necrosis, glomerular damage, and reduced renal function, characterized by increased serum creatinine and blood urea nitrogen (BUN) [7]. Under physiological conditions, oxidative radicals are neutralized by a sophisticated antioxidant defense system composed of enzymatic and non-enzymatic components. Key antioxidant enzymes include superoxide dismutase (SOD), which converts O_2^- to H_2O_2, catalase (CAT) and glutathione peroxidase (GPx), which reduce H_2O_2 to water, and reduced glutathione (GSH). This major intracellular thiol maintains redox homeostasis [8]. During gentamicin exposure, however, these antioxidant defenses are significantly impaired. Studies in rats have shown reduced renal activities of SOD, CAT, and GPx, along with depleted GSH levels, accompanied by elevated MDA concentrations [9,10]. This oxidant–antioxidant imbalance reflects a shift toward oxidative predominance, resulting in cumulative lipid and protein oxidation that exacerbates cellular injury. Given this pathophysiological background, interventions that boost antioxidant capacity or scavenge ROS directly are regarded as promising approaches for preventing gentamicin-induced renal injury. A variety of antioxidants both synthetic and natural have been evaluated for their nephroprotective effects. Vitamins C and E have shown efficacy in reducing lipid peroxidation and restoring antioxidant enzyme activity in gentamicin-treated rats [11]. Similarly, several plant-derived polyphenols and flavonoids, such as curcumin, quercetin, and naringenin, have demonstrated renoprotective potential through their free radical–scavenging and anti-inflammatory properties [12]. Among these natural agents, green tea extract (GTE) stands out due to its high content of potent polyphenols known as catechins, particularly epigallocatechin-3-gallate (EGCG), which exhibits remarkable antioxidant efficacy [4,9]. Green tea (Camellia sinensis) has long been recognized for its medicinal benefits,

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including its antioxidant, anti-inflammatory, and metal-chelating properties. EGCG, the most abundant catechin in green tea, exerts its antioxidant effects through multiple mechanisms: direct scavenging of ROS, inhibition of pro-oxidant enzymes, and upregulation of endogenous antioxidant defenses via activation of the nuclear factor erythroid 2 related factor 2 (Nrf2) signaling pathway [13,14]. Activation of Nrf2 enhances the expression of genes encoding antioxidant enzymes such as SOD, CAT, GPx, and heme oxygenase-1 (HO-1), thereby strengthening cellular defense against oxidative stress [8]. Experimental studies have provided substantial evidence supporting the renoprotective role of GTE and EGCG in gentamicin-induced nephrotoxicity. Study demonstrated that green tea extract significantly reduced serum creatinine and BUN levels, lowered renal MDA, and restored SOD and CAT activities in gentamicin-treated rats [15]. Another study showed that EGCG supplementation attenuated oxidative stress and inflammation in renal tissues by suppressing MAPK and NF-κB pathways [16]. The collective evidence suggests that oxidative stress plays a central role in gentamicin-induced nephrotoxicity and that antioxidant intervention, particularly using natural compounds like GTE, may mitigate this effect. Since MDA is a reliable indicator of lipid peroxidation and oxidative injury, and SOD, CAT, GPx, and GSH are essential markers of antioxidant defense, their assessment provides valuable insight into the redox state of renal tissues. Therefore, the present study aims to investigate the oxidative–antioxidant balance in gentamicin-treated rats and evaluate the protective role of green tea extract by analyzing renal MDA levels and key antioxidant enzyme activities.

METHODS & MATERIALS

This experimental study was conducted in the Department of Physiology, Sir Salimullah Medical College, Dhaka, from July 2019 to June 2020, following approval from the Institutional Ethics Committee. Thirty apparently healthy Long Evans male rats aged 90–120 days and weighing 150–200g was acclimatized for 14 days under standard laboratory conditions (temperature 27–28°C, 12-hour light–dark cycle) with free access to food and water. All animals received ethanolic extract of green tea (*Camellia sinensis*) orally at a dose of 300 mg/kg/day for 28 consecutive days. To induce nephrotoxicity, gentamicin was administered intraperitoneally at 80 mg/kg/day during the last three days (days 26–28). On day 29, all rats were sacrificed under light anaesthesia, and blood and kidney samples were collected for biochemical and histopathological evaluation. Renal antioxidant enzyme activities (SOD, CAT, GPx, GSH) were assayed by standard spectrophotometric methods. Serum creatinine, urea, and blood urea nitrogen (BUN) levels were measured using standard enzymatic colorimetric methods. Renal malondialdehyde (MDA) concentration, a marker of lipid peroxidation, was determined by the thiobarbituric acid reactive substances (TBARS) method. One kidney from each animal was preserved in 10% neutral-buffered formalin for histopathological examination after hematoxylin and eosin (H&E) staining to evaluate tubular degeneration, interstitial congestion, and necrosis. Data were compiled, coded, and analyzed using the Statistical Package for the Social Sciences (SPSS) for Windows version 26. Quantitative variables such as serum creatinine, urea, BUN, and MDA were expressed as mean ± standard deviation (SD). Changes in continuous variables before and after green tea and gentamicin exposure were analyzed using paired *t*-tests, while inter-parameter relationships were explored using Pearson's correlation coefficients. Histopathological findings, expressed as categorical variables (presence or absence of tubular degeneration, congestion, and necrosis), were compared using Fisher's Exact test. Statistical significance was considered at $p \leq 0.05$.

RESULTS

Among the 30 rats, most were aged between 100–109 days (53.3%), while smaller proportions were aged 90–99 days (13.3%) and 110–119 days (33.4%). Regarding baseline body weight, the largest group (33.3%) weighed between 180–189 g, followed by 26.6% in the 170–179 g range. For kidney weight, nearly half of the subjects (43.3%) had kidneys weighing 1.0–1.19 g, whereas 30% had kidneys weighing ≥1.2 g and 26.7% had kidneys weighing under 1.0 g (*Table I*).

Table I
Basic Characteristics of the Study Population ($n = 30$).

Variable	Category	Frequency (n)	Percentage (%)
Age (days)	90–99	4	13.3
	100–109	16	53.3
	110–119	10	33.4
Body weight at baseline (g)	160–169	5	16.7
	170–179	8	26.6
	180–189	10	33.3
	190–199	7	23.4
Kidney weight (g)	< 1.0	8	26.7
	1.0–1.19	13	43.3
	≥ 1.2	9	30.0

About one-third of the rats (30.0%) had MDA levels within the normal range (≤ 2.0 nmol/mg protein), suggesting normal oxidative balance. A slightly higher proportion (36.7%) showed mildly elevated levels (2.01–3.0 nmol/mg protein), while 33.3% had markedly elevated levels (> 3.0 nmol/mg protein), indicating significant oxidative stress. Overall, the results suggest that more than two-thirds of the study population exhibited elevated MDA levels, reflecting a notable presence of oxidative stress among the subjects (*Table II*).

Table II
Distribution of Oxidative-Stress Biomarker (MDA) Levels.

MDA (nmol/mg protein)	Frequency (n)	Percentage (%)
Normal range (≤ 2.0)	9	30.0
Mildly elevated (2.01–3.0)	11	36.7
Markedly elevated (> 3.0)	10	33.3
Total	30	100.0

The distribution of antioxidant enzyme activity among the 30 study subjects shows a general trend toward reduced antioxidant defense. For Superoxide Dismutase (SOD), 60.0% of participants had reduced activity (≤ 8 U/mg protein), while 40.0% maintained normal levels. Similarly, Catalase (CAT) activity was reduced in 53.3% of subjects, with 46.7% showing regular activity. Glutathione Peroxidase (GPx) had the highest proportion of reduced activity (63.3%), compared to only 36.7% with normal levels. Lastly, Reduced Glutathione (GSH) was below normal in 56.7% of individuals (*Table III*).

Table III
Distribution of Antioxidant Enzyme Activity in the Study Population.

Enzyme	Category	Frequency (n)	Percentage (%)
Superoxide Dismutase (SOD)	Normal (> 8 U/mg protein)	12	40.0
	Reduced (≤ 8 U/mg protein)	18	60.0
Catalase (CAT)	Normal (> 45 U/mg protein)	14	46.7
	Reduced (≤ 45 U/mg protein)	16	53.3
Glutathione Peroxidase (GPx)	Normal (> 10 U/mg protein)	11	36.7
	Reduced (≤ 10 U/mg protein)	19	63.3
Reduced Glutathione (GSH)	Normal (> 5 µmol/mg protein)	13	43.3
	Reduced (≤ 5 µmol/mg protein)	17	56.7

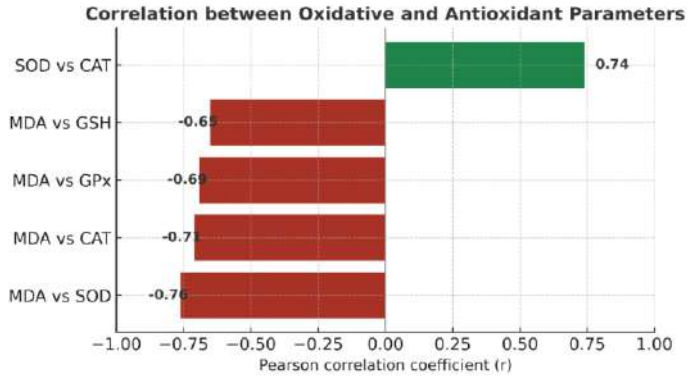

Figure I Correlation between Oxidative and Antioxidant Parameters in Experimental Rats.

Figure 1 illustrates the relationship between oxidative stress marker malondialdehyde (MDA) and key antioxidant enzymes superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPx), and reduced glutathione (GSH) in the renal tissue of experimental rats. Strong negative correlations were observed between MDA and all antioxidant enzymes (r = −0.65 to −0.76), indicating that higher lipid peroxidation corresponds to diminished antioxidant activity. Conversely, a positive correlation between SOD and CAT (r = +0.74) reflects coordinated enzymatic defense against reactive oxygen species. These findings confirm that oxidative stress is inversely linked with antioxidant defense mechanisms, supporting the protective role of green-tea polyphenols in mitigating gentamicin-induced nephrotoxicity.

The histopathological examination of renal tissues revealed varying degrees of structural alterations among the 30 study subjects. The most frequent abnormality was tubular epithelial degeneration, observed in 66.7% of cases, indicating widespread cellular damage in the renal tubules. Interstitial congestion was also common, affecting 56.7% of the subjects, suggesting vascular disturbances or inflammation. Hyaline casts were present in 46.7% of kidneys, reflecting protein leakage or tubular obstruction. Less frequent findings included glomerular shrinkage (30.0%) and severe tubular necrosis (20.0%), both indicative of more advanced or severe kidney injury (*Table IV*).

Table IV
Distribution of Histopathological Renal Findings (*n* = 30).

Finding	Presence n (%)	Absence n (%)	Total n (%)
Tubular epithelial degeneration	20 (66.7)	10 (33.3)	30 (100)
Interstitial congestion	17 (56.7)	13 (43.3)	30 (100)
Hyaline casts	14 (46.7)	16 (53.3)	30 (100)
Glomerular shrinkage	9 (30.0)	21 (70.0)	30 (100)
Tubular necrosis (severe)	6 (20.0)	24 (80.0)	30 (100)

The mean MDA level (2.77 ± 1.04 nmol/mg) exceeded the normal range (< 2.0), with only 30% of subjects within normal limits. A positive oxidative stress Z-score of +1.49 indicates elevated lipid peroxidation. In contrast, all antioxidant enzymes showed mean values below their respective normal thresholds: SOD (7.6 ± 2.1 U/mg; 40.0% normal, Z = −0.62), CAT (43.8 ± 8.4 U/mg; 46.7% normal, Z = −0.35), GPx (9.2 ± 2.8 U/mg; 36.7% normal, Z = −0.58), and GSH (4.8 ± 1.4 µmol/mg; 43.3% normal, Z = −0.42). The composite OABI value of −1.48 further indicates a shift toward oxidative predominance, suggesting that the antioxidant defense system was insufficient to counteract oxidative stress in most subjects (*Table V*).

Table V
Oxidative-Antioxidant Balance Index (OABI).

Parameter	Mean ± SD	Reference Range	Within Normal Range (%)	Oxidative Stress Index (Z-score)
Malondialdehyde (MDA, nmol/mg)	2.77 ± 1.04	< 2.0	30.0%	+1.49
Superoxide Dismutase (SOD, U/mg)	7.6 ± 2.1	> 8.0	40.0%	−0.62
Catalase (CAT, U/mg)	43.8 ± 8.4	> 45.0	46.7%	−0.35
Glutathione Peroxidase (GPx, U/mg)	9.2 ± 2.8	> 10.0	36.7%	−0.58
Reduced Glutathione (GSH, µmol/mg)	4.8 ± 1.4	> 5.0	43.3%	−0.42
Composite OABI	-	-	-	−1.48

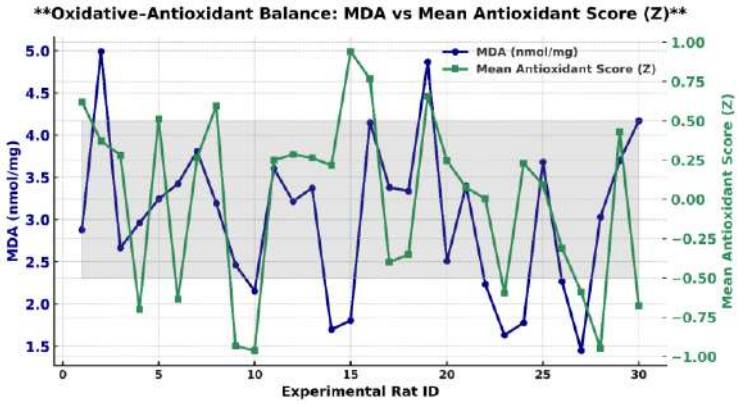

Figure 2 Oxidative-Antioxidant Balance: MDA vs Mean Antioxidant Score (Z).

Figure 2 represents the overall oxidative–antioxidant status of experimental rats, highlighting the dynamic relationship between lipid peroxidation and antioxidant defense. The navy line indicates renal malondialdehyde (MDA) concentration, an index of oxidative stress, while the green line represents the mean Z-score of major antioxidant enzymes (SOD, CAT, GPx, GSH). The grey-shaded region denotes the neutral oxidative–antioxidant balance zone (OABI =0 ± 0.5). Rats showing higher MDA values and lower antioxidant scores lie outside this balance zone, reflecting oxidative stress dominance and impaired antioxidant capacity. Conversely, animals within or near the neutral band maintain relative redox equilibrium. The figure visually demonstrates that oxidative stress and antioxidant activity are inversely related, supporting the protective influence of antioxidant mechanisms such as green-tea polyphenols against gentamicin-induced renal injury.

DISCUSSION

This study demonstrates that gentamicin induces significant oxidative stress in rat kidneys, as reflected by elevated malondialdehyde (MDA) levels and reduced antioxidant enzyme activities (SOD, CAT, GPx, GSH). Coadministration of green tea extract (GTE) mitigated these alterations, suggesting potent antioxidant and nephroprotective effects. These findings align with prior reports that oxidative stress is the principal mechanism of gentamicin-induced nephrotoxicity [17-19]. The observed rise in renal MDA and decline in antioxidant enzymes in the gentamicin-only group support earlier studies showing that gentamicin promotes lipid peroxidation while suppressing antioxidant defenses [20-22]. A study reported similar inverse correlations between MDA and renal antioxidants, confirming the oxidative nature of gentamicin injury [19]. Our results (r = –0.65 to –0.76) parallel these findings, reinforcing that excessive ROS generation overwhelms the enzymatic antioxidant system. In the present work, GTE administration reversed these biochemical changes. This agrees with Khan et al. who showed that green tea polyphenols restored SOD and CAT activity and reduced renal MDA in gentamicin-treated rats. Likewise, Abed et al. reported that GTE reduced MDA and enhanced SOD and GPx activities while improving renal histology [23,24]. The protective effects of green tea are attributed mainly to epigallocatechin-3-gallate (EGCG), which scavenges free radicals and activates Nrf2 signaling to upregulate endogenous antioxidants [25]. The histopathological findings in our gentamicin group, tubular degeneration, interstitial congestion, and hyaline casts, are consistent with those described by Bencheikh et al. and Aurori et al. who observed tubular necrosis and glomerular shrinkage accompanying elevated lipid peroxidation [2,26]. Remarkably, the GTE-treated group in our study exhibited restoration of standard tubular architecture, consistent with t2he renoprotective pattern described in other antioxidant interventions such as chrysin, formononetin, and biochanin A [27,29]. These parallels confirm that attenuation of oxidative stress correlates with structural renal recovery. Several studies corroborate our biochemical trends. Previous studies have demonstrated that flavonoids prevent gentamicin nephrotoxicity by activating the Nrf2/HO-1 pathway and enhancing SOD, CAT, and GSH levels [27,28]. Similarly, curcumin alleviated gentamicin-induced oxidative stress and apoptosis, while gallic acid reduced renal MDA and nitric oxide levels [30,31]. Oxymatrine and vitamin D have shown parallel antioxidant benefits, highlighting those multiple compounds converge on the exact protective mechanism, ROS suppression and antioxidant enzyme upregulation [32,33]. Although our findings generally agree with the literature, differences in the magnitude of antioxidant restoration were observed. For instance, some studies reported complete normalization of antioxidant markers with flavonoids such as chrysin [27]. In contrast, our GTE group showed partial recovery, possibly due to differences in dosage, bioavailability, or treatment duration. Another minor variation concerns superoxide dismutase activity: Medić-Brkić et al. observed reduced SOD despite lower MDA following chloroquine therapy, possibly due to altered redox signaling, whereas GTE in our study enhanced both SOD and CAT [34]. These variations underscore that antioxidant may differ in their mechanisms; some directly scavenge radicals; others induce endogenous enzymes. Clinically, these findings have

important implications. Gentamicin remains a vital antibiotic, but nephrotoxicity limits its use. The demonstrated renoprotective effect of GTE suggests that antioxidant co-therapy may safely enhance gentamicin's therapeutic index. Green tea extract is inexpensive, well-tolerated, and widely available, making it an appealing adjunct in patients requiring aminoglycosides. Supporting this translational potential, Aksoz et al. showed that vitamin D supplementation protected against gentamicin nephrotoxicity via similar antioxidant and anti-inflammatory mechanisms [33].

LIMITATIONS

This study was limited by its small sample size and use of an animal model, which may restrict direct applicability to humans. Only biochemical and histopathological parameters were assessed, without exploring molecular mechanisms or signaling pathways. Additionally, a single dose and duration of green tea extract were used, which prevented the evaluation of dose-dependent effects.

CONCLUSION

In conclusion, this study demonstrates that gentamicin induces significant oxidative stress and renal damage in rats, characterized by elevated MDA levels and suppressed antioxidant enzyme activities. Administration of green tea extract (200 mg/kg/day) effectively mitigated these effects by reducing lipid peroxidation and restoring antioxidant balance, leading to notable histopathological improvement. These findings suggest that the antioxidant properties of green tea polyphenols, particularly EGCG, play a crucial protective role against gentamicin-induced nephrotoxicity. Green tea extract, therefore, holds promise as a safe and accessible adjunctive therapy to minimize oxidative kidney injury associated with aminoglycoside use.

RECOMMENDATIONS

Based on the study findings, it is recommended that future research explore different doses and treatment durations of green tea extract to determine optimal protective levels against gentamicin-induced nephrotoxicity. Molecular analyses should be included to elucidate the underlying antioxidant and signaling pathways, such as Nrf2 and NF-κB. Larger animal studies and clinical trials in humans are also warranted to confirm the translational potential of green tea extract as an adjunct therapy. Additionally, the combination of GTE with other natural or pharmacological antioxidants could be investigated to enhance renal protection and improve therapeutic outcomes.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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THE PLANET

Original Article

Functional and Neurological Recovery Patterns Following Discectomy with Laminotomy for Prolapsed Lumbar Intervertebral Disc

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ABSTRACT

Background: Prolapsed lumbar intervertebral disk (PLID) remains a prominent cause of impairment in working-age people, necessitating surgical surgery when conservative treatment fails. This study aimed to assess functional and neurological recovery patterns after discectomy with laminotomy for PLID. **Methods & Materials:** This study was conducted at the Department of Orthopedic Surgery, Dhaka Medical College Hospital, from July 2019 to June 2021, on 28 radiologically confirmed PLID patients. Patients with nerve root compression and predominant leg pain unresponsive to conservative management were included. Outcome was measured using VAS, Modified Macnab criteria, and straight leg raising. **Results:** Males comprised 67.9% of the patients, and 39.3% were between the ages of 31 and 40. 67% of the patients were manual laborers. The L5 dermatome was most commonly affected by preoperative sensory impairments (57.1%), whereas the extensor hallucis longus was most commonly affected by motor weakness (57.1%). The mean VAS ratings dropped by 92%, from 3.00±0.00 before surgery to 0.24±0.64 at the last follow-up ($p<0.001$). The improvement in straight leg raising was from 42.63±6.30 degrees to 89.30±2.60 degrees ($p<0.001$). Neurological recovery revealed that 85.7% of patients had complete motor recovery and 89.3% had complete sensory recovery. The Modified Macnab criteria showed that only one superficial problem (3.6%) was documented, whereas 96.4% of patients had excellent or good results. 3.82±2.39 days was the average length of hospital stay following surgery. **Conclusion:** Excellent functional and neurological recovery with minor issues is demonstrated by discectomy combined with laminotomy for PLID. Significant pain relief, the ability to raise one's leg straight again, and a high incidence of full neurological recovery are all provided by the treatment, especially for L5 and S1 nerve root involvement.

Keywords: *Lumbar disc herniation, Discectomy, Laminotomy, Neurological recovery, Visual Analog Scale*

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INTRODUCTION

Lumbar intervertebral disc herniation (LDH) is a frequently encountered spinal disorder, in which the nucleus pulposus herniates, giving rise to nerve root compression, lower back pain, and radiculopathy that may cause substantial functional impairment. The rationale for surgical treatment of LDH is failure of conservative management and the progression of neurological deficits. However, discectomy with laminotomy has remained a classic surgical modality for LDH, in which the aim of decompression of the involved nerve roots is accomplished by excising the herniated portion of the disc via a small bony window to maintain spinal integrity. Long-term follow-up studies of LDH surgery, whether classical discectomy or its modified procedures in association with laminotomy, have shown good to excellent functional outcomes in 78% of the overall patient population [1, 2]. Postoperative functional recovery is assessed using patient-reported outcome measures, including the Visual Analogue Scale for pain and the Oswestry Disability Index for disability. There have been statistically significant changes in the Oswestry Disability Index and Visual Analogue Scale scores, reflecting the extent to which patients have had relief in the pain in the lower parts of the back and the legs, as well as in the patients' functional capability. For example, the five-year follow-up measurements in patients undergoing transforaminal full-endoscopic lumbar discectomy have shown significant changes in the Visual Analogue Scale scores for leg pain and Oswestry Disability Index scores, reflecting changes in the patients' pain and functional capability, from severe to mild disability [3]. Neurological recovery, defined as improvement in motor strength, sensory function, and reflexes, is a key outcome in patients presenting with preoperative deficits. Large longitudinal studies of simple lumbar discectomy show that many patients with preoperative motor weakness or reflex abnormalities achieve full or near-complete neurological recovery on long-term follow-up. In a one-cohort study followed for over two decades, 60% of patients with abnormal reflexes and 75% with motor weakness demonstrated normal neurological findings at long-term review and the majority reported minimal disability and high satisfaction [4]. TELD and full endoscopic discectomy have appeared safe, effective, and capable of generating significant functional and pain improvements at both short- and long-term follow-up. Among a cohort of patients undergoing transforaminal endoscopic discectomy, there was a significant postoperative decrease in both VAS and ODI scores at 1 year and beyond, coupled with low complication rates and durable outcomes. The above illustrates the theme that less invasive approaches achieve comparable recovery patterns to traditional open surgery [5,6,7]. Preoperative symptom duration, severity of neurological deficits, and comorbidities such as obesity and diabetes significantly influence the rate and extent of postoperative functional recovery. The longer the existing duration of symptoms before surgery, the less the likelihood of improvement in disability measures, underlining the need for proper selection and timing of surgery in individual patients [8, 9]. According to population-level analysis, reoperations occurring in association with primary LDH surgery have been shown to range from 4% to more than 10% at intermediate follow-up in terms of recurrence of LDH, which may be responsible for chronic disability in some cases [9,10]. The study aims to assess the functional and neurological progression of patients who have undergone discectomy with laminotomy due to a prolapsed lumbar intervertebral disc.

METHODS & MATERIALS

This is a prospective study, which was performed in the Department of Orthopedic Surgery, Dhaka Medical College Hospital, from July 2019 to June 2021. 28 consenting adults with clinically and radiologically proven prolapsed lumbar intervertebral disc, selected through purposive sampling. Inclusion criteria were patients suffering from predominant radicular leg pain and having objective signs of nerve root pressure, disc prolapse confirmed on MRI, and failure of conservative management for a period of three to six weeks. Cases of traumatic disc prolapse, patients with cauda equina syndrome, spinal tumors, infection, and previous lumbar surgery on the same level were excluded. Discectomy with laminotomy under general anesthesia through a standard posterior midline approach was conducted on all the participants. Early ambulation, routine physiotherapy, and restriction of activities were the post-operative measures followed, as per the institutional protocol. The patients were followed up at pre-specified intervals for a period of a maximum of 16 months. The efficacy-evaluating parameters included functional and neurological outcome according to the Visual Analog Scale for pain, straight leg raising test, and Modified Macnab criteria. The data were entered and analyzed using SPSS version 26. Continuous variables were expressed as mean ± SD, while categorical variables were presented as frequencies and percentages. Longitudinal changes in pain scores and straight leg raising were evaluated by repeated-measures analysis, and associations between neurological deficits and functional outcomes were assessed using Fisher's exact test and logistic regression as

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appropriate. A p-value of < 0.05 was considered statistically significant.

RESULTS

Table I shows the demographic and preoperative data of 28 patients. The age distribution reveals a predominance of the 31-40 year group (39.3%), followed by younger patients ≤30 years (28.6%). Males made up about two-thirds of the cohort (67.9%). Occupational research found that manual workers made up the majority (60.7%), followed by housewives (21.4%) and sedentary workers (17.9%).

Table I
Age, sex, occupation, and preoperative neurological status of patients (*n* = 28).

Variable	Category	(n)	(%)
Age (Years)	≤30	8	28.6
	31–40	11	39.3
	41–50	6	21.4
	≥51	3	10.7
Sex	Male	19	67.9
	Female	9	32.1
Occupation	Manual worker	17	60.7
	Sedentary worker	5	17.9
	Housewife	6	21.4

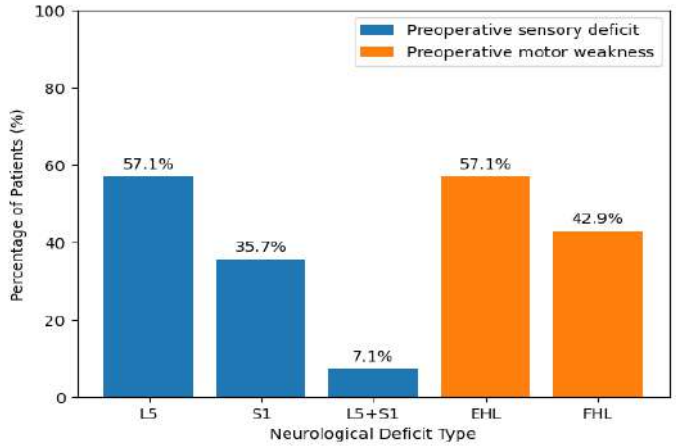

Figure 1 Patients' preoperative neurological condition.

Sensory impairments were most common in the L5 dermatome (57.1%), followed by S1 (35.7%), with only 7.1% involving both. Motor weakness examination found that 57.1% of patients had extensor hallucis longus (EHL) involvement, whereas 42.9% had flexor hallucis longus (FHL). This pattern of neurological involvement is typical of L4-L5 and L5-S1 disc herniations, the most prevalent locations of lumbar disc prolapse, and corresponds to the anatomical distribution of nerve root compression (*Figure 1*).

Table II summarizes the follow-up length and hospital stay data. The average follow-up period was 9.46±3.94 months, with 42.9% of patients followed for up to 6 months, 21.4% for 7-9 months, and 35.7% for 10 months or beyond, allowing for accurate assessment of surgical results. The average preoperative hospital stay was 11.29±5.94 days, which included evaluation and conservative care prior to surgery. The treatment was minimally invasive, resulting in a shorter postoperative hospital stay of 3.82±2.39 days. This promotes early discharge and lowers healthcare expenses.

Table II
Duration of follow-up and hospital stay (*n* = 28).

Parameter	Category	n (%) / Mean ± SD
Follow-up duration (months)	Up to 6 months	12 (42.9)
	7-9 months	6 (21.4)
	≥10 months	10 (35.7)
	Mean± SD	9.46 ± 3.94
Hospital stays (days)	Preoperative	11.29 ± 5.94
	Postoperative	3.82 ± 2.39

Table III shows a gradual improvement in discomfort and straight leg lifting. Preoperatively, all patients reported moderate discomfort (VAS=3). By the third postoperative visit, 92.9% were pain-free, and the mean VAS decreased from 3.00±0.00 to 0.24±0.64, a 92% reduction ($p<0.001$). Straight leg raising significantly improved from 42.63±6.30 degrees preoperatively to 89.30±2.60 degrees at end follow-up ($p<0.001$), representing a 109.5% increase. This progressive enhancement demonstrates efficient neural decompression, which results in the gradual resolution of nerve root inflammation and the restoration of biomechanical function over time.

Table III
Distribution of pain score and straight leg raising (SLR) during follow-up (*n* = 28).

A. Pain score distribution (VAS)

Pain score	Preoperative	1st visit	2nd visit	3rd visit
	n (%)	n (%)	n (%)	n (%)
Absent (0)	0 (0)	0 (0)	16 (57.1)	26 (92.9)

Occasional (1)	0 (0)	2 (7.1)	5 (17.9)	0 (0)
Mild (2)	0 (0)	25 (89.3)	7 (25)	2 (7.1)
Moderate (3)	28 (100)	1 (3.6)	0 (0)	0 (0)

B. Mean VAS score

Stage	Mean ± SD
Preoperative	3.00 ± 0.00
Postoperative 1st visit	1.79 ± 0.62
Postoperative 2nd visit	1.07 ± 0.84
Postoperative 3rd visit	0.24 ± 0.64

C. Straight Leg Raising

Visit	Mean ± SD
Preoperative	42.63 ± 6.30
Postoperative 1st visit	75.0 ± 5.77
Postoperative 2nd visit	83.6 ± 4.88
Postoperative 3rd visit	89.3 ± 2.60

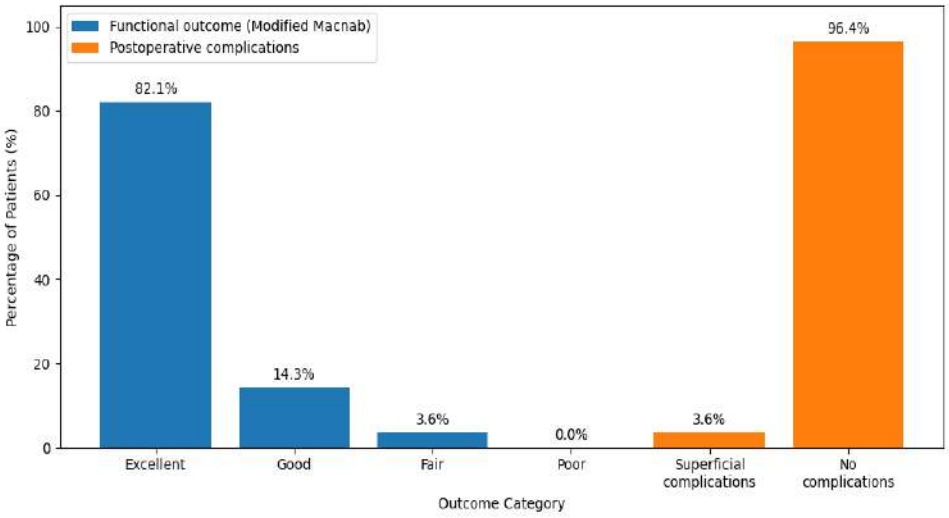

Figure 2 Final functional outcomes and complications.

Using Modified Macnab criteria in conjunction with VAS scores, 82.1% achieved excellent outcomes, 14.3% good outcomes, and 3.6% fair outcomes, with no poor results. This amounts to 96.4% favorable results (excellent/good), indicating a high surgical success rate. issue study indicated only one superficial issue (3.6%), whereas 96.4% had no complications. The low complication rate highlights the procedure's safety profile, while the large proportion of favorable outcomes confirms discectomy with laminotomy as a viable therapy method for symptomatic prolapsed lumbar intervertebral disc (*Figure 2*).

Table IV measures temporal variations in pain severity and straight leg lifting. Pain intensity improved consistently throughout all follow-up periods, with mean VAS reductions of 1.21 points (40.3%) at first visit, 1.93 points (64.3%) at second visit, and 2.76 points (92%) at third visit ($p < 0.001$). At each visit, straight leg raising improved by an average of 32.37 degrees (75.9%), 40.97 degrees (96.1%), and 46.67 degrees (109.5%) ($p<0.001$). The progressive trend of improvement suggests that brain repair, inflammation resolution, and tissue healing are continuing, with the greatest increases occurring during the first three months after surgery.

Table IV
Change in pain intensity and improvement in straight leg raising over time.

A. Change in Pain Intensity (VAS Score) Over Time

Time point	Mean ± SD	Mean change from baseline	% Reduction from baseline	p-value
Preoperative	3.00 ± 0.00	-	-	<0.001
Postoperative 1st visit	1.79 ± 0.62	-1.21	40.3%	
Postoperative 2nd visit	1.07 ± 0.84	-1.93	64.3%	
Postoperative 3rd visit	0.24 ± 0.64	-2.76	92.0%	

B. Improvement in Straight Leg Raising (SLR) Angle Over Time

Time point	Mean ± SD (degrees)	Mean improvement from baseline	% Improvement	p-value
Preoperative	42.63 ± 6.30	-	-	<0.001
Postoperative 1st visit	75.00 ± 5.77	+32.37	75.9%	
Postoperative 2nd visit	83.60 ± 4.88	+40.97	96.1%	
Postoperative 3rd visit	89.30 ± 2.60	+46.67	109.5%	

Table V compares neurological healing trends based on nerve root involvement. Complete sensory recovery was achieved in 93.8% of L5, 90% of S1, and 50% of combined L5+S1 deficiency patients, with the remainder demonstrating partial recovery and none reporting no recovery. Motor recovery resulted in complete resolution in 87.5% of EHL and 83.3% of FHL weakening cases, with 12.5% and 16.7% demonstrating partial recovery, respectively ($p=0.68$). The high percentages of complete neurological recovery corroborate the efficacy of early surgical decompression, but the absence of statistical significance between groups indicates that recovery potential is equivalent regardless of specific nerve root involvement.

Table V
Combined Sensory and Motor Neurological Recovery Pattern at Final Follow-up After Discectomy with Laminotomy.

Preoperative Neurological Profile	Complete Recovery n (%)	Partial Recovery n (%)	No Recovery n (%)	p-value
Sensory deficit	-	-	-	-
L5 (n=16)	15 (93.8)	1 (6.2)	0 (0.0)	0.21
S1 (n=10)	9 (90.0)	1 (10.0)	0 (0.0)	
L5 + S1 (n=2)	1 (50.0)	1 (50.0)	0 (0.0)	
Motor weakness	-	-	-	-
EHL (n=16)	14 (87.5)	2 (12.5)	0 (0.0)	0.68
FHL (n=12)	10 (83.3)	2 (16.7)	0 (0.0)	

Table VI shows a logistic regression study of the factors for great functional outcomes. Although younger patients (≤40 years) had superior outcomes (OR=2.10), with 89.5% having good results compared to 77.8% in older patients, the difference was not statistically significant (p=0.44). Similarly, male gender (OR=1.38), manual occupation (OR=0.92), and longer follow-up ≥10 months (OR=2.67) showed favorable tendencies but did not reach statistical significance. The lack of significant indicators shows that discectomy with laminotomy produces consistently positive results across varied patient populations, regardless of demographic or vocational characteristics.

Table VI
Logistic regression analysis of factors associated with excellent functional outcome.

Predictor Variable	Excellent Outcome n (%)	OR	95% CI	p-value
Age ≤40 years (n=19)	17 (89.5)	2.10	0.32-13.6	0.44
Male (n=19)	16 (84.2)	1.38	0.21-9.12	0.74
Manual occupation (n=17)	14 (82.4)	0.92	0.14-6.11	0.93
Follow-up ≥10 months (n=10)	9 (90)	2.67	0.29-24.5	0.39

DISCUSSION

Prolapsed lumbar intervertebral disc is a major cause of disability in the population of the working age group, and surgery is indicated when conservative management fails to provide adequate relief to the patients [11]. This is a prospective analysis of functional and neurological recovery patterns in patients who underwent discectomy with laminotomy and shows excellent results with minimal complications. Our study demonstrated male predominance of 67.9% and a peak incidence in the 31-40-year age group, an epidemiological pattern for lumbar disc herniation. Manual workers constituted the majority of the subjects, 60.7%, showing the biomechanical stress and repetitive loading from heavy physical work [12]. This demographic distribution was corroborated by Bydon et al., in their large cohort of 500 patients who underwent lumbar laminectomy with similar patterns, emphasizing the occupational impact of degenerative lumbar diseases [13]. The pain control, as measured by VAS, showed significant improvement from 3.00±0.00 preoperatively to 0.24±0.64 at final follow-up, indicating a 92% reduction (p<0.001). This goes beyond the minimal clinically significant difference and is in tandem with studies presented by Tang et al., who showed significant pain reduction after unilateral laminotomy for bilateral decompression procedures [14]. The progressive stabilization of pain values at follow-up intervals indicates a gradual recovery of the nerve and cessation of inflammation following decompression procedures. Minamide et al. also showed pain control in their 5-year follow-up study of microendoscopic laminotomy in lumbar spinal stenosis patients [15]. Improvement in straight leg raising from 42.63±6.30 degrees before surgery to 89.30±2.60 degrees at final follow-up (p<0.001) signifies successful nerve root decompression and achievement of nerve mobility. The quantitative assessment of neurological function is well associated with subjective measures of pain relief and signifies a successful surgical procedure. Continued progression signifies healing and neurological adaptation post-decompression procedure [16]. The patterns of neurological recovery showed complete sensory recovery in 89.3% and complete motor recovery in 85.7% of the patients. These findings were better than those reported by Mariconda et al., in their long-term follow-up study, found the following patient recovery percentages among those with preoperative muscle weakness; 75% regained normal strength, and among those with abnormal preoperative reflexes, 60% regained full recovery [17]. Our better recovery may be due to earlier surgery and shorter preoperative neurological deficits. Results from the study of Lønne et al. showed favorable recovery among patients with limb paresis, with 75% of them regaining full recovery at 12 months postmicrodiscectomy, especially those with mild paresis compared to those with severe paresis [18]. There were no significant differences in nerve root-specific recovery in L5 vs. S1 dermatomes (p=0.21) or in EHL vs. FHL motor recovery (p=0.68), indicating equivalent recovery capacities despite divergent compression of specific nerve roots. This is in accordance with sufficient recovery despite anatomical levels of depression after appropriate decompression [19]. Nonetheless, in the only case presenting with both L5 & S1 involvement, recovery was only partial with respect to sensory or motor components. Functional outcome measures according to Modified Macnab criteria revealed 82.1% to be excellent, 14.3% to be good, and 3.6% to be fair, while 96.4% patients achieved satisfactory outcomes which is in line with Ahn et al. [20]. The complication rate of 3.6% (one superficial wound complication) is comparable with reports by Silverplats et al. [21]. The surgical-site infections were found to be 4.3%, whereas the overall complication rate varied between 10% in a report by Lequin et al. [22]. The very low rate of complications in our study substantiates the safety profile of discectomy with laminotomy. Logistic regression analysis showed non-significant factors for excellent outcomes, such as age, gender, occupation, and duration of follow-up. It indicates that discectomy with laminotomy has consistent favorable outcomes for varying patients.

LIMITATIONS

This study's limitations include a relatively small sample size and variable follow-up duration, which may limit statistical power and long-term outcome assessment.

CONCLUSION

Discectomy with laminotomy for prolapsed lumbar intervertebral discs results in excellent functional and neurological recovery with few problems. The technique provides great pain relief (92% reduction in VAS scores), restores straight leg raising from 42.63 to 89.30 degrees, and has a high incidence of complete neurological recovery. With 96.4% attaining excellent or good outcomes according to Modified Macnab criteria and only 3.6% experiencing complications, this surgical method remains an effective and safe therapeutic option for appropriately selected patients with PLID who have failed conservative care.

RECOMMENDATIONS

Future studies should incorporate larger multicenter cohorts with standardized long-term follow-up protocols extending beyond 2-5 years, and investigate specific patient-reported outcome measures to better identify prognostic factors and optimize patient selection criteria.

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CONFLICT OF INTEREST

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The study was approved by the Institutional Ethics Committee.

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Elective laparoscopic cholecystectomy in Bangladesh: Demographics, Comorbidities, and Preoperative Risk Features in 100 Consecutive Patients

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC) is the global standard for managing symptomatic gallstone disease, yet detailed data on the preoperative characteristics of patients undergoing this procedure in Bangladesh remains limited. A clear understanding of local demographic patterns, comorbidity burdens, and preoperative risk features is essential for optimizing surgical care. **Aim:** The aim of this study was to characterize the demographic profile, comorbidity patterns, and preoperative risk features in patients undergoing elective LC at a tertiary care center in Bangladesh. **Methods & Materials:** This prospective cross-sectional observational study included 100 consecutive patients scheduled for elective LC at Shaheed Suhrawardy Medical College and Hospital, Dhaka, Bangladesh from January to December 2023. Data on demographics, comorbidities, surgical indications, and preoperative risk features from clinical assessment and imaging were systematically collected and analyzed. **Results:** The largest proportion of patients were aged 31-40 years (36.0%), with 64.0% being under 41 years of age. A female predominance was observed (59.0%). Symptomatic cholelithiasis was the primary indication for surgery (90.0%). Hypertension was the most common comorbidity (56.0%), followed by diabetes mellitus (20.0%). Preoperative risk features for difficult surgery were present in only 16.0% of patients, with gallbladder wall thickening on ultrasound being the most frequent (5.0%). **Conclusion:** Patients undergoing elective LC in Bangladesh are predominantly young to middle-aged females with a high prevalence of hypertension and diabetes, but relatively few preoperative risk factors for difficult surgery. This profile underscores the importance of preoperative comorbidity optimization and provides a valuable baseline for future studies in the region.

Keywords: *Laparoscopic cholecystectomy, Bangladesh, Demographics, Comorbidities, Preoperative risk factors*

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INTRODUCTION

Laparoscopic cholecystectomy (LC) has become the global standard for the management of symptomatic gallstone disease and remains one of the most commonly performed abdominal surgical procedures worldwide. Its adoption has been driven by clear advantages over open cholecystectomy, including reduced postoperative pain, shorter hospitalization, faster recovery, and lower morbidity, making it the preferred modality across diverse health systems. As the global burden of gallstone disease continues to rise, LC now represents a major component of routine surgical care. Recent epidemiologic analyses indicate that gallstone prevalence varies widely by region but is increasing overall; for instance, a contemporary meta-analysis confirmed rising global incidence patterns influenced by diet, obesity, and aging demographics [1]. Population-based data from high-income settings mirror these patterns, as seen in the United States, where gallstone-related morbidity remains substantial and cholecystectomy rates continue to climb [2]. Comparable trends have been documented in emerging economies, with South African data showing a notable increase in LC utilization for gallstone-related disease, underscoring the universal relevance of this operation across different socioeconomic environments [3]. Gallstone disease demonstrates well-established demographic patterns that influence both disease prevalence and operative demand. A consistent female predominance is reported globally, with biological, hormonal, and metabolic factors contributing to higher rates of gallstone formation among women. Large-scale prospective data from the MAUCO population cohort confirmed that females exhibit significantly higher gallstone disease prevalence and a correspondingly increased likelihood of requiring cholecystectomy [4]. These findings align with population studies from Scandinavia, where female sex and socioeconomic characteristics were predictive of increased operative intervention for gallstone disease [5]. Age is another critical determinant; risk rises progressively with advancing age, as documented in a population-based cohort study from Norway that identified older age as a strong predictor for subsequent cholecystectomy [6]. These demographic patterns shape operative case mix in most countries and highlight the importance of understanding local population characteristics when reporting LC outcomes. In South Asia, gallstone disease is an important contributor to surgical workload, but the epidemiology varies considerably within the region. Bangladeshi series consistently describe a predominance of female patients undergoing LC, along with a tendency toward younger operative age compared with Western populations. Local studies from tertiary centers have shown that symptomatic cholelithiasis remains the leading indication for LC, with acute cholecystitis contributing a smaller proportion of elective cases [7]. These findings reflect not only disease epidemiology but also referral patterns, healthcare access, and resource constraints. The increasing adoption of minimally invasive surgery in Bangladesh is evidenced by reports of large procedural series, including analyses of anesthesia practices and perioperative outcomes in thousands of LC cases [8]. However, most Bangladeshi publications focus on operative technique, perioperative outcomes, or complication profiles rather than systematic documentation of demographic, comorbidity, and risk-factor distributions in elective LC patients. Comorbidities and

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preoperative risk factors play an important clinical role in anticipating technical difficulty, predicting conversion to open surgery, and counseling patients. Several international studies have emphasized that metabolic and cardiovascular comorbidities, including hypertension, diabetes, and obesity, contribute significantly to gallstone disease risk and may influence perioperative outcomes [9,10]. Moreover, a substantial body of evidence identifies specific preoperative imaging and clinical markers associated with difficult LC and greater likelihood of conversion, such as gallbladder wall thickening, contracted gallbladder, elevated inflammatory markers, and dilated common bile duct. These risk associations have been synthesized in multiple high-quality systematic reviews, including a recent meta-analysis confirming that age, male sex, previous abdominal surgery, and markers of inflammation significantly increase conversion risk [11]. Additional reviews incorporating both preoperative and intraoperative variables highlight severe adhesions, unclear anatomy, and hemorrhage as principal intraoperative reasons for conversion [12]. Yet, despite these insights, there remains heterogeneity in the predictive performance of individual risk factors across different populations, particularly in low- and middle-income countries. Within Bangladesh, preoperative risk characterization is insufficiently documented, and existing data often combine elective and emergency cases, limiting interpretability. While some studies report complication patterns and conversion rates, few provide detailed analyses of comorbidities, ultrasonographic markers, or biochemical abnormalities in exclusively elective LC cohorts. This gap hampers evidence-based operative planning, risk stratification, and informed decision-making. A more complete understanding of the demographic composition, comorbidity profiles, and preoperative risk features among Bangladeshi LC patients is essential for optimizing patient selection, anticipating operative difficulty, and guiding resource allocation within surgical departments. Therefore, the present study aims to provide a detailed characterization of these parameters in 100 consecutive elective LC patients managed at a tertiary center in Bangladesh, thereby contributing contextually relevant evidence to the regional literature and addressing a notable gap in current knowledge.

METHODS & MATERIALS

This prospective cross-sectional observational study was conducted in the Department of Surgery, Shaheed Suhrawardy Medical College and Hospital, Sher-E-Bangla Nagar, Dhaka, Bangladesh. The study period extended from January 2023 to December 2023. A total of 100 consecutive patients scheduled for elective laparoscopic cholecystectomy were enrolled after meeting the inclusion criteria and providing informed written consent. Patients with acute cholecystitis for longer than seven days or with gallbladder cancer were excluded. Sampling followed a purposive convenience approach, and all eligible patients presenting during the study period were included. Data collection followed a structured workflow. Demographic variables, comorbidity profiles, previous abdominal surgery, and preoperative clinical, laboratory, and ultrasonographic risk features were recorded using a standardized proforma. Imaging findings included gallbladder wall thickness, gallbladder contracture, common bile duct diameter, and the presence of any inflammatory markers or biochemical abnormalities. All information was obtained preoperatively through clinical assessment, ultrasound reports, routine laboratory investigations, and medical history reviews. Intraoperative observations were recorded for quality assurance, though only preoperative factors and baseline characteristics were analyzed for the present manuscript. Data quality was ensured through cross-checking, verification, and systematic entry procedures. Statistical analysis was performed using SPSS version 21.0. Descriptive statistics were applied to summarize the study population. Continuous variables were reported as mean and standard deviation, while categorical variables were presented as frequencies and percentages. Ethical approval for this study was obtained from the institutional ethical review board of Shaheed Suhrawardy Medical College and Hospital. Confidentiality was maintained throughout, and all participants were informed of the study's objectives, procedures, and associated risks and benefits prior to enrollment.

RESULTS

Among the 100 patients who underwent elective laparoscopic cholecystectomy, the largest proportion were between 31 and 40 years of age (36%), followed by those aged 20–30 years (28%). Only 16% of the study population were above 50 years. Females accounted for 59% of cases, reflecting the typical female predominance of gallstone disease, while males represented 41%. Symptomatic cholelithiasis was the primary indication for surgery, comprising 90% of the cohort, and the remaining 10% underwent surgery for acute cholecystitis of less than seven days' duration (*Table I*).

Table I
Demographic characteristics and indications for surgery (n = 100).

Category	n (%)
Age group (years)	
20–30	28 (28.0)
31–40	36 (36.0)
41–50	20 (20.0)
51–60	11 (11.0)
≥61	5 (5.0)
Sex	
Male	41 (41.0)
Female	59 (59.0)
Indication for surgery	
Symptomatic cholelithiasis	90 (90.0)
Acute cholecystitis (<7 days)	10 (10.0)

Hypertension was the most frequent comorbidity in the study population, identified in 56% of patients. Diabetes mellitus was present in 20%, and chronic obstructive pulmonary disease in 15%. Ischemic heart disease was less common, reported in 5% of cases. Only 3% of patients had a history of previous abdominal surgery, and obesity was rare, documented in 1% of the cohort. Overall, the distribution shows a moderate burden of metabolic and cardiopulmonary comorbidities among elective laparoscopic cholecystectomy patients (*Table II*).

Table II
Comorbidities and previous abdominal surgery (n = 100).

Comorbidity or condition	n (%)
Hypertension	56 (56.0)
Diabetes mellitus	20 (20.0)
Chronic obstructive pulmonary disease (COPD)	15 (15.0)
Ischemic heart disease	5 (5.0)
Previous abdominal surgery	3 (3.0)
Obesity	1 (1.0)

Preoperative risk features were observed in 16% of patients. The most frequent finding was a thickened gallbladder wall on ultrasound (5%). Contracted gallbladder, dilated common bile duct on MRCP, abnormal liver function tests, and recent acute cholecystitis with elevated inflammatory markers were each detected in 2% of patients. Hypertension, when considered specifically as a perioperative risk factor, was also present in 2%, while 3% had a history of previous abdominal surgery noted as a risk factor. These findings indicate that the majority of patients had no major preoperative predictors of difficult laparoscopic cholecystectomy (*Table III*).

Table III
Preoperative risk features detected (n = 100).

Risk feature	n (%)
Ultrasound showing thickened gallbladder wall	5 (5.0)
Contracted gallbladder on imaging	2 (2.0)
MRCP showing dilated common bile duct (CBD)	2 (2.0)
Abnormal liver function test (bilirubin or ALP)	2 (2.0)
Recent acute cholecystitis with raised CBC or CRP	2 (2.0)
Hypertension considered a perioperative risk factor	2 (2.0)
History of previous abdominal surgery	3 (3.0)
Patients with ≥1 listed risk feature	16 (16.0)

DISCUSSION

This prospective study delineates the demographic and clinical profile of 100 consecutive patients undergoing elective laparoscopic cholecystectomy (LC) at a Bangladeshi tertiary center, revealing a cohort that is largely young-to-middle-aged with a significant female predominance. The largest proportion of our patients were between 31 and 40 years of age (36.0%), a finding that closely mirrors the experience from another Bangladeshi tertiary hospital where the 31-40 age group constituted 26.23% of cases [13]. Furthermore, females accounted for 59.0% of our cohort, a consistent observation in gallstone disease epidemiology. This female predominance is not merely a local phenomenon but is underpinned by robust global evidence, with a large prospective cohort study identifying female sex as a strong predictor, more than doubling the prevalence of gallstone disease compared to males [4]. Beyond demographics, our study highlights a substantial burden of cardiometabolic comorbidities, with hypertension being remarkably prevalent at 56.0%, followed by diabetes mellitus at 20.0%. This pattern is comparable to findings from a large Brazilian cohort, where hypertension and diabetes were also the most frequent comorbidities, reported in 44.1% and 15.9% of patients, respectively Critically, that same study identified these conditions as independent predictors of postoperative complications, underscoring the clinical importance of our findings and the necessity for meticulous preoperative optimization [10]. The primary surgical indication in our series was symptomatic cholelithiasis (90.0%), which is characteristic of an elective surgical pathway. Despite the comorbidity burden, preoperative imaging and biochemical risk features predictive of a difficult cholecystectomy were infrequent, present in only 16.0% of our patients. The most common finding was a thickened gallbladder wall on ultrasound (5.0%). While this prevalence was low, the clinical significance of this marker cannot be overstated. Multiple meta-analyses have confirmed that gallbladder wall thickening significantly elevates the risk of conversion to open surgery, with one analysis reporting an odds ratio of 3.44, a finding corroborated by another systematic review [11,12]. This suggests that while our patient cohort was largely low-risk based on preoperative imaging, vigilant identification of these specific markers remains paramount for operative planning. In summary, our data characterizes the elective LC population in Bangladesh as predominantly young to middle-aged females with a high prevalence of hypertension and diabetes, yet a low incidence of preoperative radiological risk factors for difficult surgery. This profile, which aligns with regional reports and is supported by global epidemiological data, provides crucial context for surgical departments in Bangladesh, informing patient counseling, resource allocation, and the development of standardized preoperative assessment protocols tailored to the local population's needs.

LIMITATIONS

This study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of our findings to other healthcare settings across Bangladesh. Furthermore, the focus on preoperative characteristics without comprehensive analysis of intraoperative outcomes or long-term follow-up restricts the scope of our conclusions.

CONCLUSION

The elective laparoscopic cholecystectomy population in Bangladesh is characterized by a predominance of young to middle-aged female patients with a significant burden of cardiometabolic comorbidities, particularly hypertension and diabetes mellitus. Despite this comorbidity profile, preoperative imaging and biochemical risk factors for difficult surgery were relatively uncommon, suggesting that most patients present with favorable profiles for successful laparoscopic intervention. These findings highlight the need for structured preoperative screening and optimization of comorbid conditions, providing valuable context for surgical planning and resource allocation in similar Bangladeshi healthcare settings.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

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Effect of Intravenous Dexmedetomidine on Shivering in Cesarean Section after Spinal Anaesthesia

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ABSTRACT

Introduction: One of the most common and disturbing side effects of spinal Anaesthesia is body shivering, especially during cesarean delivery, which severely affects the mother's comfort, and hemodynamic changes may result. The present study was designed to evaluate the effect of intravenously administered dexmedetomidine on the incidence and severity of shivering in patients undergoing cesarean section under spinal Anaesthesia. **Methods & Materials:** This prospective cross-sectional study was done in the Department of Anaesthesiology at 250 Bedded General Hospital, Gopalganj, for a period of six months from July, 2024 to December, 2024. The study population was the parturients undergoing cesarean section under spinal Anaesthesia during the study period. Inclusion and exclusion criteria were pre-set, set and a total of 102 patients were selected by purposive sampling. Statistical analysis was performed using SPSS version 26.0. **Result:** There was a marked decrease in the incidence of shivering in the dexmedetomidine group when compared to the control group (15.7% vs. 56.9%; $p < 0.001$). Most patients had no shivering in the dexmedetomidine group when compared to the control group (84.3% vs. 43.1%), and there were no cases of severe shivering in the dexmedetomidine group compared to 13.7% in the control group ($p < 0.001$). There was a more frequent occurrence of moderate sedation with dexmedetomidine (62.7% vs. 11.8%; $p < 0.001$). Compared to the control group, the dexmedetomidine group had significantly lower mean heart rate. However, the mean arterial pressure was similar in both groups. Bradycardia was noted more frequently with dexmedetomidine use, but the patients were asymptomatic. The incidence of adverse events was the same for both groups, but the requirement for rescue anti- shivering drugs was drastically less in the dexmedetomidine group (5.9% vs. 41.2%; $p < 0.001$). **Conclusion:** Intravenous dexmedetomidine may be regarded as a highly potent drug for decreasing the frequency as well as severity of shivering in parturients who have undergone cesarean section under spinal Anaesthesia. Also, it results in a proper level of sedation, complying with hemodynamic stability. Besides, the employment of dexmedetomidine markedly reduces the need for rescue anti-shivering medication while not resulting in an elevation of the adverse effects.

Keywords: *Dexmedetomidine, Shivering, Spinal Anaesthesia, Cesarean Section*

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INTRODUCTION

Shivering is one of the most common and unfortunate side effects that mainly follow spinal Anaesthesia for obstetric patients undergoing cesarean delivery. The reported figures of shivering cases after neuraxial Anaesthesia range between 40% and 60%, which indicates a very serious problem during the perioperative period [1]. Shivering in parturients is a source of discomfort; however, on the physiological side, it also triggers increased oxygen consumption, carbon dioxide production, and an increase in the metabolic rate. Thus, there is a risk of compromising maternal cardiorespiratory function, and it becomes also difficult to monitor various intraoperative parameters such as electrocardiography and pulse oximetry [2]. Excessive shivering, besides physiological implications, may adversely affect maternal satisfaction and the overall quality of Anaesthesia care during cesarean delivery. The mechanism of shivering development after spinal Anaesthesia is multifactorial. Neuraxial blockade interferes with the hypothalamic regulation of body temperature by inhibiting vasoconstriction and shivering responses below the level of the block, thereby redistributing core heat to the periphery [3]. Other factors that contribute are exposing the patient to a cold operating room, giving unwarmed intravenous fluids, and the pregnancy, related hormonal changes [4]. On the whole, these conditions reduce the core body temperature, and shivering, as a thermoregulatory reaction, is then initiated. Various drugs have been assessed for their effectiveness in the prevention as well as the treatment of shivering after spinal Anaesthesia. A few examples of such drugs are opioids, clonidine, tramadol, ketamine, and magnesium sulfate [5]. However, it should be noted that most of these drugs have side effects such as nausea, vomiting, very profound sedation, hallucinations, or respiratory depression; therefore, their usage in obstetric Anaesthesia is highly restricted/not routine [6]. This means a perfect agent to shivering would be one that is powerful, entirely safe for both the mother and the baby, and does not cause any marked respiratory or hemodynamic compromise. Dexmedetomidine, a highly selective 2, adrenergic agonist, has recently been the subject of a great deal of research as to its potential role in the prevention and treatment of shivering during neuraxial Anaesthesia. It can, in a dose-dependent manner, produce sedation, anxiolysis, and analgesia, but, at the same time, there is no respiratory compromise [7]. Dexmedetomidine may prevent shivering by cutting out the shivering threshold through central inhibition of noradrenergic neurons in the locus coeruleus and modulation of hypothalamic thermoregulation in the brain [8]. Therefore, from a pharmacological point of view, the use of dexmedetomidine in obstetric patients is quite logical. Several randomized controlled trials have demonstrated that dexmedetomidine is effective in reducing the frequency and intensity of shivering following spinal Anaesthesia for cesarean section. One randomized controlled study with low-dose intravenous

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dexmedetomidine reported that the incidence of shivering was significantly reduced compared to the placebo group. Moreover, the use of the drug was linked to stable hemodynamic parameters and improved patient comfort [9]. Meta-analyses have also documented the effects of dexmedetomidine, which is more effective than the placebo and equal to or better than other anti-shivering medications without increasing the risk of hypotension or bradycardia at the right dose of the drug [10]. Hence, the study was performed to investigate the influence of intravenously administered dexmedetomidine on the incidence and severity of shivering in patients undergoing cesarean section under spinal Anaesthesia.

METHODS & MATERIALS

This prospective cross-sectional study was conducted at the Department of Anaesthesiology, 250 Bedded General Hospital, Gopalganj, for a period of six months from July, 2024 to December, 2024. The study population consisted of parturients who received spinal Anaesthesia during their cesarean section. Purposive sampling method was employed to select 102 patients in total based on inclusion and exclusion criteria that were set prior. The inclusion criteria were pregnant women aged 18 to 40 years, ASA physical status I or II, and undergoing cesarean section, either elective or emergency, with spinal Anaesthesia. The study excluded patients who had contraindications for spinal Anaesthesia, those allergic to dexmedetomidine, patients with pre-existing cardiac conduction abnormalities, severely ill patients systemically, or those who were on drugs affecting thermoregulation. After obtaining the informed written consent, patients were randomly allocated into two groups of equal numbers: Group D (dexmedetomidine group, n=51) and Group C (control group, n=51). Group D was administered intravenous dexmedetomidine after spinal Anaesthesia according to the institutional protocol, while Group C was given an equal volume of normal saline. The patients' heart rate, non-invasive blood pressure, oxygen saturation, and electrocardiography were continuously monitored. Core temperature was indirectly measured, and the patients were checked during the operation and after the operation for possible shivering. Shivering was scored using a standard shivering scale. Sedation was scored by the modified Ramsay Sedation Scale. Hemodynamic parameters were recorded at regular time intervals. Hypotension, bradycardia, nausea, vomiting, respiratory depression, and any other adverse events were recorded. A structured data collection sheet was used to collect the data. SPSS 26.0 was used for statistical analysis. Measurements such as age and weight were expressed as mean standard deviation, while gender distribution was presented as frequencies and percentages. Comparison between the two groups was carried out using the independent sample t-test for continuous variables and the chi-square test for categorical variables. A p-value of <0.05 was regarded as statistically significant.

RESULTS

The mean age in Group D was 26.9 ± 4.8 years, compared to 27.3 ± 5.1 years in Group C (p = 0.68). Mean body weight was 62.4 ± 6.7 kg in Group D and 61.9 ± 7.1 kg in Group C (p = 0.74), while mean height was 155.6 ± 5.4 cm and 156.1 ± 5.8 cm, respectively (p = 0.62). ASA physical status I was observed in 38 patients (74.5%) in Group D and 36 patients (70.6%) in Group C, whereas ASA II was present in 13 (25.5%) and 15 (29.4%) patients, respectively (p = 0.65) *Table I*.

Table I
Baseline Demographic Characteristics of the Study Participants (*n*=102).

Variable	Group D (n=51)	Group C (n=51)	p value
Age (years), mean ± SD	26.9 ± 4.8	27.3 ± 5.1	0.68
Weight (kg), mean ± SD	62.4 ± 6.7	61.9 ± 7.1	0.74
Height (cm), mean ± SD	155.6 ± 5.4	156.1 ± 5.8	0.62
ASA I / II	38 (74.5%) / 13 (25.5%)	36 (70.6%) / 15 (29.4%)	0.65

Shivering occurred in 8 patients (15.7%) in the dexmedetomidine group compared to 29 patients (56.9%) in the control group, while absence of shivering was noted in 43 patients (84.3%) and 22 patients (43.1%), respectively. This difference was statistically significant (p < 0.001) *Table II*.

Table II
Incidence of Shivering After Spinal Anaesthesia (*n*=102).

Shivering	Group D (n=51)	Group C (n=51)	p value
Present	8 (15.7%)	29 (56.9%)	<0.001
Absent	43 (84.3%)	22 (43.1%)	

Grade 0 (no shivering) was observed in 43 patients (84.3%) in Group D and 22 patients (43.1%) in Group C. Grade 1 shivering occurred in 5 patients (9.8%) in Group D and 12 patients (23.5%) in Group C, while grade 2 shivering was noted in 3 patients (5.9%) and 10 patients (19.6%), respectively. Grade 3 (severe) shivering occurred in no patients (0%) in Group D but in 7 patients (13.7%) in Group C. The overall difference in shivering severity between the groups was statistically significant (p < 0.001) *Table III*.

Table III
Severity of Shivering (*n*=102).

Grade	Group D (n=51)	Group C (n=51)	p value
Grade 0	43 (84.3%)	22 (43.1%)	<0.001
Grade 1	5 (9.8%)	12 (23.5%)	
Grade 2	3 (5.9%)	10 (19.6%)	
Grade 3	0 (0%)	7 (13.7%)	

Sedation scores of 1–2 were observed in 19 patients (37.3%) in Group D compared to 45 patients (88.2%) in Group C, whereas higher sedation scores of 3–4 were recorded in 32 patients (62.7%) in Group D and only 6 patients (11.8%) in Group C. This difference was statistically significant ($p < 0.001$) *Table IV*.

Table IV
Sedation Scores (Modified Ramsay Sedation Scale) (n=102).

Sedation Score	Group D (n=51)	Group C (n=51)	p value
Score 1–2	19 (37.3%)	45 (88.2%)	<0.001
Score 3–4	32 (62.7%)	6 (11.8%)	

The mean heart rate was 68.5 ± 6.9 beats/min in Group D and 74.8 ± 7.4 beats/min in Group C, showing a statistically significant difference ($p < 0.001$). Mean arterial pressure was 78.6 ± 6.1 mmHg in Group D and 80.2 ± 6.4 mmHg in Group C, with no significant difference ($p = 0.18$). Bradycardia occurred in 6 patients (11.8%) in Group D and 1 patient (2.0%) in Group C ($p = 0.05$) *Table V*.

Table V
Hemodynamic Parameters (*n*=102).

Parameter	Group D	Group C	p value
Mean heart rate (beats/min)	68.5 ± 6.9	74.8 ± 7.4	<0.001
Mean arterial pressure (mmHg)	78.6 ± 6.1	80.2 ± 6.4	0.18
Bradycardia	6 (11.8%)	1 (2.0%)	0.05

Hypotension was observed in 7 patients (13.7%) in Group D and 6 patients (11.8%) in Group C ($p = 0.77$). Nausea and vomiting occurred in 4 patients (7.8%) in Group D compared to 9 patients (17.6%) in Group C ($p = 0.13$). No cases of respiratory depression were noted in either group. The need for rescue anti-shivering medication was significantly lower in Group D (3 patients, 5.9%) compared to Group C (21 patients, 41.2%) ($p < 0.001$) *Table VI*.

Table VI
Adverse Effects and Need for Rescue Medication (*n*=102).

Outcome	Group D (n=51)	Group C (n=51)	p value
Hypotension	7 (13.7%)	6 (11.8%)	0.77
Nausea/vomiting	4 (7.8%)	9 (17.6%)	0.13
Respiratory depression	0 (0%)	0 (0%)	-
Rescue anti-shivering drug	3 (5.9%)	21 (41.2%)	<0.001

DISCUSSION

The present study consisted of 102 parturients; baseline demographic characteristics like age, weight, height, and ASA physical status were almost similar between the dexmedetomidine and control groups. The average age in the dexmedetomidine group was 26.9 ±4.8 years and 27.3 ±5.1 years in the control group. Nesioonpour et al. also found an average age of 28.1 ±5.6 years in the dexmedetomidine group and 27.6 ±5.2 years in the placebo group, with no difference being significant difference between the two groups [9]. The incidence rate of shivering in our study was 15.7% in the dexmedetomidine group and 56.9% in the control group ($p < 0.001$). For instance, Wan Md Adnan et al. recorded shivering in 3.2% of patients receiving intravenous dexmedetomidine versus 64.5% in the control group during cesarean section under spinal Anaesthesia [11]. When the severity of shivering was studied, 84.3% of patients in the dexmedetomidine group in our study were at Grade 0 shivering, whereas only 43.1% of control patients were free of shivering. Remarkably, no patients at all (0%) in the dexmedetomidine group developed Grade 3 (severe) shivering, while 13.7% of the patients in the control group did. Usta et al. in their study also indicated that severe shivering was seen in 0% of patients treated with dexmedetomidine versus 26.7% in the placebo group under spinal Anaesthesia [8]. The fact that we had fewer patients with severe shivering in the control group might be due to differences in how the ambient temperature was controlled or the use of warming perioperatively, but the benefit's direction and size are still consistent. Sedation scores obtained from the present study indicated that 62.7% of patients in the dexmedetomidine group had a Ramsay sedation score of 34, while only 11.8% of the control group achieved such scores ($p < 0.001$). Wan Md Adnan et al. found moderate sedation in 51.6% of patients treated with dexmedetomidine, and none of the patients in the control group (0%) reached the same level of sedation [11]. The sedation rate being a bit higher in our study could be due to differences in dosage; however, both studies demonstrate that dexmedetomidine offers valuable sedation without being too deep. The hemodynamic assessment revealed that our group receiving dexmedetomidine had a significantly lower average heart rate (68.5 ±6.9 bpm) than the controls (74.8 ±7.4 bpm), and bradycardia was present in 11.8% versus 2.0%, respectively. Wang et al., in a meta-analysis, reported bradycardia incidences of 8% to 14% in dexmedetomidine groups while 2% to 4% in placebo groups, almost exactly matching our results [12]. Mean arterial pressure did not differ significantly in our study (78.6 ± 6.1 mmHg vs 80.2 ± 6.4 mmHg), consistent with pooled data showing no significant increase in hypotension with dexmedetomidine. With respect to adverse events, 13.7% of patients receiving dexmedetomidine experienced hypotension in comparison to 11.8% of controls; nausea and vomiting were recorded for 7.8% of dexmedetomidine and 17.6% of control patients, respectively. According to Botros et al., the number of patients suffering from nausea and vomiting who were treated with dexmedetomidine was 10%, whereas it was 22% for the comparator group, which is consistent with the fewer gastrointestinal side effects seen in our study [6]. The need

for rescue anti-shivering medication was lower by a large margin in the dexmedetomidine group (5.9%) than in the control group (41.2%). Nesioonpour et al. also showed that rescue medication was given to 6.7% of dexmedetomidine patients and 46.7% of controls [9].

LIMITATIONS

The research was carried out at one site only with a relatively small number of participants, which might limit the extent to which the results can be applied to other populations. The study looked at only one administration of dexmedetomidine; it was not possible to evaluate dose and response effects.

CONCLUSION

Intravenous dexmedetomidine administration is a simple, convenient, and safe method to reduce the incidence and severity of shivering in parturients undergoing cesarean section under spinal Anaesthesia. Additionally, it provides sedation and hemodynamic stability. It lowers the number of cases in which a rescue anti-shivering drug is required significantly. Furthermore, it does not increase the risk of side effects.

RECOMMENDATION

Intravenous dexmedetomidine is a potentially safe and effective drug that can be used for prophylaxis of shivering in cesarean section under spinal Anaesthesia. It may contribute to maternal comfort and decrease the necessity of additional anti-shivering drugs. With adequate monitoring of hemodynamics, it can be introduced to regular clinical practice.

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CONFLICT OF INTEREST

None declared

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Functional and Clinical Outcomes of Endoscopic Sinus Surgery in Patients with Chronic Rhinosinusitis

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ABSTRACT

Background: Chronic rhinosinusitis (CRS) is a common inflammatory disorder that affects the paranasal sinuses, severely limiting quality of life and daily functioning. Endoscopic sinus surgery (ESS) has emerged as the major surgical treatment option for medically resistant CRS. This study aims to assess the functional and clinical outcomes of ESS in individuals with chronic rhinosinusitis who have failed conservative medical treatment. **Methods & Materials:** Thisprospective observational study was conducted among 80 patients at Department of Otolaryngology-Head & Neck Surgery, Bangladesh Medical University, Dhaka with chronic rhinosinusitis undergoing endoscopic sinus surgery between July 2023 and June 2024. Patients with CT-confirmed CRS who had failed at least 12 weeks of acceptable medical therapy were eligible for inclusion. Patients with cancer, immunodeficiency, or a history of sinus surgery were excluded. The Sino-Nasal Outcome Test-22 (SNOT-22) questionnaire was used to measure functional results before surgery, as well as three and six months later. Clinical indicators such as nasal blockage, facial pain, and endoscopic results were assessed. Data were entered and analyzed using SPSS version 26. **Results:** At 3 and 6 months, the mean SNOT-22 score dropped from 52.6±11.4 to 24.8±8.9 and 18.2±7.1, respectively ($p<0.001$). Significant progress was made in the following major symptoms: nasal discharge dropped from 82.5% to 17.5%, facial pain from 72.5% to 12.5%, and nasal blockage went from 90.0% to 20.0%. On endoscopy, 70.0% of patients showed normal mucosal status at the 6-month follow-up. Just 10.0% of patients experienced synechiae development, and 7.5% had persistent illness, indicating low complications. **Conclusion:** Endoscopic sinus surgery provides excellent functional and clinical outcomes in individuals with medically resistant chronic rhinosinusitis, with persistent improvement in quality of life and symptom control at 6-month follow-up.

Keywords: *Chronic rhinosinusitis, Endoscopic sinus surgery, SNOT-22, Functional outcomes*

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INTRODUCTION

The nasal cavity and the paranasal sinuses are an arrangement of air-filled spaces coated with respiratory mucosa intended for the warming, humidification, and filtration of inspired air, as well as the implementation of the sense of smell. The sinuses, which include the maxillary, frontal, ethmoid, and sphenoid sinuses, connect through narrow openings termed ostia, whose patency depends on mucociliary clearance. CRS is characterised by the occurrence of an inflammatory condition of the sinonasal tract persisting for 12 or more weeks, in which the appropriate medical care does not result in the alleviation of the symptoms. Functional endoscopic sinus surgery is intended for the recovery of sinus ventilation and drainage, as well as the perpetuation of mucosal function, after conservative care has failed [1,2]. CRS exhibits a high global prevalence and serves as a significant indication for sinonasal surgical interventions. Sequential data have revealed significant improvement in disease-specific quality of life, as assessed by the Sino Nasal Outcome Test 22 (SNOT 22), up to five years post-FESS, demonstrating considerable improvement in symptoms relating to rhinologic, sleep, and facial quality of life [3]. In addition, systematic reviews and meta-analyses have documented significant postoperative improvements in quality of life, as well as postoperative recurrence, in CRS patients undergoing FESS [4,5]. In Asia, similar analysisss has reported significant improvements in symptoms as well as quality of life in CRS patients undergoing ESS. In Bangladesh, prospective and cross-sectional studies have revealed significant improvements in postoperative symptoms scored by CRS patients with refractory CRS undergoing FESS, demonstrating an improvement in quality of life [6,7]. The functional outcome for endoscopic sinus surgery (ESS) has demonstrated a variety of improvements, which are subjective and objective. The SNOT-22 scores indicate that the nasal flow is improved, there is alleviation of facial pressure, and there is an enhancement in health status. The endoscopic examination outcome indicates that there is less disease seen on the mucosa and more patent sinuses after ESS. The benefits for patients are marked, but certain factors that influence outcomes include the presence of nasopharyngeal polyps, asthma, and the extent of disease. The revision rate for ESS surgery is estimated at 15 to 20 percent [8,9]. Despite the extensive studies regarding ESS outcomes, the following limitations exist: the available literature includes few institutional or subgroup-based studies, including those of CRS secondary to nasal polyps, as well as few long-term studies from low and middle-resource countries. Heterogeneity of outcome measures and follow-up also limits the comparability of various studies, while few South Asian studies evaluate the functional and clinical outcomes of heterogeneous CRS cases. In this analysis, it is intended to bridge the gaps and create a more contextually specific body of evidence in existing knowledge by comprehensively evaluating the functional and clinical outcomes of ESS in patients with CRSS to further understand the efficacy of the treatment modality for various patient populations. Therefore, this study aims to evaluate the functional and clinical outcomes after endoscopic sinus surgery for chronic rhinosinusitis

METHODS & MATERIALS

This prospective observational study was conducted at Department of Otolaryngology-Head & Neck Surgery, Bangladesh Medical University, Dhaka over one year from July 2023 to June 2024.

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A total of 80 patients who had endoscopic sinus surgery for their chronic rhinosinusitis were included in this study. Sample size calculations were based on previous literature using a 95% confidence interval and 80% power to detect clinically significant differences.CT scan evidence of chronic rhinosinusitis; persistence of chronic symptoms for over 12 weeks despite appropriate medical treatment with oral antibiotics, nasal corticosteroids, and saline irrigations; evidence of having one or more of the following symptoms or their variants: nasal obstruction, nasal discharge, facial pain or tenderness, or a change in smell; evidence of failure of treatment after at least 3 months were included in the study. History of endoscopic sinus surgery, malignancy or granulomatous disease in the sinonasal tract; immunodeficiency states or immunosuppression, pregnancy or lactation, severe systemic diseases that prevent general anesthesia, and lack of follow-up information were excluded. Demographic variables included age, sex, place of residence, and smoking habits. Clinical variables consisted of duration of symptoms, nasal polyps, allergic rhinitis, and asthma. Symptoms reported in the preoperative period included nasal obstruction, nasal discharge, facial pain, headache, loss of smell, and sleep. The functional result was evaluated by SNOT-22 scoring at baseline, 3 months, and 6 months postoperatively. The endoscopic findings at the 6-month follow-up consisted of the status of the mucosa, formation of synechiae, and extent of disease. The collected data were entered, analyzed, and interpreted through IBM SPSS version 26. For describing demographic features, various parameters have been calculated, and for that, continuous variables have been presented as mean±SD. For categorical variables, they have been compared with a chi-square test, considering a p-value of <0.05 as significant.

RESULTS

Table I represents the demographic profile of 80 patients suffering from chronic rhinosinusitis. It was observed that patients were distributed almost similarly in both the lower age groups (30% each for ≤30 and 31-40 years), while the frequency reduced with every increment in the age category. The majority of participants in this study were males, with 57.5%. 60% of the study population consisted of urban residents. The majority had a non-smoking history, while the active smoking history was observed in 27.5% of the respondents.

Table I
Demographic characteristics of the study population (*n* = 80).

Variable	Category	Frequency (%)
Age (years)	≤30	24 (30)
	31-40	24 (30)
	41-50	20 (25)
	>50	12 (15)
Sex	Male	46 (57.5)
	Female	34 (42.5)
Residence	Urban	48 (60)
	Rural	32 (40)
Smoking status	Smoker	22 (27.5)
	Non-smoker	58 (72.5)

Table II describes the baseline characteristics of our study population of the cohort of patients, and it shows that a significant number of our population, that is, 52.5%, had symptoms for 1-3 years. Furthermore, nasal polyps were present in 42.5%, which is a significant number of polypous CRs. Allergic rhinitis co-existed with CRS in 37.5%, and 15.0% of our population had coexisting asthma. Most importantly, there was a failure of appropriate medical therapy, and all of our study population had this finding, that is, 100%.

Table II
Baseline clinical profile of patients with chronic rhinosinusitis.

Variable	Category	Frequency (%)
Duration of symptoms	<1 year	18 (22.5)
	1-3 years	42 (52.5)
	>3 years	20 (25)
Nasal polyps	Present	34 (42.5)
Allergic rhinitis	Present	30 (37.5)
Asthma	Present	12 (15)
Failed medical therapy	Yes	80 (100)

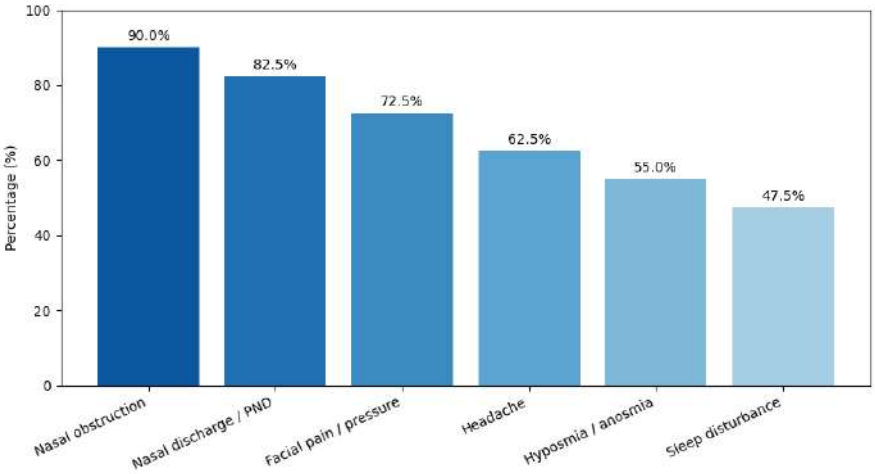

Figure 1 Preoperative symptom distribution (n = 80).

Figure 1 depicts the prevalence of preoperative symptoms among the participating patients. The most predominant symptom was a feeling of nasal obstruction, present in 90.0% of the patients. It was then followed by nasal discharge and post-nasal drip at 82.5%. In addition, 72.5% of the patients reported facial pain or pressure. Other symptoms included headache (62.5%), hyposmia or anosmia as signs of an olfactory dysfunction (55.0%), and sleep disturbance (47.5%).

Table III indicates the progression of functional outcomes using a validated SNOT-22 questionnaire. The preoperative SNOT-22 scores were high at 52.6 ± 11.4. However, postoperative SNOT-22 scores at the 3rd month were remarkably reduced to 24.8 ± 8.9. This indicates a significant improvement of 52.9%. In this case, such improved outcomes continued progressively at 6 months to 18.2 ± 7.1. This indicates a general reduction of 65.4%. It was analyzed that there were highly significant differences at all these times ($p < 0.001$).

Table III
Functional outcome assessment using SNOT-22 score.

Time point	Mean ± SD	p-value
Preoperative	52.6 ± 11.4	-
3 months postoperative	24.8 ± 8.9	<0.001
6 months postoperative	18.2 ± 7.1	<0.001

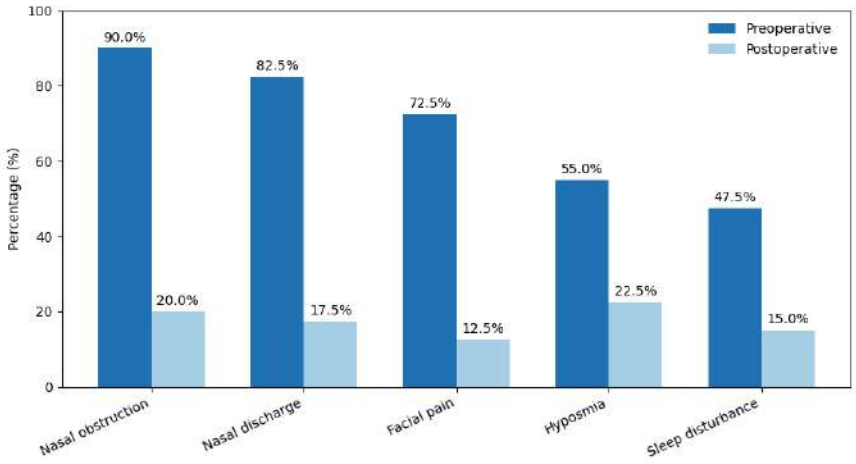

Figure 2 Comparison of key clinical symptoms before and after surgery.

Figure 2 illustrates a comparative analysis of the cardinal symptoms pre- and post-surgery. Nasal obstruction exhibited the most significant changes post-operatively, showing a reduction from 90.0% pre-surgery to 20.0% post-surgery. In addition, nasal discharge post-surgery showed a reduction from 82.5%, while facial pain showed a significant reduction from 72.5%. Olfactory dysfunction showed improved changes post-surgery. Hyposmia, used to measure olfactory dysfunction, showed a significant reduction from 55.0%, with many patients showing decreased occurrences at 22.5%. Sleep disturbance showed improved changes post-surgery.

Table IV presents the findings from the endoscopic evaluation performed to observe the effects of the surgical intervention. Six months after the surgical procedure, out of the total patients treated, 70.0% exhibited a normal mucosal appearance following surgery. Some of the patients, 22.5%, showed mild mucosal edema, while 7.5% showed edema that required medical management. Complications were rare since 10.0% of the patients showed the formation of synechiae, while 7.5% showed the presence of the disease following surgery. These results were promising based on the subjective evaluation of the effectiveness of the surgical procedure.

Table IV
Postoperative endoscopic findings at 6-month follow-up.

Finding	Category	Frequency (%)
Mucosal status	Normal	56 (70.0)
	Mild edema	18 (22.5)
	Persistent edema	6 (7.5)
Synechiae	Present	8 (10.0)
Residual disease	Present	6 (7.5)

Table V provides a complete quantitative comparison of objective and subjective outcome variables. All metrics showed statistically substantial improvement ($p < 0.001$). The SNOT-22 score decreased by 65.4% compared to baseline. Individual symptom scores showed significant decreases: nasal obstruction from 3.6±0.8 to 1.2±0.6 (66.7% reduction), facial pain from 3.1±0.9 to 0.9±0.5 (71.0% reduction), and endoscopic edema from 2.4±0.7 to 0.8±0.5 (66.7% reduction). This simultaneous improvement in subjective symptoms and objective endoscopic results validates ESS efficacy.

Table V
Comparison of pre- and postoperative outcomes.

Parameter	Preoperative Mean ± SD	Postoperative Mean ± SD	p-value
SNOT-22 score	52.6 ± 11.4	18.2 ± 7.1	<0.001
Nasal obstruction score	3.6 ± 0.8	1.2 ± 0.6	<0.001
Facial pain score	3.1 ± 0.9	0.9 ± 0.5	<0.001
Endoscopic edema score	2.4 ± 0.7	0.8 ± 0.5	<0.001

DISCUSSION

CRS, or chronic rhinosinusitis, is a substantial healthcare issue that affects the world's population, covering approximately 12% of the adult population and causing substantial impacts on the quality of life [10]. This study assessed the functional and clinical outcomes of ESS in 80 patients with medically refractory chronic rhinosinusitis, showing marked improvements in outcome measures. These results correlate with those ofRosenfeld et al. regarding ESS as the definitive surgical intervention, even after the failure of medical management [11]. The demographic distribution of our study showed a slight male dominant pattern (57.5%), which was in line with Smith et al., who showed an almost identical distribution in the study cohort [12]. The peak age distribution was in the younger age groups, with an incidence of ≤40 years old in 60%, contrasting with the study by Abdalla et al., who found a bimodal distribution with an increased peak in the elderly [13]. The higher incidence in the urban areas (60%) might likely be due to the exposure rate of environmental pollution, as reported in the studies of Chalermwatanachai et al., showing a correlation with the prevalence of CRS [14]. Baseline clinical characteristics showed that symptoms were present for 1-3 years before surgical intervention in 52.5% of patients. This duration reflects appropriate patient selection after trials of adequate medical therapy. The prevalence of nasal polyps was 42.5% in our cohort and was within the range reported in CRS populations of 25-50% [15]. Also, allergic rhinitis in 37.5% and asthma in 15.0% point toward the unified airway disease concept, with these comorbidities recognized to impact surgical outcomes [16]. All patients had documented failure of medical therapy, meeting consensus criteria for surgical candidacy [17]. The main finding of the study is a reduction in the SNOT-22 score from 52.6±11.4 to 18.2±7.1 at 6 months. This constitutes a 65.4% improvement and is well above the minimal clinically important difference of 8.9 points as reported by Hopkins et al. [18]. The results were comparable with a large prospective cohort reported by Decode et al. with mean improvements of SNOT-22 scores of 28.4 points [19]. The progressive improvement from 3 to 6 months suggests continued healing and adaptation and underlines the importance of longer follow-up for outcome assessment. Results of the individual symptom evaluation indicated remarkable improvement in all major symptoms of CRS. Nasal obstruction, being the most common presenting symptom (90%), showed a marked reduction to 20% postoperatively. The reduction of 70% is more significant than the 55% improvement rates reported by Soler et al. [20]. Complete resolution of facial pain from 72.5% to 12.5% is a marked improvement in the effectiveness of ESS in managing sin nasal pain, which is a difficult symptom domain to address. An improvement in olfactory dysfunction from 55.0% to 22.5% reflects the literature stating that olfactory recovery is related to the removal of polyps and mucosal healing [21]. In addition, the endoscopic results obtained after a follow-up period of 6 months showed positive mucosal healing, with the mucosa returning to normal in 70% of the patients. These results compare favorably with Psaltis et al., who noted only 65% normal mucosal patterns in the patients who underwent follow-up after similar periods [22]. These findings indicate the minimal rate of associated complications like synechiae (10%) and the disease itself (7.5%). These findings may be related to the present technology used for the procedure compared to the previously noted rates of complication, ranging between 15-20%. The simultaneous improvement of subjective SNOT-22 measures and objective endoscopic findings reinforces the construct validity of the multidimensional concept of surgical success in CRS. This congruence between patient-reported outcomes and objective clinical measures is an added confidence booster in the effectiveness of the procedure.

LIMITATIONS

The study was limited by its single-center design and relatively short follow-up period of 6 months, which may not capture long-term outcomes or recurrence patterns that could emerge beyond this timeframe.

CONCLUSION

Our study demonstrates that endoscopic sinus surgery is beneficial in bringing about dramatic improvements in both functional and clinical parameters in patients with chronic rhinosinusitis of medically intractable origin. The profound decrease in SNOT-22 scores, resolution of cardinal symptoms, and endoscopic healing patterns suggest that ESS is an effective therapy with excellent outcomes at 6 months.

RECOMMENDATIONS

Future studies should incorporate multicenter randomized controlled trials

with extended follow-up periods of at least 2-3 years to assess long-term efficacy, recurrence rates, and the impact of emerging adjunctive therapies on surgical outcomes.

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CONFLICT OF INTEREST
None declared

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Patterns of Acute Coronary Syndrome and Risk Factor Profile Analysis in Patients with Impaired Renal Function

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ABSTRACT

Background: Acute coronary syndrome remains one of the cardinal causes of cardiovascular mortality, and renal dysfunction has become an important prognostic factor. This study aimed to assess the patterns of ACS and the risk factor profile of patients with impaired renal function who presented to a tertiary care hospital in Bangladesh. **Methods & Materials:** This prospective observational study was conducted in the Department of Cardiology, Mymensingh Medical College Hospital, from January 2022 to December 2022. They were grouped based on creatinine clearance into normal renal function (≥70 ml/min) and impaired renal function (<70 ml/min). Demography, cardiovascular risk factors, patterns of ACS presentation, and in-hospital course regarding heart failure, arrhythmias, cardiogenic shock, mechanical complications, and mortality were noted. Data were analyzed on SPSS version 26, with $p<0.05$ considered significant. **Results:** Of 100 patients, 69% had impaired renal function with a mean age of 53.4±8.4 years compared to 47.8±7.2 years in the normal function group (p=0.002). Diabetes mellitus was significantly more prevalent in patients with impaired renal function (56.5% vs 22.6%, p=0.002). Patients with reduced creatinine clearance experienced significantly higher rates of heart failure (28.9% vs 9.6%, p=0.03), ventricular tachycardia (28.9% vs 6.4%, p=0.01), post-MI angina (34.7% vs 6.4%, p=0.002), and cardiogenic shock (21.7% vs 3.2%, p=0.02). Overall morbidity was markedly elevated in the impaired renal function group (84.0% vs 29.0%, p=0.001). **Conclusion:** Impaired renal function is highly prevalent among patients with ACS and is strongly related to an increase at in-hospital cardiac complications and morbidity. Systematic assessment of renal function is crucial for risk stratification and optimization of management strategies in patients with ACS.

Keywords: *Acute coronary syndrome, Risk factor profile, Impaired renal function, Creatinine clearance*

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INTRODUCTION

Acute coronary syndrome remains one of the leading causes of cardiovascular morbidity and mortality in a global perspective, affecting millions of individuals annually and causing substantial healthcare burdens [1]. ACS represents a broad spectrum of clinical presentations, including STEMI, NSTEMI, and UA, all with the same pathophysiology, acute myocardial ischemia [2]. The prognosis of patients with ACS depends on many variables, such as age, comorbidities, hemodynamic status, and, importantly, renal function [3]. Renal dysfunction has emerged as a critical prognostic factor in the setting of ACS, where a growing body of evidence points to a significant inverse correlation between glomerular filtration rate and adverse cardiovascular outcomes [4]. Even for patients with mild or moderate impairment of creatinine clearance, there is an association with increased rates of in-hospital complications, longer hospital stays, and higher mortality [5]. The occurrence of impaired renal function varies between 30% and 40% of all populations presenting with ACS, hence being a very common clinical case in cardiology [6]. The pathophysiological mechanisms that link renal dysfunction to poor cardiovascular outcomes are multifactorial and complex. Renal impairment contributes to endothelial dysfunction, accelerated atherosclerosis, heightened oxidative stress, chronic inflammation, and disturbances in calcium-phosphate metabolism [7]. Furthermore, patients with reduced creatinine clearance usually present with several concomitant cardiovascular risk factors, including hypertension, diabetes mellitus, and dyslipidemia, which could further complicate their risk profile [8]. They also show altered pharmacokinetics of cardiovascular drugs, which can lead to suboptimal therapeutic interventions or increased vulnerability to adverse drug reactions. Despite the recognized importance of renal function to ACS prognosis, there is still a lack of data from South Asian populations, particularly from Bangladesh, where the burden of cardiovascular disease continues to rise [9]. Demographic characteristics, risk factor profiles, and clinical outcomes may substantially vary in ACS patients with impaired renal function across geographical regions and ethnic populations due to genetic predisposition, environmental factors, and healthcare accessibility [10]. Such regional variations should be understood for targeted prevention strategies and optimization of management protocols. Moreover, based on high-risk stratification according to renal function status, this can facilitate risk stratification and enable clinical decisions regarding intensive monitoring, aggressive medical therapy, and consideration for invasive interventions [11]. The use of renal function assessment as a prognostic determinant in the setting of ACS is an evolving concept, but local data are urgently needed to inform clinical practice and healthcare policy. This study was, therefore, aimed at assessing the clinical profile and analysis outcomes in acute coronary syndrome patients with impaired renal function attending a tertiary care hospital in Bangladesh. By comparing clinical features, cardiovascular risk factors, and in-hospital outcomes across patients with normal and lower creatinine clearance, we aimed to improve knowledge of the influence of renal dysfunction on the presentation and prognosis of ACS in our local population.

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METHODS & MATERIALS

This prospective observational study was conducted in the Department of Cardiology, Mymensingh Medical College Hospital, over twelve months from January 2022 to December 2022. A total of 100 consecutively admitted patients presenting with acute coronary syndrome were enrolled through purposive sampling after obtaining informed written consent. Adult patients aged 18-65 years of both sexes presenting with their first episode of acute coronary syndrome (STEMI, NSTEMI, or unstable angina) within 24 hours of symptom onset were included in the study. Patients older than 65 years, those with a previous history of ACS, known valvular heart disease, cardiomyopathy, prior heart failure, history of previous revascularization procedures (percutaneous transluminal coronary angioplasty with stenting or coronary artery bypass grafting), and patients with incomplete data were excluded from the study. After enrollment, a detailed clinical history regarding cardiovascular risk factors (smoking, hypertension, diabetes mellitus, dyslipidemia, family history of ischemic heart disease) was obtained. Comprehensive physical examination, including vital signs and cardiovascular assessment, was performed. Baseline investigations, including 12-lead electrocardiography, cardiac biomarkers (troponin), serum creatinine, fasting blood glucose, and lipid profile, were completed for all participants. Creatinine clearance was calculated using the Cockcroft-Gault formula, and patients were stratified into two groups: Group I with creatinine clearance ≥70 ml/min (normal renal function) and Group II with creatinine clearance <70 ml/min (impaired renal function). All patients were monitored throughout hospitalization for in-hospital outcomes, including heart failure (Killip class II-IV), cardiogenic shock, significant arrhythmias (atrial fibrillation, ventricular tachycardia, ventricular fibrillation, heart blocks), mechanical complications, post-myocardial infarction angina, reinfarction, and mortality. Data were entered and analyzed using SPSS version 26. Categorical variables were compared using chi-square tests, while continuous variables were analyzed using Student's t-test and ANOVA where appropriate. A p-value <0.05 was considered statistically significant.

RESULTS

Table I shows the study population's baseline demographics and the distribution of cardiovascular risk factors. Of the 100 patients, 88% were men and 12% were women. The average age was 51.7±8.5 years, and 43% of them were between the ages of 50 and 59. The most common condition was smoking (71%), which was closely followed by hypertension (59%), diabetes mellitus (46%), dyslipidaemia (46%), and a family history of ischaemic heart disease (43%). The average number of risk factors per patient was 2.6±0.9, and there was no discernible difference between males and females (p=0.250). There was no significant gender difference in age distribution as well (p=0.230).

Table I
Demographic and distribution of the study patients (*n*=100).

Category	Male (n= 88)		Female (n=12)		Total(N=100)		p-value
	Number	%	Number	%	Number	%	-
Age (in years)	-	-	-	-	-	-	-
30 - 39	7	8.0	1	8.3	8	8.0	-
40 - 49	24	27.3	1	8.3	25	25.0	-
50 - 59	37	42.0	6	50.0	43	43.0	-
60 - 65	20	22.7	4	33.3	24	24.0	-
Mean ± SD (Range)	51.3±8.5 (30-65)		54.4±8.1 (30-65)		51.7±8.5 (30-65)		0.230
Risk Factors	-	-	-	-	-	-	-
Smoking	70	79.5	1	8.3	71	71.0	-
Hypertension	48	54.5	11	91.7	59	59.0	-
Diabetes mellitus	38	43.2	8	66.7	46	46.0	-
Dyslipidaemia	42	47.7	4	33.3	46	46.0	-
Family H/O IHD	39	44.3	4	33.3	43	43.0	-
Mean ± SD (Range)	2.7±0.9 (1-5)		2.3±1.1 (1-5)		2.6±0.9 (1-5)		0.250

Table II demonstrates demographic distribution according to renal function status. Out of 100 patients, 31% had normal creatinine clearance (≥70 ml/min), while 69% had impaired clearance (<70 ml/min). Patients with impaired renal function were significantly older (mean age 53.4±8.4 years) compared with patients with normal renal function (47.8±7.2 years, p=0.002). The 60-65 age group had the highest proportion with renal dysfunction, 33.3%. The gender distribution was similar in both renal function groups (p=0.63), males constituting approximately 88-90% in both groups, hence suggesting that renal impairment in this ACS population is proportionally.

Table II
Demographic distribution of the study population with normal and abnormal renal function (*n*=100).

Category	Creatinine Clearance						p value
	Normal clearance (≥70)		Abnormal clearance (<70)		Total		
	n	%	n	%	n	%	
Age (in years)	-	-	-	-	-	-	-
30 - 39	3	9.7	5	7.2	8	8.0	-
40 - 49	13	41.9	12	17.4	25	25.0	-
50 - 59	14	45.2	29	42.0	43	43.0	-
60 - 65	1	3.2	23	33.3	24	24.0	-
Total	31	100	69	100	100	100.0	-
Mean ± SD (Range)	47.8±7.2 (30-60)		53.4±8.4 (35-65)		51.7±8.5 (30-65)		0.002[s]
Sex	-	-	-	-	-	-	-
Male	28	90.3	60	87.0	88	88.0	0.63 [NS]
Female	3	9.7	9	13.0	12	12.0	-

Table III Risk factors, acute coronary syndrome patterns, and cardiac complications in patients with normal and impaired renal function are denoted in Table 3. Diabetes mellitus was observed to occur significantly more often in patients with impaired renal function (56.5% vs.22.6%, p=0.002), whereas other risk factors did not differ significantly. Impaired renal function was substantially higher in heart failure (28.9% vs 9.6%, p=0.03), as was ventricular tachycardia (28.9% vs 6.4%, p=0.01), angina post-MI (34.7% vs 6.4%, p=0.002), and cardiogenic shock (21.7% vs 3.2%, p=0.02). Other complications were also higher in the impaired renal function group but did not always reach statistical significance.

Table III
Risk factors, acute coronary syndrome patterns, and cardiac complications in patients with normal and abnormal creatinine clearance (*n*=100).

Category	Creatinine Clearance						p-value
	Normal clearance (≥70) (n=31)		Abnormal clearance (<70) (n=69)		Total (N=100)		
	n	%	n	%	n	%	
Risk factors	-	-	-	-	-	-	-
Smoking	22	71.0	49	71.0	71	71.0	0.99^{NS}
Hypertension	16	51.6	43	62.3	59	59.0	0.31^{NS}
Family history of IHD	15	48.4	28	40.6	43	43.0	0.46^{NS}
Diabetes mellitus	7	22.6	39	56.5	46	46.0	0.002^{S}
Dyslipidemia	17	54.8	29	42.0	46	46.0	0.23^{NS}
Mean ± SD (Range)	2.45±0.76 (1-4)		2.72±1.01 (1-5)		2.64±0.98 (1-5)		0.19^{NS}
Pattern of ACS	-	-	-	-	-	-	-
Anterior	19	61.3	27	39.1	46	46.0	0.20^{NS}
Inferior	9	29.0	34	49.3	43	43.0	
NSTEMI	1	3.2	4	5.8	5	5.0	
UA	2	6.5	4	5.8	6	6.0	
Complications	Creatinine Clearance						p-value
	Normal clearance (≥70) (n=31)		Abnormal clearance (<70) (n=69)		Total (N=100)		
	Number	%	Number	%	Number	%	
Heart failure (Killip II- IV)	3	9.6	20	28.9	23	23.0	0.03^{S}
Atrial fibrillation	3	9.6	14	20.2	17	17.0	0.19^{NS}
Ventricular tachycardia	2	6.4	20	28.9	22	22.0	0.01^{S}
Ventricular fibrillation	0	0.0	4	5.7	4	4.0	0.17^{NS}
Post MI angina	2	6.4	24	34.7	26	26.0	0.002^{S}
Heart Block	0	0.0	7	10.1	7	7.0	0.06^{NS}
Mechanical complication	0	0.0	2	2.9	2	2.0	0.33^{NS}
Cardiogenic shock	1	3.2	15	21.7	16	16.0	0.02^{S}

Table IV showcases the overall in-hospital mortality and morbidity. Mortality was seen only in the impaired renal function group, at a rate of 5.8% vs 0%, p=0.17, though this did not reach statistical significance, likely due to small sample size. However, overall morbidity was significantly higher in patients with impaired renal function, 84.0% vs 29.0%, p=0.001, indicating that the overwhelming majority of patients with reduced creatinine clearance suffered at least one major cardiac complication during their hospital stay, compared with less than one-third in the normal renal function group.

Table IV
In-hospital mortality and morbidity of the study population with normal and abnormal creatinine clearance (*n*=100).

Category	Creatinine Clearance						P value
	Normal clearance (≥70) (n=31)		Abnormal clearance (<70) (n=69)		Total		
	Number	%	Number	%	Number	%	
Mortality	-	-	-	-	-	-	-
Yes	0	0.0	4	5.8	4	4.0	0.17^{NS}
No	31	100	65	94.2	96	96.0	
Morbidity	-	-	-	-	-	-	-
Yes	9	29.0	58	84.0	67	67.0	0.001^{S}
No	22	71.0	11	16.0	33	33.0	

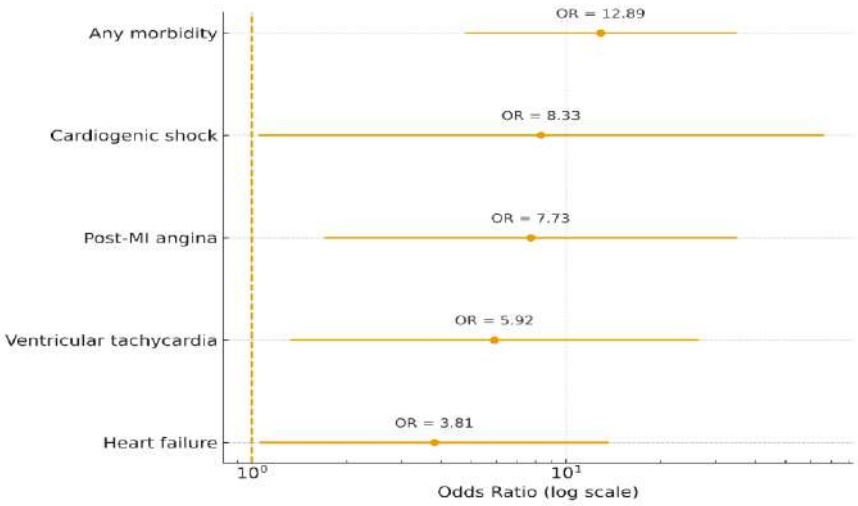

Figure 1 Unadjusted Odds Ratio for Major Cardiac Complications by Renal Function Status.

Figure 1 illustrates the unadjusted odds ratios for major cardiac complications comparing subjects with impaired versus normal renal function. The odds ratio (5.92) was seen for ventricular tachycardia, post-MI angina (7.73), cardiogenic shock (8.33), heart failure (3.81), and any morbidity (12.89). All the CIs exclude 1.0, suggesting all associations are statistically significant.

DISCUSSION

This prospective study demonstrated the patterns of acute coronary syndrome and associated risk factors in patients with impaired renal function, showing significant associations between reduced creatinine clearance and adverse cardiovascular outcomes. Our results showed that impaired renal function, as manifested by a creatinine clearance less than 70 ml/min, was found in 69% of ACS patients, which is much higher compared to a study by Santopinto et al. [12]. This high prevalence indicates a very substantial burden of renal dysfunction in our local ACS population and suggests that renal function assessment is a necessary task for all patients presenting with acute coronary events. In our results, only diabetes mellitus was identified among the traditional cardiovascular risk factors, showing a significant association with impaired renal function (56.5% vs 22.6%, p=0.002). It is consistent with Afkarian et al., where a bidirectional relationship is established between diabetes and chronic kidney disease; diabetes accelerates renal deterioration, while renal dysfunction accelerates glycemic control and cardiovascular risk [13]. The diabetic milieu promotes both microvascular and macrovascular complications via multiple pathways, including advanced glycation end-products, oxidative stress, and chronic inflammation, thus increasing susceptibility to renal impairment and coronary artery disease [14]. Our results showed that patients with impaired renal function were significantly older than those with normal renal function (53.4±8.4 years vs 47.8±7.2 years, p=0.002), in keeping with a study by Levey et al. [15]. Indeed, this age difference, though statistically significant, may well reflect the natural course of renal senescence, coupled with the long-term exposure to cardiovascular risk factors. The most notable findings emerged in the analysis of in-hospital complications. Patients with impaired renal function demonstrated significantly elevated rates of heart failure (28.9% vs 9.6%, p=0.03), ventricular tachycardia (28.9% vs 6.4%, p=0.01), post-MI angina (34.7% vs 6.4%, p=0.002), and cardiogenic shock (21.7% vs 3.2%, p=0.02). These findings are corroborated by Marenzi et al., who demonstrated that even mild-to-moderate renal dysfunction substantially increases the risk of major adverse cardiac events following ACS [16]. The mechanisms underlying these associations likely involve multiple factors, including endothelial dysfunction, heightened inflammatory states, increased thrombogenicity, volume overload, electrolyte imbalances, and altered drug metabolism [17]. Overall, morbidity was significantly higher in patients with impaired renal function, at 84% versus 29% (p = 0.001); hence, the vast majority of these patients developed at least one significant complication during their hospitalization. This finding has considerable implications for resource allocation, clinical monitoring intensity, and prognostic counseling. The odds ratio analysis further quantified this risk, demonstrating 4-8 fold increased odds of major cardiac complications in patients with reduced creatinine clearance as compared to those with preserved renal function. Although our study showed a trend for increased mortality in the impaired renal function group (5.8% versus 0%, p=0.17) [18]. Beattie et al. demonstrated increased short-term and long-term mortality associated with renal dysfunction in ACS patients [19]. Our study also identified noteworthy patterns in the ACS presentation, where anterior myocardial infarction was more common in patients with normal renal function and inferior MI predominated among those with impaired function, though these differences were not statistically significant. The findings from this study contribute significant South Asian data and further support the increasing body of evidence that renal dysfunction is a critical determinant of ACS outcomes in acute coronary syndrome.

LIMITATIONS

his was a single-center study with a relatively small sample size and short-term follow-up, restricted to in-hospital outcomes, which may not capture long-term mortality and morbidity patterns.

CONCLUSION

Impaired renal function occurs in a majority of patients with acute coronary syndrome and is a strong predictor of in-hospital adverse outcome. In fact, patients with impaired creatinine clearance had significantly higher rates of major cardiac complications, with overall morbidity exceeding 84%. Impaired renal function was also strongly associated with diabetes mellitus. Routine calculation of creatinine clearance should be done in all ACS patients for accurate risk stratification, prognostication, and individualization of treatment decisions to improve outcomes.

RECOMMENDATIONS

Long-term prognostic implications of renal dysfunction in ACS patients can be established in future multicenter studies with a larger sample size and for an extended follow-up period. Further study is needed to investigate the optimal

management strategy, including tailored pharmacological interventions and timing of revascularization procedures, specifically designed for ACS patients with varying degrees of renal impairment.

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CONFLICT OF INTEREST

None declared

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Improving Patient Safety through Pharmacovigilance – A Review of Spontaneous ADR Reporting Trends in Clinical Practice

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ABSTRACT

Introduction: Adverse drug reactions (ADRs) are a leading cause of hospitalization and morbidity worldwide and pose a significant challenge to patient safety. Early detection is important through effective pharmacovigilance by spontaneous reporting of ADRs by clinicians. The current study will assess trends, determinants, and impact of spontaneous adverse drug reaction (ADR) reporting in clinical practice to achieve optimal patient safety through effective pharmacovigilance. **Methods & Materials**: This cross-sectional, observational study was conducted in 56 patients who had experienced adverse drug reactions (ADRs) during their course of treatment in Dhaka Medical College from January 2024 to December 2024. Data were analyzed according to the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics such as mean, frequency, and percentage were used for categorical variables. **Result**: Fifty of the 56 participants (89.3%) had heard about pharmacovigilance, but only 24 (42.9%) had ever submitted an ADR report, and 16 (28.6%) reported to a national authority. Antibiotics (18; 34.6%) and NSAIDs (10; 19.2%) were the most common drug classes involved. While 32 (57.1%) were aware of the WHO-UMC reporting form and 28 (50.0%) of the causality assessment criteria, barriers like time constraints (22; 39.3%) and fear of legal consequences (18; 32.1%) were interfering with reporting. **Conclusion**: It is concluded by this study that most ADRs occurred with antibiotics and analgesics, were of mild to moderate intensity, and were largely avoidable. Despite the importance of spontaneous reporting for improving patient safety, underreporting is a critical problem due to low training and awareness.

Keywords: *Pharmacovigilance, Adverse drug reaction, Reporting Trend*

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INTRODUCTION

Adverse drug reactions (ADRs) remain a major and preventable threat to patient safety worldwide, contributing substantially to morbidity, hospital admissions, and health-care costs. Spontaneous reporting systems - where health-care professionals (HCPs), and increasingly patients, submit suspected ADRs to national pharmacovigilance centres - are cornerstone tools for post-marketing safety surveillance and signal detection. Despite their central role in identifying rare and unexpected harms, these systems suffer from chronic under-reporting and variable report quality, which limit their sensitivity and timeliness in protecting patients [1,2]. A growing body of evidence shows that reporting behaviour and reporting volume have evolved over the last decade as a result of regulatory change, technological advances, and increased patient engagement. Regulatory reforms in major jurisdictions (for example, the EU's strengthened pharmacovigilance legislation and encouragement of direct patient reporting) have been associated with marked increases in patient-originated reports and shifts in the types of events captured, broadening the safety signal landscape beyond HCP-reported data [3–6]. Several national and regional analyses have documented upward trends in total ADR submissions over time, but also heterogeneity in reporter mix (physicians, pharmacists, nurses, patients) and in the therapeutic areas and age groups most cited in reports [7,8]. However, quantity alone is not sufficient: the usefulness of spontaneous reporting depends on report completeness and clinical detail. Recent research highlights persistent problems with incomplete or poorly documented case reports - a limitation that can delay causality assessment and signal validation [9]. Equally important are the human factors that determine whether and what clinicians report. Systematic reviews show that knowledge gaps, attitudes (ignorance, lethargy, complacency), and practical barriers (time constraints, lack of feedback, and unfamiliarity with reporting channels) remain the dominant drivers of under-reporting among HCPs, even where reporting infrastructures exist [1,2]. Intervention studies and syntheses indicate there are effective strategies to improve reporting rates and report quality. Educational programmes, targeted workshops, electronic reporting tools integrated with clinical systems, and simple engineering changes (for example, hyperlinks to online forms or timely feedback) have been associated with measurable increases in reporting and improvements in reporter knowledge and confidence [2,10]. Therefore, this study aims to assess the trends, determinants, and impact of spontaneous adverse drug reaction (ADR) reporting in clinical practice to enhance patient safety through effective pharmacovigilance.

METHODS & MATERIALS

This observational, cross-sectional study was conducted among 56 patients who experienced adverse drug reactions (ADRs) during their treatment in Dhaka Medical College from January 2024 to December 2024. Data were collected prospectively from spontaneous ADR reports submitted by healthcare professionals and verified through patient medical records. All ADRs were assessed using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale

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and categorized based on their severity using the Modified Hartwig and Siegel scale. Demographic details, drug classes involved, system organ classification, and outcomes were recorded using a predesigned data collection form. Inclusion criteria included all patients of any age and gender who developed ADRs during hospitalization or outpatient treatment and had complete clinical documentation. Exclusion criteria included cases with incomplete records, doubtful causality, or ADRs related to drug overdose, poisoning, or medication errors. Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics such as mean, frequency, and percentage were used for categorical variables. Ethical clearance was taken from the Institutional Review Board. Informed written consent was taken from all the participants.

RESULTS

The participants were evenly distributed by gender, with half male and half female. The largest age group was 31–40 years (48.2%), and physicians represented the highest proportion (42.9%). Most respondents had 5–10 years of professional experience, indicating a balanced mix of mid-level practitioners actively involved in clinical care (*Table I*).

Table I
Socio-Demographic Characteristics of Study Participants (*n* = 56).

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	≤30	18	32.1
	31–40	27	48.2
	>40	11	19.7
Gender	Male	28	50.0
	Female	28	50.0
Profession	Physician	24	42.9
	Pharmacist	18	32.1
	Nurse	14	25.0
Experience (years)	<5	16	28.6
	5–10	28	50.0
	>10	12	21.4

The majority of participants (89.3%) were familiar with the concept of pharmacovigilance. However, only about two-thirds knew the correct reporting channels, and less than half had received formal training. This highlights a gap between theoretical awareness and practical competence in ADR monitoring and reporting (*Table II*).

Table II
Awareness and Knowledge of Pharmacovigilance (*n* = 56).

Knowledge Domain	Correct Response n (%)
Aware of the term “Pharmacovigilance”	50 (89.3)
Knows where to report ADRs	39 (69.6)
Familiar with the WHO-UMC reporting form	32 (57.1)
Knows ADR causality assessment criteria	28 (50.0)
Received prior training on pharmacovigilance	22 (39.3)

Most participants viewed ADR reporting as an ethical and professional responsibility and believed it improves patient safety. However, a significant portion cited time constraints and legal apprehensions as barriers. The majority agreed that regular feedback from pharmacovigilance authorities would encourage more consistent reporting (*Table III*).

Table III
Attitude Toward ADR Reporting (*n* = 56).

Statement	Agree n (%)	Neutral n (%)	Disagree n (%)
ADR reporting is a professional obligation	46 (82.1)	6 (10.7)	4 (7.1)
Reporting ADRs improves patient safety	50 (89.3)	4 (7.1)	2 (3.6)
Reporting takes too much time	22 (39.3)	20 (35.7)	14 (25.0)
Fear of legal consequences discourages reporting	18 (32.1)	14 (25.0)	24 (42.9)
Feedback from authorities encourages reporting	48 (85.7)	5 (8.9)	3 (5.4)

Almost all participants (92.9%) encountered ADRs in their professional practice, yet only 42.9% had ever reported one. Reporting to the national authority was notably low (28.6%), and few participants used electronic systems. This reflects a significant under-reporting trend despite widespread clinical exposure to ADRs (*Table IV*).

Table IV
Practice of ADR Reporting Among Participants (*n* = 56).

Practice Parameter	Yes n (%)	No n (%)
Ever encountered an ADR	52 (92.9)	4 (7.1)
Ever reported an ADR	24 (42.9)	32 (57.1)
Reported ADR to the national authority (DGDA/WHO)	16 (28.6)	40 (71.4)
Frequency of reporting (>1 per year)	10 (17.9)	46 (82.1)
Used an electronic or online reporting system	14 (25.0)	42 (75.0)

Antibiotics were the most frequently implicated drug class (34.6%), followed by NSAIDs and antihypertensives. Cutaneous and gastrointestinal manifestations were the most commonly reported reaction types. This pattern suggests that ADRs associated with widely prescribed drug categories remain predominant in clinical practice (*Table V*).

Table V
Types and Frequency of ADRs Encountered by Participants (*n* = 52*).

Drug Class Involved	Common ADR Observed	Frequency (n)	Percentage (%)
Antibiotics	Skin rash, gastrointestinal upset	18	34.6
NSAIDs	Gastritis, urticaria	10	19.2
Antihypertensives	Hypotension, dizziness	8	15.4
Antiepileptics	Sedation, rash	6	11.5
Antidiabetics	Hypoglycemia, nausea	6	11.5
Others	Miscellaneous (e.g., antipsychotics, antivirals)	4	7.8

**Among 52 participants who had encountered ADRs.*

Most participants favored periodic training and digital reporting systems to improve ADR reporting. Regular feedback and integration of pharmacovigilance into continuing education programs were also highly endorsed, reflecting a proactive attitude toward system-level improvement (*Table VI*).

Table VI
Suggested Measures to Improve ADR Reporting (*n* = 56).

Suggested Intervention	Frequency (n)	Percentage (%)
Regular training/workshops	48	85.7
Simplified online reporting system	42	75.0
Feedback from pharmacovigilance authorities	40	71.4
Inclusion in CME/CPD programs	38	67.9
Institutional ADR monitoring committees	36	64.3

DISCUSSION

In this study of 56 healthcare professionals, 89.3% reported awareness of the term "pharmacovigilance," yet only 42.9% had ever submitted an ADR report. A recent systematic update found that knowledge and attitudes remain primary determinants of under-reporting, and reported awareness levels in surveyed samples ranged widely; the review described persistent gaps between awareness and reporting behaviour but did not present a single pooled "ever reported" percentage, noting large heterogeneity across studies [1]. When compared with single-centre and national cross-sectional studies, our 42.9% "ever reported" rate is higher than the 13.1% reported in one multi-site survey (where actual reporters were a small minority) but is close to the 39.7% "ever reported" documented in a separate hospital-based study from the same region that found 39.7% had ever reported an ADR and 35-40% had seen the reporting form [11]. Thus, our cohort appears to sit toward the mid-range of observed reporting practice: substantially above some low-reporting settings but short of universal reporting. Formal pharmacovigilance training was reported by 39.3% of participants in our sample. Intervention and evaluation studies demonstrate that training rates and the provision of education vary considerably; multifaceted interventions produce marked increases in knowledge and reporting, with studies showing knowledge scores rising from ~73% to >99% after training interventions and reporting increasing substantially post-intervention [12]. Compared with those intervention results, our 39.3% baseline training prevalence indicates a clear opportunity for improvement through targeted education at this centre. Use of electronic or online reporting systems was low (25.0%) in our sample. Overviews of interventions emphasize engineering solutions - notably electronic reporting - as one of the most consistently effective measures to stimulate reporting activity. An overview that categorized interventions under education, engineering, economics, and enforcement reported that electronic tools frequently yield larger short-term gains in report volume than single educational sessions alone [13]. The relatively low uptake of electronic reporting in our cohort aligns with settings where systems are available but underutilized and supports prioritizing user-friendly electronic integration locally. Perceived barriers in this study included time constraints (39.3% agreement) and fear of legal consequences (32.1%). A contemporary systematic update reported similar dominant barriers - lack of time, uncertainty about causality, and absence of feedback - and quantified high median under-reporting rates across studies (median under-reporting ~90% in many settings) [1]. Our measured barrier frequencies echo that pattern: although fewer than half of respondents flagged each barrier individually, their combined effect corresponds with the substantial under-reporting observed. Regarding the types of ADRs encountered, antibiotics accounted for 34.6% of implicated drugs and NSAIDs for 19.2% in our sample. Drug-class distributions from pharmacovigilance databases and hospital series commonly list antimicrobials and NSAIDs among the most frequently implicated groups, with skin and gastrointestinal reactions predominating; for example, hospital ADR audits often show antibiotics and NSAIDs among the top contributors to reported ADRs [14,15]. Our proportions are therefore consistent with the commonly observed clinical profile where widely prescribed antimicrobial and analgesic agents produce the bulk of spontaneously detected events. In this study, the suggested measures from participants - regular training (85.7%) and simplified online reporting (75.0%) - reflect the two intervention domains shown to increase reporting when combined. Overviews and systematic reviews report the greatest and most sustained gains when educational measures are paired with system-level engineering changes and timely feedback [12,13].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

This study highlights that most ADRs occurred with antibiotics and analgesics,

were mild to moderate, and largely preventable. Despite the importance of spontaneous reporting in improving patient safety, underreporting remains a major concern due to limited awareness and training. Strengthening pharmacovigilance systems and promoting a proactive reporting culture are essential to minimize drug-related harm and enhance patient care.

RECOMMENDATION

Regular training programs should be implemented to improve healthcare professionals' awareness and participation in ADR reporting. Establishing user-friendly digital reporting systems, integrating pharmacovigilance into clinical workflows

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CONFLICT OF INTEREST

None declared

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Virulence Factor Profiles of Uropathogenic *Escherichia coli* in Community-Acquired and Health-Care Associated Urinary Tract Infections

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ABSTRACT

Background: Urinary tract infections are among the most common bacterial infections worldwide, with most cases caused by a single bacterium, uropathogenic *Escherichia coli* (*E. coli*). The study aimed to compare virulence factor patterns and antibiotic resistance profiles of Uropathogenic *E. coli* (UPEC) isolates from community-acquired and healthcare-associated UTIs. **Methods & Materials:** This cross-sectional analytical study was carried out at Sir Salimullah Medical College, Dhaka, Bangladesh from January to December 2020, including a total of 164 urine specimens collected from patients with clinically suspected UTI. Group I consisted of 82 outpatients with CA-UTI, and Group II consisted of 82 inpatients with HA-UTI (catheterized and non-catheterized subgroups). The *E. coli* isolates were tested for virulence factors such as haemolysin production, haemagglutination (mannose-sensitive and mannose-resistant), serum resistance, gelatinase production, and fimH gene detection by PCR. Antimicrobial susceptibility test was performed by the Kirby-Bauer disc diffusion method. **Results:** *E. coli* was isolated from 65.9% of CA-UTI cases compared to 46.3% of HA-UTI cases. Virulence factors were significantly more prevalent in CA-UTI isolates: haemolysin production (22% vs 3.7%), serum resistance (20.7% vs 6.1%), mannose-resistant haemagglutination (13.4% vs 2.4%), and fimH gene (56.1% vs 40.2%). Multiple virulence factors (≥3 factors) were observed in 25.6% of CA-UTI isolates versus 7.3% in HA-UTI. Carbapenems demonstrated the highest sensitivity rates (meropenem 61% and imipenem 58.5% in CA-UTI), while high resistance was noted to cephalosporins and amoxiclav. **Conclusion:** Community-acquired strains of UPEC showed a significantly higher expression of virulence factors than their healthcare-associated counterparts, thus indicating different pathogenic mechanisms. The correlation between virulence profiles and the source of infection may have implications for both therapeutic strategies and infection control measures.

Keywords: *Escherichia coli, Uropathogenic, Urinary tract infections.*

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INTRODUCTION

Urinary tract infections pose a significant public health burden, with an estimated 150 million cases occurring annually worldwide and standing out as one of the most common indications for antibiotic prescription [1]. Uropathogenic *E. coli* is responsible for 70-95% of community-acquired UTIs and for 50-65% of healthcare-associated ones, thus representing the predominant uropathogen across diverse clinical settings [2]. The clinical spectrum of UTI encompasses conditions that range from uncomplicated cystitis to severe pyelonephritis and urosepsis, while management complexity increases owing to rising antimicrobial resistance and variability in bacterial virulence attributes [3]. This burden is further increased in low- and middle-income countries due to limitations in diagnostics, empirical use of antibiotics, and high rates of catheter use, all of which accelerate the emergence of drug-resistant strains and complicate patient outcomes. The pathogenesis of UPEC infections is mediated through a complex array of virulence factors, which enable colonization, invasion, and persistence within the urinary tract [4]. These include adhesins like type 1 fimbriae, encoded by the fimH gene, and P fimbriae; toxins like haemolysin; iron acquisition systems; capsular polysaccharides that confer serum resistance; and various enzymes such as gelatinase [5]. Type 1 fimbriae allow bacteria to attach to uroepithelial cells via mannose-sensitive interactions, while P fimbriae mediate a mannose-resistant tropism to kidney tissue, both of these being important for establishing ascending infection [6]. The pore-forming toxin haemolysin causes tissue injury and promotes bacterial dissemination, while serum resistance mechanisms confer protection against complement-mediated bacterial killing in the bloodstream, a factor particularly pertinent to life-threatening UTI cases [7]. These virulence elements work in concert, enabling UPEC to efficiently establish infection despite host immune defenses. It is emerging that virulence factor profiles are very different between community-acquired and healthcare-associated UTIs, impacting on the severity of disease, the outcome of treatments, and epidemiological surveillance [8]. Community-acquired UPEC strains usually have a full virulence repertoire, allowing infection of an anatomically normal urinary tract, while healthcare-acquired strains depend more on host compromise and instrumentation than on intrinsic virulence mechanisms [9]. This is particularly relevant in the case of catheter-associated UTI, where biofilm formation, frequent exposure to antibiotics, and extended urinary catheterization do provide ecological niches different from those of non-catheterized infections [10]. These differences mold the behavior of the pathogen, its antimicrobial susceptibility, and the presence of persistence or recurrence. In Bangladesh, UTIs pose an important clinical problem, data on virulence determinants of circulating UPEC strains are scant, and information regarding any differences between community and hospital settings is particularly limited [11]. The few local studies have focused primarily on antimicrobial resistance patterns, with limited investigation of the interplay between resistance patterns and virulence traits. Information on these virulence profiles is critical for the forecasting of disease progress, guiding

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empirical therapy, and formulating targeted prevention strategies. A more precise view of the differences between strains can support evidence-based decisions on catheter care, antimicrobial stewardship, and infection control practices. Therefore, this study aimed to characterize and compare the virulence factor profiles of UPEC isolates from community-acquired versus healthcare-associated UTIs and to assess their antimicrobial susceptibility patterns in a tertiary care setting in Dhaka, Bangladesh.

METHODS & MATERIALS

This cross-sectional analytical study was conducted in the Department of Microbiology at Sir Salimullah Medical College, Dhaka, Bangladesh from January to December 2020, enrolling patients of any age and sex presenting with clinically suspected urinary tract infections at Mitford Hospital. The study population comprised two groups: outpatients with community-acquired UTI (Group I) and inpatients with healthcare-associated UTI (Group II), the latter further divided into catheterized and non-catheterized subgroups. Inclusion criteria for Group I required a clinically diagnosed UTI without hospitalization within the preceding 28 days, while Group II participants were hospitalized for at least 72 hours (non-catheterized) or catheterized for a minimum of 48 hours, with relevant urinary symptoms. Patients on antibiotics or those who had taken antibiotics within 14 days were excluded. Purposive sampling yielded 82 samples per group, totaling 164 urine specimens. Data were collected using a structured questionnaire capturing demographic and clinical variables. Midstream urine was collected aseptically from non-catheterized patients, whereas catheterized samples were drawn using sterile technique proximal to the catheter-urobag junction. All samples were cultured on MacConkey and blood agar, followed by incubation at 37°C for 24 hours [12]. Bacterial isolates were identified through colony morphology, Gram stain, and standard biochemical tests. Antimicrobial susceptibility testing was performed by Kirby-Bauer disc diffusion on Mueller-Hinton agar in accordance with CLSI 2019 guidelines, using *E. coli* ATCC 25922 as the control strain [13,14]. Identified *E. coli* isolates were preserved on Mueller-Hinton agar slants and evaluated for virulence determinants, including haemolysin production, haemagglutination (mannose-sensitive and mannose-resistant), serum resistance, and gelatinase production using standard procedures. The fimH gene was detected by conventional PCR following genomic DNA extraction, primer preparation, amplification, and agarose gel electrophoresis [15]. Data were entered and analyzed using SPSS version 26.

RESULTS

Table I shows that the positivity rate of culture was 82.9% in Group I (community-acquired UTI) and 68.3% in Group II (healthcare-associated UTI). Isolation rates for *E. coli* were significantly different between groups (65.9% in community-acquired cases vs 46.3% in healthcare-associated cases). Culture negativity was more common among healthcare-associated infection cases (31.7%) than community infections (17.1%).

Table I
Growth Culture Results of UTI Cases among the study population.

Growth	Group-I (n=82)	Group-II (n=82)
	n (%)	n (%)
Culture Positive	68 (82.9%)	56 (68.3%)
Culture Negative	14 (17.1%)	26 (31.7%)
E. coli	54 (65.9%)	38 (46.3%)

Table II shows that *E. coli* predominated in both groups but had a higher prevalence in community-acquired UTI, 65.9% compared with healthcare-associated UTI, 46.3%. Healthcare-associated infections, however, manifested greater bacterial diversity, including increased proportions of *Klebsiella* spp., 12.2% versus 8.5%, and *Pseudomonas* spp., 8.5% versus 3.7%. Community isolates included a few unique organisms, such as *Citrobacter*, *Serratia*, and *Staphylococcus aureus*, although the overall distribution reflected typical patterns of uropathogenic species in different acquisition settings.

Table II
Distribution of Bacterial Isolates of UTI Patients.

Bacterial Isolates	Group-I (n=82) (n) (%)	Group-II (n=82) (n) (%)
E. coli	54 (65.9%)	38 (46.3%)
Klebsiella spp.	07 (8.5%)	10 (12.2%)
Pseudomonas spp.	03 (3.7%)	07 (8.5%)
Citrobacter spp.	01(1.2%)	00 (0%)
Proteus spp.	01(1.2%)	01 (1.2%)
Serratia spp.	01(1.2%)	00 (0%)
Staphylococcus aureus	01(1.2%)	00 (0%)

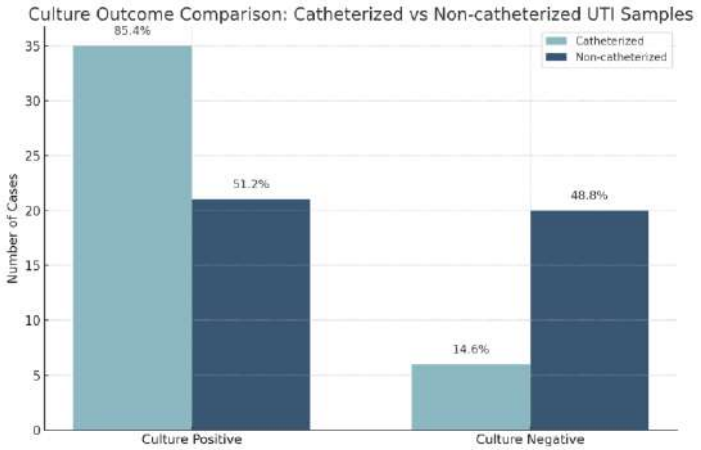

Figure 1 Culture Outcome Comparison between Catheterized and Non-Catheterized UTI Samples.

Figure 1 illustrates bacterial distribution between catheterized and non-catheterized samples within healthcare-associated UTI cases. *E. coli* had a marked predominance in catheterized samples, 65.9% versus 26.8% in non-catheterized samples. By contrast, the non-*E. coli* organisms, especially the species *Pseudomonas* and *Klebsiella*, were more common in non-catheterized samples. Such a distribution pattern reflects the differential bacterial ecology related to catheterization versus spontaneous healthcare-acquired infections.

Table III demonstrates that *E. coli* isolations among healthcare-associated infections in catheterized patients were 65.9%, significantly higher than that found among non-catheterized patients at 26.8%. *Pseudomonas* spp. had comparable prevalence between the subgroups, 12.2% catheterized versus 14.6% non-catheterized. *Klebsiella* spp. was lower in the catheterized population compared to the non-catheterized at 4.9% and 9.8%, respectively. This distribution would seem to suggest that the catheterization selects for *E. coli* colonization despite the hospital environment.

Table III
Distribution of Bacterial Isolates among Catheterized and Non-Catheterized UTI Patients.

Isolates	Growth from catheterized urine (n=41)	Growth from non-catheterized urine (n=41)
	n (%)	n (%)
Escherichia coli	27 (65.9%)	11 (26.8%)
Pseudomonas spp.	05 (12.2%)	06 (14.6%)
Klebsiella spp.	02 (4.9%)	04 (9.8%)
Proteus spp.	01 (2.4%)	00 (0%)

Table IV shows that carbapenems had the highest susceptibility rates with meropenem at 61% CA-UTI, 39% HA-UTI, and imipenem at 58.5% CA-UTI, 37.8% HA-UTI, showing superior efficacy. Resistance to cephalosporins was significant in both groups, with ceftazidime resistance at 37.8% in the community and 30.9% in healthcare settings. Fluoroquinolone susceptibility was moderate, with levofloxacin performing better (42.7% CA-UTI) than ciprofloxacin (31.7% CA-UTI). Nitrofurantoin maintained reasonable sensitivity at 50% CA-UTI and 29.3% HA-UTI, while amoxicillin showed high resistance rates of over 36% in both groups.

Table IV
Antimicrobial Susceptibility Patterns of Uropathogens in Community-Acquired and Health-Care Associated UTI Cases.

Antimicrobial Agents	Group-I (n=82)			Group-II (n=82)		
	Sensitive	Intermediate	Resistant	Sensitive	Intermediate	Resistant
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Mecillinam	29 (35.5%)	3 (3.7%)	22 (26.8%)	22 (26.8%)	3 (3.7%)	13 (15.9%)
Ceftazidime	20 (24.4%)	3 (3.7%)	31 (37.8%)	9 (10%)	4 (4.9%)	25 (30.9%)
Cefuroxime	15 (18.3%)	3 (3.7%)	36 (43.9%)	24 (29.3%)	21 (25.6%)	13 (15.9%)
Ceftriaxone	23 (28%)	2 (2.4%)	29 (35.4%)	10 (12.2%)	3 (3.7%)	25 (30.9%)
Cefixime	18 (22%)	2 (2.4%)	34 (41.5%)	11 (13.4%)	3 (3.7%)	24 (29.3%)
Meropenem	50 (61%)	0 (0%)	4 (4.9%)	32 (39%)	0 (0%)	6 (7.3%)
Imipenem	48 (58.5%)	1 (1.2%)	5 (6.1%)	31 (37.8%)	0 (0%)	7 (8.5%)
Amoxiclav	14 (17.1%)	2 (2.4%)	38 (46.3%)	5 (6.1%)	3 (3.7%)	30 (36.6%)
Ciprofloxacin	26 (31.7%)	3 (3.7%)	25 (30.9%)	16 (19.5%)	2 (2.4%)	20 (14.4%)
Levofloxacin	35 (42.7%)	3 (3.7%)	16 (19.5%)	17 (20.7%)	2 (2.4%)	19 (23.2%)
Nalidixic acid	12 (14.6%)	4 (4.9%)	38 (46.3%)	15 (18.3%)	4 (4.9%)	19 (23.2%)
Gentamicin	40 (48.9%)	1 (1.2%)	13 (15.9%)	17 (20.7%)	3 (3.7%)	18 (22%)
Amikacin	47 (57.3%)	0 (0%)	7 (8.5%)	32 (39%)	0 (0%)	6 (7.3%)
Co-trimoxazole	26 (31.7%)	2 (2.4%)	26 (31.7%)	16 (19.5%)	3 (3.7%)	19 (23.2%)
Nitrofurantoin	41 (50%)	0 (0%)	13 (15.9%)	24 (29.3%)	1 (1.2%)	13 (15.9%)
Aztreonam	16 (19.5%)	3 (3.7%)	35 (42.9%)	22 (26.8%)	3 (3.7%)	13 (15.9%)

Table V denotes that within the healthcare-associated infections, the samples from catheterized patients showed broader antibiotic resistance, with ceftazidime resistance at 46.3%, compared to 14.6% in the non-catheterized ones. Carbapenem sensitivity remained the highest in both subgroups (meropenem 53.7% catheterized vs 24.4% non-catheterized), but the absolute sensitivity was lower in catheterized patients. Amoxiclav demonstrated particularly high resistance in catheterized samples (51.2%), while nitrofurantoin maintained reasonable efficacy (43.9% sensitive in catheterized patients), suggesting its potential utility in catheter-associated infections.

Table V
Comparative Antimicrobial Susceptibility Patterns between Catheterized and Non-Catheterized UTI Samples.

Antimicrobial Agents	Catheterized urine (n=41)			Non-catheterized urine (n=41)		
	Sensitive	Intermediate	Resistant	Sensitive	Intermediate	Resistant
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Mecillinam	15 (36.9%)	2 (4.9%)	10 (24.4%)	7 (17%)	1 (2.4%)	3 (7.3%)
Ceftazidime	6 (14.6%)	2 (4.9%)	19 (46.3%)	3 (7.3%)	2 (4.9%)	6 (14.6%)
Cefuroxime	16 (39%)	0 (0%)	11 (26.8%)	8 (19.5%)	1 (2.4%)	2 (4.9%)
Ceftriaxone	7 (17%)	2 (4.9%)	18 (43.9%)	3 (7.3%)	1 (2.4%)	7 (17%)
Cefixime	8 (19.5%)	2 (4.9%)	17 (41.5%)	3 (7.3%)	1 (2.4%)	7 (17%)
Meropenem	22 (53.7%)	0 (0%)	5 (12.2%)	10 (24.4%)	0 (0%)	1 (2.4%)
Imipenem	22 (53.7%)	0 (0%)	5 (12.2%)	9 (22%)	0 (0%)	2 (4.9%)
Amoxiclav	4 (9.8%)	2 (4.9%)	21 (51.2%)	1 (2.4%)	1 (2.4%)	9 (22%)
Ciprofloxacin	12 (29.7%)	2 (4.9%)	13 (31.7%)	4 (9.8%)	0 (0%)	7 (17%)
Levofloxacin	13 (31.7%)	2 (4.9%)	12 (29.7%)	4 (9.8%)	1 (2.4%)	6 (14.6%)
Nalidixic acid	10 (24.4%)	3 (7.3%)	14 (34.1%)	5 (12.2%)	1 (2.4%)	5 (12.2%)
Gentamicin	14 (34.1%)	2 (4.9%)	11 (26.8%)	3 (7.3%)	1 (2.4%)	7 (17%)
Amikacin	22 (53.7%)	0 (0%)	5 (12.2%)	10 (24.4%)	0 (0%)	1 (2.4%)
Co-trimoxazole	11 (26.8%)	2 (4.9%)	14 (34.1%)	5 (12.2%)	1 (2.4%)	5 (12.2%)
Nitrofurantoin	18 (43.9%)	1 (2.4%)	8 (19.5%)	6 (14.6%)	0 (0%)	5 (12.2%)
Aztreonam	15 (36.9%)	2 (4.9%)	10 (24.4%)	7 (17%)	1 (2.4%)	3 (7.3%)

Table VI shows that community-acquired *E. coli* isolates showed significantly higher rates of virulence factors such as haemolysin production (22% vs 3.7%), serum resistance (20.7% vs 6.1%), and mannose-resistant haemagglutination (13.4% vs 2.4%). The fimH gene was present in 56.1% of strains from the community versus 40.2% from healthcare. As many as 25.6% of community strains but only 7.3% of healthcare strains expressed multiple virulence factors ≥3, indicating that community-acquired UPEC possess more extensive virulence repertoires.

Table VI
Comparative analysis of virulence factor profiles of *E. coli.*

Variable	Category	**Group-I (n=82)** n (%)	**Group-II (n=82)** n (%)
Virulence Factors	Haemolysin production	18 (22%)	3 (3.7%)
	Serum resistance	17 (20.7%)	5 (6.1%)
	Gelatinase production	3 (3.7%)	0 (0%)
	fimH gene	46 (56.1%)	33 (40.2%)
Haemagglutination	Mannose-Sensitive Haemagglutination	38 (46.3%)	26 (31.7%)
	Mannose-Resistant Haemagglutination	11 (13.4%)	2 (2.4%)
Virulence Factors	All VF	1 (1.2%)	0 (0%)
	Any 4 VF	10 (12.2%)	1 (1.2%)
	Any 3 VF	10 (12.2%)	5 (6.1%)
	Any 2 VF	26 (31.7%)	22 (26.8%)
	Any 1 VF	6 (7.3%)	6 (7.3%)
	No Virulence Factors	1 (1.2%)	4 (4.9%)

Table VII unveils the prevalence of the fimH gene was higher in catheterized samples among healthcare-associated infections than among non-catheterized samples, at 58.5% compared to 22%, indicating the importance of adhesin-mediated colonization in catheter-associated UTI. Mannose-sensitive haemagglutination was highly increased in catheterized samples (51.2% vs 12.2%), reflecting type 1 fimbriae expression. Haemolysin production and serum resistance showed minimal differences between subgroups and generally remained low, showing that healthcare-associated strains depend less on classical virulence mechanisms independent of catheterization.

Table VII
Virulence Factors in Catheterized vs Non-Catheterized Samples.

Virulence Factors	Catheterized urine (n=41)	Non-catheterized (n=41)
	n (%)	n (%)
Haemolysin production	1 (2.4%)	2 (4.9%)
Haemagglutination	-	-
Mannose-Sensitive Haemagglutination	21 (51.2%)	5 (12.2%)
Mannose-Resistant Haemagglutination	0 (0%)	2 (4.9%)
Serum resistance	3 (3.7%)	2 (4.9%)
Gelatinase production	0 (0%)	0 (0%)
fimH gene	24 (58.5%)	9 (22%)

DISCUSSION

This study demonstrates the differences in the virulence factor profiles between community-acquired and healthcare-associated uropathogenic *E. coli*, where community strains had significantly higher expression of classical virulence determinants. The differences observed reflect a fundamental divide in pathogenic strategy, wherein community-acquired UPEC must maintain complete virulence arsenals to initiate infection in otherwise immunocompetent hosts possessing an anatomically normal urinary tract, whereas healthcare-associated strains can leverage host compromise and instrumentation [16]. These data reinforce the notion that UPEC virulence is context-dependent, not absolute, driven by ecological pressures and by the host environment. In the community environment, only strains capable of adhesion, invasion, and evasion of host immunity are naturally selected. In contrast, the hospital setting, characterized by prolonged catheterization, antibiotic pressure, and host comorbidities, provides a selective environment for the predominance of less intrinsically virulent but highly resistant organisms. Infection rates of *E. coli* were higher in community-acquired UTI (65.9%) compared to healthcare-associated UTI (46.3%), consistent with Tandogdu et al. [17]. The higher bacterial diversity of healthcare-associated infections, particularly increased *Klebsiella* and *Pseudomonas* species, reflects nosocomial ecological pressures and selective antimicrobial exposure typical of the hospital environment [18]. This diversification has therapeutic implications, given that these opportunistic pathogens often exhibit enhanced antimicrobial resistance and distinct virulence mechanisms compared to community *E. coli* strains [19]. Their presence complicates empirical therapy and emphasizes the need for risk stratification based on the infection setting. The virulence factor analysis showed striking differences between infection sources. Haemolysin production, present in 22% of community-acquired isolates versus only 3.7% of healthcare-associated strains, is an important tissue-damaging toxin associated with severe disease manifestations such as pyelonephritis and bacteremia [20]. Similarly, serum resistance (a correlate of invasive disease potential) was threefold more prevalent among community strains (20.7% vs 6.1%), consistent with Sartor et al., who reported increased complement resistance among community UPEC [21]. These findings indicate that healthcare-associated strains may have experienced fitness cost trade-offs, losing metabolically expensive virulence factors in order to acquire antimicrobial resistance determinants [22]. Such trade-offs have been described as evolutionary responses to sustained antibiotic pressure and biofilm-associated growth. The presence of the fimH gene, encoding the adhesin component of type 1 fimbriae, was detected in 56.1% of community isolates and 40.2% in healthcare isolates, but notably higher expression was found in catheterized patients, at 58.5%. This paradox-lower overall prevalence in healthcare settings but highest expression in the catheterized subgroup-suggests that though the healthcare-associated non-catheterized UTIs may involve less virulent opportunistic strains, the catheter-associated infections still depend on adhesin-mediated biofilm formation for persistence [23]. This mechanism is further supported by the mannose-sensitive haemagglutination pattern, which shows 51.2% positivity in catheterized samples versus 12.2% in noncatheterized healthcare samples [24]. These findings thus support the central role of surface adhesins in the establishment of catheter biofilms as a key driver of chronic and recurrent infections. The trend for antimicrobial resistance was a cause of concern, with high rates of resistance to commonly used agents. Community-acquired infection rates of resistance to cephalosporins exceeded 35% for several agents, considerably higher than those reported for developed countries but consistent with reports by Shaifali et al. [25]. Carbapenem sensitivity remained relatively preserved at 61% for community infections with meropenem, although the 39% sensitivity in healthcare settings has raised concerns about emerging carbapenem resistance in hospital settings [26]. The inverse relationship between virulence factor expression and antimicrobial resistance provides evidence of evolutionary trade-offs in which healthcare-associated strains sacrifice virulence determinants for survival mechanisms [27]. This complicates infection management, as strains may be less virulent yet more difficult to eradicate. These findings have significant clinical implications. Empirical therapy for CA-UTI must be based on local resistance patterns, while being cognizant of the increased virulence potential of such strains, which may require more aggressive management in complicated infections. Management of HA-UTI, however, requires consideration of broader resistance profiles and the possibility of polymicrobial infection [28]. Distinct virulence profiles, as discussed above, support differential approaches to diagnosis and therapy based on the setting of acquisition of infection and emphasize the importance of effective infection control, antimicrobial stewardship, and catheter management. Enhancing routine diagnostic capability, including the introduction of virulence markers into infection surveillance programs, and strategies for empirical treatment, may make a significant difference in resource-constrained settings.

LIMITATIONS

This single-center cross-sectional design limits the generalizability. Further, the lack of molecular characterization of resistance genes limits the understanding of resistance mechanisms. The sample size is relatively small and may not reflect complete bacterial diversity; seasonal variations in pathogen distribution were also not assessed.

CONCLUSION

Community-acquired uropathogenic *E. coli* demonstrates considerably higher expression of virulence factors such as the production of haemolysin, serum resistance, and adhesin determinants, in comparison with healthcare-associated strains. This virulence-resistance dichotomy reflects distinct evolutionary pressures, with community strains needing comprehensive pathogenic mechanisms while healthcare strains prioritize antimicrobial survival. The findings provide a basis for tailored therapeutic strategies and infection control

measures depending on the setting of acquisition and catheterization status.

RECOMMENDATIONS

Whole-genome sequencing characterizing the virulence and resistance gene repertoire should be included in future studies. Prospective, multicenter studies should also correlate virulence profiles with clinical outcomes such as treatment failure and recurrence rates. Investigation of biofilm formation capacity and clonal relatedness would enhance the understanding of nosocomial transmission dynamics.

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CONFLICT OF INTEREST

None declared

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A comparative study on complications developed in mothers and neonates among pregnant women with or without gestational diabetes mellitus

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ABSTRACT

Introduction: Gestational diabetes mellitus (GDM) is defined as glucose intolerance first recognized during pregnancy and is one of the most common metabolic complications in obstetrics. This study aimed to compare maternal and neonatal complications in women with and without GDM and to assess the impact of GDM on pregnancy and neonatal outcomes in a tertiary care setting. **Methods & Materials:** This comparative cross-sectional study was conducted in the Department of Obstetrics and Gynecology at Rangpur Medical College Hospital, Rangpur, Bangladesh, from January 2025 to June 2025, including 96 pregnant women-48 with gestational diabetes mellitus (GDM) and 48 without GDM, matched for age and parity. **Result:** Among 96 pregnant women (48 GDM, 48 non-GDM), maternal complications were higher in the GDM group, with pregnancy-induced hypertension in 20.8% vs. 8.3%, polyhydramnios in 12.5% vs. 2.1%, and cesarean delivery in 66.7% vs. 50%. Neonates of GDM mothers had higher mean birth weight (3.42 kg vs. 2.98 kg) and macrosomia (14.6% vs. 2.1%), with increased rates of hypoglycemia (18.8% vs. 4.2%) and NICU admission (29.2% vs. 12.5%). Respiratory distress (14.6% vs. 6.3%) and birth asphyxia (10.4% vs. 4.2%) were also more common in the GDM group. **Conclusion:** This study shows that gestational diabetes mellitus is associated with higher maternal complications-such as hypertensive disorders, polyhydramnios, and cesarean delivery-as well as increased neonatal risks including macrosomia, hypoglycemia, and NICU admission.

Keywords: *Neonatal Complications, Maternal Complications, Gestational Diabetes Mellitus*

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INTRODUCTION

Gestational Diabetes Mellitus (GDM), formerly known as "glucose intolerance occurring for the first-time during pregnancy," is now growing as an important contributor to maternal and neonatal morbidity and mortality. The rise in prevalence, attributable mainly to increasing maternal age, high rates of obesity, and the changed criteria used for diagnosis, brought gestational diabetes into the focus of research on perinatal health. Atlas D et al. [1] and Guariguata et al. [2] brought attention to the fact that "hyperglycemia in pregnancy is increasing, and the need for comparison of outcomes in women with and without GDM is evident." Comparative studies are essential for evaluating the risks attributable to gestational diabetes, the complications that are potentially preventable, and the development of evidence-based antenatal practices, adapted for both maternal and neonatal health. Women with gestational diabetes are known to develop various complications. The risks associated with pregnancy are high for women with gestational diabetes, namely, pregnancy-induced hypertension, preeclampsia, polyhydramnios, as well as other obstetric complications of induction of labour and cesarean delivery. Ye et al. [3] substantiated the fact that "even mild hyperglycemia is associated with an increased risk of hypertensive disorders and operative delivery." But gestational diabetes poses risks for women's health in the long term as well. Vounzoulaki et al. [4] brought to light the increased risk of type 2 diabetes and cardiovascular disease later in life for women with gestational diabetes. The comparison of maternal health between women with and without gestational diabetes enables estimation of the risks and development of antenatal practices against those risks. In pregnancies complicated by gestational diabetes, there are neonatal complications as well. The increased level of insulin within the fetus, due to the mother's hyperglycemia, poses risks for both high birth weight and hypertrophic newborn, shoulder dystocia, hypoglycemia, respiratory distress, and admission to neonatal intensive care units. Balsells et al. [5] conveyed facts to light, stating significant increases in hypertrophic births, hypoglycemia, respiratory distress, and neonatal intensive care unit admissions, compared to those born to women without gestational diabetes. Moreover, evidence based on HAPO follow-up studies, under the author Lowe et al. [6], indicates growth within childhood into obesity, insulin resistance, and "high risk of metabolic disease, highlighting the long-term effects of exposure within the womb through maternal hyperglycemia." The comparison of neonatal outcomes to those in normoglycemic pregnancies enables a better understanding of the real effect of GDM on the health of newborns. In spite of improvements in management and decreased rates of adverse outcomes, disparities still exist. In this case, Poolsup et al. [7] show that management lowers the risk of macrosomic infants and shoulder dystocia, whereas disparities still affect the outcome. Son H et al. [8] and Daniells et al. [9] strongly emphasise, through their studies, the crucial role of factors of the target population, significantly affecting the risk profile in the case of pregnancies complicated by GDM, and hence the value of context-specific comparative research. Comparative studies of pregnancies with and without gestational diabetes mellitus are therefore crucial to evaluate the efficiency of antenatal care and improve maternal and neonatal outcomes. Wendland et al. [10] brought into focus the actual clinical burden of gestational diabetes mellitus and helped legitimise evidence-based approaches toward decreasing perinatal morbidity. The study aims to evaluate the comparison of maternal and neonatal complications

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between women with and without gestational diabetes mellitus.

METHODS & MATERIALS

The present comparative cross-sectional study was carried out in the Department of Obstetrics and Gynecology at Rangpur Medical College Hospital, Rangpur, Bangladesh, from January 2025 to June 2025, on 96 pregnant women comprising 48 subjects with gestational diabetes mellitus and 48 without gestational diabetes mellitus, matched for age and parity. Women aged 18–40 years with singleton pregnancies were included. All the GDM cases were diagnosed using the 75 g oral glucose tolerance test according to IADPSG criteria between 24–28 weeks of gestation. Exclusion criteria were pre-existing diabetes, multiple pregnancy, chronic hypertension, renal, and hepatic diseases. Data analyzed will include demographic data, obstetric history, and antenatal records, maternal outcome in the form of pregnancy-induced hypertension, polyhydramnios-oligohydramnios, preterm labor, and mode of delivery, while neonatal outcomes included birth weight, macrosomia, low birth weight, hypoglycemia, respiratory distress syndrome, birth asphyxia, and NICU admission. Data were analyzed using SPSS version 26, with continuous variables expressed as mean ± SD, and compared by independent t-tests, whereas categorical variables expressed as frequency and percentage were compared by Chi-square. A p-value of <0.05 was regarded as statistically significant. The study was approved by the Institutional Review Board and written informed consent was obtained from all participants after explaining the purpose of the study, assuring confidentiality throughout.

RESULTS

The baseline characteristics between the two groups were comparable. The mean maternal age was 28.9 years in the GDM group and 27.8 years in the non-GDM group, while BMI values were also similar (27.3 vs. 26.8 kg/m²). Parity distribution showed 41.7% primigravida in the GDM group compared to 47.9% in non-GDM mothers (*Table I*).

Table I
Baseline Characteristics of Study Participants (*n* = 96).

Variable	GDM (n=48) Mean ± SD / n (%)	Non-GDM (n=48) Mean ± SD / n (%)	p-value
Maternal age (years)	28.9 ± 4.5	27.8 ± 4.2	0.21
BMI (kg/m²)	27.3 ± 3.1	26.8 ± 3.4	0.46
Primigravida	20 (41.7%)	23 (47.9%)	0.54
Multigravida	28 (58.3%)	25 (52.1%)	-

Maternal complications occurred more frequently among GDM mothers. Pregnancy-induced hypertension was observed in 20.8% vs. 8.3%, and polyhydramnios in 12.5% vs. 2.1% of the GDM and non-GDM groups, respectively. Cesarean delivery was also higher at 66.7% in the GDM group compared with 50.0% among non-GDM women (*Table II*).

Table II
Maternal Complications Among Study Participants (*n* = 96).

Maternal Complication	GDM (n=48) n (%)	Non-GDM (n=48) n (%)	p-value
Pregnancy-induced hypertension	10 (20.8%)	4 (8.3%)	0.09
Polyhydramnios	6 (12.5%)	1 (2.1%)	0.05
Oligohydramnios	3 (6.3%)	2 (4.2%)	0.64
Preterm labor	8 (16.7%)	5 (10.4%)	0.36
Cesarean delivery	32 (66.7%)	24 (50.0%)	0.10

Mean birth weight was significantly higher in infants of GDM mothers (3.42 kg) compared to non-GDM mothers (2.98 kg). The macrosomia rate was also markedly higher at 14.6% in the GDM group versus 2.1% in non-GDM babies. Low birth weight showed the opposite trend but was not statistically significant (8.3% vs. 12.5%) *Table III*.

Table III
Neonatal Anthropometric Outcomes (*n* = 96).

Outcome	GDM (n=48) Mean ± SD / n (%)	Non-GDM (n=48) Mean ± SD / n (%)	p-value
Birth weight (kg)	3.42 ± 0.52	2.98 ± 0.48	<0.001
Macrosomia (>4 kg)	7 (14.6%)	1 (2.1%)	0.03
Low birth weight (<2.5 kg)	4 (8.3%)	6 (12.5%)	0.51
Length (cm)	49.6 ± 2.3	48.8 ± 2.4	0.12

Neonatal hypoglycemia was significantly higher among infants born to GDM mothers (18.8% vs. 4.2%). NICU admission was also more common in the GDM group (29.2%) than in the non-GDM group (12.5%). Rates of respiratory distress (14.6% vs. 6.3%) and birth asphyxia (10.4% vs. 4.2%) were higher among GDM infants as well (*Table IV*).

Table IV
Neonatal Morbidity Among Study Groups (*n* = 96).

Morbidity	GDM (n=48) n (%)	Non-GDM (n=48) n (%)	p-value
Hypoglycemia	9 (18.8%)	2 (4.2%)	0.03
Respiratory distress syndrome	7 (14.6%)	3 (6.3%)	0.19
Birth asphyxia	5 (10.4%)	2 (4.2%)	0.26
NICU admission	14 (29.2%)	6 (12.5%)	0.04

Induction of labor occurred in 37.5% of GDM mothers compared to 27.1% of non-GDM mothers. Emergency cesarean section was also higher in the GDM group (43.8% vs. 31.3%). Although not statistically significant, meconium-stained liquor (16.7% vs. 10.4%) and postpartum hemorrhage (6.3% vs. 4.2%) were more frequent in the GDM group (*Table V*).

Table V
Pregnancy and Delivery Characteristics (*n* = 96).

Variable	GDM (n=48) n (%)	Non-GDM (n=48) n (%)	p-value
Induction of labor	18 (37.5%)	13 (27.1%)	0.27
Emergency cesarean	21 (43.8%)	15 (31.3%)	0.20
Meconium-stained liquor	8 (16.7%)	5 (10.4%)	0.37
Postpartum hemorrhage	3 (6.3%)	2 (4.2%)	0.64

DISCUSSION

In the present study comparing maternal and neonatal outcomes between women with and without gestational diabetes mellitus (GDM), several important findings emerged. Pregnancy-induced hypertension was observed in 20.8% of GDM mothers compared with 8.3% of non-GDM mothers. Bellamy et al. in Bangladesh also documented a high rate of gestational hypertension (14%) among women with GDM, supporting the increased hypertensive risk associated with diabetic pregnancies [11]. Similarly, Metzger et al. found gestational hypertension in 17.6% of GDM cases, whereas none of the non-GDM women developed hypertension, further reinforcing the pattern seen in our findings [12]. Polyhydramnios occurred in 12.5% of GDM women versus 2.1% of non-GDM mothers in our study. A recent study in the SAS Journal reported a comparable polyhydramnios rate (12.9%) among GDM pregnancies, attributing the condition to fetal osmotic diuresis caused by maternal hyperglycemia [13]. Regarding mode of delivery, 66.7% of GDM mothers in our study underwent cesarean section, compared with 50% in the non-GDM group. Barakat et al. reported an even higher cesarean rate (70%) in Bangladeshi women with GDM, relative to 36% in non-GDM women, attributing the increased operative delivery to macrosomia and poor glycemic control [14]. Ciobanu et al. also reported a markedly elevated cesarean rate (96.1%) among GDM mothers versus 78.3% in controls, although their values were higher than ours due to differences in population characteristics and clinical protocols [12]. Neonatal outcomes in our study further support the established risks associated with GDM. Mean birth weight was significantly higher in the GDM group (3.42 kg) than in non-GDM infants (2.98 kg), with 14.6% of GDM neonates being macrosomic. A similar pattern was reported in a study in which the mean birth weight was 3.689 kg in GDM infants versus 3.143 kg in non-GDM infants, with macrosomia significantly associated with maternal hyperglycemia [15]. Neonatal hypoglycemia occurred in 18.8% of infants in the GDM group compared with 4.2% among non-GDM infants. This aligns with the findings of the same study, which reported a hypoglycemia rate of 17% among GDM neonates [15]. Metzger et al. also noted significantly higher hypoglycemia rates in the GDM group, confirming the metabolic vulnerability of these newborns [12]. NICU admission was required for 29.2% of GDM infants in our study, compared with 12.5% in non-GDM infants. Barakat et al. similarly found NICU admission rates of 36% among GDM infants and 12% in non-GDM infants, comparable to our relative difference, though slightly higher in absolute values [14]. A prospective study from a low-resource setting documented a NICU admission rate of 17.9% among GDM newborns, with poorer glycemic control correlating with higher rates [16]. Respiratory distress syndrome (RDS) was observed in 14.6% of GDM neonates compared with 6.3% among non-GDM infants. Metzger et al. also found higher rates of RDS among GDM newborns, supporting the heightened pulmonary risk associated with maternal diabetes [12]. Although our p-value was not statistically significant, the clinical pattern corresponds with prior evidence.

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

This study shows that gestational diabetes mellitus is associated with higher maternal complications—such as hypertensive disorders, polyhydramnios, and cesarean delivery—as well as increased neonatal risks including macrosomia, hypoglycemia, and NICU admission.

RECOMMENDATION

Routine early screening for gestational diabetes, close monitoring throughout pregnancy, and strict glycemic control are recommended to reduce maternal and neonatal complications. Healthcare providers should ensure timely referral, individualized dietary and medical management, and adequate follow-up to improve outcomes in pregnancies complicated by GDM.

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CONFLICT OF INTEREST

None declared

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Correlation of Serum Ferritin Level and Number of Blood Transfusion in Thalassemic Patients

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ABSTRACT

Introduction: Thalassemia is a prevalent hereditary disorder of hemoglobin causing chronic anemia that necessitates regular blood transfusions. Unfortunately, these treatments often cause iron overload. In order to evaluate the accumulation of iron and adjust chelation therapy, it is necessary to monitor serum ferritin. The present study was conducted to determine the relationship between serum ferritin levels, transfusion frequency, and nutritional status of thalassemic children. **Methods & Materials:** This study was a cross-sectional study conducted in the Department of Pediatrics, Chittagong Medical College Hospital, Chittagong, over a period of six months from December 2013 to May 2014. The study population included 50 patients admitted to the Pediatrics Wards. **Result:** The study result indicated that patients who received transfusions more frequently recorded higher serum ferritin levels. The patients who were transfused at intervals of less than 1 month had the highest mean ferritin (4192.45 ng/mL), whereas those with intervals of over 2 months had the lowest mean ferritin (408.70 ng/mL), although most patients historically had transfusions every 1, 2 months. Serum ferritin levels did not show any significant correlation with weight for height, height for age, or weight for age, thus iron overload in this case was more linked to stunting and chronic malnutrition than to wasting. Almost half of the patients (46%) were severely stunted and 40% moderately stunted, with mean ferritin levels of 2542.13 ng/mL and 2689 ng/mL, respectively. On the other hand, the majority (88%) were nonwasted. **Conclusion:** The elderly patients received more blood transfusions and had higher levels of serum ferritin, with most of them having levels above 1000 ng/mL, which is an indication of severe iron overload. Higher levels of ferritin were strongly associated with stunting and chronic malnutrition, while wasting was uncommon.

Keywords: *Thalassemia, Blood Transfusion, Serum Ferritin*

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INTRODUCTION

Thalassemia is considered among the top inherited hemoglobin disorders globally and it is especially common in South and Southeast Asia, the Middle East, and the Mediterranean region. The most severe form beta thalassemia major, is due to a deficiency or absence of beta, globin chain synthesis, which results in ineffective erythropoiesis, chronic hemolytic anemia, and growth and developmental problems. Patients with transfusion, dependent thalassemia need to be given blood transfusions regularly and for their entire life to keep up their hemoglobin levels, to prevent the expansion of the bone marrow and to improve their quality of life [1,2]. Besides the fact that the transfusion is a life, saving procedure, it will still lead to iron overload as iron cannot be actively removed from the body since it has no physiological mechanism for active iron excretion. Each unit of concentrated red blood cells is estimated to have 200250 mg of iron. Thus, the excess iron from repeated transfusions gradually accumulates in such major organs as the liver, the heart, and the endocrine glands [3]. In addition, thalassemia, related ineffective erythropoiesis suppresses hepcidin secretion, resulting in increased intestinal iron absorption, which also exacerbates the systemic iron overload condition [4]. Without reassurance by iron chelation therapy, iron overload may cause serious complications such as hepatic fibrosis, cardiomyopathy, diabetes mellitus, hypogonadism, and growth retardation, which are still the leading causes of morbidity and mortality in thalassemic patients [5,6]. Hence, the evaluation of the bodys iron stores plays a very crucial role in the management of transfusion, dependent thalassemia. Among the different methods, serum ferritin measurement is the most common and feasible lab marker for total body iron load due to its low cost, easiness to get, and non, invasive character. Relative high serum ferritin concentration over time is mainly representative of the increased iron stores and thus, can be used to determine when to start and how to adjust chelation therapy [7]. Advanced methods such as MRI T2* are capable of quantifying the iron level in the organ with greater accuracy and they allow a more precise assessment of iron overload; however, these methods are not always accessible in many places with limited resources. Thus, serum ferritin is the main monitoring instrument in routine clinical practice, particularly in developing countries [8]. Even with different studies, it was found that serum ferritin levels have a positive relationship with the transfusion load such as the frequency and the total number of transfusions given. Patients who have received larger numbers of transfused blood units usually have much higher ferritin levels, which indicate that there is a progressively increasing amount of iron in the body over time [9]. Knowing this association well is quite helpful in clinical practice since it enables doctors to predict the extent of iron overload from the history of blood transfusions and to start iron chelation treatment on time so that irreversible damage to the organs can be avoided. On the other hand, serum ferritin is one of the markers of inflammation, and its concentration may go up in cases of infection, inflammation, or liver disease, which are some of the factors that can influence its reliability as a single test for determining iron overload [3]. Accordingly, it is essential to localize a patient population and study the correlation between serum ferritin levels and the number of blood transfusions in it, so that the issue of the clinical reliability of serum ferritin and its value as a monitoring parameter can be further resolved.

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METHODS & MATERIALS

This study was a cross-sectional study conducted in the Department of Pediatrics, Chittagong Medical College Hospital, Chittagong, over a period of six months from December 2013 to May 2014. The study population included patients admitted to the Pediatrics Wards who met the inclusion criteria. A total of 50 consecutive cases of thalassemia were enrolled, comprising children aged 1–12 years diagnosed with beta-thalassemia major or transfusion-dependent Hb E beta-thalassemia, confirmed by hemoglobin electrophoresis, and receiving regular blood transfusions. Patients were excluded if they had received chelation therapy prior to inclusion, did not maintain a dietary chart for thalassemia, had previously received blood transfusions at an incompatible center, or exhibited signs of infection or inflammation such as hepatitis. Data were analyzed using SPSS version 15, applying appropriate statistical methods including Pearson's correlation coefficient, Spearman's rank-order correlation, and Student's t-test according to the nature of the variables. Frequencies and proportions were calculated for categorical variables, while means and standard deviations were determined for quantitative variables. A p-value of <0.05 was considered statistically significant. Ethical approval for the study was obtained from the relevant department and authority of Chittagong Medical College Hospital following the due procedure.

RESULTS

Out of 50 patients, 32 (64%) were male and 18 (36%) were female, with a male-to-female ratio of 1.77:1. The majority of patients, 35 (70%), had Hb E β-thalassemia (severe/transfusion dependent), while 15 (30%) had β-thalassemia major. Most patients were from rural areas (31, 62%) compared to urban areas (19, 38%). Regarding guardians' occupation, the largest group was in service (14, 28%), followed by day labor (11, 22%), business (11, 22%), farming (10, 20%), and others (4, 8%). In terms of socioeconomic status, most patients belonged to the middle class (27, 54%), followed by poor (20, 40%) and very poor (7, 14%), and no patient belonged to the rich category (*Table I*).

Table I
Socio-demographic and Clinical Characteristics of the Patients (*n* = 50).

Variable	Category	Frequency (n)	Percentage (%)
Gender	Male	32	64
	Female	18	36
Type of Thalassemia	Hb E β-thalassemia (severe/transfusion dependent)	35	70
	β-thalassemia major	15	30
Locality	Rural	31	62
	Urban	19	38
Guardian's Occupation	Service	14	28
	Day labor	11	22
	Business	11	22
	Farming	10	20
	Others	4	8
Socioeconomic Status	Middle class	27	54
	Poor	20	40
	Very poor	7	14
	Rich	0	0

The mean age of the patients was 8.16 ± 3.40 years, ranging from 1 to 12 years. The mean duration of illness was 5.44 ± 3.09 years, with a range of 1 to 12 years. The average age at first blood transfusion was 2.81 ± 2.22 years, ranging from 1 to 9 years. The mean serum ferritin level was 2444.76 ± 3159.25 ng/mL, with values ranging from 164 ng/mL to 18,500 ng/mL, indicating wide variability in iron overload among the patients (*Table II*).

Table II
Quantitative variables and biochemical test results of the study patients (*n* = 50).

Variables	N	Minimum	Maximum	Mean	Std. Deviation
Age of the patients (years)	50	1	12	8.16	3.395
Duration of illness (years)	50	1	12	5.44	3.085
Age at first blood transfusion (years)	50	1	9	2.81	2.215
Serum ferritin level (ng/mL)	50	164	18500	2444.76	3159.245

Regarding recent transfusion practice, 21 patients (42%) received blood at 1–2-month intervals with a mean serum ferritin level of 1637.24 ng/mL. Twenty patients (40%) received transfusions at intervals of less than 1 month and had the highest mean serum ferritin level (4192.45 ng/mL). Nine patients (18%) received transfusions at intervals greater than 2 months and showed the lowest mean ferritin level (408.70 ng/mL), indicating higher iron burden with more frequent transfusions (*Table III).*

Table III (a)
Recent blood transfusion (BT) interval during the last 1 year and mean serum ferritin level (*n* = 50).

Recent BT interval (last 1 year)	Number of patients	Percentage (%)	Mean serum ferritin (ng/mL)
<1 month	20	40.0	4192.45
1–2 months	21	42.0	1637.24
>2 months	9	18.0	408.70
Total	50	100.0	—

Previously, the majority of patients, 28 (56%), received blood transfusions at 1–2-month intervals. Seventeen patients (34%) had transfusions at intervals of more than 2 months, while only 5 patients (10%) required transfusions at intervals of less than 1 month. This indicates that most patients were maintained on a moderate transfusion schedule in the past *Table III* (b).

Table III (b)
Previous blood transfusion interval of the patients (n = 50).

Previous BT interval	Number of patients	Percentage (%)
<1 month	5	10.0
1–2 months	28	56.0
>2 months	17	34.0
Total	50	100.0

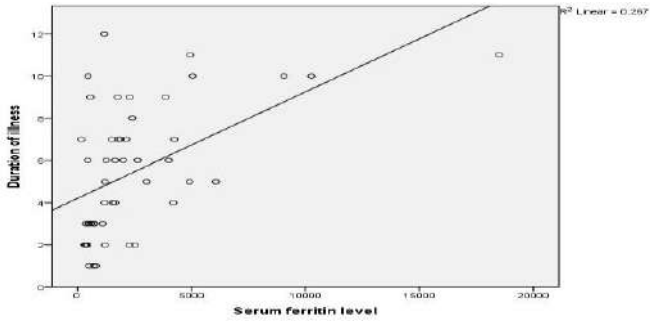

Figure 1 Correlation of serum ferritin level with duration of illness.

Figure 1 indicate that there is a positive correlation between ferritin levels in the blood and the duration of the illness. The higher the ferritin levels, the longer the duration of the illness, although the spread of the points indicates that there is some variation in the levels of the variables. The R^2 value of 0.267 indicates that the relationship is moderate in prediction.

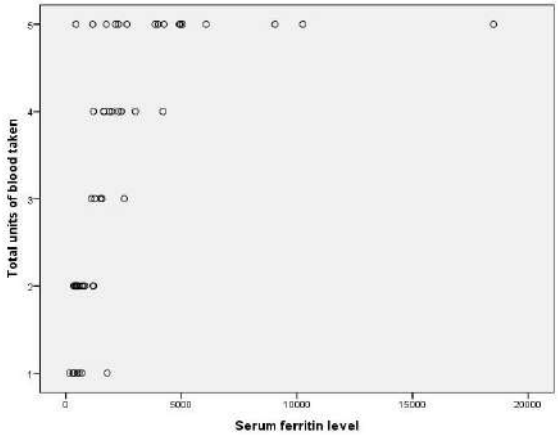

Figure 2 Correlation of serum ferritin level with total number of blood taken.

Figure 2 illustrates the positive correlation between the total units of blood drawn and the levels of serum ferritin. The graph has approximately 50 points, suggesting that the higher the blood units, the higher the iron levels in the blood, though the variation is significant in all categories.

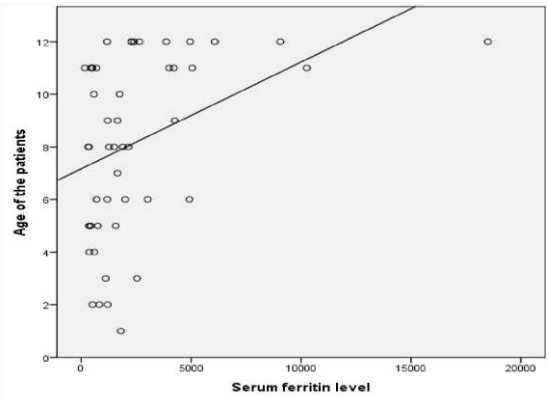

Figure 3 Correlation of age of patients with serum ferritin level.

Figure 3 depicts a positive correlation between patient age and serum ferritin levels. With increasing age, serum ferritin levels tend to rise, indicating a progressive accumulation of iron. The scatter plot indicates around 50 data points and shows considerable variability among individuals.

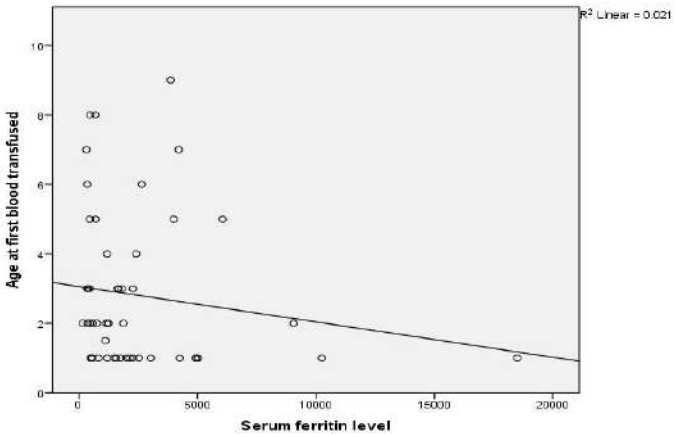

Figure 4 Correlation of Age of first BT and serum ferritin.

Figure 4 indicates a weak negative correlation where R^2=0.021. The graph has approximately 50 points, suggesting that the earlier the transfusions begin, the higher the iron levels that may accumulate in the body. However, the predictability of the levels is low.

Serum ferritin level showed a weak positive correlation with weight-for-height (r = 0.003, p = 0.981) and a weak negative correlation with height-for-age (r = -0.040, p = 0.784) and weight-for-age (r = -0.129, p = 0.374); however, none of these associations were statistically significant (p > 0.05). This suggests that higher serum ferritin levels were not significantly associated with wasting but tended to be related to stunting and chronic undernutrition. Regarding nutritional status based on height-for-age, 23 patients (46%) were severely stunted, 20 patients (40%) were moderately stunted, and only 7 patients (14%) had normal height. The mean serum ferritin level was 2542.13 ng/mL among severely stunted patients, 2689 ng/mL among moderately stunted patients, and 1087 ng/mL among those with normal height. Based on weight-for-age, 24 patients (48%) had moderate malnutrition, 12 patients (24%) had severe malnutrition, and 14 patients (28%) had normal nutritional status. In terms of weight-for-height, the majority of patients, 44 (88%), had no wasting, while only 6 patients (12%) had moderate wasting, indicating that chronic malnutrition (stunting) was more prevalent than acute malnutrition (wasting) in the study population (*Table IV*).

Table IV
Correlation of serum ferritin with growth parameters (*n* = 50).

Variables	Serum ferritin level	Height for age	Weight for height	Weight for age
Serum ferritin level	r = 1	r = -0.040	r = 0.003	r = -0.129
	—	p = 0.784	p = 0.981	p = 0.374
Height for age	r = -0.040	r = 1	r = 0.776**	r = 0.649**
	p = 0.784	—	p < 0.001	p < 0.001
Weight for height	r = 0.003	r = 0.776**	r = 1	r = 0.591**
	p = 0.981	p < 0.001	—	p < 0.001
Weight for age	r = -0.129	r = 0.649**	r = 0.591**	r = 1
	p = 0.374	p < 0.001	p < 0.001	—

Note: Correlation is significant at the 0.01 level (2-tailed)

DISCUSSION

In the present study, out of 50 patients, transfusion dependent Hb E-ß thalassemia is 35 (70%) and beta thalassemia major is 15 (30%), which is similar to other studies done in Bangladesh and 32 (64%) of patients were male and 18(36%) of the patients were female. Male to female ratio was 1.77:1 [10,11]. Patients with thalassemia major in the early transfusional period need to have some ferritin levels determined every 1-2 months in order to have a baseline value of iron load to initiate iron chelation therapy which should be started when serum ferritin levels exceed 1000 ng/ml and periodic monitoring of serum ferritin every 3 months should be done for patients on iron chelation therapy. Serum ferritin level was found higher as the duration of illness was more with repeated history of blood transfusion. Close to our results, Cario et al found that 76/102 patients (75%) younger than 10 years had serum ferritin less than 1800 ng/ml while 51/98 (52%) of thalassaemic patients who were older than 10 years had serum ferritin above 2500ng/ml [12]. In this study previously 28(56%) patients were transfused at 1-2 months interval, 17(34%) patients at >2 months interval and only 5(10%) patients at<1month interval, but recent blood transfusion interval was 1-2 month in 21 (42%) patients with mean serum ferritin level 1637ng/ml, <1 month in 20(40%) patients with mean serum ferritin level 4192.45 ng/ml and > 2 months in 9(18%) patients with mean serum ferritin level 408.7 ng/ml. It suggests that with increasing age of the patient the frequency of blood transfusion and serum ferritin level increases. Mishra A K, Tiwari A also found that serum ferritin level increases as the frequency of blood transfusion and the age of patient increases as in this study [13]. Another study by Ikram N et al also found mean serum ferritin levels 3396 ng/ml with gradually increasing frequency of blood transfusion with age [14]. In the present study results of serum ferritin were significantly correlated with both advancing age of the patients and increased number of blood transfusion to date which is comparable to those of Faris Y et al study [15]. Significant positive correlation was found between serum ferritin level with age of

patients(r=0.233, p<0.02) and total number of blood transfused(r= 0.365, p<0.001).In their study they found the patients not started using DFO had significantly lower mean serum ferritin values 1462.96 ng/ml compared to both groups on DFO therapy those with good compliance to DFO (mean serum ferritin of 1701.19 ng/ml) and those with poor compliance to desferrioxamine therapy with a mean serum ferritin of 2395.28 ng/ml. The probable cause for this lower mean serum ferritin value in the group of patients not started using desferrioxamine was the younger mean age of these patients compared to other groups on desferrioxamine therapy (3.4 years mean age of patients not use desferrioxamine versus 9.4 years in patients with compliance and 9.49 years in patients with poor compliance to desferrioxamine respectively) [15]. In the present study patients who were using DFO were excluded so we are unaware about this condition. Cario et al study also found that serum ferritin values correlate to total amount of blood transfusions [12]. Another study by Shah N R et al reported similar result to the present study. They found a linear relationship between the age of thalassemia major patients and total number of blood transfusions received so far. Their study depicted with increase in age, frequency of blood transfusions received per month also goes up [16]. In terms of pre transfusion hemoglobin level (taking 10 gm% as cut off), 53.5% of patients are under transfused. In this study 34 patients were found severely anemic with pretransfusion Hb level <7gm/dl, and 16 patients were found moderately anemic with pre transfusion hemoglobin <9gm/dl, where it should be 9.5 to 10.5 mg/ dl. This might be a reflection of less awareness of the people and general physician about the disease management. Among 50 patients 45(90%) have hemolytic facies, 5 (10%) patients have normal facies and all patients have organomegaly. Massive hepatomegalaly and splenomegaly is present in 20 and 33 patients respectively, moderate hepatomegaly and splenomegaly is present in 19 and 15 patients respectively and mild hepatomegaly and splenomegaly presents in11 and 4 patients respectively. This picture corresponds with other study where severe anemia, facial dysmorphism and hepatoslenomegaly were found in all cases [17]. In the present study significant correlation was found among different parameters of nutritional status and serum ferritin level. Serum feritin level was found positively correlated with weight for height (P<0.05) and negatively correlated with height for age and weight for age (P>0.05). In this study 23(46%) patients are found severely stunted, 20(40%) patients are moderately stunted and 7(14%) patients have normal height. Mean serum ferritin level in severe stunted patients is 2542.13 ng/ml and moderate stunting patient is 2689 ng/ml and in normal height is 1087 ng/ml which corresponds with other study [16]. Among 50 patients, 24(48%) patients have moderate malnutrition, 12(24%) patients have severe malnutrition and 14(28%) patients had normal nutritional status. Regarding W/H 44(88%) patients had no wasting only 6(12%) patients had moderate wasting. Similar result was reported by Hashemi A MD, Ghilian R MD et al on seventy patients with transfusion dependent thalassemia major patients and found mean serum ferritin level 2664+/-1446 ng/ml and 46(65.71%) of patients had height less than five percentile, and 24(34.29%) more than five percentile. Mean serum ferritin in patients with height more than five percentile was 2252+/-1040 and with height less than was 2962+/-1606 (p value=0.072) [17]. Shah N K etal study also found out of 142 patients 103(72%) were below 2standard deviations of ICMR 1990 standards of weight for age (<80% of W/A) and 76(53%) were 2SD below ICMR 1990 standards of height for age (<90% of H/A). While 63 (44%) were lagging behind in both W/A and H/A, they were both wasted and stunted [16].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

The results of the present study revealed that increasing age of the patients, number of blood transfusions to date and increased frequency of blood transfusion are associated with increased serum ferritin level. Majority of the patients have high serum ferritin level more than 1000 ng/ml. Significant correlation was found among different parameters of nutritional status and serum ferritin level. With increased serum ferritin level more patients present with stunting and chronic malnutrition but no wasting.

RECOMMENDATION

Routine monitoring of serum ferritin at regular intervals (every 3–6 months) should be performed in transfusion-dependent thalassemic patients and ideally initiated after 10–20 transfusions to enable early detection of iron overload. Patients with serum ferritin levels exceeding 1000 ng/mL should be promptly started on appropriate iron chelation therapy to prevent organ damage. Regular screening for growth retardation, endocrine dysfunction, and cardiac complications is essential, particularly in patients with persistently elevated ferritin levels, along with proper counseling of patients and guardians regarding the risks of iron overload and the importance of adherence to treatment. In resource-limited settings where serum ferritin testing may not be feasible due to cost, chelation therapy may be judiciously initiated in patients with a long history of frequent transfusions. Furthermore, larger-scale studies are recommended to better understand the burden of iron overload and optimize management strategies.

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CONFLICT OF INTEREST

None declared

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Role of HPV Genotyping and p16 Expression in the Detection of Precancerous Cervical Lesions

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ABSTRACT

Background: Persistent infection with high-risk human papillomavirus (HPV) is the primary cause of cervical cancer. Although HPV DNA testing is widely used for screening, its specificity for high-grade cervical lesions is limited. p16 immunohistochemistry has emerged as a surrogate marker of transforming HPV infection. This study aimed to evaluate the role of HPV genotyping and p16 expression in detecting precancerous cervical lesions, particularly high-grade squamous intraepithelial lesions (HSIL). **Methods & Materials**: This cross-sectional study included 72 screen-positive women aged 30–60 years attending the colposcopy clinic of Bangladesh Medical University (BMU), Shahbagh, Dhaka in 2022-2023. Colposcopy-directed cervical biopsy and/or LEEP specimens were examined histopathologically as the gold standard. p16 immunohistochemistry was performed and interpreted as diffuse (positive) or focal/negative. HPV genotyping was conducted to detect high-risk HPV types. Diagnostic performance indicators including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated. **Results**: Histopathology confirmed HSIL (CIN II/III) in 61.1% of cases. Diffuse p16 expression was significantly associated with HSIL ($p < 0.001$; OR 142.7, 95% CI 16.6–1229.1). p16 demonstrated high sensitivity (84.1%) and specificity (96.4%), with PPV of 97.4%, NPV of 79.4%, and overall accuracy of 88.9%. In contrast, HPV genotyping was not significantly associated with HSIL ($p = 0.675$) and showed lower diagnostic performance. **Conclusion**: Diffuse p16 expression shows superior diagnostic performance compared with HPV genotyping alone for detecting high-grade precancerous cervical lesions. Incorporating p16 immunohistochemistry into routine diagnostic evaluation may enhance risk stratification and reduce overtreatment.

Keywords: *Cervical intraepithelial neoplasia (CIN); p16 immunohistochemistry; Human papillomavirus (HPV); High-grade squamous intraepithelial lesion (HSIL); Cervical cancer screening.*

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INTRODUCTION

Cervical cancer remains one of the leading causes of cancer-related morbidity and mortality among women worldwide, particularly in low- and middle-income countries (LMICs). Persistent infection with high-risk human papillomavirus (HPV), especially genotypes 16 and 18, is well established as the primary etiological factor in the development of cervical intraepithelial neoplasia (CIN) and invasive cervical carcinoma [1]. Although most HPV infections are transient and resolve spontaneously, persistent high-risk HPV infection can lead to the development of precancerous cervical lesions, which may progress to invasive cancer if left untreated [2]. Early detection of precancerous lesions, particularly high-grade squamous intraepithelial lesions (HSIL; CIN II/III), is crucial for preventing progression to invasive disease. Conventional cytology (Pap smear) has significantly reduced cervical cancer incidence in many countries; however, its sensitivity is limited and subject to interobserver variability. As a result, adjunctive biomarkers have been increasingly investigated to improve diagnostic accuracy and risk stratification [3]. HPV DNA testing has emerged as a highly sensitive screening tool for detecting high-risk HPV infection. While HPV testing is valuable for identifying women at risk, its specificity for predicting high-grade lesions is relatively low, as many infections are transient and not associated with clinically significant disease. Therefore, additional biomarkers that reflect transforming HPV infection are needed to distinguish transient infections from lesions with malignant potential [4]. p16INK4a (p16) is a cyclin-dependent kinase inhibitor that is overexpressed in cells affected by oncogenic HPV due to inactivation of the retinoblastoma (Rb) pathway by the viral E7 oncoprotein. Diffuse, strong p16 expression is considered a surrogate marker of transforming HPV infection and is strongly associated with high-grade cervical lesions. Immunohistochemical detection of p16 has therefore been incorporated into routine diagnostic practice to improve the accuracy and reproducibility of CIN grading [5-7]. Despite the established roles of HPV genotyping and p16 expression and their relative diagnostic performance in detecting precancerous cervical lesions remain areas of ongoing investigation, particularly in resource-constrained settings. This study aimed to evaluate the role of HPV genotyping and p16 immunohistochemical expression in the detection of precancerous cervical lesions and to assess their diagnostic accuracy in identifying high-grade disease.

METHODS & MATERIALS

Study Design and Setting

This cross-sectional observational study was conducted at the Colposcopy Clinic of Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbagh, Dhaka, from October 2022 to March 2023.

Study Population and Sampling

The study population comprised screen-positive women (VIA, Pap smear, and/or HPV DNA positive) aged 30–60 years who were referred to the colposcopy clinic and

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had colposcopically suspected high-grade squamous intraepithelial lesions (HSIL). Purposive sampling was used to recruit eligible participants. Women who were pregnant or lactating, had a history of hysterectomy, known cervical cancer, prior treatment for CIN, or refused consent were excluded. A total of 72 eligible women were enrolled in this study.

Study Procedure

After obtaining informed written consent, demographic, obstetric, and clinical information were collected using a semi-structured questionnaire. Colposcopy was performed using the Swede scoring system [8]. Colposcopy-directed punch biopsy or Loop Electrosurgical Excision Procedure (LEEP) specimens were obtained from suspected HSIL cases. Histopathological examination served as the reference standard. Cervical intraepithelial neoplasia was graded as CIN I (LSIL) and CIN II/III (HSIL) [9].

p16 Immunohistochemistry

Formalin-fixed paraffin-embedded tissue blocks were sectioned at 4 µm and mounted on poly-L-lysine–coated slides. Immunohistochemical staining for p16INK4a was performed using monoclonal mouse anti-human p16 antibody (E6H4 clone, DAKO, Denmark) with EnVision secondary detection system. Diffuse, strong nuclear with or without cytoplasmic staining extending from the basal layer upward was interpreted as positive (block-positive). Focal, patchy, or absent staining was considered negative according to LAST criteria [10].

HPV Genotyping

HPV genotyping was performed to detect high-risk HPV types, particularly HPV 16 and 18 [11].

Outcome Measures and Statistical Analysis

The primary outcome was histologically confirmed HSIL (CIN II/III). Diagnostic performance of p16 expression and HPV genotyping was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy.

Data were analyzed using SPSS version 26. Descriptive statistics were expressed as mean ± standard deviation or frequency and percentage. Associations were evaluated using chi-square tests, and $p < 0.05$ was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the IRB of BSMMU. Written informed consent was obtained from all participants. Confidentiality was maintained throughout the study.

RESULTS

A total of 72 women were included in the study. The majority of participants were aged 30–39 years (45.8%), followed by 40–49 years (36.1%), while 18.1% were aged 50 years or older. The mean age was 40.96 ± 7.69 years (range: 30–60 years). *Table I* shows that 16.7% had CIN I, 27.8% CIN II, and 33.3% CIN III, with HSIL (CIN II/III) comprising 61.1% of cases. Benign lesions accounted for 22.2%. Diffuse p16 expression was observed in 52.8% of cases, while HPV DNA was detected in 16.7%, predominantly HPV 16 (15.3%), with HPV 18 identified in 1.4%.

Table I
Distribution of histopathological diagnoses, p16 immunohistochemistry expression, and HPV genotyping results among study participants (n = 72).

Variable	Frequency (n=72)	Percentage (%)
Histopathology		
CIN I	12	16.7
CIN II	20	27.8
CIN III	24	33.3
Chronic cervicitis	6	8.3
Chronic cervicitis with squamous metaplasia	10	13.9
P16 IHC		
Diffuse/full thickness	38	52.8
Negative	22	30.6
Focal/patchy	12	16.7
HPV genotyping		
Not detected	60	83.3
HPV 18	1	1.4
HPV 16	11	15.3

In *Table II*, a strong association was observed between diffuse p16 expression and HSIL ($p < 0.001$). Among p16-positive cases, 84.1% had HSIL, compared with 15.9% among p16-negative cases. Diffuse p16 positivity significantly increased the odds of high-grade lesions (OR 142.7; 95% CI: 16.6–1229.1). In contrast, HPV genotyping was not significantly associated with HSIL ($p = 0.675$; OR 1.26; 95% CI: 0.43–3.67).

Table II
Association of HPV DNA and p16 expression with high-grade cervical lesions (n=72).

	Histopathology		p value OR (95%CI)
	HSIL (n=44)	LSIL/Benign (n=28)	
P16 IHC			
Positive (n=38)	37 (84.1)	1 (3.6)	<0.001
Negative (n=34)	7 (15.9)	27 (96.4)	142.7 (16.6 –1229.1)
HPV genotyping			
HPV 16/18/others (n=20)	13 (29.5)	7 (25.0)	0.675
Not detected (n=52)	31 (70.5)	21 (75.0)	1.26 (0.43-3.67)

As shown in *Table III*, diffuse p16 expression demonstrated high sensitivity (84.09%; 95% CI: 69.93–93.36) and specificity (96.43%; 95% CI: 81.65–99.91) for detecting CIN II/III. The positive predictive value (PPV) was 97.37%, negative predictive value (NPV) was 79.41%, and overall diagnostic accuracy was 88.89%. HPV DNA testing showed lower diagnostic performance, with sensitivity of 29.55% (95% CI: 16.76–45.20), specificity of 75.00% (95% CI: 55.13–89.31), and overall accuracy of 47.22%. Overall, diffuse p16 expression demonstrated superior diagnostic performance compared with HPV genotyping for detecting high-grade cervical lesions.

Table III
Diagnostic performance of p16 Expression and HPV DNA for detecting high-grade cervical lesions (CIN II/III) (*n*=72).

Diagnostic Parameter	p16 Diffuse % (95% CI)	HPV DNA % (95% CI)
Sensitivity	84.09 (69.93–93.36)	29.55 (16.76–45.20)
Specificity	96.43 (81.65–99.91)	75.00 (55.13–89.31)
PPV	97.37 (84.32–99.61)	65.00 (45.80–80.32)
NPV	79.41 (66.08–88.42)	40.38 (33.71–47.44)
Overall accuracy	88.89 (79.28–95.08)	47.22 (35.33–59.35)

DISCUSSION

This study evaluated the diagnostic role of HPV genotyping and p16 immunohistochemical expression in detecting precancerous cervical lesions, particularly high-grade squamous intraepithelial lesions (HSIL). Histopathology confirmed HSIL (CIN II/III) in 61.1% of cases, highlighting the high burden of clinically significant lesions among colposcopy-suspected women.

A key finding of this study is the strong association between diffuse p16 expression and HSIL. Diffuse p16 positivity was significantly associated with high-grade lesions ($p < 0.001$), with an odds ratio of 142.7. The diagnostic performance of p16 was notable, demonstrating high sensitivity (84.1%) and excellent specificity (96.4%), along with a high positive predictive value (97.4%). These findings support the established biological role of p16 as a surrogate marker of transforming high-risk HPV infection. Overexpression of p16 occurs due to inactivation of the retinoblastoma (pRb) pathway by the HPV E7 oncoprotein, leading to deregulated cell cycle progression. Therefore, diffuse "block-positive" staining reflects oncogenic HPV activity and correlates strongly with high-grade dysplasia [12].

Our findings are consistent with previous studies demonstrating that p16 immunostaining improves diagnostic accuracy and reduces interobserver variability in grading CIN lesions [13-15]. Several authors have reported comparable sensitivity and specificity values for p16 in detecting CIN II/III, reinforcing its value as an adjunctive diagnostic tool, particularly in morphologically equivocal cases [15-17]. The Lower Anogenital Squamous Terminology Standardization Project for HPV-Associated Lesions (LAST) recommendations also endorse p16 immunostaining to distinguish HSIL from LSIL when histological interpretation is uncertain [18].

In contrast, HPV genotyping alone did not show a statistically significant association with HSIL in our study ($p = 0.675$). Although HPV 16 was the most frequently detected genotype among positive cases, overall HPV detection rates were relatively low. This may reflect transient infections, viral clearance, sampling variability, or limitations of genotype detection. While HPV DNA testing is highly sensitive for identifying women at risk, its specificity for high-grade lesions is limited because many infections do not result in clinically significant disease. This finding underscores the importance of combining virological and biomarker-based approaches rather than relying solely on HPV detection.

This study has several limitations. The sample size was relatively small and derived from a single tertiary care center, which may limit generalizability. Purposive sampling may introduce selection bias. Additionally, long-term follow-up was not performed to assess progression or regression outcomes.

Despite these limitations, our findings demonstrate that diffuse p16 expression has superior diagnostic accuracy compared with HPV genotyping alone for detecting high-grade cervical lesions. Incorporating p16 immunohistochemistry into diagnostic algorithms may improve risk stratification and optimize management of women with precancerous cervical lesions.

CONCLUSION

Diffuse p16 expression demonstrates high diagnostic accuracy for detecting high-grade precancerous cervical lesions and performs better than HPV genotyping alone. Incorporating p16 immunohistochemistry into routine evaluation may improve diagnostic precision and help reduce unnecessary treatment in women with suspected cervical intraepithelial neoplasia.

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Use of Red Cell Distribution Width Index for Screening and Differentiation of Iron Deficiency Anemia and Beta Thalassemia Trait During Pregnancy

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ABSTRACT

Background: Microcytic anemia is commonly caused by iron deficiency anemia (IDA) and beta thalassemia trait (BTT). Differentiating these conditions is crucial for appropriate management, but conventional hematologic parameters often overlap. The Red Cell Distribution Width Index (RDWI) has been proposed as a reliable discriminative tool. Aim of the study: To evaluate the diagnostic accuracy of RDWI in distinguishing IDA from BTT and to compare its performance with established discrimination indices. **Methods & Materials**: A cross-sectional study was conducted on 240 newly diagnosed anemic individuals (IDA, n = 150; BTT, n = 90) at the Department of fetomaternal, Bangladesh Medical University, Bangladesh], Bangladesh. Complete blood counts and serum ferritin levels were measured, and RDWI, Mentzer, Green & King, and Shine & Lal indices were calculated. ROC curve analysis was performed to determine optimal cut-offs, and multivariable logistic regression identified independent predictors of IDA. **Result**: Participants with IDA exhibited lower hemoglobin, RBC count, MCH, MCHC, and serum ferritin, but higher RDW and RDWI compared to BTT (all $p < 0.001$). RDWI demonstrated superior diagnostic performance (AUC = 0.92; sensitivity 89.3%; specificity 86.7%) compared with Mentzer (AUC = 0.85), Green & King (AUC = 0.87), and Shine & Lal (AUC = 0.78) indices. Multivariable analysis identified RDWI >220 (adjusted OR = 7.42; 95% CI: 3.48–15.81), elevated RDW, and female sex as independent predictors of IDA. **Conclusion**: RDWI is a simple, reliable, and highly accurate index for differentiating IDA from BTT, outperforming conventional hematologic indices. Its implementation in routine laboratory practice could facilitate timely and precise diagnosis of microcytic anemia.

Keywords: *Red Cell Distribution Width Index, Iron Deficiency Anemia, Beta Thalassemia Trait, Microcytic Anemia, Diagnostic Accuracy*

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INTRODUCTION

Iron-deficiency anemia (IDA) is a hematological disorder characterized by a decrease in hemoglobin concentration and iron stores, resulting in impaired oxygen delivery to tissues and leading to microcytic hypochromic erythrocytes [1]. Beta thalassemia trait (β-TT) is an inherited hemoglobinopathy caused by mutations in the β-globin gene that reduce β-chain synthesis and result in mild anemia, often remaining clinically silent [2]. Anemia affects approximately 27% of the global population, posing a major public health burden, with iron deficiency accounting for up to half of all cases worldwide [3]. In Bangladesh, anemia prevalence is notably high; up to 61.23% of under-five children are reported to be anemic, reflecting nutritional and socioeconomic challenges, with iron deficiency being a major contributor [4]. The major causes of iron-deficiency anemia include nutritional iron insufficiency, chronic blood loss (gastrointestinal bleeding, menstruation), parasitic infections, poor dietary absorption, and increased iron demands in pregnancy and growth [5]. In contrast, β-thalassemia trait arises from autosomal recessive mutations in the HBB gene, leading to an imbalance in globin chain production, ineffective erythropoiesis, and reduced hemoglobin synthesis [6]. These conditions frequently present with microcytic hypochromic red blood cells, with overlapping hematological indices, which makes them difficult to distinguish on routine complete blood count (CBC) alone [7]. Accurate differentiation between IDA and β-TT is crucial because misdiagnosis may lead to inappropriate iron therapy in thalassemia carriers, causing potential iron overload, without improving anemia, while undiagnosed IDA remains untreated, worsening morbidity and functional outcomes [8]. Moreover, β-thalassemia carriers form a significant health concern in regions like Bangladesh where hemoglobinopathies are common, due to high carrier frequency, and approximately 2–3% of the population are β-thalassemia carriers, with a higher prevalence of combined hemoglobin variants including HbE in some regions [9]. Red cell distribution width (RDW) and the red cell distribution width index (RDWI) are hematological parameters derived from standard CBCs that reflect anisocytosis and combined RBC indices, providing indirect diagnostic clues, respectively [10]. RDWI, calculated from the mean corpuscular volume (MCV), RDW, and RBC count, has been proposed as a cost-effective discriminant tool between IDA and β-TT, particularly useful for screening purposes, especially in resource-limited settings where definitive tests like hemoglobin electrophoresis are unavailable [11]. In clinical practice, the adoption of such indices could improve screening efficiency, optimize early diagnosis, reduce the need for expensive iron studies or electrophoresis, and inform timely and appropriate management strategies [12]. Despite numerous discriminant indices proposed over the years, there remains a need for robust validation of RDWI in diverse populations, particularly in regions

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with a high dual burden of IDA and hemoglobinopathies. This study aims to evaluate the effectiveness of the Red Cell Distribution Width Index (RDWI) in screening for and differentiating iron-deficiency anemia from beta thalassemia trait in a clinical population.

METHODS & MATERIALS

This cross-sectional study was conducted at the Department Fetomaternal Medicine, Bangladesh Medical University, Bangladesh**,** between January 2024 and December 2025**.** A total of 240 anemic individuals were consecutively enrolled in the study based on predefined eligibility criteria. Participants were classified into two diagnostic groups: iron deficiency anemia (IDA, *n* = 150) and beta thalassemia trait (BTT, *n* = 90). Only newly diagnosed cases were included to avoid the influence of prior treatment on hematologic parameters.

Inclusion and Exclusion Criteria

Individuals aged ≥15 years with microcytic anemia (hemoglobin below age- and sex-specific reference ranges and mean corpuscular volume MCV <80 fL) were eligible for inclusion. IDA was defined by reduced hemoglobin concentration with low serum ferritin levels (<15 ng/mL), while BTT was diagnosed based on characteristic hematological features and confirmatory hemoglobin electrophoresis demonstrating elevated HbA_2 (≥3.5%).

Patients with anemia of chronic disease, sideroblastic anemia, hemoglobinopathies other than BTT, acute infection, chronic inflammatory conditions, liver or renal disease, recent blood transfusion, pregnancy, or current iron therapy were excluded.

Data Collection and Sociodemographic Information

Demographic data, including age and sex, were recorded using a structured questionnaire. Baseline clinical evaluation was performed to exclude confounding conditions.

Hematologic and Biochemical Analysis

Peripheral venous blood samples were collected in EDTA and plain tubes. Complete blood counts (CBC), including red blood cell (RBC) count, hemoglobin (Hb), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and red cell distribution width (RDW), were measured using an automated hematology analyzer (Model, Manufacturer). Serum ferritin was measured using a chemiluminescence immunoassay (Model, Manufacturer) to confirm iron status. All laboratory analyses were performed according to standard operating procedures, and internal quality controls were maintained throughout the study period.

Calculation of Discrimination Indices

The Red Cell Distribution Width Index (RDWI) was calculated using the formula:

$$\text{RDWI}=\frac{MCV\times RDW\ (\%)}{RBC\ count\ (\times 10^6/\mu L)}$$

Other discrimination indices, including Mentzer Index, Green & King Index, and Shine & Lal Index, were also calculated using established formulas to compare their diagnostic performance in differentiating IDA and BTT.

Statistical Analysis

Data were analyzed using SPSS version (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequency and percentage. Group comparisons were performed using the independent samples t-test for continuous variables and the chi-square test for categorical variables. Receiver operating characteristic (ROC) curve analysis was performed to evaluate the diagnostic performance of RDWI and other indices. The optimal cut-off value for RDWI was determined using Youden's index. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratios (LR+ and LR−), and overall diagnostic accuracy were calculated. Multivariable logistic regression was used to identify independent predictors of IDA, adjusting for sex, RBC count, and RDW. Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were reported. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study protocol was approved by the Institutional Review Board. All procedures were conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from all participants prior to enrollment.

RESULT

Table I shows that the mean age was 23.8±7.9 years, with no significant difference between iron deficiency anemia at 24.4±7.6 years and beta thalassemia trait at 22.9±8.2 years (p=0.192). Overall, 39.17% were male, with higher male proportion in beta thalassemia trait (57.78%) than iron deficiency anemia (28.00%) (p<0.001). Mean hemoglobin was 9.1±1.5 g/dL, lower in iron deficiency anemia (8.5±1.3) compared with beta thalassemia trait (10.0±1.2) (p<0.001). Mean corpuscular volume 70.5±6.1 versus 60.7±6.8 and serum ferritin 11.4±5.6, whereas 32.1±10.3, p<0.001.

Table I
Sociodemographic and baseline hematologic characteristics of the study population (*n* = 240).

Variable	Total (N = 240)	IDA (n = 150)	BTT (n = 90)	p-value
Age (years), mean ± SD	23.8 ± 7.9	24.4 ± 7.6	22.9 ± 8.2	0.192
Gender, n (%)				
Male	94 (39.17)	42 (28.00)	52 (57.78)	<0.001
Female	146 (60.83)	108 (72.00)	38 (42.22)	
Hemoglobin (g/dL), mean ± SD	9.1 ± 1.5	8.5 ± 1.3	10.0 ± 1.2	<0.001
MCV (fL), mean ± SD	66.8 ± 7.6	70.5 ± 6.1	60.7 ± 6.8	<0.001
Serum ferritin (ng/mL), mean ± SD	18.6 ± 9.2	11.4 ± 5.6	32.1 ± 10.3	<0.001

In iron deficiency anemia, mean red blood cell count was 4.05±0.52×10⁶/µL, red cell distribution width 17.9±2.1%, mean corpuscular hemoglobin 21.4±2.8 pg, mean corpuscular hemoglobin concentration 30.1±1.9 g/dL, and red cell distribution width index 238.6±36.9. In beta thalassemia trait, red blood cell count was 5.71±0.63×10⁶/µL, red cell distribution width 14.2±1.6%, mean corpuscular hemoglobin 18.8±2.4 pg, mean corpuscular hemoglobin concentration 31.6±1.7 g/dL, and red cell distribution width index 165.4±28.7, with all p-values <0.001 (*Table II*).

Table II
Comparison of red cell indices between IDA and BTT.

Parameter	IDA (Mean ± SD)	BTT (Mean ± SD)	p-value
RBC (×10⁶/µL)	4.05 ± 0.52	5.71 ± 0.63	<0.001
RDW (%)	17.9 ± 2.1	14.2 ± 1.6	<0.001
MCH (pg)	21.4 ± 2.8	18.8 ± 2.4	<0.001
MCHC (g/dL)	30.1 ± 1.9	31.6 ± 1.7	<0.001
RDWI	238.6 ± 36.9	165.4 ± 28.7	<0.001

Red cell distribution width index represents an AUC of 0.92 (95% CI 0.88–0.95) with an optimal cut-off >220, sensitivity 89.3% and specificity 86.7%. Mentzer index had AUC 0.85, cut-off >13, sensitivity 81.4% and specificity 79.2%. Green & King index AUC 0.87, cut-off >65, sensitivity 83.2%, specificity 81%. Shine & Lal index AUC 0.78, cut-off >1530, sensitivity 72.6%, specificity 74.4% (*Table III*).

Table III
ROC curve analysis of RDWI and other discrimination indices.

Index	AUC (95% CI)	Optimal Cut-off	Sensitivity (%)	Specificity (%)
RDWI	0.92 (0.88–0.95)	>220	89.3	86.7
Mentzer	0.85	>13	81.4	79.2
Green & King	0.87	>65	83.2	81
Shine & Lal	0.78	>1530	72.6	74.4

Red cell distribution width index >220 showed sensitivity 89.3% (95% CI 83.1–93.7), specificity 86.7% (78.0–92.7), positive predictive value 91.1% (85.4–95.0), negative predictive value 83.5% (74.6–90.1), overall diagnostic accuracy 88.3% (83.4–92.1), positive likelihood ratio 6.71 (3.84–11.72), negative likelihood ratio 0.12 (0.07–0.21), and area under ROC curve 0.92 (0.88–0.95) *Table IV*.

Table IV
Diagnostic accuracy of RDWI (>220) for identifying IDA.

Diagnostic Parameter	Estimate	95% Confidence Interval
Sensitivity (%)	89.3	83.1 – 93.7
Specificity (%)	86.7	78.0 – 92.7
Positive Predictive Value (PPV, %)	91.1	85.4 – 95.0
Negative Predictive Value (NPV, %)	83.5	74.6 – 90.1
Overall Diagnostic Accuracy (%)	88.3	83.4 – 92.1
Positive Likelihood Ratio (LR+)	6.71	3.84 – 11.72
Negative Likelihood Ratio (LR−)	0.12	0.07 – 0.21
Area Under ROC Curve (AUC)	0.92	0.88 – 0.95

Multivariable logistic regression identified RDWI >220 (adjusted OR 7.42, 95% CI 3.48–15.81, p<0.001), RDW percent (OR 1.39, 1.16–1.67, p<0.001), lower RBC count (OR 0.51, 0.37–0.71, p<0.001), and female sex (OR 2.46, 1.29–4.71, p=0.006) as significant predictors of iron deficiency anemia (*Table V*).

Table V
Multivariable logistic regression for predictors of IDA.

Variable	Adjusted OR	95% CI	p
RDWI >220	7.42	3.48–15.81	<0.001
RDW (%)	1.39	1.16–1.67	<0.001
RBC count	0.51	0.37–0.71	<0.001
Female sex	2.46	1.29–4.71	0.006

DISCUSSION

Microcytic anemias, particularly Iron Deficiency Anemia (IDA) and Beta Thalassemia Trait (BTT), represent significant public health challenges in many regions, especially where nutritional deficiencies and inherited hemoglobinopathies are prevalent [12]. Although both conditions share overlapping hematologic features, accurate and timely differentiation is critical, as management strategies differ substantially: IDA requires iron supplementation, whereas BTT does not benefit from iron therapy and necessitates genetic counseling [13-14]. Traditional red cell indices have been employed to discriminate these entities; however, their sensitivity and specificity vary across populations, often leading to misdiagnosis and unnecessary confirmatory tests [8]. Consequently, there is increasing interest in integrated indices such as the Red Cell Distribution Width Index (RDWI), which combines anisocytosis and microcytosis parameters to enhance diagnostic accuracy [10]. In the present study, we evaluated the utility of the Red Cell Distribution Width Index (RDWI) for distinguishing Iron Deficiency Anemia (IDA) from Beta Thalassemia Trait (BTT) in a study. Our findings demonstrate that RDWI is a highly reliable discriminator, with an AUC of 0.92, sensitivity of 89.3%,

and specificity of 86.7%. These results align with existing evidence that RDWI and related indices provide robust diagnostic performance in resource-limited settings. Notably, Farghaly *et al.* reported that RDWI significantly discriminated between IDA and βTT with an AUC of 0.83, sensitivity of 83.3%, and specificity of 80%, supporting RDWI's utility as a practical screening tool [15]. Furthermore, large cohort evaluations have shown RDWI to be among the most consistent indices, with sensitivity and specificity as high as 100% and 93%, respectively, in distinguishing β-thalassemia trait from iron deficiency anemia where hemoglobin electrophoresis may not be feasible [11]. Regional studies, including analyses from Bangladesh, also confirm that RDWI reliably differentiates these conditions, maintaining diagnostic accuracy above 80% across diverse patient populations [10]. Consistent with the pathophysiology of microcytic anemias, our study observed significantly lower mean hemoglobin (Hb) and mean corpuscular volume (MCV) in the iron deficiency anemia (IDA) group compared with β-thalassemia trait (BTT), while red blood cell (RBC) counts were markedly higher in BTT. Several studies evaluating RBC indices in microcytic hypochromic anemia report patterns consistent with our findings, showing lower Hb and MCV in IDA and elevated RBC counts in BTT [16]. Comparative analyses indicate that RBC count and red cell distribution width index (RDWI) serve as the most reliable discriminators between IDA and BTT, with higher Youden's indices than other formulas [16]. Mondal et al. also reported significantly lower RBC count, Hb, hematocrit, MCV, mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC) in IDA versus BTT, with elevated RDW and RDWI [8]. Similarly, a cross-sectional study confirmed higher RBC counts and lower MCV in BTT compared with IDA [17]. Furthermore, RDW was significantly higher in IDA (17.9 ± 2.1%) than in BTT (14.2 ± 1.6%), reflecting the heterogeneous erythropoiesis characteristic of iron deficiency, whereas BTT displayed relatively uniform microcytosis. These findings align with Hegde et al., who reported markedly elevated RDW in IDA versus BTT (18.2 ± 3.8% vs 15.1 ± 1.2%, $p < 0.001$), with values above 17.1% strongly indicative of iron deficiency [18]. Across pediatric and adult cohorts, RDWI has consistently demonstrated superior discriminative performance over RDW alone, underscoring the clinical utility of these indices for screening and differentiating common microcytic anemias [19]. Notably, the RDWI consistently outperformed individual hematologic indices in diagnostic accuracy. In our cohort, an RDWI threshold >220 yielded a positive likelihood ratio (LR+) of 6.71 and a negative likelihood ratio (LR–) of 0.12, underscoring excellent discriminative ability. These findings align with a larger study by Munir et al. in Pakistan, where RDWI demonstrated positive predictive values exceeding 90% and LR+ values between 6 and 7 for identifying IDA [20,21]. Moreover, RDWI has shown superior performance compared with RDW alone, with AUC values of approximately 0.83 and balanced sensitivity and specificity across diverse populations [15]. Additionally, multivariable logistic regression in our study confirmed that RDWI >220 independently predicted IDA (adjusted OR 7.42, 95% CI 3.48–15.81, $p < 0.001$), even after adjusting for RBC count, RDW, and sex. This finding highlights RDWI as a robust, independent hematologic marker for distinguishing IDA from other microcytic anemias. Consistent with our results, Xu et al. demonstrated that multivariable models based on red cell parameters, including RBC indices, can reliably differentiate thalassemia trait from IDA, confirming the predictive potential of hematologic indices in multivariate analyses [21]. Moreover, multiple clinical studies report significantly higher RDWI values in IDA compared with β-thalassemia trait, further supporting its discriminative utility in routine screening [15, 20]. In the present study, the sex distribution differed markedly between iron deficiency anemia (IDA) and beta thalassemia trait (BTT). Females accounted for a substantially greater proportion of the IDA group (72%) compared with males (28%), whereas the BTT subgroup demonstrated a male predominance (57.8%). These findings align with prior research in a cohort of 100 individuals with microcytic anemia, in which females were more frequently diagnosed with IDA, while BTT cases were distributed across both sexes. The elevated prevalence of IDA in women has been consistently attributed to physiological and reproductive factors, including menstrual blood loss and increased iron requirements, which contribute to higher rates of iron depletion across diverse populations [22]. In contrast, studies of BTT carriers typically report a more balanced sex distribution or a slight male skew. Nevertheless, given the high background prevalence of iron deficiency in females, careful assessment for concurrent IDA in female BTT carriers remains important [23]. Although indices such as the Mentzer and Green & King indices have demonstrated respectable discriminatory performance (with reported AUCs of 0.85 and 0.87, respectively), they do not match the diagnostic efficacy of the Red Cell Distribution Width Index (RDWI) in distinguishing iron deficiency anemia (IDA) from β-thalassemia trait (BTT). Multiple comparative investigations have consistently shown that while traditional indices can be useful, their sensitivity and specificity are generally lower than those of RDWI. For example, Nesa and colleagues found that RDWI outperformed both the Mentzer and Green & King indices, an advantage attributed to RDWI's integration of red cell size variability and erythrocyte count, which more accurately reflects the underlying pathophysiological differences between IDA and BTT [10]. In a similar vein, Demir et al. reported that although the Mentzer index achieved acceptable sensitivity, RDWI provided a more balanced diagnostic profile, particularly in borderline cases [16]. Subsequent ROC analyses by Ehsani, Urrechaga, and others have reaffirmed that RDWI consistently yields higher AUC values than these conventional indices, underscoring its superiority as a screening tool [24-25].

LIMITATIONS

This study has several limitations. First, the cross-sectional design precludes longitudinal assessment of RDWI dynamics during treatment or disease progression. Second, the single-center setting may limit generalizability across diverse populations with varying prevalence of IDA and BTT. Third, coexisting mild inflammatory states or subclinical nutritional deficiencies, which were not exhaustively screened, could have influenced hematologic indices.

CONCLUSION & RECOMMENDATIONS

RDWI emerges as a sensitive and specific discriminator between iron deficiency anemia and beta thalassemia trait, reflecting the distinct erythropoietic perturbations underlying these disorders. In IDA, anisocytosis predominates due to impaired hemoglobin synthesis, whereas in BTT, microcytosis dominates with relatively uniform cell size, generating characteristic RDWI profiles. By integrating RDWI into routine hematologic assessment, clinicians can achieve rapid, mechanistically informed differentiation of microcytic anemias, enabling timely, targeted interventions and reducing reliance on more costly or labor-intensive confirmatory assays.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Functional Outcomes of Posteromedial Condylar Tibial Plateau Fractures Using Locking Compression Plates

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ABSTRACT

Background: Posteromedial condylar tibial plateau fractures are challenging intra-articular injuries that compromise knee stability and joint congruity. These fractures, often resulting from high-energy trauma, are biomechanically significant but frequently underdiagnosed or inadequately addressed, leading to suboptimal outcomes. Locking compression plates (LCPs) have emerged as a promising fixation method, offering angular stability and improved outcomes in complex fracture patterns. Aim of the study: To assess the functional and radiological outcomes of posteromedial tibial plateau fractures treated with locking compression plates and to identify factors influencing recovery. **Methods & Materials**: This prospective observational study included 55 adult patients with isolated posteromedial tibial plateau fractures treated at a tertiary care center. All patients underwent surgical fixation using the posteromedial approach with anatomically contoured LCPs. Functional outcomes were assessed using the Lysholm Knee Scoring Scale and the Knee injury and Osteoarthritis Outcome Score (KOOS) at final follow-up. Radiological union, weight-bearing milestones, and complications were also recorded. Statistical analyses included t-tests, Pearson correlation, and multivariate linear regression. Data analysis was conducted using SPSS version26. **Result**: The majority of patients showed favorable recovery, with good to excellent functional scores and a mean Lysholm score of 86.3±8.4. KOOS subscale scores also reflected high patient satisfaction and restored function. Younger age, Schatzker type IV fractures, shorter time to surgery, and earlier radiological union were significantly associated with better functional outcomes ($p < 0.05$). The complication rate was low, with minimal cases of infection, malunion, or implant failure. **Conclusion**: Locking compression plate fixation offers a reliable and biomechanically stable solution for posteromedial tibial plateau fractures, particularly when combined with early surgical intervention and targeted rehabilitation. The findings support its use as a preferred method in managing these complex injuries. Larger, multicenter trials are recommended to further validate these outcomes.

Keywords: *Tibial plateau fracture, posteromedial condyle, locking compression plate, Schatzker classification, Lysholm score, KOOS, functional outcome*

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INTRODUCTION

Tibial plateau fractures are complex intra-articular injuries involving the proximal portion of the tibia, which play a critical role in load transmission and weight-bearing at the knee joint [1]. These fractures can significantly impair joint congruity, alignment, and long-term function if not properly addressed [2]. Posteromedial condylar tibial plateau fractures refer to fractures involving the posteromedial aspect of the tibial plateau, often characterized by shearing forces due to axial loading and varus stress [3]. This particular fracture pattern is increasingly recognized for its biomechanical importance in maintaining knee stability, yet it has historically received less focused attention in both diagnosis and treatment compared to other tibial plateau fracture subtypes [4]. Tibial plateau fractures represent approximately 1% of all fractures globally, with a marked incidence in the elderly due to falls and low-energy trauma [5]. High-energy mechanisms such as motor vehicle accidents or fall from heights are more common causes in younger patients [6]. According to recent data from orthopedic centers across Bangladesh, tibial plateau fractures account for nearly 27.0% of all lower limb fractures, and among these, the posteromedial condylar involvement is frequently underreported or misclassified due to limitations in imaging modalities or a lack of surgeon familiarity with the fracture morphology [7]. The posteromedial fragment is biomechanically significant due to its load-bearing function and contribution to posterior and varus stability of the knee [8]. Fractures in this region, if inadequately stabilized, can result in joint instability, early-onset post-traumatic osteoarthritis, persistent pain, and reduced range of motion [9]. Traditional treatment approaches often relied on anterolateral incisions or conservative management, which frequently failed to provide adequate reduction and stability for the posteromedial fragment [10]. Inadequate fixation may lead to malunion, varus deformity, and poor functional outcomes, particularly in active patients or those with high physical demands [11]. Surgeons are now better equipped to identify and classify these fractures. Anatomically oriented surgical approaches, particularly the direct posteromedial approach, have been developed to allow better visualization and accurate reduction of the posteromedial condylar fragment [12]. Among the internal fixation options, locking compression plates (LCPs) have shown biomechanical superiority due to their angular stability, especially in osteoporotic bone or multi-fragmentary fractures. These plates facilitate rigid fixation, allowing for early mobilization and potentially improved functional recovery [13]. Despite these advancements, there remains a scarcity of high-quality studies evaluating the functional outcomes of isolated posteromedial tibial plateau fractures treated specifically with locking compression plates. Most existing studies either include mixed fracture types or fail to stratify outcomes based on fracture location and fixation method [14]. Orthopedic surgeons often rely on anecdotal evidence or extrapolated data, which may not be applicable to isolated posteromedial injuries. Therefore, a focused evaluation of this specific fracture pattern is warranted to guide clinical decision-making, optimize surgical techniques, and improve patient outcomes [15]. The aim of this study is to

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assess the functional outcomes of posteromedial condylar tibial plateau fractures managed with locking compression plates, based on clinical, radiological, and patient-reported parameters.

METHODS & MATERIALS

This prospective observational study was conducted at the Department of Orthopedic Surgery, Bangladesh Medical, Dhaka, Bangladesh from January 2023 to December 2024.

Inclusion criteria were patients aged 18 years or older presenting with posteromedial condylar tibial plateau fractures classified as Schatzker type IV or V who underwent surgical fixation with locking compression plates (LCP). Patients were required to have a minimum follow-up duration of 12 months.

Exclusion criteria included pathological fractures, polytrauma patients with multiple limb injuries, prior surgery on the affected knee, pre-existing knee joint disorders (e.g., osteoarthritis, ligament injuries), inability to comply with postoperative rehabilitation or follow-up, and those lost to follow-up before 12 months.

Surgical Technique

All procedures were performed under spinal or general anesthesia by experienced orthopedic trauma surgeons using a standardized posteromedial approach. After adequate exposure, anatomical reduction of the fracture fragments was achieved under fluoroscopic guidance. Fixation was secured using anatomically contoured locking compression plates specifically designed for the posteromedial tibial plateau. Wound closure was performed in layers, and sterile dressings were applied.

Postoperative Management

Postoperatively, patients followed a standardized rehabilitation protocol. Initially, partial weight-bearing was permitted based on surgeon discretion and radiographic healing, progressing to full weight-bearing typically around 12 to 16 weeks post-surgery. Range-of-motion exercises and muscle strengthening were initiated early to optimize functional recovery.

Outcome Measures

The primary outcome was the functional assessment using the Lysholm Knee Scoring Scale at the final follow-up. Secondary outcomes included the Knee Injury and Osteoarthritis Outcome Score (KOOS), subdivided into Pain, Symptoms, Activities of Daily Living (ADL), Sports/Recreation, and Quality of Life (QOL). Radiological evaluation of fracture union was conducted with standard anteroposterior and lateral knee radiographs, defining union by the presence of bridging callus in at least three cortices.

Postoperative complications, including malunion, nonunion, infection, implant failure, and re-operation, were documented.

Data Collection and Follow-up

Baseline demographic and injury characteristics were recorded at admission. Patients were assessed postoperatively at 6 weeks, 3 months, 6 months, and 12 months or later. Functional evaluations were performed by blinded assessors to reduce bias.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. Between-group comparisons were performed using independent t-tests or Mann-Whitney U tests, as appropriate. Pearson's correlation coefficient was used to evaluate relationships between variables. Multivariate linear regression analysis identified independent predictors of functional outcome. Statistical significance was set at $p < 0.05$. Data analysis was conducted using SPSS version26.

RESULT

A total of 55 patients with posteromedial condylar tibial plateau fractures were included in this study. The mean age of the participants was 41.2±11.0 years, with a nearly equal distribution of patients aged <40 years (49.09%) and ≥40 years (50.91%). Males comprised the majority of the study cohort (65.45%). The right side was more frequently involved (52.73%) compared to the left (47.27%). Road traffic accidents were the leading cause of injury (36.36%), followed by falls from height (9.09%). According to Schatzker classification, Type IV fractures were predominant (70.91%), while Type V accounted for 29.09%. The mean interval from injury to surgery was 5.0±1.6 days, and the mean follow-up duration was 19.4±3.5 months (*Table I*).

Table I
Baseline demographic and injury characteristics of the study population ($n = 55$).

Variable	Frequency (n)	Percentage (%)
Age (years)		
< 40 years	27	49.09
≥ 40 years	28	50.91
Mean ± SD	41.2 ± 11.0	
Gender		
Male	36	65.45
Female	19	34.55
Injury Side		
Right	29	52.73
Left	26	47.27
Mechanism of Injury		
Road Traffic Accident (RTA)	20	36.36
Fall from Height	5	9.09
Others	2	3.64
Schatzker Classification		
Type IV	39	70.91
Type V	16	29.09
Time from Injury to Surgery (days)		
Mean ± SD	5.0 ± 1.6	
Follow-up Duration (months)		
Mean ± SD	19.4 ± 3.5	

Table II showed that mean time to radiological union was 13.2±2.3 weeks. Partial weight-bearing was initiated at a mean of 6.9±1.1 weeks, while full weight-bearing was achieved by 14.7±2.2 weeks. Postoperative complications included superficial infection in 7.27% of cases, deep infection in 3.64%, malunion in 3.64%, nonunion in 1.82%, and implant failure in 1.82%. A re-operation was required in 5.45% of patients.

Table II
Radiographic healing times and postoperative complications following locking compression plate fixation.

Outcome	Frequency (n)	Percentage (%)
Time to Radiological Union (weeks)		
Mean ± SD	13.2 ± 2.3	
Time to Partial Weight-bearing (weeks)		
Mean ± SD	6.9 ± 1.1	
Time to Full Weight-bearing (weeks)		
Mean ± SD	14.7 ± 2.2	
Malunion	2	3.64
Nonunion	1	1.82
Superficial Infection	4	7.27
Deep Infection	2	3.64
Implant Failure	1	1.82
Re-operation	3	5.45

At the final follow-up, functional outcomes assessed by the Lysholm knee scoring scale revealed that 23.64% had excellent, 54.55% good, 16.36% fair, and 5.45% poor outcomes, with an overall mean score of 86.3±8.4 (*Table III*).

Table III
Functional outcome categorization based on lysholm knee scoring scale at final follow-up.

Score Range	Functional Outcome Category	Frequency (n)	Percentage (%)
95–100	Excellent	13	23.64
84–94	Good	30	54.55
65–83	Fair	9	16.36
<65	Poor	3	5.45
Mean ± SD		86.3 ± 8.4	

KOOS scores further demonstrated favorable outcomes, with mean values of 88.8±6.7 for pain, 82.1±8.1 for symptoms, 91.9±5.4 for activities of daily living, 77.5±9.0 for sports/recreation, and 81.7±7.6 for quality of life (*Table IV*).

Table IV
Functional outcome classification based on KOOS Scales.

Outcome Measure	Mean ± SD	95% Confidence Interval (CI)
Pain	88.8 ± 6.7	86.9 – 90.5
Symptoms	82.1 ± 8.1	79.7 – 84.5
ADL	91.9 ± 5.4	89.9 – 92.9
Sports/Recreation	77.5 ± 9.0	74.2 – 79.4
Quality of Life (QOL)	81.7 ± 7.6	79.3 – 83.9

Table V represented that younger patients (<40 years) achieved significantly higher Lysholm scores compared to those ≥40 years (88.4±7.3 vs. 83.9±8.9, p=0.020). Similarly, Type IV fractures were associated with better functional outcomes compared to Type V (87.3±7.7 vs. 79.7±9.8, p=0.009). Early surgical intervention (≤5 days) yielded superior scores compared to delayed surgery (>5 days) (88.7±7.5 vs. 82.1±9.3, p=0.027).

Table V
Comparative analysis of lysholm knee scores by age group, schatzker fracture type, and surgical timing.

Subgroup	n	Mean ± SD	95% CI	p-value
Age				
< 40 years	27	88.4 ± 7.3	85.7 – 91.1	0.020*
≥ 40 years	28	83.9 ± 8.9	80.6 – 87.2	
Fracture Type (Schatzker)				
Type IV	39	87.3 ± 7.7	84.9 – 89.7	0.009*
Type V	16	79.7 ± 9.8	74.9 – 84.5	
Time to Surgery				
≤ 5 days	34	88.7 ± 7.5	86.2 – 91.2	0.027*
> 5 days	21	82.1 ± 9.3	78.1 – 86.1	

Pearson's correlation demonstrated significant negative associations of Lysholm scores with age (r=-0.29, p=0.031), time to surgery (r=-0.34, p=0.012), and time to radiological union (r=-0.30, p=0.024). Follow-up duration did not show a statistically significant correlation with outcomes (p=0.188) *Table VI*.

Table VI
Correlation of lysholm knee scores with clinical and surgical variables.

Variable	Pearson's r	p-value
Age	-0.29	0.031*
Time to Surgery (days)	-0.34	0.012*
Time to Radiological Union	-0.3	0.024*
Follow-up Duration	0.17	0.188

Multivariate regression analysis identified increasing age (β=-0.26, p=0.008), Schatzker Type V fractures (β=-6.12, p=0.007), longer time to surgery (β=-1.03, p=0.019), and delayed radiological union (β=-0.91, p=0.003) as independent predictors of poorer Lysholm scores. Gender showed no significant association with outcomes (p=0.298) *Table VII*.

Table VII
Multivariate linear regression identifying independent predictors of functional outcome (Lysholm Score).

Predictor	β Coefficient	95% CI	p-value
Age (years)	-0.26	[-0.45, -0.07]	0.008**
Schatzker Type V (vs IV)	-6.12	[-10.52, -1.72]	0.007**
Time to Surgery (days)	-1.03	[-1.88, -0.18]	0.019*
Time to Radiological Union	-0.91	[-1.50, -0.32]	0.003**
Sex (Male vs Female)	1.82	[-1.62, 5.26]	0.298

DISCUSSION

This study evaluates the functional and radiological outcomes of locking compression plate fixation in Schatzker type IV and V tibial plateau fractures, aiming to identify predictors of recovery and compare results with existing clinical evidence. Overall, the findings indicate a favorable postoperative recovery profile, as reflected in both radiographic healing timelines and functional outcome scores [16]. These results are largely consistent with previously published studies evaluating similar cohorts and surgical techniques. In terms of radiological healing and weight-bearing milestones, the observed timeframes align closely with prior research, suggesting that LCP fixation provides stable internal support conducive to early mobilization [17]. Studies by Hanasoge et al. reported comparable durations for radiological union and progression to partial and full weight-bearing, reinforcing the reliability of the LCP method for complex tibial plateau fractures [18]. Functional outcomes in the current study, evaluated through Lysholm and KOOS scoring systems, demonstrate generally high levels of recovery, with a majority of patients achieving good to excellent scores [19]. Similar patterns were observed in studies by Ritter et al., where early surgical intervention and accurate anatomic reduction significantly influenced long-term knee function [20]. The high functional scores in this cohort may also be attributed to adherence to early physiotherapy protocols and the use of locking plates that maintain reduction despite potential comminution or osteoporotic bone [21]. Subgroup analysis in this study revealed that younger patients had significantly better functional outcomes than older individuals, a finding echoed by Munter et al., who emphasized that patient age is a critical determinant in postoperative recovery due to factors such as bone healing capacity and pre-injury activity levels [22]. Likewise, fractures classified as Schatzker type IV were associated with superior functional scores compared to type V injuries, which is in agreement with the findings of Prajwal et al., who noted that bicondylar fractures often lead to more complex joint involvement and prolonged rehabilitation [23]. Surgical timing also emerged as a significant factor influencing functional outcomes. Patients undergoing surgery within five days of injury tended to have better postoperative scores, a result supported by the findings of Henle et al., who observed increased complication rates and poorer outcomes in delayed interventions [24]. Early fixation, when soft tissue conditions permit, likely contributes to better alignment, reduced inflammation, and more efficient initiation of rehabilitation [25]. The analysis further identified age, fracture type, time to surgery, and time to radiological union as independent predictors of functional outcome. These associations are corroborated by prior multivariate studies, such as those by Manidakis et al. and Kumar et al., who similarly identified these variables as key influencers of long-term functional success following tibial plateau fracture fixation [26,27]. Conversely, sex was not found to be a significant predictor in the present study, a result consistent with previous findings suggesting that gender differences do not play a major role in surgical outcomes for lower limb fractures when other clinical variables are controlled [28]. Complication rates observed in this study, including superficial and deep infections, malunion, and implant failure, were within acceptable ranges and comparable to those reported in large clinical series. The relatively low incidence of serious complications reflects careful patient selection, adherence to surgical principles, and proper postoperative monitoring [29]. The current findings support the efficacy of locking compression plate fixation in managing complex tibial plateau fractures, particularly when surgical intervention is performed early and tailored to the specific fracture pattern [30]. These results are in concordance with a growing body of literature advocating for stable fixation methods, early mobilization, and individualized patient care in orthopedic trauma. Further prospective, multicenter studies with larger sample sizes and longer follow-up durations are warranted to validate these observations and optimize treatment algorithms.

LIMITATIONS

This study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings to broader populations. The short follow-up period restricts the ability to assess long-term complications such as post-traumatic osteoarthritis or late implant failure. Additionally, the study did not include a control group or compare different fixation techniques, which limits comparative analysis. Some degree of

selection bias may have occurred due to exclusion criteria and loss to follow-up. Multicenter studies with larger cohorts are recommended for more robust conclusions.

CONCLUSION & RECOMMENDATIONS

Locking compression plate fixation represents an effective treatment approach for Schatzker type IV and V tibial plateau fractures, offering stable fixation and favorable recovery. Early surgical timing, younger patient age, less complex fracture patterns, and quicker radiological union were associated with improved functional outcomes. The low incidence of complications supports the safety and reliability of this method. These findings are in line with previous literature and emphasize the need for timely intervention and tailored rehabilitation strategies. Further multicenter studies with extended follow-up are necessary to confirm these results and refine clinical decision-making.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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THE PLANET

Original Article

Assessment of Maternal Stress, Anxiety, Well-Being, and Sleep Quality during Different Stages of Gestation

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ABSTRACT

Background: Maternal stress, anxiety, overall well-being, and sleep quality are important determinants of both maternal and fetal health outcomes. Elevated stress and anxiety, poor well-being, and disrupted sleep during pregnancy have been associated with adverse outcomes including preterm birth, low birth weight, hypertensive disorders, impaired maternal functioning, and long-term neurodevelopmental effects in offspring. Despite their clinical importance, the temporal patterns of these psychological and behavioral measures across different stages of gestation remain underexplored, particularly in low-resource settings such as Bangladesh. Aim of the study: This study aimed to evaluate the levels and changes of maternal stress, anxiety, well-being, and sleep quality across the first, second, and third trimesters of pregnancy, identify associated risk factors, and determine critical gestational periods of vulnerability. **Methods & Materials**: A cross-sectional observational study was conducted involving 300 pregnant women attending the Department of Obstetrics and Gynaecology, Bangladesh Medical University, Dhaka, Bangladesh, stratified equally by trimester (n = 100 per trimester). Validated instruments, including the 10-item Perceived Stress Scale (PSS-10), State-Trait Anxiety Inventory (STAI), WHO-5 Well-Being Index, and Pittsburgh Sleep Quality Index (PSQI), were used to assess maternal psychological and behavioral outcomes. Data were analyzed using ANOVA with post-hoc Bonferroni comparisons, chi-square tests, Pearson correlations, and multiple linear regression to determine predictors of sleep quality. **Results**: Maternal stress, state anxiety, and poor sleep quality significantly increased across gestation, while overall well-being significantly declined ($p<0.001$ for all). The third trimester demonstrated the highest prevalence of high stress (41%), clinical anxiety (35%), and poor sleep quality (78%). Strong correlations were observed among stress, anxiety, well-being, and sleep quality measures. Regression analyses identified stress and anxiety as independent and significant predictors of impaired maternal sleep quality. **Conclusion**: Late pregnancy represents a critical period for psychological and behavioral disturbances. Systematic assessment and timely interventions targeting maternal stress and anxiety may improve sleep quality, overall well-being, and potentially maternal and fetal health outcomes.

Keywords: *Maternal stress; Anxiety; Well-being; Sleep quality; Pregnancy; Gestation*

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INTRODUCTION

Maternal stress, anxiety, well-being, and sleep quality during pregnancy refer to a range of psychological and physiological conditions-stress and anxiety signify heightened emotional strain, well-being indicates overall mental health status, and sleep quality reflects restorative rest-each of which can influence maternal and fetal outcomes throughout gestation [1]. Worldwide, the prevalence rate of mental disorder, primarily depression or anxiety is approximately 10% of pregnant women [2]. In Bangladesh, perinatal generalized anxiety disorders affect about 22-28% of women [3]. Pregnancy involves complex physiological and emotional adjustments, where hormonal shifts, bodily changes, and psychosocial pressures influence maternal stress, anxiety, well-being, and sleep quality. To evaluate these psychological and behavioral changes, validated tools are used, such as: the Perceived Stress Scale (PSS) for stress, the State-Trait Anxiety Inventory (STAI) for anxiety, the WHO-5 Well-Being Index for overall mental health, and the Pittsburgh Sleep Quality Index (PSQI) for sleep assessment. Applying these instruments at multiple stages of gestation enables observation of how maternal mental states evolve from early to late pregnancy. It helps to identify vulnerable periods, understand risk factors, and guide timely interventions for maternal and fetal health [4-6]. Elevated stress and anxiety and poor sleep quality during pregnancy are linked to adverse outcomes including preterm birth, low birth weight, hypertensive disorders, impaired maternal functioning, and adverse child neurodevelopmental outcomes, increased risk of cesarean section, and longer hospital stays, along with longer-term mental health effects for both mother and child. Co-occurrence of anxiety and depression can exacerbate risks beyond either condition alone [7]. The advantages include the real-world clustering of psychosocial risks, supports integrated screening during antenatal care, identifies high-risk groups who may benefit from targeted interventions and helps identify modifiable targets such as diet, physical activity, social support, and resilience. Enhanced understanding can improve prenatal care planning and maternal support policies [8,9]. However, disadvantages include reliance on self-report tools, heterogeneity in instruments and cut-offs, limited longitudinal follow-up, cultural differences in questionnaire interpretation, difficulty in capturing fluctuations over time and under-representation of low-resource settings such as Bangladesh [10,11]. The importance of this study lies in understanding how maternal psychological states across gestation is critical to improving maternal-child health, reducing perinatal complications, and enhancing long-term developmental

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outcomes for children, as early maternal stress and anxiety may have both immediate and lasting effects [12]. Existing researches often focus on single components (e.g., anxiety alone), lack repeated measurements across trimesters, and may not consider how socio-demographic factors interact with psychological outcomes in diverse populations [13]. So, there is a need for comprehensive assessments that simultaneously evaluate maternal stress, anxiety, well-being, and sleep quality at multiple gestational stages to understand temporal patterns and associated risk factors, especially in under-represented settings like South Asia. The study aimed to evaluate the levels and changes of maternal stress, anxiety, well-being, and sleep quality throughout different stages of pregnancy, identify associated risk factors, and determine whether specific gestational windows present higher vulnerability for psychological disturbances.

METHODS & MATERIALS

This cross-sectional observational study was conducted at the Department of Obstetrics and Gynaecology, Bangladesh Medical University, Dhaka, Bangladesh, between January 2023 and December 2024. A total of 300 pregnant women were enrolled and stratified equally into three groups based on gestational age: first trimester (n = 100), second trimester (n = 100), and third trimester (n = 100).

Inclusion and Exclusion Criteria

Inclusion Criteria

Participants were eligible for the study if they met all of the following criteria:

1. Pregnant women aged 18–40 years.
2. Singleton pregnancy.
3. Gestational age corresponding to the first (≤12 weeks), second (13–26 weeks), or third trimester (≥27 weeks).
4. Ability to provide written informed consent and complete study questionnaires.

Exclusion Criteria

Participants were excluded if they met any of the following conditions:

1. Multiple pregnancies (e.g., twins or higher-order multiples).
2. Known psychiatric disorders or current use of psychotropic medication.
3. Severe obstetric complications at the time of recruitment (e.g., preeclampsia, placenta previa).
4. Chronic medical illnesses that could affect stress, anxiety, or sleep (e.g., uncontrolled diabetes, chronic kidney disease).
5. Inability to comprehend the study questionnaires due to language barriers or cognitive impairment.

Data Collection

Data were collected through a combination of structured interviews, self-administered questionnaires, and review of participants' medical records. Trained research assistants conducted face-to-face interviews to obtain detailed information on maternal demographics, including age, educational level, employment status, and parity. Height and weight were measured using standardized equipment to calculate body mass index (BMI) as weight in kilograms divided by height in meters squared. Medical records were reviewed to document a history of pregnancy complications, chronic health conditions, and previous obstetric outcomes.

Maternal psychological and behavioral data were collected using validated instruments. Perceived stress was measured using the 10-item Perceived Stress Scale (PSS-10), which assesses the degree to which participants appraised their lives as unpredictable, uncontrollable, or overloaded over the past month. Anxiety was evaluated using the State-Trait Anxiety Inventory (STAI), which distinguishes between temporary, situational anxiety (state anxiety) and stable, long-term tendencies to experience anxiety (trait anxiety). Well-being was assessed using the World Health Organization 5-item Well-Being Index (WHO-5), capturing subjective positive mood, vitality, and general interest in life. Sleep quality was measured using the Pittsburgh Sleep Quality Index (PSQI), which evaluates multiple domains including sleep latency, duration, efficiency, disturbances, and daytime dysfunction. Higher scores on the PSS-10, STAI, and PSQI indicated greater stress, anxiety, and poor sleep quality, respectively, whereas higher WHO-5 scores reflected better overall well-being.

All participants completed the questionnaires in a private setting to ensure confidentiality and minimize reporting bias. For participants with literacy challenges, trained assistants provided verbal explanations and assisted in completing the forms without influencing responses. Data collection was systematically scheduled according to gestational stage, ensuring that each participant was assessed during the first, second, or third trimester as appropriate. Quality control procedures included double-checking entries, cross-verifying questionnaire scores with medical records, and periodic supervisory audits to ensure accuracy, completeness, and consistency of the data.

Statistical Analysis

All statistical analyses were performed using SPSS version 28.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages. The Shapiro-Wilk test was used to assess the normality of continuous data. To examine differences in maternal stress, anxiety, well-being, and sleep quality across gestational stages, one-way analysis of variance (ANOVA) was conducted, followed by post-hoc pairwise comparisons using the Bonferroni correction to control for multiple testing. Chi-square tests were applied to compare categorical outcomes, such as the prevalence of clinically significant stress, anxiety, and poor sleep, across trimesters. Pearson correlation coefficients were calculated to explore the relationships among stress, anxiety, well-being, and sleep quality measures. Furthermore, multiple linear regression analyses were performed to identify significant predictors of maternal sleep quality, adjusting for stress, anxiety, and well-being scores. Effect sizes were reported as partial eta-squared (η^2) for ANOVA and R^2 for regression models to provide an estimate of the magnitude of associations. A two-tailed p-value <0.05 was considered statistically significant throughout the study.

Ethical Considerations

The study was approved by the Institutional Ethics Committee and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants, and data were anonymized to ensure confidentiality.

RESULT

Mean maternal age was comparable across trimesters (27.0±4.0, 27.3±4.2, 27.6±4.3 years, F=1.02, p=0.36). Similarly, mean BMI showed no significant variation (23.5±3.0, 23.8±3.2, 24.1±3.4 kg/m²; F=1.73, p=0.18) among trimesters. Primiparous and multiparous women were nearly balanced (48.00% and 52.00%, χ^2=1.98, p=0.37). Educational attainment was 32.00% (≤high school) and 68.00% (college & above) (χ^2=2.58, p=0.28). Employment status (employed: 36.00% and homemaker: 64.00%; χ^2=1.41) were not statistically significant (p=0.49). History of pregnancy complications was reported in 18.00% of participants, while 9.00% had chronic health conditions, without significant inter-trimester differences (*Table I*).

Table I
Maternal demographics and clinical characteristics among the study population (n = 300).

Characteristic	1st Trimester (n=100)	2nd Trimester (n=100)	3rd Trimester (n=100)	Total (N=300)	Test Statistic	p-Value
Age (years)						
Mean ± SD	27.0 ± 4.0	27.3 ± 4.2	27.6 ± 4.3	27.3 ± 4.2	F=1.02	0.36
BMI (kg/m²)						
Mean ± SD	23.5 ± 3.0	23.8 ± 3.2	24.1 ± 3.4	23.8 ± 3.2	F=1.73	0.18
Parity						
Primiparous	50 (50.00)	46 (46.00)	48 (48.00)	144 (48.00)	χ^2=1.98	0.37
Multiparous	50 (50.00)	54 (54.00)	52 (52.00)	156 (52.00)		
Education						
≤ High school	32 (32.00)	30 (30.00)	34 (34.00)	96 (32.00)	χ^2=2.58	0.28
College & above	68 (68.00)	70 (70.00)	66 (66.00)	204 (68.00)		
Employment						
Employed	36 (36.00)	34 (34.00)	38 (38.00)	108 (36.00)	χ^2=1.41	0.49
Homemaker	64 (64.00)	66 (66.00)	62 (62.00)	192 (64.00)		
History of pregnancy complications, n (%)	14 (14.00)	18 (18.00)	21 (21.00)	53 (18.00)	χ^2=1.87	0.39
Chronic health conditions, n (%)	7 (7.00)	9 (9.00)	11 (11.00)	27 (9.00)	χ^2=1.04	0.59

Notes: SD = standard deviation; BMI = body mass index; χ^2 = chi-square; F = one-way ANOVA.

Table II shows perceived stress (PSS-10) increased from 16.5±5.2 in the 1st trimester, 18.0±5.5 in the 2nd trimester, 20.4±5.9 in the 3rd trimester, respectively (F=11.4, p<0.001, η^2=0.07). State anxiety (STAI-S) rose from 35.2±8.6 to 40.2±9.4 (F=13.1, p<0.001, η^2=0.08), and trait anxiety (STAI-T) increased modestly from 33.0±7.6 to 35.4±8.3 (F=3.1, p=0.047, η^2=0.02). Well-being (WHO-5) declined from 69.0 ± 12.5 to 61.5±14.5 (F=9.8, p<0.001, η^2=0.06), while sleep quality (PSQI) increased from 5.9±2.5 to 7.9±3.0 (F=14.2, p<0.001, η^2=0.09).

Table II
Maternal stress, anxiety, well-being, and sleep quality across gestation.

Measure	1st Trimester (Mean ± SD)	2nd Trimester (Mean ± SD)	3rd Trimester (Mean ± SD)	F (df)	p-Value	Partial η^2
Perceived Stress (PSS-10)	16.5 ± 5.2	18.0 ± 5.5	20.4 ± 5.9	11.4 (2,297)	<0.001	0.07
State Anxiety (STAI-S)	35.2 ± 8.6	37.6 ± 9.0	40.2 ± 9.4	13.1 (2,297)	<0.001	0.08
Trait Anxiety (STAI-T)	33.0 ± 7.6	34.0 ± 7.9	35.4 ± 8.3	3.1 (2,297)	0.047	0.02
Well-Being (WHO-5)	69.0 ± 12.5	65.0 ± 13.3	61.5 ± 14.5	9.8 (2,297)	<0.001	0.06
Sleep Quality (PSQI)	5.9 ± 2.5	6.7 ± 2.7	7.9 ± 3.0	14.2 (2,297)	<0.001	0.09

Perceived stress (PSS-10) increased significantly from the 1st to 2nd trimester (MD=1.5, 95% CI: 0.3-2.7), 2nd to 3rd (MD=2.4, 95% CI:1.2-3.6), and 1st to 3rd (MD=3.9, 95% CI:2.5-5.3). State anxiety (STAI-S) showed a similar rise in mean difference (2.4, 2.6, 5.0, respectively). Conversely, well-being (WHO-5) declined across trimesters (MD=4.0, MD=3.5, MD=7.5, respectively). Sleep quality (PSQI) progress favorably (MD=0.8, MD=1.2, MD=2.0, respectively) across trimesters. All comparisons remained statistically significant (*Table III*).

Table III
Post-hoc pairwise comparisons of maternal stress, anxiety, well-being, and sleep quality across gestational stages (Bonferroni).

Outcome	Comparison	Mean Difference	95% CI	p-Value
PSS-10	1st vs 2nd	1.5	0.3 – 2.7	0.01
PSS-10	2nd vs 3rd	2.4	1.2 – 3.6	<0.001
PSS-10	1st vs 3rd	3.9	2.5 – 5.3	<0.001
STAI-S	1st vs 2nd	2.4	0.8 – 4.0	0.003
STAI-S	2nd vs 3rd	2.6	1.0 – 4.2	0.001
STAI-S	1st vs 3rd	5	3.2 – 6.8	<0.001
WHO-5	1st vs 2nd	-4.0	-6.6 – -1.4	0.002
WHO-5	2nd vs 3rd	-3.5	-6.1 – -0.9	0.004
WHO-5	1st vs 3rd	-7.5	-10.1 – -4.9	<0.001
PSQI	1st vs 2nd	0.8	0.2 – 1.4	0.01
PSQI	2nd vs 3rd	1.2	0.6 – 1.8	<0.001
PSQI	1st vs 3rd	2	1.3 – 2.7	<0.001

Table IV demonstrates the prevalence of high stress (PSS≥20) increased from 22.00% in the 1st trimester to 41.00% in the 3rd trimester (p<0.001). Clinical anxiety (STAI-S ≥40) rose from 15.00% to 35.00% (p<0.001), and poor sleep quality (PSQI>5) affected 48.00%, 62.00%, and 78.00% of women in the 1st, 2nd, and 3rd trimesters, respectively (p<0.001).

Table IV
Prevalence of maternal stress, anxiety, and poor sleep quality across gestation.

Outcome	1st Trimester n (%)	2nd Trimester n (%)	3rd Trimester n (%)	Total n (%)	χ^2	p-Value
High stress (PSS ≥ 20)	22 (22.00)	30 (30.00)	41 (41.00)	93 (31.00)	14.6	<0.001
Clinical anxiety (STAI-S ≥ 40)	15 (15.00)	26 (26.00)	35 (35.00)	76 (25.00)	13.7	<0.001
Poor sleep quality (PSQI > 5)	48 (48.00)	62 (62.00)	78 (78.00)	188 (63.00)	24.2	<0.001

Strong correlations were observed between stress, anxiety, well-being, and sleep quality (PSS-10 & STAI-S: r=0.72, PSS-10 & PSQI: r=0.53, STAI-S & PSQI: r=0.58). All analysis were statistically significant (*Table V*).

Table V
Correlations between maternal stress, anxiety, well-being, and sleep quality across gestation.

Variables	r	95% CI	p-Value
PSS-10 & STAI-S	0.72	0.66 – 0.77	<0.001
PSS-10 & WHO-5	-0.56	-0.64 – -0.47	<0.001
PSS-10 & PSQI	0.53	0.44 – 0.60	<0.001
STAI-S & WHO-5	-0.52	-0.60 – -0.42	<0.001
STAI-S & PSQI	0.58	0.50 – 0.65	<0.001
WHO-5 & PSQI	-0.50	-0.59 – -0.41	<0.001

In Model 1, perceived stress (PSS-10) was a significant predictor (β=0.44, SE=0.06, t=7.33, p<0.001, 95% CI: 0.33-0.55). In Model 2, both stress (PSS-10) (β=0.29, SE=0.06, t=4.83, 95% CI: 0.17-0.41) and anxiety (STAI-S) (β=0.38, SE=0.05, t=7.6, p<0.001; 95% CI: 0.28-0.48) were statistically significant (both p<0.001). In the full model (Model 3), stress (PSS-10)(β=0.23, SE=0.06, t=3.83, 95% CI: 0.11-0.35), anxiety (STAI-S)(β=0.33, SE=0.05, t=6.6, 95% CI: 0.23-0.43), and well-being (WHO-5) (β=−0.28, SE=0.06, t=-4.67, 95% CI: -0.40 to -0.16) were all statistically significant (all p<0.001) *Table VI*.

Table VI
Predictors of maternal sleep quality across gestation (multiple regression analysis).

Predictor	β	SE	t	p-Value	95% CI
Model 1: Stress only					
PSS-10	0.44	0.06	7.33	<0.001	0.33 – 0.55
Model 2: Stress + Anxiety					
PSS-10	0.29	0.06	4.83	<0.001	0.17 – 0.41
STAI-S	0.38	0.05	7.6	<0.001	0.28 – 0.48
Model 3: Full Model (Stress + Anxiety + Well-Being)					
PSS-10	0.23	0.06	3.83	<0.001	0.11 – 0.35
STAI-S	0.33	0.05	6.6	<0.001	0.23 – 0.43
WHO-5	-0.28	0.06	-4.67	<0.001	-0.40 – -0.16

DISCUSSION

Maternal psychological distress during pregnancy—manifesting as stress, anxiety, impaired well-being, and poor sleep quality—represents a multifaceted public health concern that may vary across different stages of gestation and influence both maternal and fetal outcomes [14]. The present study evaluated maternal stress, anxiety, well-being, and sleep quality across different stages of gestation among 300 pregnant women. The three trimester groups were comparable in demographic and clinical characteristics. The mean age increased slightly across trimesters (27.0 ± 4.0 years in the 1st trimester, 27.3 ± 4.2 in the 2nd, and 27.6 ± 4.3 in the 3rd), but this difference was not statistically significant (F = 1.02, p = 0.36). Similarly, BMI showed a gradual increase (23.5 ± 3.0 to 24.1 ± 3.4 kg/m²), without statistical significance (F = 1.73, p = 0.18). Parity distribution remained balanced (primiparous: 50%, 46%, and 48%; χ^2 = 1.98, p = 0.37). Education, employment status, history of pregnancy complications (14%, 18%, 21%; χ^2 = 1.87, p = 0.39), and chronic health conditions (7%, 9%, 11%; χ^2 = 1.04, p = 0.59) also showed no significant variation. This homogeneity indicates that gestational stage, rather than sociodemographic variability, likely accounts for the observed psychological differences. Comparable baseline uniformity has been reported by Rees et al. in antenatal cohort studies [12]. Perceived stress (PSS-10) increased significantly from 16.5 ± 5.2 in the 1st trimester to 18.0 ± 5.5 in the 2nd and 20.4 ± 5.9 in the 3rd trimester (F(2,297) = 11.4, p < 0.001, partial η^2 = 0.07). This progressive elevation is consistent with the theoretical framework proposed by Monk et al., who emphasized increasing pregnancy-related stress as childbirth approaches [15]. State anxiety (STAI-S) followed a similar trajectory, rising from 35.2 ± 8.6 to 37.6 ± 9.0 and 40.2 ± 9.4 (F(2,297) = 13.1, p < 0.001, partial η^2 = 0.08). These findings align with observations by Newham et al., who documented higher anxiety levels in late pregnancy [16]. Trait anxiety (STAI-T) showed a smaller increase (33.0 ± 7.6 to 35.4 ± 8.3), reaching statistical significance (F(2,297) = 3.1, p = 0.047, partial η^2 = 0.02), reflecting relatively stable personality factors with modest gestational influence [16]. Sleep quality (PSQI) demonstrated the largest effect size (partial η^2 = 0.09), increasing from 5.9 ± 2.5 in early pregnancy to 6.7 ± 2.7 and 7.9 ± 3.0 in late pregnancy (F(2,297) = 14.2, p < 0.001). These findings correspond closely with the systematic review by Sedov et al., who reported escalating sleep disturbances across trimesters, particularly in the third trimester [17]. Bonferroni-adjusted analyses confirmed significant differences between trimesters. For perceived stress, the mean difference between the 1st and 3rd trimester was 3.9 (95% CI: 2.5–5.3, p < 0.001), while the 2nd vs 3rd trimester difference was 2.4 (95% CI: 1.2–3.6, p < 0.001). For state anxiety, the

largest difference was observed between the 1st and 3rd trimester (mean difference = 5.0; 95% CI: 3.2–6.8; $p < 0.001$). Well-being showed a significant decline between the 1st and 3rd trimester (mean difference = 7.5; 95% CI: 4.9–10.1; $p < 0.001$). Sleep quality also worsened significantly, with a 2-point increase in PSQI score between the 1st and 3rd trimester (95% CI: 1.3–2.7; $p < 0.001$). These graded differences are consistent with longitudinal findings reported in previous studies, which described incremental increases in distress markers across gestation [17,18,19,20]. The prevalence of high stress (PSS ≥ 20) increased from 22% in the 1st trimester to 30% in the 2nd and 41% in the 3rd ($\chi^2 = 14.6$, $p < 0.001$). Clinical anxiety (STAI-S ≥ 40) rose from 15% to 26% and 35% ($\chi^2 = 13.7$, $p < 0.001$). Poor sleep quality (PSQI > 5) increased markedly from 48% in early pregnancy to 62% and 78% in late pregnancy ($\chi^2 = 24.2$, $p < 0.001$). Comparable trimester-related increases in anxiety prevalence have been reported by Dennis et al., while high rates of poor sleep in late pregnancy were similarly described by Dennis et al. and Mindell et al [3,21]. A strong positive correlation was observed between perceived stress and state anxiety ($r = 0.72$, 95% CI: 0.66–0.77, $p < 0.001$). Stress also correlated with poor sleep quality ($r = 0.53$, $p < 0.001$) and inversely with well-being ($r = -0.56$, $p < 0.001$). State anxiety correlated positively with sleep disturbance ($r = 0.58$, $p < 0.001$) and negatively with well-being ($r = -0.52$, $p < 0.001$). These findings support the integrative stress–anxiety framework proposed by Guardino and Dunkel (2014) [22]. In regression analysis, stress alone significantly predicted poor sleep ($\beta = 0.44$, $p < 0.001$). When anxiety was added, both stress ($\beta = 0.29$, $p < 0.001$) and state anxiety ($\beta = 0.38$, $p < 0.001$) remained significant predictors. In the fully adjusted model, stress ($\beta = 0.23$, $p < 0.001$), state anxiety ($\beta = 0.33$, $p < 0.001$), and reduced well-being ($\beta = -0.28$, $p < 0.001$) independently predicted sleep disturbance. These findings are consistent with research by Okun ML et al., who demonstrated that prenatal stress and anxiety independently contribute to impaired sleep quality [23].

LIMITATIONS

The study's cross-sectional design precludes causal inferences and limits the ability to capture individual trajectories of psychological changes across gestation. Reliance on self-reported questionnaires may introduce reporting bias, and literacy or comprehension differences could affect responses. Additionally, the single-center setting may restrict generalizability to broader populations, particularly in diverse socio-cultural or low-resource contexts. Longitudinal studies incorporating objective measures and multi-center cohorts are warranted to validate these findings and further elucidate temporal patterns, predictors, and outcomes of maternal stress, anxiety, well-being, and sleep quality throughout pregnancy.

CONCLUSION

This study demonstrates a progressive increase in maternal stress, state anxiety, and poor sleep quality across gestation, accompanied by a concomitant decline in overall well-being. The highest vulnerability was observed during the third trimester, indicating that late pregnancy represents a critical period for psychological disturbances. Strong correlations among stress, anxiety, well-being, and sleep quality highlight their interdependence, while regression analysis identifies stress and anxiety as significant predictors of impaired sleep. These findings underscore the importance of routine psychosocial assessment and timely interventions during pregnancy, particularly in the later stages, to mitigate adverse maternal and fetal outcomes. Targeted strategies may improve maternal mental health, sleep quality, and overall pregnancy experiences.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Anthropometric Assessment of Lower Limb Dimensions among Van Drivers in Relation to Work Pattern and Load Bearing

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ABSTRACT

Background: Occupational workload affects health and performance, and anthropometry helps tailor ergonomic interventions to reduce musculoskeletal risk. Drivers face long hours, static postures, and high physical demands, often linked to musculoskeletal complaints, yet few studies examine how workload relates to lower limb dimensions. In Bangladesh, data on driver anthropometry are limited. This study explores the association between work exposure and lower limb measures among van drivers in Dhaka to inform ergonomic design and occupational health strategies. **Methods & Materials:** A cross-sectional study of 50 male van pullers in Dhaka (25–55 years, ≥5 years' experience) measured demographics, workload, and lower limb dimensions following ISAK guidelines. Data were analyzed descriptively, and Pearson correlation assessed associations between workload and limb measurements ($p<0.05$, SPSS v27). **Results:** Among 50 male van pullers (mean age 39.0 ± 6.5 years; mean BMI 21.9 ± 2.7 kg/m²), lower limb measurements showed moderate variability (lateral tibial condyle to floor 44.8 ± 3.0 cm, total limb length 84.1 ± 5.5 cm, knee 30.7 cm, calf 32.3 cm, ankle 17.6 cm). Participants worked long hours (11.9 ± 2.4/day, ~7 days/week, 11.6 ± 1.5 months/year), but correlations between daily working hours and lower limb dimensions were weak and non-significant ($r = 0.08–0.14$, $p > 0.05$). **Conclusion:** Lower limb dimensions of Dhaka van pullers show moderate variability and appear largely unaffected by prolonged occupational workload.

Keywords: *Anatomy, Anthropometry, Nutritional status, Van puller/ drivers, occupational workload, Girth*

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INTRODUCTION

Occupational workload and human body dimensions are central to understanding how physical job demands influence health and performance outcomes in working populations. Anthropometry, the systematic measurement of human body dimensions, is widely applied in ergonomics and workplace design to assess human variability and inform ergonomic interventions that improve safety, comfort, and productivity across occupational settings. Anthropometric data guide the fitting of workstations, equipment, and tools to the physical attributes of workers, thereby reducing musculoskeletal strain and injury risk[1].

Professional drivers are exposed to prolonged and repetitive physical workloads, including extended durations of driving, static postures, and complex task demands, which have been repeatedly linked with a high prevalence of musculoskeletal complaints and disorders [2, 3, 4]. Studies of urban transit operators show that increased physical workload—often quantified by duration of driving and cumulative exposure—correlates with higher prevalence of musculoskeletal symptoms, particularly in the back and neck regions [5, 6, 7]. Similarly, evidence among international truck drivers indicates that longer work hours are associated with musculoskeletal symptoms across multiple anatomical regions, highlighting the impact of both physical and organizational workload factors on driver health [8, 9]. Although these studies emphasize symptomatic outcomes, relatively few investigations have examined how workload exposures relate to morphological characteristics such as lower limb anthropometry, which may affect posture, biomechanical load distribution, gait, and overall functional capacity during work tasks.

Lower limb dimensions—including bone lengths and circumferences of the knee, calf, and ankle—not only reflect intrinsic anatomical variation but can also be influenced by habitual occupational activities. Anthropometric profiles vary substantially among occupational groups, suggesting that prolonged physical tasks and workload exposures may be associated with particular morphological patterns [10]. Body segment measurements have been used in ergonomic research to tailor workplace and equipment design, yet there is a gap in literature specifically linking occupational workload to lower limb anthropometric variation among transport workers. Furthermore, research on driver anthropometry in Bangladesh remains limited, though some work has highlighted substantial differences in body dimensions of Bangladeshi drivers compared with other populations, underscoring the need for

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localized anthropometric data in ergonomic planning.

In the context of Bangladesh, van drivers in urban settings such as Dhaka city often endure long working hours and high physical demands, but ergonomic research in this group is scarce. Understanding how occupational workload aligns with specific lower limb anthropometric measures can provide crucial insights for ergonomic assessment, vehicle design adaptation, and occupational health interventions. Therefore, this study aims to examine the association between occupational workload—operationalized through daily working hours, weekly workdays, and annual work exposure—and lower limb anthropometry among van drivers in Dhaka. The findings are intended to inform ergonomic strategies, contribute to a better understanding of occupational health risks in this understudied population, and support evidence-based design and policy recommendations.

METHODS & MATERIALS

Study Design and Sampling: This study was a cross-sectional descriptive study with analytical components, conducted to examine the lower limb anthropometry and occupational workload of van pullers in Dhaka city. A convenient sampling technique was used to recruit 50 participants between January 1, 2025, and August 31, 2025.

Study Population and Selection Criteria: The study population comprised 50 male van pullers aged 25–55 years, each with a minimum of five years of occupational experience. Participants were selected based on availability and willingness to participate. Individuals were excluded if they had a history of major lower limb trauma, musculoskeletal disorders, congenital anomalies, or any deformities affecting the lower extremities, to prevent interference with accurate anthropometric measurement.

Ethical Considerations: Informed written consent was obtained from all participants prior to data collection. Confidentiality and privacy were strictly maintained, and participation was entirely voluntary. The study posed no physical, social, or legal risks, and all data collected were used exclusively for research purposes.

Variables: Demographic variables included age, body weight, stature, and body mass index (BMI). Occupational workload variables included working hours per day, working days per week, and working months per year. The primary outcome variables were lower limb anthropometric measures: lateral condyle of tibia to standing surface, total lower limb length, and circumferences of the knee, calf, and ankle.

Anthropometric Measurements: All measurements were performed following the International Society for the Advancement of Kinanthropometry (ISAK) guidelines. Participants were informed about the study objectives and provided voluntary consent before measurement. A single trained researcher conducted all measurements to reduce inter-observer variability, assisted by an assistant who recorded the data.

Lower limb lengths were measured using a segmometer:

Lateral condyle of tibia to standing surface was measured with participants in a standing position. Circumferences of the knee, calf, and ankle were measured using a non-elastic tape at standardized anatomical landmarks. Stature was measured using a stadiometer, and body weight was recorded using a calibrated digital scale. All measurements were taken twice, and the mean value was used in the analysis to ensure accuracy and reliability. Anatomical landmarks were carefully identified and marked, with supplementary audio and photographic documentation used to maintain consistency.

Occupational Workload Assessment: Data on occupational workload were collected through structured interviews, which included the number of hours worked per day, days worked per week, and months worked per year. These variables provided quantitative insight into the physical demands of the van pullers' occupation.

Data Analysis: Descriptive statistics were used to summarize demographic, anthropometric, and occupational workload variables. Continuous variables were presented as mean ± standard deviation (SD) or median and range, while categorical variables were reported as frequencies and percentages. The relationship between occupational workload and lower limb anthropometry was evaluated using **Pearson correlation analysis**. A p-value <0.05 was considered statistically significant. All statistical analyses were conducted using [insert software, e.g., SPSS version 27.

RESULTS

Demographic and Anthropometric Characteristics

The study included 50 van pullers with an age range of 25 to 55 years (mean ± SD: 39.02 ± 6.50 years). The majority of participants were aged 36–40 years (26%), followed by 41–45 years (18%). Body weight of the participants ranged from 44.05 to 81.55 kg, with a median of 55.70 kg, while stature ranged from 145 to 174 cm (mean ± SD: 160.15 ± 6.02 cm). The mean body mass index (BMI) was 21.91 ± 2.73 kg/m², with most van pullers (78%) falling within the normal weight category (18.5–24.9 kg/m²), 14% overweight, and 8% underweight. No participants were classified as obese (BMI ≥ 30 kg/m²) *Table I*.

Table I
Distribution of age, body weight, stature, and BMI of van pullers (n = 50).

Variable	Category	n (%)
Age (years)	25–30	5 (10)
	31–35	6 (12)
	36–40	13 (26)
	41–45	9 (18)
	46–50	5 (10)
	51–55	2 (4)
	Mean ± SD	39.02 ± 6.50
Body weight (kg)	71–80	3 (6)
	81–90	1 (2)
	Median (range)	55.70 (44.05–81.55)
Stature (cm)	145–154	9 (18)
	155–164	23 (46)
	165–174	18 (36)
	Mean ± SD	160.15 ± 6.02
BMI (kg/m²)	<18.5	4 (8)
	18.5–24.9	39 (78)
	25–29.9	7 (14)
	≥30	0 (0)
	Mean ± SD	21.91 ± 2.73

Lower Limb Anthropometry

Lower limb measurements demonstrated variability among the van pullers. The distance from the lateral condyle of the tibia to the standing surface ranged from 36 to 53 cm, with the majority (70%) falling between 42–47 cm (mean ± SD: 44.75 ± 2.96 cm). Total lower limb length varied from 69 to 98 cm, with a mean of 84.12 ± 5.53 cm, and most participants (58%) measuring 79–88 cm. Knee girth was predominantly 28–31 cm (80%), with a median of 30.66 cm (range: 29.25–37.15 cm), while calf girth had a median of 32.33 cm (range: 29.35–39.53 cm). Ankle girth measurements were mostly in the 17–19 cm range (72%), with a median of 17.55 cm (range: 17.50–24.65 cm). The medial condyle of tibia to medial malleolus distance had a median of 36.37 cm, with 56% of participants measuring between 36–40 cm (*Table II*).

Table II
Lower limb anthropometric measurements of van pullers (*n* = 50).

Trait	Measurement range (cm)	n (%)	Summary statistic
Lateral condyle of tibia to standing surface	36–41	7 (14)	
	42–47	35 (70)	
	48–53	8 (16)	
			Mean ± SD: 44.75 ± 2.96
Length of lower limb	69–78	8 (16)	
	79–88	29 (58)	
	89–98	13 (26)	
			Mean ± SD: 84.12 ± 5.53
Knee girth	28–31	40 (80)	
	32–35	9 (18)	
	36–39	1 (2)	
			Median (range): 30.66 (29.25–37.15)
Calf girth	29–32	31 (62)	
	33–36	17 (34)	
	37–40	2 (4)	
			Median (range): 32.33 (29.35–39.53)
Ankle girth	17–19	36 (72)	
	20–22	11 (22)	
	23–25	3 (6)	
			Median (range): 17.55 (17.50–24.65)
Medial condyle of tibia to medial malleolus	26–30	3 (6)	
	31–35	19 (38)	
	36–40	28 (56)	
			Median (range): 36.37 (26.43–39.60)

Occupational Workload

The occupational workload of the van pullers was considerable. Participants reported working an average of 11.88 ± 2.43 hours per day, nearly 7 days per week (6.96 ± 0.20), and approximately 11.62 ± 1.50 months per year (*Table III*).

Table III
Occupational workload characteristics of van drivers (*n* = 50).

Variable	Mean ± SD	Minimum	Maximum
Working hours per day	11.88 ± 2.43	5	16
Working days per week	6.96 ± 0.20	6	7
Working months per year	11.62 ± 1.50	4	12

Association Between Occupational Workload and Lower Limb Anthropometry

Correlation analysis revealed weak and non-significant associations between daily working hours and lower limb anthropometric measures. Specifically, working hours per day showed a Pearson correlation of 0.14 with the lateral condyle of tibia to standing surface (p = 0.33), 0.08 with medial condyle of tibia to medial malleolus (p = 0.57), and 0.12 with total lower limb length (p = 0.40), indicating no statistically significant linear relationships (*Table IV*).

Table IV
Association between occupational workload and lower limb anthropometry among van drivers (*n* = 50).

Occupational workload variable	Anthropometric variable	Pearson r	p value
Working hours per day	Lateral condyle of tibia to standing surface	0.14	0.33
Working hours per day	Medial condyle of tibia to medial malleolus	0.08	0.57
Working hours per day	Total lower limb length	0.12	0.40

DISCUSSION

This study examined the relationship between occupational workload and lower limb anthropometry among van drivers in Dhaka city. The participants were predominantly of normal BMI, with moderate stature and body weight, reflecting a relatively uniform demographic profile consistent with other urban transport workers in South Asia [2]. Lower limb measurements indicated that most drivers had lateral condyle to standing surface lengths of 42–47 cm and total lower limb lengths of 79–88 cm, with knee, calf, and ankle circumferences reflecting lean morphology.

Despite the high occupational workload—nearly 12 hours per day, six to seven days per week—correlation analysis showed no significant associations between workload and lower limb dimensions. These findings align with prior research suggesting that static anthropometric characteristics, such as bone lengths and segmental circumferences, are largely established in adulthood and are minimally influenced by repetitive occupational exposure [11]. While physical workload may induce musculoskeletal strain and functional fatigue, it appears insufficient to produce measurable morphological changes in the lower limbs of adult drivers.

Comparative studies in transport and industrial workers support this observation, showing that while long hours and repetitive tasks contribute to musculoskeletal discomfort, they do not significantly alter static body dimensions [12]. In contrast, occupations involving dynamic, high-impact physical activity, such as manual load carriers or athletes, may exhibit subtle morphological adaptations over time [13]. This distinction highlights that the type and intensity of physical activity, rather than the duration alone, are critical for anthropometric changes.

From an ergonomic perspective, these findings emphasize that interventions should prioritize reducing functional strain rather than expecting occupational adaptation in limb morphology. Vehicle design, seating ergonomics, and scheduled breaks should consider the documented lower limb dimensions to minimize musculoskeletal risk. Furthermore, localized anthropometric data, as provided by this study, are essential for ergonomic planning in Bangladeshi urban transport contexts.

Therefore, occupational workload in Dhaka van drivers exerts a functional impact on musculoskeletal health without producing significant changes in lower limb anthropometry, underscoring the need for ergonomic interventions tailored to existing body dimensions.

CONCLUSION

Despite high occupational workload, lower limb dimensions of van drivers showed no significant relationship with work pattern or load exposure. These findings suggest that adult lower limb morphology is largely unaffected by prolonged driving. Ergonomic interventions should focus on functional strain reduction rather than morphological adaptation, with localized anthropometric data informing vehicle design and occupational health strategies.

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