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ISSN: 2617-0817 E-ISSN: 2789-5912

Original Article

Glycemic Status at Presentation and One Month after Treatment with Insulin in Gestational Diabetes Mellitus Patients Attending Tertiary Level Hospital

DOI: dx.doi.org

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Received: 28 Jan 2024
Accepted: 4 Feb 2024
Published: 14 Nov 2024

Published by:
Sher-E-Bangla Medical College, Barishal, Bangladesh

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ABSTRACT

Introduction: *Gestational diabetes mellitus (GDM) is a global disease that requires good glycemic control. Insulin is considered to be the most effective pharmacological management. The objective of this study is to monitor the glycemic status of gestational diabetes mellitus patients at presentation and 1 month after treatment with insulin.* ***Methods & Materials:*** *A prospective analytical study was done in the Endocrinology Outpatient Department of Dhaka Medical College Hospital, selected by purposive sampling from January 2022 to December 2022. Patient information was noted in a structured data collection sheet which included socio-demographic characteristics, relevant medical history, glycemic status at presentation, and 1 month after treatment with insulin. The study was analyzed using SPSS version 26.0.* ***Result:*** *The highest age distribution was in the 26-30 years group (41.0%), with a mean age of 27.78±4.03 years. Most patients were overweight (52.2%), followed by obese (23.1%) and normal BMI (24.6%). Regarding insulin regimens, rapid-acting insulin analog was most common (40.3%), followed by basal-bolus (35.1%). A significant association was found between insulin regimen and parity (p=0.021). Only 17.9% had a previous history of GDM, while 68.7% had no comorbidities. Glycemic control improved significantly after one month of insulin therapy, with fasting glucose, post-prandial glucose, and HbA1c levels showing marked reductions (p<0.001).* ***Conclusion:*** *In Gestational Diabetes Mellitus patients at a tertiary hospital, insulin significantly improves FBG, PPBG, and HbA1c levels, with basal-bolus and rapid-acting insulin being the most effective and commonly used regimens.*

Keywords: *Gestational diabetes mellitus, Insulin, Glycemic Status, HbA1c*

(The Planet 2023; 7(2): 270-275)

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INTRODUCTION

Gestational diabetes mellitus (GDM) is considered a major global health problem because of its increasing prevalence and the well-known association between hyperglycemia in pregnancy and feto-maternal morbidity [1]. Fetal outcomes are closely linked to the severity of maternal hyperglycemia, influencing both short-term perinatal and neonatal complications, including macrosomia, shoulder dystocia, respiratory distress, hypoglycemia, polycythemia, and hyperbilirubinemia. Additionally, maternal hyperglycemia increases the risk of long-term sequelae, such as obesity and diabetes, later in the child's life [2]. As the pregnancy advances insulin resistance and diabetogenic stress due to placental contra-insulin hormones (estrogen, cortisol, and human placental lactogen) necessitate a compensatory increase in insulin secretion. When this mechanism fails due to pancreatic β cell inadequacy, gestational diabetes develops [3]. So a timely diagnosis and proper therapeutic strategies to achieve glycaemic control in the shortest time possible is crucial. As per global estimates of hyperglycemia in pregnancy, 20.9 million or 16.2% of live births to women were expected to have some form of hyperglycemia during pregnancy; 85.1% of these cases were estimated to be due to GDM, 7.4% cases due to other types of diabetes first detected pregnancy and 7.5% cases due to diabetes detected before pregnancy [4]. Women with GDM have an approximately 50% risk of developing type II diabetes over the next 10 years [5]. The prevalence of GDM varies from 1-28% depending on population characteristics, diagnostic measurement, and screening methods. The South East Asian region has a high prevalence of 24.2% [6]. In another study, the most recent prevalence of gestational diabetes mellitus in Bangladesh was 9.7% according to the WHO criteria [7]. Screening should be done for women having risk factors (at booking or as early as possible) and women aged≥ 25 years with no risk factors at 24-28 weeks gestation. Risk factors are, BMI >27kg/m^2, previous history of GDM, first-degree relative with GDM, ADA, ACOG guidelines are in support of providing stringent glycemic targets in pregnancy

ISSN: 2617-0817 E-ISSN: 2789-5912

and recommended FBG level ≤95 mg/dL (5.3mmol/L) and 1 hour and 2-hour postprandial glucose concentration to be ≤ 140mg/dL (7.8mmol/L) and ≤120mg/dL (6.7mmol/L) respectively [8,9,4]. A recent study in Bangladesh regarding postpartum persistence of GDM revealed frequencies of glycemic status defined by ADA and WHO were normal glucose tolerance 57.4% and 50%; impaired fasting glucose (IFG) 0.9% and 8.3%; impaired glucose tolerance (IGT): 23.1% and 12% and diabetes mellitus (DM): 14.8% and 14.8% respectively [10]. The NICE guideline recommends an individualized target of SBMG with due consideration of the risk of hypoglycemia. The guideline recommended maintaining capillary plasma glucose (CPG) fasting level as 96mg/dL (5.3 mmom/l) and 1-hour and 2-hour post prandial CPG as 140 mg/dL and 116 mg/dL (7.8 mmol/L and 6.4mmol/L) [4]. Fasting glucose over 90 mg/dl, 1-h after glucose load over 110 mg/dl, and HbA_{1c} levels of more than 5.3% increase the risk of macrosomia [11]. Insulin therapy is one of the key strategies in managing diabetes in pregnancy, medical nutritional therapy (MNT) and lifestyle changes alone are not enough for adequate glycemic control. When it fails to achieve glycemic goals after 1 week, insulin is prescribed. Intermediate acting human insulin Neutral Protamine Hagedorn (NPH) and a rapid-acting analog is used (either insulin lispro or aspart) which have been tested and found to be safe during pregnancy. Fifty percent of the insulin is given as a basal using the Neutral Protamine Hagedorn (NPH) and the other 50% as boluses before meals with one of the two rapid analogs to start. The regimens are based on predicted total daily insulin requirements according to current weight and stage of pregnancy as follows pre-pregnancy, 0.6 U/kg; first trimester (week 1–12), 0.7 U/kg; second trimester (week 13– 28), 0.8 U/kg; third trimester (week 29 –34), 0.9 U/kg; and term (week 35–39), 1.0 U/kg. These doses are starting doses only and it is necessary to rapidly adjust them to achieve glucose goals using home glucose monitoring data and HbA_{1C} testing [12]. Short acting insulin tends to lower post prandial glucose level, reduce the risk postmeal hypoglycaemia and improving glycemic control in women with GDM [13]. Long acting ones allow to control basal glycemia providing a flat and protracted pharmacodynamics profile [13,14]. This study aimed to assess glycemic status at presentation and one month after treatment with insulin in gestational diabetes mellitus patients.

METHODS & MATERIALS

This prospective analytical study was conducted from January 2022 to December 2022 in the Department of Pharmacology and Therapeutics, Dhaka Medical College. Data was collected from the Endocrinology Outpatient Department (OPD) of Dhaka Medical College Hospital, Dhaka. All the pregnant women of the 2nd and 3rd trimester aged from 18 years to 35 years visiting the Endocrinology Outpatient Department of Dhaka Medical College who had met the selection criteria were considered as the study population. A total of 134 patients were selected as study subjects by purposive type of non-probability sampling. Baseline data of fasting blood glucose (FBG), post-prandial blood glucose (PPBG), and HbA_{1c}, height, and weight were recorded in a data collection sheet during their first visit and expressed as data at presentation. Data was analyzed by The IBM® *SPSS* (Statistical Package for the Social Sciences) *Software Version 26.0*. Data were engineered into categorical variables based on the distribution of the data. Demographic characteristics were expressed as frequencies and percentages as applicable to be presented in tables and graphs. Glycemic status at presentation was compared to 1 month after treatment with insulin by a Paired t-test. In all analyses, differences were considered statistically significant at the 95% level. The study was done after approval of the Research Review Committee of Dhaka Medical College and ethical clearance was undertaken by the Ethical Review Committee of the same institute. Informed written consent was taken from each respondent.

Inclusion criteria:

- Pregnant women aged between 18 to 35 years
- Patients in their 2nd or 3rd trimester.
- Diagnosed with Gestational Diabetes Mellitus (GDM) and prescribed insulin therapy.

Exclusion criteria:

- Pregnant patients having Type I DM or previously diagnosed with Type II DM
- Patients who did not give consent to participate in the study.

RESULTS

Table – I: Age distribution of the study patients (*n*=134)

Age group	Number	Percentage
<20	6	4.5
21-25	37	27.6
26-30	55	41.0
31-35	36	26.9
Mean± SD	27.78±4.03	
Range (min-max)	18-35	

Table I shows the distribution of study patients by their age in years. The highest number of patients are in the 26-30 years age group which occupied 55 (41%), followed by the age group 21-25 years which occupied 37 (27.6%), 31-35 years which occupied 36 (26.9%) and the lowest patients are in age group <20 years which occupied 6 (4.5%). Mean± SD 27.78±4.03, Range (min-max) 18-35.

Table – II: Distribution of the study patients according to BMI (*n*=134)

BMI (kg/m²)	Number	Percentage
Normal (18.5-24.9)	33	24.6
Overweight (25.0-29.9)	70	52.2
Obese (>30.0)	31	23.1
Mean± SD	27.4±3.66	
Range (min-max)	20.03-39.64	

Table II shows the distribution of study patients according to BMI. Patients having normal BMI (18.5-24.9) were 33 (24.6%) in number, overweight (25.0-29.9) were 70 (52.2%) and obese (>30.0) were about 31 (23.1%). Mean± SD 27.4±3.66, Range (min-max) (20.03-39.64).

Table – III: Distribution of the study patients according to trimester (*n*=134)

Trimester	Number	Percentage
2nd trimester	69	51.5
3rd trimester	65	48.5

ISSN: 2617-0817 E-ISSN: 2789-5912

Table III shows the Distribution of the study patients according to trimester. Most of them 69 (51.5%) are from 2nd trimester and 3rd trimester 65 (48.5%).

Table – IV: Distribution of the study by insulin regimen (*n*=134)

Insulin Regimen	Number	Percentage
Rapid-Acting Insulin Analogue	54	40.3
Basal-Bolus	47	35.1
Split-Mix	15	11.2
Short-Acting Human Insulin	12	9.0
Pre-Mix	6	4.5

Table IV shows the distribution of the study patients by insulin regimen. Among them pre-mix 6 (4.5%), split mix 15 (11.2%), basal-bolus 47 (35.1%), rapid-acting insulin analog 54 (40.3%), and short-acting human insulin 12 (9.0).

Table – V: Association of insulin regimen with parity (*n*=134)

Insulin regimen	Primiparous (n=44)	Multiparous (n=90)	*p*-value
Pre-mix	1(2.3%)	5(5.6%)	0.021
Split-mix	2(4.5%)	13(14.4%)	
Basal bolus	12(27.3%)	35(38.9%)	
Rapid-acting insulin analogue	21(47.7%)	33(36.7%)	
Short-acting human insulin	8(18.2%)	4(4.4%)	

p-value obtained by Chi-square

Table V shows an association of insulin regimen with parity. In the case of primiparous, 21 (47.7%), 12 (27.3%), and 8 (18.2%) were rapid-acting insulin analog, basal-bolus regimen, and short-acting human insulin respectively. In the case of multiparous, 35 (38.9%), 33 (36.7%), and 13 (14.4%) were basal-bolus, rapid-acting insulin analog, and split mixed respectively.

Table – VI: Distribution of the study patients according to previous history of GDM (*n*=134)

Previous history of GDM	Number	Percentage
Yes	24	17.9
No	110	82.0

Table VI shows the distribution of the study patients according to previous history of GDM. Out of the total 134 patients, 24 (17.9%) had a previous history of GDM, and 110 (82%) had no history of previous GDM.

Table – VII: Distribution of the study patients according to comorbidity (*n*=134)

Comorbidity	Number	Percentage
Hypothyroidism	23	17.2
Others	19	14.2
None	92	68.7

Table VII shows the distribution of study patients according to comorbidity. 92 (68.7) patients didn't have any co-morbidity. 23 (17.2%) had hypothyroidism and others were 19 (14.2%).

Table – VIII: Comparison of glycemic status at presentation and after 1 month of treatment with insulin (*n*=134)

Parameters	Glycemic status		p-value
	At presentation	After treatment	
Fasting blood glucose (FBG)	6.94±2.51	6.11±1.80	<0.001*
Range	(3.70-18.40)	(3.6-16.4)	
Post-prandial blood glucose (PPBG)	10.69±3.51	8.88±2.96	<0.001*
Range	(5.40-27.40)	(4.8-24.6)	
HbA1c	7.40±2.17	6.71±1.83	<0.001*
Range	(4.6-16.0)	(4.0-14.0)	

Data were expressed as mean±SD. The P-value was obtained by Paired t-test and considered significant throughout the whole study.

Table VIII shows the mean FBG level at presentation and 1 month after treatment with insulin significantly reduced from 6.94±2.51 to 6.11±1.80 (p-value <0.001). Also the PPBG level at presentation and 1 month after treatment with insulin significantly reduced from 10.69±3.51 to 8.88±2.96 (p-value <0.001). HbA_{1c} also significantly reduced from 7.40±2.17 to 6.71±1.83 (p-value <0.001).

Table – IX: Comparison of fasting blood glucose (FBG) at presentation and after 1 month treatment with insulin on the basis of insulin regimen (*n*=134)

Insulin Regimen	FBG At presentation	FBG After 1 month	p-value
Pre-mix (n=6)	7.87±1.86 (5.4-10.0)	6.02±1.15 (4.1-7.2)	0.129
Split-mix (n=15)	7.93±2.61 (4.80-15.60)	6.32±1.37 (4.4-8.9)	0.022*
Basal bolus (n=47)	7.09±2.52 (3.70-18.4)	6.33±2.34 (4.0-16.4)	<0.001

ISSN: 2617-0817 E-ISSN: 2789-5912

Rapid acting insulin analogue (lispro/aspart) (n=54)	6.64±2.70 (3.90-18.4)	5.79±1.50 (3.6-12.2)	<0.001
Short acting human insulin (regular) (n=12)	6.08±1.11 (4.40-8.90)	6.43±1.30 (4.2-8.8)	0.431

Data were expressed as mean± SD p-value obtained by Paired t-test, and considered significant throughout the whole study.

Table IX shows comparison between FBG at presentation and 1 month treatment with pre-mix insulin (Mixtard 30/70) shows decrease in mean value from 7.87±1.86 to 6.02±1.15 and not significant. Here, FBG at presentation and 1 month treatment with split-mix insulin (actrapid 100U+insulatard 100U) shows decrease in mean value from 7.93±2.61 to 6.32±1.37 and not significant. FBG at presentation and 1 month after treatment with basal bolus insulin shows decrease 7.09±2.55 to 6.33±2.34 (p value <0.001). Treatment with rapid acting insulin analogue shows significant decrease in fasting blood glucose (FBG) is 6.64±2.70 to 5.79±1.50 (p value <0.001). Treatment with short acting human insulin shows increase in FBG from presentation to 1 month after treatment, which is, 6.08±1.11 to 6.43±1.30 and not significant throughout the study.

Table – X: Comparison of post prandial blood glucose (PPBG) at presentation and after 1 month treatment with insulin on the basis of insulin regimen (*n*=134)

Insulin regimen	At presentation	After 1m	p-value
Pre-mix (n=6)	11.32±3.63 (5.80-15.20)	9.17±1.97 (5.4-11.0)	0.083
Split-mix (n=15)	10.91±2.91 (7.30-1.30)	9.59±2.65 (5.2-15.1)	0.219
Basal bolus (n=47)	11.43±3.73 (5.60-22.4)	9.15±3.21 (5.0-20.0)	<0.001
Rapid acting insulin analogue (lispro/aspart) (n=54)	10.33±3.67 (5.40-27.40)	8.51±3.16 (4.8-24.6)	<0.001
Short acting human insulin (regular) (n=12)	8.86±1.69 (6.60-12.70)	8.48±1.46 (6.0-11.0)	0.253

Data were expressed as mean±SD p-value obtained by Paired t-test, and considered significant throughout the whole study.

Table X shows comparison between PPBG at presentation and 1 month treatment with pre-mix insulin (Mixtard 30/70) shows decrease in mean value from 11.32±3.63 to 9.17±1.97 and not significant. Here, PPBG at presentation and 1 month treatment with split-mix insulin (actrapid 100U+insulatard 100U) shows decrease in mean value from 10.91±2.91 to 9.59±2.65 and not significant (p value 0.219). PPBG at presentation and 1 month after treatment with basal bolus insulin shows decrease 11.43±3.73 to 9.15±3.21 and significant throughout the whole study (p value <0.001). Treatment with rapid acting insulin analogue shows significant decrease post-prandial blood glucose (PPBG) which is 10.33±3.67 to 8.51±3.16 (p value <0.001). Treatment with short acting human insulin shows decrease PPBG in at presentation to 1 month after treatment from 8.86±1.69 to 8.48±1.46 and not significant throughout the study.

Table – XI: Comparison of HbA_{1c} at presentation and after 1 month treatment with insulin on the basis of insulin regimen (*n*=134)

Insulin regimen	At presentation	After 1m	p-value
Pre-mix (n=6)	7.93±1.81 (5.0-10.0)	7.65±1.57 (5.0-8.90)	0.200
Split-mix (n=15)	8.11±1.69 (5.0-11.2)	7.09±1.20 (5.20-8.80)	0.005*
Basal bolus (n=47)	7.56±2.45 (5.0-16.0)	6.91±2.19 (4.0-14.0)	<0.001
Rapid acting insulin analogue (lispro/aspart) (n=54)	7.14±2.12 (4.6-16.0)	6.43±1.72 (4.0-12.0)	<0.001
Short acting human insulin (regular) (n=12)	6.77±1.82 (5.5-11.9)	6.18±1.36 (4.0-9.80)	0.420

Table XI shows comparison between HbA_{1c} at presentation and 1 month treatment with pre-mix insulin (Mixtard 30/70) shows decrease in mean value from 7.93±1.81 to 7.65±1.57 and not significant. Here, HbA_{1c} at presentation and 1 month treatment with split-mix insulin (actrapid 100U+insulatard 100U) shows decrease in mean value from 8.11±1.69 to 7.09±1.20 and significant throughout the whole study (p value 0.005). HbA_{1c} at presentation and 1 month after treatment with basal bolus insulin shows decrease 7.56±2.45 to 6.91±2.19 and significant throughout the whole study (p value <0.001). Treatment with rapid acting insulin analogue shows significant decrease in HbA_{1c} which is 7.14±2.12 to 6.43±1.72 (p value <0.001). Treatment with short acting human insulin shows decrease in HbA_{1c} from presentation to 1 month after treatment, which is, 6.77±1.82 to 6.18±1.36 and not significant throughout the study.

DISCUSSION

In this study the maximum number of study patients were in the age group 26-30 years, which is 55 (41%). Similar studies have been shown by Haque et al., which show the highest number of patients are in the age group 25-29 years, 44 (41.9%) in number [15]. Also, Nahar et al. showed in their study, that most of the patients are from the age group 26-30 years (43.5%) [16]. Considering BMI (Body Mass Index), it was found that 70 (52.2%) study patients were overweight, 33(24.6%) were normal and 31 (23.1%) were obese respectively. Studies by Nigatu et al. showed that 69% of GDM patients had BMI<25 and 31% had BMI >25 [17]. Nilofer et al. found obesity as a risk factor in 88.89% of GDM patients [18]. Distribution of study patients by trimester shows most of the patients are from 2nd trimester. A similar study done by Mazumder et al., showed most of the patients were from 2nd trimester as well, about 36 (36.5%) [19]. Association of insulin regimen with parity shows in the case of primiparous, 21 (47.7%), 12 (27.3%), and 8 (18.2%) were rapid-acting insulin analog, basal-bolus regimen, and short-acting human insulin respectively. In the case of multiparous, 35 (38.9%), 33 (36.7%), and 13 (14.4%) were basal bolus, rapid-acting insulin analog and split mixed respectively. Skajaa GØ et al. showed in their study that insulin requirement increases with

ISSN: 2617-0817 E-ISSN: 2789-5912

parity [20]. Among 134 patients, 110 (82%) patients had no previous history of gestational mellitus, and 24 (17.9%) had previous history of gestational diabetes mellitus. Similar to the study of Nigatu et al. where there was no history in 386 (99%) patients compared to 4 (1%) patients who had a previous history of gestational diabetes mellitus [17]. Haque et al. also showed in their study about 50% of patients had no history of GDM [15]. The presence of co-morbidities is very common in GDM patients. Number of patients 92 (68.7%) patients didn't have any co-morbidity, 23 (17.2%) had hypothyroidism and others were 19 (14.2%). It is dissimilar to the study conducted by Haque et al. [15]. The study showed that the majority of the patients (50%) were hypertensive. However, Uchamprina et al. showed in their study that in the presence of hypothyroidism, gestational diabetes mellitus develops more often, nearly 8 times more [21]. Here, the most frequently prescribed insulin regimen is basal 40.3% and basal-bolus 35.1 %. Gangopadhyay et al. show in his study about using rapid-acting insulin and also bolus/intermediate insulin for better control of glycemic status [4]. Comparison of glycemic status at presentation and 1 month after treatment with insulin causes a significant reduction in fasting blood glucose (FBG) which is 6.94±2.51 to 6.11±1.80 (p value <0.001), post prandial blood glucose (PPBG) which is 10.69±3.51 to 8.88±2.96 (p value <0.001) and HbA_{1c} 7.40±2.17 to 6.71±1.83 (p-value <0.001) respectively. Brown et al. show in his study, a similar reduction with insulin [22]. A comparison of glycemic status before and after one month of insulin treatment demonstrated significant improvements across different regimens. Basal-bolus therapy showed a reduction in fasting blood glucose (FBG) from 7.09±2.55 to 6.33±2.34, postprandial blood glucose (PPBG) from 11.43±3.73 to 9.15±3.21, and HbA1c from 7.56±2.45 to 6.91±2.19 ($p < 0.001$), with no hypoglycemic events. Rezai et al. and Seufart et al. also reported superior glycemic control with basal-bolus regimens [23,24]. Rapid-acting analogs (aspart, lispro) significantly improved FBG from 6.64±2.70 to 5.79±1.50, PPBG from 10.33±3.67 to 8.51±3.16, and HbA1c from 7.14±2.12 to 6.43±1.72 ($p < 0.001$). Banerjee et al., and Garcia-Dominguez et al., highlighted the effectiveness of analogs in improving glycemic control and reducing hypoglycaemia [25,26]. Split-mixed insulin (actrapid + insulatard) decreased FBG from 7.93±2.61 to 6.32±1.37 and HbA1c from 8.11±1.69 to 7.09±1.20 ($p = 0.005$), though the change in PPBG from 10.91±2.91 to 9.59±2.65 was not significant. O'Neill et al. found low-quality evidence supporting mixed insulin outcomes [28]. Pre-mixed insulin (Mixtard 30/70) reduced FBG from 7.87±1.86 to 6.02±1.15 and PPBG from 11.32±3.63 to 9.17±1.97, with HbA1c showing a minor decrease from 7.93±1.81 to 7.65±1.57 (non-significant). Short-acting human insulin led to an increase in FBG from 6.08±1.11 to 6.43±1.30, a non-significant decrease in PPBG from 8.86±1.69 to 8.48±1.46, and a slight reduction in HbA1c from 6.77±1.82 to 6.18±1.36. Pooransari et al. noted that human insulin required higher doses and longer treatment durations [28].

Limitations of The Study

The study participants were recruited from one selected tertiary hospital in Dhaka city. The result may not reflect the exact picture of the entire country. The present study was conducted in a very short period. The study recruited a relatively small sample size, which was also a limitation.

CONCLUSION

In Gestational Diabetes Mellitus patients attending a tertiary-level hospital, treatment with insulin provides a significant change in fasting blood glucose (FBG), post-prandial blood glucose (PPBG), and HbA_{1c}. Among the regimens used, Basal bolus and rapid-acting insulin provide the most significant change in the Fasting blood glucose (FBG), postprandial blood glucose (PPBG), and HbA_{1c} and are now used most commonly and efficiently. There was no history of hypoglycemia recorded during the study period. So, recommending these regimens can be useful for patients with gestational diabetes mellitus.

RECOMMENDATION

The study provides several recommendations for future research. First, it is suggested that the study be conducted with a larger sample size to enhance the reliability and generalizability of the findings. Additionally, extending the treatment period and incorporating a longer follow-up phase would provide more comprehensive insights into the outcomes. Finally, conducting the study across multiple hospitals would help ensure that the results are applicable to diverse healthcare settings and populations.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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