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ORIGINAL ARTICLE

Assessment of Glycosylated Fibronectin Level in Maternal Serum as a Predictor of Gestational Diabetes Mellitus

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ABSTRACT

Background: *Gestational diabetes mellitus (GDM) is associated with substantial maternal and neonatal risks, yet conventional screening at 24–28 weeks identifies hyperglycemia only after metabolic alterations are established. Early biomarkers may improve detection and intervention. Glycosylated fibronectin, a glycoprotein involved in cellular adhesion and endothelial function, has been suggested as a potential early predictor.* ***Objective:*** *This study aimed to assess maternal serum glycosylated fibronectin levels measured at 10–15 weeks of gestation as a predictor of subsequent GDM.* ***Methods & Materials:*** *A prospective cohort study was conducted at Dhaka Medical College Hospital from December 2020 to November 2021. Ninety-five pregnant women met the inclusion criteria after initial recruitment of 100 participants. Sociodemographic and clinical data were collected and serum glycosylated fibronectin levels were measured using ELISA. Participants underwent OGTT at booking, 24–28 weeks, with repeat testing at 34–36 weeks when required. Statistical analyses included ROC curve estimation and calculation of sensitivity, specificity, predictive values and relative risk.* ***Results:*** *GDM developed in 12.6% of participants. Mean glycosylated fibronectin was significantly higher in GDM compared with non-GDM women (226.7 ± 73.3 vs 114.2 ± 57.9 µg/ml). ROC analysis yielded an AUC of 0.895 (95% CI: 0.822–0.967). A cut-off value ≥145 µg/ml provided 83.3% sensitivity, 89.2% specificity and an accuracy of 88.4%. Women with elevated levels had a 20-fold increased risk of developing GDM.* ***Conclusion:*** *Elevated glycosylated fibronectin in early pregnancy is a strong predictor of GDM and may serve as a valuable biomarker for early screening.*

Keywords: *Gestational diabetes mellitus, glycosylated fibronectin, early prediction, biomarker*

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INTRODUCTION

Gestational diabetes mellitus (GDM) has emerged as a significant global public health concern, primarily because of its rising prevalence and the substantial short- and long-term complications it poses for mothers and their offspring. The global upward trend is largely attributable to the increasing burden of obesity, sedentary lifestyle and advanced maternal age, with reported prevalence varying widely between 3% and 25% depending on population characteristics and diagnostic criteria [1]. Population-based studies from Bangladesh similarly indicate a rising trend, with prevalence rates between 6% and 14%, reflecting both demographic changes and greater implementation of screening strategies [2]. GDM is defined as hyperglycemia first detected during pregnancy and according to the World Health Organization, the diagnosis is confirmed if one or more plasma glucose thresholds are met during a 75-g oral glucose tolerance test (OGTT). Although glucose intolerance often resolves following delivery, a considerable proportion of women subsequently

develop type 2 diabetes, suggesting shared pathophysiological pathways [3].

The maternal–fetal risks associated with GDM are well established. Adverse outcomes such as macrosomia, polyhydramnios, hypertensive disorders and increased risk of cesarean delivery are frequently reported, along with neonatal hypoglycemia and long-term metabolic disorders among offspring [4]. Pregnancy itself represents a diabetogenic state, driven by progressive insulin resistance induced by placental hormones including somatotrophin, cortisol, prolactin, progesterone and estrogen. Physiologically, pancreatic β-cell hypertrophy and hyperplasia aim to compensate for the rising insulin demand; however, when this compensatory response is inadequate, hyperglycemia develops [5,6]. Although the underlying mechanisms remain incompletely understood, evidence suggests that genetic predisposition, inflammatory pathways and fetoplacental endocrine signals collectively contribute to the manifestation of GDM [7,8].

Current international guidelines recommend universal screening using OGTT at 24–28 weeks' gestation [9]. However, this strategy often identifies GDM only after metabolic alterations have already occurred, limiting opportunities for early intervention. Researchers have therefore focused on identifying first-trimester biomarkers that may predict subsequent GDM. Several maternal serum markers—including metabolites, adipocyte-derived markers, placental proteins and glycosylated fibronectin—have been investigated, although results remain variable and sometimes contradictory [10]. Glycosylated fibronectin, a modified form of cellular fibronectin involved in cell adhesion, differentiation and matrix stability, has attracted particular interest. Altered patterns of glycosylation significantly influence protein structure and function and glycosylated fibronectin levels appear to be elevated in diverse pathological processes, including chronic inflammation, endothelial dysfunction and diabetes [11].

Evidence suggests that glycosylated fibronectin may be elevated during early pregnancy among women who later develop GDM, underscoring its potential as an early predictive marker. Only a limited number of studies have evaluated this biomarker, but several have reported promising diagnostic performance, with encouraging sensitivity and specificity profiles [12,13]. Proposed mechanisms include low-grade inflammation of pancreatic β-cells and increased endothelial dysfunction, both of which may enhance fibronectin release into maternal circulation. Additionally, leakage of amniotic fluid into the maternal bloodstream and hepatic production of fibronectin as an acute-phase reactant have been suggested as contributing factors [14].

Given the burden of GDM in Bangladesh and the limitations of current screening strategies, there is a compelling need for early, accessible and reliable biomarkers. Glycosylated fibronectin offers a non-invasive, potentially cost-effective option that may improve early detection and reduce GDM-associated complications. This study, therefore, evaluates maternal serum glycosylated fibronectin measured at 10–15 weeks' gestation as a predictive marker for GDM.

OBJECTIVES

The objective of this study was to evaluate whether maternal serum glycosylated fibronectin measured at 10–15 weeks of gestation can predict the subsequent development of gestational diabetes mellitus.

METHODS & MATERIALS

This prospective cohort study was conducted in the Department of Obstetrics & Gynecology, Dhaka Medical College Hospital, Dhaka, Bangladesh, from December 2020 to November 2021. A total of 100 pregnant women were initially enrolled at 10–15 weeks' gestation. After accounting for five losses to follow-up due to mid-trimester miscarriage and relocation, the final sample comprised 95 participants. The study population included pregnant women with viable singleton pregnancies who met the predefined eligibility criteria.

Selection Criteria

Inclusion criteria

- Singleton pregnancy at 10–15 weeks
- Age 18–35 years
- Willingness to participate and provide informed consent

Exclusion criteria

- Known diabetic or diagnosed with GDM at enrollment
- History of GDM in the previous pregnancy
- Family history of diabetes
- BMI >35 kg/m^2
- Medications affecting glucose or thyroid regulation
- Comorbid renal, hepatic, cardiac, pituitary, or thyroid disease
- Chronic infections
- Fetal abnormalities detected early in pregnancy
- Maternal age <18 or >35 years

Data Collection Procedure

Eligible women attending the antenatal clinic were identified through purposive sampling. After explaining the study procedures and obtaining informed consent, sociodemographic information, medical history and obstetric background were recorded using a pre-tested semi-structured questionnaire. Physical examination included measurement of height, weight and blood pressure using standardized equipment and protocols. Gestational age was confirmed by crown-rump length measured in an early ultrasound scan.

For biochemical assessment, 3 mL of venous blood was collected at 10–15 weeks of gestation. Serum was separated by centrifugation and stored at −20°C to −80°C until analysis. Glycosylated fibronectin concentrations were measured using ELISA kits processed according to the manufacturer's guidelines at the Clinical Pathology Laboratory, Dhaka Medical College Hospital. The Siemens Access Immunoassay Analyzer SMT-680 was used for quantification. As no universal biological reference range for glycosylated fibronectin exists, the study determined a cut-off value through ROC curve analysis conducted on the resulting dataset.

Participants were followed longitudinally through the second and third trimesters. A 75-g OGTT was performed at 24–28 weeks; if results were normal, a repeat OGTT was conducted at 34–36 weeks. Diagnosis of GDM was based on the WHO criteria. All GDM cases were followed biweekly or more frequently, depending on clinical need. Data collection

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followed a structured approach designed to ensure completeness, reliability and uniformity across all participants.

Ethical Considerations

Ethical approval was granted by the Institutional Review Board of Dhaka Medical College Hospital. Informed written consent was obtained from all participants after explaining the study processes and risks in understandable language. Confidentiality was ensured through anonymized data handling and secure storage.

Statistical Analysis

Statistical analyses were conducted using SPSS version 23.0. Continuous variables were summarized as means with standard deviations, while categorical variables were expressed as frequencies and percentages. Independent t-test and ANOVA assessed associations between glycosylated fibronectin and maternal characteristics. Chi-square tests evaluated relationships between categorical variables. ROC curve analysis determined optimal cut-off levels with corresponding sensitivity, specificity, predictive values and accuracy. P-values <0.05 were considered statistically significant.

RESULTS

Table I showed that almost two-thirds (66.3%) of patients belonged to the age group 21-30 years. Almost half (47.4%) of the patients completed secondary and above education level, 84(88.4%) patients were housewife, 57(60.0%) patients came from middle-income group families and 41(43.2%) of the patients were primiparous.

Table – I: Sociodemographic and Obstetric Characteristics of Study Population (*n* = 95)

Variables		Number of patients	Percentage
Age (years)	≤20	22	23.2
	21-30	63	66.3
	>30	10	10.5
Educational status	Illiterate	1	1.1
	Only can sign her name	7	7.4
	Primary	42	44.2
	Secondary and above	45	47.4
Occupational status	Housewife	84	88.4
	Working	11	11.6
Socio economic status	Lower	20	21.1
	Middle	57	60.0
	Upper	18	18.9
Parity	Nulliparous	25	26.3
	Primiparous	41	43.2
	Multiparous	29	30.5

Table II showed that mean age was found 24.6±4.6 years, mean BMI was 26.0±2.3 kg/m^2, mean parity was 1.1±0.8, mean gravida was 2.3±1.0 and mean serum glycosylated fibronectin 128.4±70.5 µg/ml.

Table – II: Distribution of Physical and Biochemical Parameters of Study Population

Characteristics	Mean±SD	Range
Age (years)	24.6±4.6	18.0-38.0
BMI (kg/m^2)	26.0±2.3	17.5-31.6
Parity	1.1±0.8	0.0-3.0
Gravida	2.3±1.0	1.0-5.0
Glycosylated fibronectin (µg/ml)	128.4±70.5	70.0-325.0

Table III showed that 2(16.7%) patients developed GOM with Glycosylated fibronectin <1450 ml and 10(83.3%) patients developed GDM with Glycosylated fibronectin 2145.0 µg/ml. The mean serum glycosylated fibronectin was significantly higher in patients with GDM than in non-GDM 22067873.26 № 114.22:57.93 µg/ml. That was statistically significant, p <0.001.

Table – III: Comparison of Glycosylated Fibronectin Among GDM and Non GDM Women

GDM	Number	Glycosylated fibronectin (µg/ml)		Mean±SD	p-value
		<145.0 (n=76)	≥145.0 (n=19)		
GDM	12	02 (16.7)	10 (83.3)	226.7±73.3	<0.001
Non GDM	83	74 (89.2)	09 (10.8)	114.2±57.9	

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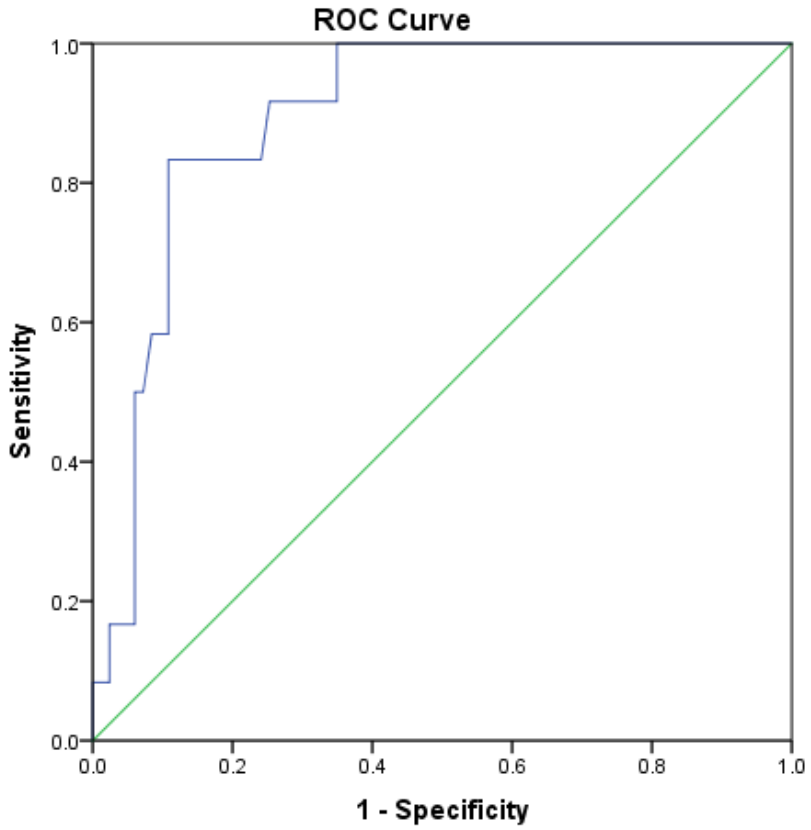

Figure – 2: ROC Curve of Glycosylated Fibronectin Level for Prediction of GDM

ROC analysis

Figure 1 shows ROC analysis of glycosylated fibronectin to predict GDM among pregnant women found an AUC value of 0.895 (95% CI, 0.822-0.967), which was statistically significant (p<0.001) (Table IV).

Table IV: Area Under Curve

Area Under the Curve				
Area under curve	Std. Error	p-value	95% Confidence Interval	
			Lower Bound	Upper Bound
0.895	0.037	<0.001	0.822	0.967

ROC analysis of glycosylated fibronectin to predict GDM among pregnant women found an AUC value of 0.895 (95% CI, 0.822-0.967) which was statistically significant (p<0.001).

A cut-off value of ≥145.0 µg/ml showed the highest Youden index (0.725) with 83.3% sensitivity, 89.2% specificity, 88.4% accuracy, 52.6% PPV and 97.4% NPV (Table V).

Table V: Youden Index of Serum Glycosylated Fibronectin (µg/ml) in Prediction of GDM

Cutoff value	Sensitivity	Specificity	PPV	NPV	Accuracy	Youden index (j=sen+spe-1)
123.5	0.833	0.867	0.476	0.973	0.863	0.701
145	0.833	0.892	0.526	0.974	0.884	0.725
177.5	0.75	0.892	0.5	0.961	0.874	0.642

Table VI shows that 10 out of 12 patients had GDM with serum glycosylated fibronectin ≥145.0 µg/ml. 9 out of 83 patients had no GDM with serum glycosylated fibronectin ≥145.0 µg/ml.

Table VI: Cross Tabulation of GDM Development with Glycosylated Fibronectin Level Based on Derived Cut-off Value

Glycosylated fibronectin (µg/ml)	GDM		Non GDM		Total
	n	%	n	%	
≥145.0	10	83.3	9	10.8	19 (TP+FP)
<145.0	2	16.7	74	89.2	76 (FN+TN)
Total	12	100	83	100	95
	(TP+FN)		(FP+TN)		(TP+FP+FN+TN)

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Table VII shows that the derived cut-off value of maternal serum glycosylated fibronectin (≥145.0 µg/ml) demonstrated strong diagnostic performance for predicting gestational diabetes mellitus, with a sensitivity of 0.83 (95% CI: 62.25–99.42%), specificity of 0.89 (95% CI: 82.47–95.85%), positive predictive value of 0.53 (95% CI: 30.18–75.08%), negative predictive value of 0.97 (95% CI: 93.77–99.97%) and an overall accuracy of 0.88 (95% CI: 81.99–94.86%).

Table – VII: Sensitivity, specificity, PPV, NPV and Accuracy Gained by the Derived Cutoff of Glycosylated Fibronectin with 95% Confidence Interval

Statistic	Value	95% CI
Sensitivity	0.8333	62.25% to 99.42%
Specificity	0.8916	82.47% to 95.85%
Positive Predictive Value	0.5263	30.18% to 75.08%
Negative Predictive Value	0.9737	93.77% to 99.97%
Accuracy	0.8842	81.99% to 94.86%

Table VIII showed that 2(16.7%) patients developed GDM with Glycosylated fibronectin <145.0 µg/ml and 10(83.3%) patients developed GDM with Glycosylated fibronectin ≥145.0 µg/ml. On the other hand, that 74(89.2%) patients did not develop GDM with Glycosylated fibronectin <145.0 µg/ml and 09(10.8%) patients did not develop GDM with Glycosylated fibronectin ≥145.0 µg/ml. Relative risk (RR) 20, 95% CI (3.95-14.97%). The difference was statistically significant (p<0.05).

Table VIII: Relative risk (RR) of development of GDM with serum glycosylated fibronectin ≥ 145.0 µg/ml.

GDM	Number	Glycosylated fibronectin (µg/ml)		RR (95% CI)	p value
		<145.0 n (%)	≥145.0 n (%)		
GDM	12	02 (16.7)	10 (83.3)	20	<0.001
Non GDM	83	74 (89.2)	09 (10.8)		

DISCUSSION

This prospective cohort study evaluated maternal serum glycosylated fibronectin levels measured between 10 and 15 weeks of gestation as an early predictor of gestational diabetes mellitus (GDM). The findings demonstrated a clear association between elevated glycosylated fibronectin and subsequent GDM development, supporting earlier observations that metabolic dysregulation begins well before standard screening at 24–28 weeks. The prevalence of GDM identified in this cohort (12.6%) corresponded with previous reports from South Asian populations, where rates ranging from 11% to more than 30% have been documented depending on diagnostic criteria and population characteristics. Behboudi-Gandevani et al. reported pooled prevalence exceeding 11% in the region, highlighting the regional significance of early detection strategies [15]. Similarly, Mazumder et al. demonstrated a prevalence of 35% in Bangladesh using DHS data, reflecting rising metabolic risks among reproductive-aged women [16].

The socio-demographic distribution in this study, characterized by a predominance of participants aged 21–30 years and high proportions of housewives and those from middle-income households, is consistent with prior observations indicating that GDM in South Asia often manifests among young multiparous women. The physical and biochemical characteristics observed here, including a mean BMI of 26.0 kg/m^2 and a mean fibronectin concentration of 128.4 µg/ml, also fall within ranges previously reported in similar cohorts.

One of the central findings of this study is the substantially higher mean glycosylated fibronectin level among women who developed GDM (226.7 ± 73.3 µg/ml) compared with those who did not (114.2 ± 57.9 µg/ml). This result aligns closely with the seminal work of Rasanen et al., who documented significantly elevated glycosylated fibronectin in first-trimester samples of women who later developed GDM [11]. Their study reported median concentrations notably higher in GDM cases, supporting the biomarker's discriminatory potential. The present results mirror that pattern and further confirm its reproducibility in a South Asian population. Although Alanen et al. observed no statistically significant difference between GDM and non-GDM groups in their Finnish cohort, they nonetheless reported elevated levels in the GDM group, indicating potential population variability in diagnostic thresholds [17]. Aker et al. similarly found no significant association with parity, maternal age, or BMI, echoing the current study's findings regarding demographic factors [18]. The consistency across studies suggests that while absolute values may differ by assay or population, the direction of association remains robust.

The ROC curve analysis in this study yielded an AUC of 0.895, demonstrating strong predictive capability. This performance is comparable to the AUC of 0.91 reported by Rasanen et al., who described glycosylated fibronectin as one of the most promising early biomarkers for GDM prediction [19]. The optimal cut-off value identified here (≥145 µg/ml) achieved a Youden index of 0.725, with 83.3% sensitivity and 89.2% specificity. These metrics suggest that incorporating glycosylated fibronectin into first-trimester screening could meaningfully improve early identification of at-risk women. Studies examining other biochemical markers, such as C-reactive protein, adiponectin, or SHBG, have often demonstrated lower sensitivity or specificity when used alone, reinforcing the comparative strength of glycosylated fibronectin [12,20].

Several biological mechanisms may explain the elevation of glycosylated fibronectin in early GDM. Previous research highlights the role of chronic low-grade inflammation and endothelial dysfunction in the pathogenesis of GDM. These processes contribute to increased secretion of cellular fibronectin, potentially altering glycosylation patterns [11]. Although this study did not evaluate mechanistic pathways directly, the current findings are consistent with the

understanding that glycosylated fibronectin reflects early disturbances in metabolic and endothelial functioning.

The cross-tabulation of fibronectin levels with GDM outcomes revealed that women with concentrations ≥145 µg/ml were 20 times more likely to develop GDM, a magnitude of relative risk that reflects the strong predictive value of this biomarker. This aligns with the diagnostic performance described by Rasanen et al. and supports its potential utility in early screening programs [19]. Moreover, the extremely high negative predictive value observed here (97.4%) suggests that low levels of glycosylated fibronectin may reliably exclude the risk of GDM, reducing the need for intensive surveillance among low-risk women.

Overall, these findings substantiate the role of glycosylated fibronectin as a strong early predictor of GDM. Integrating this biomarker into first-trimester screening may enable earlier lifestyle or pharmacological interventions, potentially reducing adverse maternal and neonatal outcomes. The study contributes valuable regional data to the evolving literature and underscores the importance of larger-scale investigations to validate cut-off thresholds and optimize clinical utility.

CONCLUSION

This study demonstrates that elevated maternal serum glycosylated fibronectin measured at 10–15 weeks of gestation is strongly associated with the subsequent development of GDM. Women with levels ≥145 µg/ml exhibited significantly higher risk and the biomarker showed excellent diagnostic performance, with high sensitivity, specificity and overall accuracy. These findings support the potential clinical utility of glycosylated fibronectin as an early predictor of GDM, allowing timely preventive interventions. Larger population-based studies are needed to validate the cut-off point and explore integration into routine antenatal screening programs.

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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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