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ORIGINAL ARTICLE

Association of Insulin-Like Growth Factor level in maternal serum as a predictor of Gestational Diabetes Mellitus

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ABSTRACT

Background: *Gestational Diabetes Mellitus (GDM) is a well-known complication in which spontaneous hyperglycemia develops during pregnancy. Insulin resistance is the key pathophysiological mechanism of GDM. The aim of this study was to assess the association of Insulin-Like Growth Factor-I (IGF-I) in maternal serum as a Predictor of GDM.* ***Methods & Materials:*** *Prospective cohort study was conducted in the Department of Obstetrics & Gynecology, Dhaka Medical College Hospital, Dhaka, Bangladesh during December 2020 to November 2021.* ***Results:*** *The age, parity and BMI of study population were not statistically significant (p>0.05) when compared with Insulin–Like Growth Factor-I. The mean serum Insulin –Like Growth Factor-I was significantly higher in patients with GDM than non GDM (387.4±110.5 vs 254.1±73.8 ng/ml). ROC analysis of Insulin –Like Growth Factor-I to predict GDM among the pregnant women found an AUC value of 0.875 (95% CI, 0.763-0.986) which was statistically significant (p<0.001). A cut-off value of ≥352.1 showed the highest youden index (0.771) with 85.7% sensitivity and 91.4% specificity, 90.5% accuracy, 63.2% PPV and 97.4% NPV. Increased serum Insulin –Like Growth Factor-I was found in 12(85.7%) in GDM group and 7(8.6%) in non GDM group with RR 24.0, 95% CI (5.86-98.31%). The difference was statistically significant (p<0.05) between GDM and non GDM groups.* ***Conclusion:*** *These findings revealed that increased maternal serum Insulin –Like Growth Factor-I at 8-12 weeks of gestation is associated with subsequent development of GDM. Elevated maternal serum Insulin –Like Growth Factor-I at 8-12 weeks of gestation can be used as a biomarker for prediction of GDM.*

Keywords: *Gestational Diabetes Mellitus, Insulin –Like Growth Factor-I, predictive biomarker*

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INTRODUCTION

Gestational Diabetes Mellitus is one of the most common pregnancy complications, affects 5% to 15% of pregnant women worldwide [1], which parallels the growing global epidemic of type 2 diabetes [2]. Prevalence of GDM varies significantly among different populations, ethnicities as well as with diagnostic criteria. Some population- based studies conducted in Bangladesh at different time points have revealed an increasing trend of GDM ranging from 6% to 14%. Gestational diabetes mellitus (GDM) is defined as glucose intolerance diagnosed during pregnancy that is not clearly preexisting diabetes [3]. According to WHO-2019 criteria which states that gestational diabetes mellitus should be diagnosed at any time in pregnancy if one or more of the following criteria are met: -

- Fasting plasma glucose 5.1-6.9 mmol/l (92 -125 mg/dl)
- 1-hour plasma glucose ≥ 10.0 mmol/l (180 mg/dl) following a 75g oral glucose load
- 2-hour plasma glucose 8.5-11.0 mmol/l (153 -199 mg/dl) following a 75g oral glucose load.

Diabetes in pregnancy should be diagnosed by the 2006 WHO criteria for diabetes if one or more of the following criteria are met:

- Fasting plasma glucose ≥ 7.0 mmol/l (126 mg/ dl)
- 2-hour plasma glucose ≥ 11.1 mmol/l (200 mg/dl) following a 75g oral glucose load
- Random plasma glucose ≥ 11.1 mmol/l (200 mg/ dl) in the presence of diabetes symptoms.

This condition usually returns to normal after pregnancy and those who have persistence glucose intolerance will develop type 2 Diabetes Mellitus (DM). Similarly, offspring of mothers with GDM have an increased risk of developing metabolic

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abnormalities during childhood, which may partly result from exposure to the altered intrauterine environment associated with GDM pregnancy [4].

Current concepts regarding the pathophysiology of GDM suggest that affected women have an underlying defect in pancreatic β-cell function, which becomes clinically evident when they are unable to adequately compensate for the pronounced insulin resistance that develops in the later stages of pregnancy. This insufficiency leads to the typical hyperglycaemia observed in the late second or third trimester [5,6]. It is now well established that metabolic disturbances precede the onset of GDM by a considerable period, prompting the identification of numerous biomarkers that may allow early detection of women at risk during the first trimester or even before conception [7,8,9,10].

The insulin-like growth factor (IGF) axis is an evolutionarily conserved regulatory system that plays a central role in cellular growth, proliferation, and survival, influencing almost all organ systems in the body. This axis comprises two principal growth factors, IGF-I and IGF-II, six IGF-binding proteins (IGFBP-1 to IGFBP-6), and nine IGFBP-related proteins (IGFBP-rPs) [11]. IGF-I is a peptide hormone with approximately 50% amino-acid sequence homology to proinsulin and, similar to insulin, consists of α- and β-chains linked by disulfide bonds [12]. The majority of circulating IGF-I is synthesized in the liver [13].

The objective of this study was to assess the association of Insulin-Like Growth Factor-1 (IGF-I) as a Predictor of GDM.

METHODS & MATERIALS

This prospective cohort study was conducted in the outpatient Department of Obstetrics and Gynaecology at Dhaka Medical College Hospital, Dhaka, Bangladesh from December 2020 to November 2021. A total of 95 pregnant women with viable singleton pregnancies between 8 and 12 weeks of gestation were enrolled using purposive sampling. Women aged 18–35 years without prior or current gestational diabetes mellitus (GDM), diabetes mellitus, family history of diabetes, obesity (BMI > 30 kg/m^2), or medical disorders affecting glucose or thyroid metabolism were included. Participants with hepatic, renal, pituitary, thyroid, cardiac diseases, chronic infections, medication influencing glycaemic status, prior pelvic surgery, fetal anomalies, or extreme maternal age were excluded.

After informed consent, socio-demographic, obstetric, and clinical data were collected using a pre-tested semi-structured questionnaire. Anthropometric measurements including height and weight were recorded using standardized procedures, and BMI was calculated. Gestational age was confirmed by early ultrasonography. At enrollment, fasting blood glucose and 2-hour plasma glucose after a 75-g oral glucose load were measured. Additionally, 5 mL of maternal venous blood was collected at 8–12 weeks for estimation of serum insulin-like growth factor-I (IGF-I). Serum was separated by centrifugation, stored at −80 °C, and analyzed by ELISA in the Department of Clinical Pathology laboratory. An IGF-I cutoff value of ≥352.1 ng/mL for prediction of GDM was determined from receiver operating characteristic (ROC) analysis.

Participants were followed throughout pregnancy. Oral glucose tolerance testing (OGTT) was repeated at 24–28 weeks and, if normal, again at 34–36 weeks. GDM was diagnosed according to WHO 2013 criteria. Data were analyzed using SPSS version 25. Continuous variables were expressed as mean ± SD and categorical variables as frequencies and percentages. Chi-square, Student's t-test, and ANOVA were applied as appropriate. Sensitivity, specificity, predictive values, accuracy, and ROC curves were calculated, and $p < 0.05$ was considered statistically significant. Ethical approval was obtained from the institutional ethics committee, and confidentiality was maintained throughout the study.

RESULTS

Table I shows that majority (66.3%) patients belonged to 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 family and 41(43.2%) of the patients were primiparous.

Table – I: Socio-demographic and obstetric characteristics of the study population (*n*=95)

Variables	Number of patients	Percentage
Age (years)		
18-20	23	24.2
21-30	63	66.3
31-35	9	9.5
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	27	28.4
Primiparous	41	43.2
Multiparous	27	28.4

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Table II Demonstrates that mean age was found 24.6±4.3 years, mean BMI was 25.8±2.0 kg/m², mean parity was 1.03±0.82, mean gravida was 2.17±0.99 and mean serum Insulin –Like Growth Factor-I was 273.7±92.6 ng/ml.

Table – II: Distribution of physical and biochemical parameters of study population (*n*=95)

Characteristics	Mean±SD	Range
Age (years)	24.6±4.3	18.0-35.0
BMI (kg/m²)	25.8±2.0	21.0-30.8
Parity	1.03±0.82	0.0-3.0
Gravida	2.17±0.99	1.0-5.0
Insulin –Like Growth Factor (nmol/L)	273.7±92.6	93.2-700.0

Table III shows that age, parity and BMI were not statistically significant (p>0.05) when compared with Insulin –Like Growth Factor-I.

Table – III: Mean variation of Insulin –Like Growth Factor-I among the study population (*n*=95)

Variables	Number	Insulin –Like Growth Factor-I (ng/ml) Mean± SD	p-value
Age (years)			
≤20	23	306.6±114.1	0.096
21-30	63	259.4±78.3	
>30	9	289.7±111.4	
Parity			
Nulliparous	27	273.5±120.1	0.695
Primiparous	41	265.9±86.7	
Multiparous	27	285.7±69.2	
BMI			
Normal (18.5-22.9 kg/m²)	10	275.0±78.9	0.836
Overweight (23.0-24.9 kg/m²)	15	260.5±100.0	
Pre-obese (25.0-29.9 kg/m²)	70	276.3±93.8	

p-value obtained from ANOVA test

Table IV it appears from the table that a significant difference of serum insulin-like growth factor-I was found between GDM and non GDM pregnant women (p<0.001). The mean±SD of maternal serum insulin-like growth factor-I was 387.4 ± 110.5 ng/ml for GDM, whereas it was 254.1± 73.8 ng/ml for women who were normal.

Table – IV: Comparison of Insulin –Like Growth Factor-I among GDM patients (*n*=95)

GDM	Number	Insulin –Like Growth Factor-I (ng/mL)		p-value
		Mean	Std. Deviation	
GDM	14	387.4	110.5	<0.001
Non GDM	81	254.1	73.8	

p-value obtained from unpaired t-test

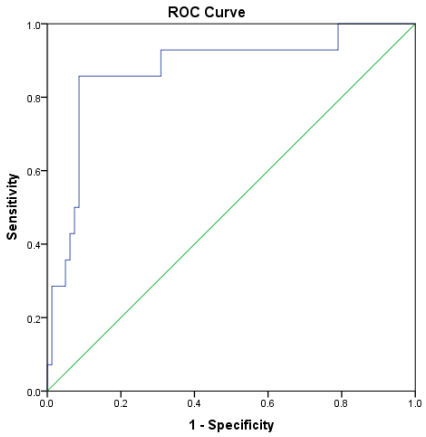

Figure – 1: ROC curve of Insulin –Like Growth Factor-I for prediction of GDM

Figure 1 shows ROC analysis of Insulin –Like Growth Factor-I to predict GDM among the pregnant women found an AUC value of 0.875 (95% CI, 0.763-0.986) which was statistically significant (p<0.001). A cut-off value of ≥352.1 showed the highest youden index (0.771) with 85.7% sensitivity and 91.4% specificity, 90.5% accuracy, 63.2% PPV and 97.4% NPV (*Table V*).

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Table – V: Youden index of Insulin –Like Growth Factor-I for prediction of GDM

Cutoff value	Sensitivity	Specificity	PPV	NPV	Accuracy	youden index (j=sen+spe-1)
348.0	0.857	0.901	0.600	0.973	0.894	0.758
352.1	0.857	0.914	0.632	0.974	0.905	0.771
356.8	0.786	0.914	0.611	0.961	0.895	0.699

It appears from table 3.8 that 12 out of 14 patients had GDM with serum Insulin –Like Growth Factor-I ≥352.1 ng/ml, 7 out of 81 patients had no GDM with IGF-I ≥352.1 ng/ml (*Table VI*).

Table – VI: Cross tabulation of GDM development with Insulin –Like Growth Factor-I based on derived cut-off value ≥352.1 ng/ml (*n*=95)

Insulin –Like Growth Factor-I (ng/ml)	GDM		Non GDM		Total
	n	%	n	%	
≥352.1	12	85.7	7	8.6	19 (TP+FP)
<352.1	2	14.3	74	91.4	76 (FN+TN)
Total	14 (TP+FN)	100.0	81 (FP+TN)	100.0	95 (TP+FP+FN+TN)

Table VII shows the diagnostic performance of maternal serum Insulin-Like Growth Factor-I (IGF-I) for predicting gestational diabetes mellitus (GDM) using the derived cutoff value (≥352.1 ng/mL). The sensitivity of IGF-I was 85.71% (95% CI: 67.38–99.04%), indicating that most women who developed GDM had elevated IGF-I levels in early pregnancy. The specificity was 91.36% (95% CI: 85.24–97.48%), demonstrating a high ability of the test to correctly identify non-GDM mothers. The positive predictive value was 63.16% (95% CI: 41.47–84.85%), whereas the negative predictive value was very high at 97.37% (95% CI: 93.77–99.97%), suggesting that women with IGF-I below the cutoff were unlikely to develop GDM. Overall diagnostic accuracy of IGF-I for prediction of GDM was 90.53% (95% CI: 84.64–96.42%).

Table – VII: Sensitivity, specificity, PPV, NPV and accuracy gained by the derived cutoff of Insulin –Like Growth Factor-I with 95% confidence interval

Statistic	Value	95% CI
Sensitivity	85.71%	67.38% to 99.04%
Specificity	91.36%	85.24% to 97.48%
Positive Predictive Value	63.16%	41.47% to 84.85%
Negative Predictive Value	97.37%	93.77% to 99.97%
Accuracy	90.53%	84.64% to 96.42%

Table VIII shows that Relative Risk (RR) is 24.0 which means the women who had IGF-I ≥352.1ng/ml has 24 times more chance to develop GDM.

Table – VIII: Relative risk (RR) of development of GDM with serum insulin-Like growth factor-I ≥352.1 ng/ml

Insulin –Like Growth Factor (ng/ml)	GDM		Non GDM		RR (95% CI)	P value
	n	%	n	%		
<352.1	2	14.3	74	91.4	24.0 (.763-.986)	<0.001
≥352.1	12	85.7	7	8.6		

p-value obtained from chi square test

DISCUSSION

Table I shows that majority 63(66.3%) patients belonged to age group 21-30 years. Almost half 45(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 family and 41(43.2%) of the patients were primiparous. According to Zhu et al. study, 17 (15.9%) had less than a high school diploma, 15 (14.0%) had a high school diploma or equivalent, and 75 (70.1%) had more than a high school diploma [14]. Nulliparity was identified in 48 (44.9%). Pre-pregnancy BMI (kg/m2) was 25.0 (34.6%), 25.0-29.9 (32.7%), 30.0-34.9 (20 (18.7%), and 35.0-44.9 (15 (14.0%).

In this study observed that the mean age was found 24.6±4.3 years, mean BMI was 25.8±2.0 kg/m^2, mean parity was 1.03±0.82, mean gravida was 2.17±0.99 and mean serum Insulin –Like Growth Factor was 273.7±92.6 ng/ml. Similar observation was found Kumru et al., study they showed the mean age were 28.6 ± 4.6 year, mean gravida 1.9 ± 0.9 , mean parity 0.5 ± 0.8, and mean BMI were 24.9 ± 2.8 [15]. Luo, et al., reported mean serum IGF-I was found 315.5±131.2 ng/ml [16]. Yang, et al. observed the mean age was found 29.9±4.0 years, parity was 0.7±0.7, gravida was 2.3±1.2 and BMI was 26.3±3.0 kg/m^2 [17]. Another study Zhu et al., and Lappas reported that mean age was found 30.5±5.7 years and 34.8±5.3 years [14,18]. Liao, et al., reported mean maternal age was found 31.4±0.9 years [19].

Table III Demonstrate that mean variation of insulin-Like Growth Factor-I among different categories of study population like, age, parity & BMI. No statistical significance was found between the variables and IGF-I level (p>0.05). Alanen et al., demonstrate that mean variation of insulin-Like Growth Factor-I among different categories of study population like, age, parity & BMI [20]. No statistical significance relation was found between the variables and IGF-I level (p=>0.05).

Table III showed that age, parity, and BMI were not substantially related to GDM p-value (>0.05.) According to Wagan et al., the major determinants of GDM were high maternal age (>30 years), high parity (>3), previous history of GDM, and family history of GDM [21]. Because of our inclusion criteria, this does not correspond with our study. Our age ranged from 18 to 35 years, and our BMI was ≤30 kg/m^2, majority of the patients were primi parous (43.2%).

Our study showed that the mean serum Insulin –Like Growth Factor-I was significantly higher in patients with GDM than non GDM (387.4±110.5 vs 254.1±73.8 nmol/L). Luo et al., reported that mean IGF-I was found 403.6±171.8 ng/ml in GDM and 307.0±123.6 ng/ml in control groups [16]. Another study Ramirez et al., found that mean IGF-I was found 173.96±65.04 ng/ml in GDM and 197.0±191.1 ng/ml in control groups [22]. Zhu et al., reported that mean IGF-I was found 217.5±92.2 ng/ml in GDM and 181.9 ±70.3 ng/ml in control groups [14]. Liao et al., reported maternal IGF-1 concentrations in GDM pregnancies were significantly higher than in controls (275.7 ± 11.5 ng/ml vs. 218.5 ± 11.1 ng/ml, p <0.001) [19]. Geca, et al. observed Mean maternal IGF-1 was found 262.98 ng/ml in patients with GDM [23]. Wang et al., reported IGF-I concentrations in mid-gestation were elevated in GDM vs euglycemic pregnancies P < 0.0001 [24].

As value of IGF-I varies with maternal age, gestational age, BMI no definite value of IGF-I was identified. In this study ROC curve of IGF-I level showed AUC value of 0.875 (95% CI, 0.763-0.986) which was statistically significant (p<0.001). Optimum predictive value was calculated from the co-ordinates of the curve table. According youden index (0.771) the best of Cut-off value was ≥352.1 ng/ml with highest youden index (0.771) with 85.7% sensitivity, 91.4% specificity, 90.53% accuracy, 63.16% PPV and 97.4% NPV.

Considering predictive value of IGF-I level the study population divided into two groups. GDM group (n=12) had the cut-off value of IGF-I ≥352.1 ng/ml and non GDM group (n=74) had cut-off value <352.1 ng/ml. Geca et al., reported a statistically significant positive correlation was observed between the concentrations of IGF-I in the peripheral blood of women with GDM (p< 0.0001) [23]. Zhu et al., reported maternal serum IGF-I may be implicated in the pathogenesis of GDM, with significant associations and incremental predictive value detected as early as gestational weeks 10–14 earlier before GDM is typically screened for [14].

This study showed among the study population with insulin-like growth factor-I level ≥352.1 ng/ml, 12(85.7%) patient were found to developed GDM and 7(8.6%) patients did not developed GDM with RR 24.0% CI (.763-.986%) which means the women who had IGF-I ≥352.1ng/ml has 24 times more chance to develop GDM. The difference was statistically significant (p<0.05) between GDM and non GDM patients. According to Wang et al., IGF-I concentration at 10-14 weeks of gestation was positively associated with subsequent development of GDM [24]. Compared to the highest vs. lowest quartiles in IGF-I concentration, there was a 2.87-fold increased risk of GDM after adjusting for major risk factors (RR = 2.87, 95% CI 1.28-6.42, P = 0.02).

Early disease identification may reduce the adverse fetal and maternal consequences of that disease. Women at risk for GDM identified 8-12 weeks of pregnancy could follow the lifestyle modifications earlier than usual pregnancy. Large scale prospective study involving diverse group of population are warranted to clarify the association between first trimester Insulin-like growth factor level and development of GDM.

LIMITATIONS

The study population was selected from one selected hospital in Dhaka city, so that the results of the study may not reflect the exact picture of the country. Small sample size was also a limitation of the present study. Therefore, in future further study may be under taken with large sample size.

RECOMMENDATIONS

Further studies on a large scale are recommended for the well establishment of the fact that Insulin –Like Growth Factor-I in maternal serum at 8-12 weeks of gestation is a good predictor for GDM. So that, people like ours can get the benefit of this simple non-invasive biomarker. Awareness should be developed among obstetricians towards prediction and early intervention of pregnancy complication by using different biomarkers.

CONCLUSION

The result of this study indicated that pregnant women with high serum Insulin –Like Growth Factor-I ≥352.1 ng/ml at 8-12 weeks had greater risk of developing GDM. Sensitivity, Specificity, PPV, NPV of this diagnostic test was 85.71%, 91.36%, 63.16%, 97.37% respectively and accuracy is 90.53%. Among these 95 respondents, those having serum Insulin –Like Growth Factor-I level ≥352.1 ng/ml relative risk (RR) of development of GDM was 24.0. As measurement of serum Insulin –Like Growth Factor-I level is simple and easy to carry out, it can be used as a predictive biomarker for those who are at increased risk for the subsequent development of GDM.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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