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Original Research Article

Early diagnosis of gestational diabetes mellitus by HbA1c as a predictor-Prospective observational study

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Abstract

Background: Gestational diabetes mellitus (GDM) is a common pregnancy complication linked to various maternal and neonatal risks. Early diagnosis is crucial for timely intervention and reducing complications. This study evaluates the efficacy of HbA1c as an early diagnostic adjunct for GDM, combined with fasting blood sugar (FBS) levels, to establish a cost-effective first-trimester screening method.

Materials and Methods: A prospective observational study was conducted from 2023 to 2025 at Shri B. M. Patil Medical College, Karnataka, India, involving 123 antenatal women. Inclusion criteria encompassed women aged ≥18 years, in their first trimester, with confirmed intrauterine pregnancy, and no prior diabetes or GDM history. HbA1c and FBS were measured in the first trimester. Those with abnormal FBS or HbA1c were further tested using the DIPSI method and oral glucose tolerance test (OGTT) for GDM diagnosis. The HbA1c threshold of 6.5% was used in line with ADA standards for overt diabetes. Maternal and neonatal outcomes were assessed, and data analyzed using SPSS software.

Results: A total of 16 women were diagnosed with GDM (13%). The mean HbA1c in the first trimester was significantly higher in the GDM group (5.64 ± 0.32) compared to the non-GDM group (4.99 ± 0.46). HbA1c showed high sensitivity (97.1%) and specificity (100%) for diagnosing GDM. Abnormal FBS was noted in 75% of the GDM group compared to 9.3% in the non-GDM group. Neonatal outcomes, including higher birth weight and NICU admissions, were significantly worse in the GDM group.

Conclusion: HbA1c, when used alongside FBS, may serve as an effective early predictor for GDM but cannot substitute the standard DIPSI or OGTT diagnostic criteria. Early identification through combined screening enables timely intervention and may help reduce maternal and neonatal risks.

Keywords: Gestational diabetes mellitus, Early diagnosis, HbA1c.

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1. Introduction

Gestational diabetes mellitus (GDM) is defined as a condition characterized by varying levels of carbohydrate intolerance that is first identified during pregnancy.[1] The physiological changes during pregnancy, particularly in the second and third trimesters, are characterized by increasing insulin resistance, primarily due to the secretion of placental hormones like human placental lactogen, progesterone, cortisol, and growth hormone.[2] This metabolic shift is crucial for fetal growth but can unmask glucose intolerance in susceptible women. Pregnant women diagnosed with GDM are at heightened risk of several maternal and neonatal complications, making early identification and management vital.[3] Adverse maternal outcomes include hypertensive disorders, preeclampsia, polyhydramnios, increased cesarean section rates, and long-term risk of developing type 2 diabetes mellitus (T2DM).[4] For the fetus, GDM increases the risk of macrosomia, neonatal hypoglycemia, respiratory distress, congenital malformations, and future obesity or metabolic syndrome.[5]

Globally, GDM affects approximately 7% of pregnancies, but the prevalence varies widely across

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populations and regions, influenced by ethnicity, lifestyle, and screening methods used.[6,7] In India, GDM prevalence is around 6–9% in rural areas and rises significantly to 12–21% in urban populations, primarily due to increasing urbanization, sedentary lifestyle, and dietary transitions.[7] Asian Indian women, in particular, exhibit higher insulin resistance and genetic predisposition, making them more susceptible to GDM. Studies have shown that GDM is diagnosed at different gestational stages — with 16.3% diagnosed at or before 16 weeks, 22.4% diagnosed from 17 to 23 weeks, 61.3% diagnosed beyond 23 weeks.[6,8] This highlights the importance of early detection to prevent adverse outcomes and reduce long-term risks to both the mother and the child, as GDM is now considered a condition affecting two generations.

Despite its growing significance, global consensus on the optimal screening strategies, timing, and diagnostic criteria for GDM remains lacking. Variations exist in fasting requirements, glucose doses, sample types (venous vs. capillary), and diagnostic thresholds, resulting in inconsistent practices worldwide.[9] In India, the Ministry of Health and Family Welfare recommends universal screening of all pregnant women as per the National Guidelines for Diagnosis and Management of GDM (2018), following WHO criteria.[7] Additionally, the Diabetes in Pregnancy Study Group India (DIPSI) and the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) guidelines are commonly used for diagnosis.[10,11] However, challenges remain in balancing affordability, accuracy, and feasibility of universal GDM screening, particularly in low-resource settings, necessitating the exploration of alternative screening tools.

Glycated hemoglobin (HbA1c), widely used for diabetes screening and monitoring outside pregnancy, has emerged as a potential adjunctive marker for early GDM detection. Since HbA1c reflects average blood glucose levels over the preceding 2–3 months, its utility during early phase of pregnancy could help identify women who are at high risk of GDM before glucose intolerance becomes clinically evident. Recent study suggests that HbA1c may be useful for prognosis and early risk stratification in pregnancies complicated by diabetes.[12]

The present study aims to evaluate the efficacy of HbA1c combined with fasting blood sugar (FBS) as a first-trimester screening method for GDM. By establishing a predictive model incorporating these parameters, the study seeks to contribute towards simplifying early screening, enabling timely interventions, and ultimately reducing maternal and fetal morbidity associated with GDM.

2. Materials and Methods

This prospective observational study has been conducted from 2023 to 2025, at Shri B. M. Patil Medical College, Karnataka. The study population comprised antenatal women with confirmed intrauterine pregnancies attending the OBG outpatient department. A total of 123 pregnant women were enrolled in the study. The sample size was initially calculated using the formula $n = (1.96)^2pq/d^2$, where p was 17.5% based on previous literature, q was 82.5%, and d was 7% absolute precision. The minimum calculated sample size was 114; however, during the study period, 123 eligible participants were recruited and included in the study.

Antenatal women aged 18 years or above, with a singleton pregnancy in the first trimester, not previously known to have diabetes mellitus or gestational diabetes, and willing to provide written informed consent were included in the study. Women were excluded if they had known hypertension, diabetes mellitus, GDM, systemic illnesses like coronary artery disease, liver disease, or renal disease. Ethical clearance was obtained from the Institutional Ethics Committee prior to study initiation. All participants were thoroughly informed about the study's purpose and procedures before enrolment.

Eligible antenatal women were screened during their first trimester. A thorough clinical history was taken, along with a physical examination, focusing on risk factors for gestational diabetes mellitus (GDM) such as family history of diabetes, past GDM, intrauterine death, recurrent pregnancy loss, macrosomia, and polycystic ovarian syndrome. Venous blood samples were collected from all participants for fasting blood glucose (FBS), glycated hemoglobin (HbA1c), and other routine antenatal investigations. Women with FBS >92 mg/dl or HbA1c <6.5% were considered for further testing in the second trimester using the DIPSI method with 75 grams of oral glucose. Based on plasma glucose levels after two hours, values <140 mg/dl were normal, 140–200 mg/dl indicated glucose tolerance was impaired, and >200 mg/dl confirmed overt diabetes.

For women with HbA1c levels <6.5% and DIPSI values between 140–200 mg/dl, a confirmatory 75g oral glucose tolerance test (OGTT) was performed following WHO 2013 guidelines. All women received standard antenatal care throughout the pregnancy. Those diagnosed with GDM received appropriate treatment and follow-up. Neonatal outcomes, including birth weight and NICU admissions, were recorded. Fasting blood glucose levels were monitored during follow-up visits to assess glycaemic control. Data were entered into Microsoft Excel and analyzed with SPSS version 26.0. Quantitative variables were reported as mean and standard deviation, and categorical variables were assessed using chi-square analysis. A p-value of ≤ 0.05 was deemed statistically significant.

3. Results

This study included 123 antenatal cases with confirmed intrauterine pregnancies of gestational age who were attending the Obstetrics and Gynecology OPD. The study population was divided into two groups: non-GDM (n=107)

and GDM (n=16). Both groups showed no significant differences in age distribution; the majority were aged 21-25 years, with 59.8% in the non-GDM group and 43.8% in the GDM group. Similarly both groups showed no significant differences in terms of BMI with most women in both groups having a BMI between 18.5 and 22.9. The parity distribution indicated that 40.2% of the non-GDM group were primiparous, compared to 18.7% in the GDM group, but this difference was not statistically significant (**Table 1**).

In the first trimester, the mean HbA1C was 4.99 ± 0.46 in non-GDM group, while in the GDM group it was 5.64 ± 0.32 (p = 0.0001). In the second trimester, the difference was even more pronounced, with HbA1C levels of 5.19 ± 0.41 in the non-GDM group and 6.36 ± 0.39 in the GDM group (p = 0.0001). The third trimester showed similar results, with the non-GDM group having a mean OGTT value of 100.47 ± 12.38, whereas the GDM group had a significantly higher mean of 152.00 ± 7.63 (p = 0.0001). Furthermore, a higher percentage of women in the GDM group had abnormal fasting blood sugar (FBS) (75%) compared to the non-GDM group (9.3%), which was statistically significant (p = 0.0001) (**Table 2**).

The majority of both groups delivered term infants (non-GDM 97.2%, GDM 100%), with no significant difference in preterm birth rates. However, the mode of delivery differed significantly between the two groups, with 93.7% of women in the GDM group delivering via cesarean section, compared to 26.2% in the non-GDM group (p = 0.002). Additionally, infants born to women with GDM had a higher birth weight (mean 3.39 ± 0.11 kg) compared to those born to women without GDM (mean 2.94 ± 0.26 kg), with a statistically significant difference (p = 0.0001). NICU admission was statistically significant with 87.5% of infants admitted in GDM group compared to 19.6% in the non-GDM group (p = 0.0001) (**Table 3**).

A moderate positive correlation was observed between FBS and HbA1C in both the first and second trimesters, with Pearson correlation coefficients of 0.518 (p = 0.0001) and 0.523 (p = 0.0001), respectively, indicating that as FBS levels increased, HbA1C levels also tended to rise (**Table 4**).

Table 1: Demographic and anthropometric comparison

Parameter		Non-GDM (n=107)	GDM (n=16)	p value
Age	< 20 years	11 (10.3%)	2 (12.5%)	0.67 (NS)
	21-25 years	64 (59.8%)	7 (43.8%)	
	26-30 years	27 (25.2%)	6 (37.5%)	
	> 30 years	5 (4.7%)	1 (6.3%)	
BMI	18.5-22.9	44 (41.1%)	7 (43.8%)	0.17 (NS)
	23-24.9	19 (17.8%)	0	
	25-29.9	44 (41.1%)	9 (56.2%)	
Parity	Primi	43 (40.2%)	3 (18.7%)	0.99 (NS)
	Multi	64 (59.8%)	13 (81.3%)	

Table 2: Glycaemic profile

Parameter	Non-GDM (n=107)	GDM (n=16)	p-value
1st Trimester HbA1C (Mean ± SD)	4.99 ± 0.46	5.64 ± 0.32	0.0001 (S)
2nd Trimester HbA1C (Mean ± SD)	5.19 ± 0.41	6.36 ± 0.39	0.0001 (S)
3rd Trimester OGTT (Mean ± SD)	100.47 ± 12.38	152.00 ± 7.63	0.0001 (S)
FBS Abnormal (%)	10 (9.3%)	12 (75%)	0.0001 (S)

Table 3: Pregnancy and neonatal outcomes

Parameter		Non-GDM (n=107)	GDM (n=16)	p-value
Maturity of baby	Preterm (%)	3 (2.8%)	0	0.49 (NS)
	Term (%)	104 (97.2%)	16 (100%)	
Mode of Delivery	LSCS (%)	28 (26.2%)	15 (93.7%)	0.002 (S)
	Vaginal (%)	79 (73.8%)	1 (6.3%)	
Birth Weight (Mean ± SD)		2.94 ± 0.26	3.39 ± 0.11	0.0001 (S)
NICU Admission (%)		21 (19.6%)	14 (87.5%)	0.0001 (S)

Table 4: Correlation between FBS and HbA1C

Parameter	Pearson Correlation	p value
1st Trimester	0.518	0.0001 (S)
2nd Trimester	0.523	0.0001 (S)

The utility of HbA1C and FBS for screening gestational diabetes mellitus was further evaluated using receiver operating characteristic (ROC) curves. **Figure 1** illustrates that HbA1C had a high sensitivity (97.1%) and specificity (100%) for diagnosing GDM, with a cut-off value of 5.61. In contrast, **Figure 2** shows that FBS had a sensitivity of 93.8% but a lower specificity of 52.8%, with a cut-off value of 86.5 for diagnosing GDM. These findings suggest that while both HbA1C and FBS are useful for screening GDM, HbA1C may offer more accurate results (**Figure 1** and **Figure 2**).

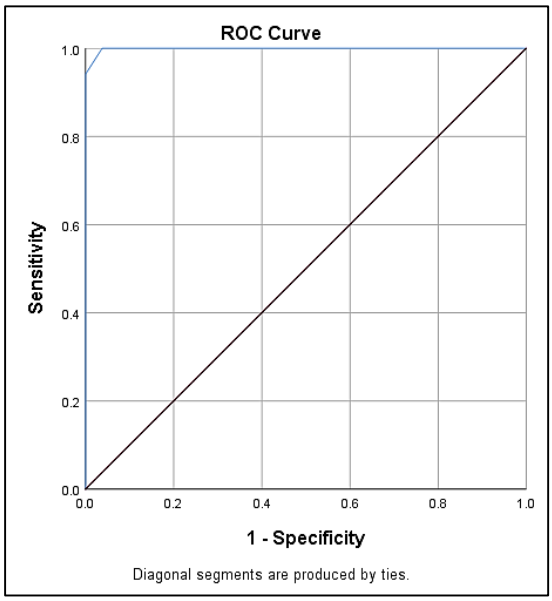

Figure 1: ROC curve of HBA1C for diagnosing gestational diabetes mellitus

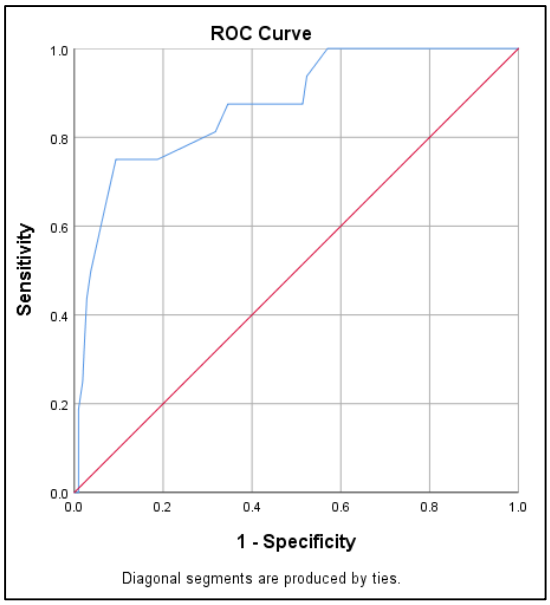

Figure 2: ROC curve of FBS for diagnosing gestational diabetes mellitus

4. Discussion

The present observational study conducted among 123 antenatal women aimed to evaluate the efficacy of HbA1c as an early predictive marker for gestational diabetes mellitus (GDM). The findings revealed a GDM incidence of 13%, which aligns closely with previous studies such as Shrivastava N et al. (13.6%) and Tong JN et al. (14.4%),[11,13] slight variation in prevalence across studies can be attributed to differences in diagnostic criteria and screening methods, including variations in oral glucose tolerance tests (OGTTs) and the use of adjunctive markers such as HbA1c. Importantly, this study demonstrated that HbA1c testing in the first trimester enables early identification of borderline GDM cases, which is critical for timely interventions to reduce pregnancy-related complications. However, it is important to note that HbA1c alone may not sufficient for a definitive diagnosis of GDM and should be interpreted alongside standard diagnostic protocols like DIPSI and OGTT. This supports the growing evidence that HbA1c is a practical and reliable supportive marker for GDM screening. While DIPSI and OGTT remain the gold standards as per guidelines, HbA1c offers a practical first-trimester screening option. Its use as a preliminary stratification tool can streamline identification of high-risk women before formal glucose testing is undertaken. However, current Indian guidelines do not formally recommend HbA1c in early pregnancy due to concerns about accuracy, underscoring the need for further research before national integration.

Demographic analysis revealed that most participants were aged 21–25 years, with a mean age of 24.42 ± 3.38 years, consistent with studies by Shrivastava N et al. (24.34 ± 3.7) and Singh A et al. (25.71 ± 3.39).[11,14] The similarity suggests that younger women are more likely to access antenatal care, making them an ideal population for early screening programs. Interestingly, no significant age difference was observed between diabetic and non-diabetic participants, consistent with Singh A et al.,[14] but contrasting with Valadan M et al.,[15] who reported higher mean ages for diabetic cases, these discrepancies may be from differences in study inclusion criteria or population demographics, highlighting the importance of tailoring diagnostic strategies to specific populations.

The study also found significant differences in BMI and fasting blood sugar (FBS) levels between diabetic and non-diabetic participants. Diabetic participants had a mean BMI of 24.58 ± 3.89 compared to 26.18 ± 5.02 for non-diabetics, which aligns with findings from Singh A et al.[14] Similarly, higher FBS levels were observed among diabetics (85.72 ± 6.52) compared to non-diabetics (95.81 ± 6.23), consistent with studies by Valadan M et al. and Parsaei M et al.[15,16] These results underscore the role of metabolic factors in GDM risk and reinforce the utility of HbA1c as a non-fasting screening tool that simplifies screening for both patients and healthcare providers.

Finally, HbA1c demonstrated high sensitivity (94.1%) and specificity (86.5%) for diagnosing GDM, comparable to Shrivastava N et al.'s findings.[11] Its positive predictive value

(PPV) of 98.1% further validated its reliability as a supportive marker. Although the ROC-derived optimal cut-off was 5.61%, the threshold of 6.5% was used for practical and comparative purposes with existing diagnostic criteria for overt diabetes. This approach allows for early identification of high-risk individuals while preserving specificity. Nevertheless, this underscores the need for further studies to refine cut-off values specifically for pregnant populations. Early HbA1c testing allowed timely lifestyle modifications that reduced adverse outcomes such as macrosomia and NICU admissions, emphasizing its clinical utility in antenatal care settings. Nevertheless, it should be emphasized that HbA1c cannot currently replace the DIPSI or OGTT diagnostic standards.

A key limitation of this study is its single-center design, which restricts the generalizability of the findings. Moreover, the use of HbA1c in pregnancy poses specific challenges, particularly in the Indian population where conditions like anemia and hemoglobinopathies are common. These factors can alter red blood cell turnover and influence HbA1c values independent of actual glycaemic control, potentially leading to misclassification. Future multi-center studies with larger and more diverse populations are essential to validate these findings, refine appropriate HbA1c cut-off levels, and account for such confounding variables to improve diagnostic accuracy.

5. Conclusion

This study highlights the potential of HbA1c, in combination with FBS, as a practical early predictive marker for gestational diabetes mellitus (GDM). HbA1c demonstrated higher sensitivity, specificity, positive predictive value, and negative predictive value, making it a feasible option to support early GDM risk stratification, especially in resource-limited settings. Its non-fasting requirement and single sample collection offer convenience for both antenatal care providers and patients. However, HbA1c should not replace established diagnostic criteria like DIPSI or OGTT but may serve as a helpful adjunct to improve early detection. Early identification of borderline GDM cases using HbA1c in the first trimester offers the advantage of timely intervention, potentially reducing adverse maternal and neonatal outcomes. Further larger, multi-centric studies are necessary to validate these findings and to determine appropriate thresholds before HbA1c can be routinely recommended as part of standard GDM screening algorithms.

6. Source of Funding

No.

7. Conflict of Interest

None declared.

8. Ethical Approval

Ethical committee approval: BLDE(DU)/IEC/878/2022-23.

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