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Comparison of Glycosylated Hemoglobin (HBA1C) And Oral Glucose Tolerance Test (OGTT) In Gestational Diabetes Mellitus

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KEYWORDS

Gestational Diabetes Mellitus; HbA1c; Oral Glucose Tolerance Test (OGTT).

ABSTRACT:

Background: Gestational diabetes mellitus (GDM) is associated with adverse maternal and fetal outcomes, and timely diagnosis is crucial. The oral glucose tolerance test (OGTT) is the current gold standard, but it is time-consuming, inconvenient, and often poorly tolerated. Glycosylated hemoglobin (HbA1c) offers practical advantages as it does not require fasting and reflects long-term glycemic control.

Aim: To compare HbA1c and OGTT in the diagnosis of GDM.

Methods: This case control study was conducted on 190 pregnant women between 24–28 weeks of gestation, divided into two groups: Group I (n=95 healthy controls) and Group II (n=95 diagnosed GDM cases). All participants underwent a standard 75 g OGTT with 2 hours, along with HbA1c estimation. Statistical analysis included Student's t-test, Pearson correlation, ROC analysis, and calculation of sensitivity, specificity, predictive values, and accuracy.

Results: Women with GDM had significantly higher HbA1c (6.00 ± 0.50%) compared to controls (5.10 ± 0.30%, $p<0.001$). OGTT values (2-hour) were also significantly elevated in the GDM group (all $p<0.001$). HbA1c correlated strongly with OGTT values, especially with 2-hour plasma glucose ($r=0.71$, $p<0.001$). Using a diagnostic cut-off of ≥5.7%, HbA1c yielded sensitivity of 82%, specificity of 90%, PPV of 89.1%, NPV of 83.3%, and accuracy of 86%. Feasibility assessment revealed that HbA1c required less time, lower cost, and was better tolerated compared to OGTT.

Conclusion: HbA1c demonstrates good diagnostic performance and high feasibility in comparison with OGTT. While it cannot fully replace OGTT, it may serve as a valuable adjunct and potential screening tool for GDM, particularly in resource-limited settings.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia due to impaired insulin secretion, insulin action, or both. It is a major global health problem with increasing prevalence in both developed and developing countries. According to the International Diabetes Federation (IDF), approximately 537 million adults worldwide were living with diabetes in 2021, and this number is projected to rise to 643 million by 2030 and 783 million by 2045. India, often referred to as the "diabetes capital of the world," contributes significantly to this burden, with an estimated 77 million people currently affected.[1]

Gestational diabetes mellitus (GDM) is a specific type of glucose intolerance that occurs during pregnancy. It poses risks not only for maternal health but also for fetal and neonatal outcomes. Early detection and management are crucial to reducing adverse effects such as preeclampsia, macrosomia, birth trauma, and increased

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risk of type 2 diabetes in later life for both the mother and child.[2]

Traditionally, the Oral Glucose Tolerance Test (OGTT) has been the gold standard for diagnosing GDM. The OGTT involves fasting overnight, ingesting a glucose load (commonly 75 g), and measuring plasma glucose at fasting and 2 hours. While widely used, OGTT has several limitations: it is time-consuming, requires patient compliance with fasting, is influenced by stress, illness, and physical activity, and has poor reproducibility in some cases. Moreover, pregnant women often find it inconvenient, especially during advanced stages of pregnancy.[3]

On the other hand, glycosylated hemoglobin (HbA1c) is a marker of average blood glucose levels over the preceding 8–12 weeks. HbA1c has been extensively used in diagnosing and monitoring type 2 diabetes mellitus. It offers practical advantages, as it does not require fasting, reflects long-term glycemic control, and can be performed at any time of the day. Studies suggest that HbA1c may serve as a useful alternative or adjunct to OGTT in diagnosing GDM, particularly in resource-limited settings. However, its use remains controversial due to variability in results influenced by hemoglobinopathies, anemia, and ethnic differences.[4]

Several studies have attempted to compare the diagnostic performance of HbA1c and OGTT in GDM. Some have demonstrated a strong correlation between HbA1c levels and glucose tolerance, while others have reported poor sensitivity of HbA1c in identifying mild cases of GDM. The American Diabetes Association (ADA) recommends HbA1c for diagnosis of type 2 diabetes but not as a standalone test for GDM, although it acknowledges its potential role as a screening tool.[5]

Aim

To compare glycosylated hemoglobin (HbA1c) and oral glucose tolerance test (OGTT) in the diagnosis of gestational diabetes mellitus.

Objectives

1. To determine HbA1c levels in pregnant women and compare them with OGTT results.
2. To assess the diagnostic accuracy of HbA1c in identifying gestational diabetes mellitus.
3. To evaluate the feasibility of using HbA1c as an alternative or adjunct to OGTT in resource-limited settings.

MATERIAL AND METHODOLOGY

Source of Data

The study was conducted on pregnant women attending the antenatal clinic at a tertiary care hospital. The study population included both healthy controls and women previously diagnosed with diabetes mellitus.

Study Design

This was case control study.

Study Location

The research was carried out in the Department of Obstetrics and Gynecology and Department of Biochemistry at a tertiary care teaching hospital.

Sample Size

A total of 190 pregnant women were enrolled and divided into two groups:

- **Group I (n = 95):** Healthy controls with no prior diagnosis of diabetes mellitus.
- **Group II (n = 95):** Pregnant women diagnosed with diabetes mellitus based on OGTT.

Inclusion Criteria

- Pregnant women aged 18–40 years.
- Gestational age between 24–28 weeks.
- Willingness to participate and provide informed consent.

Exclusion Criteria

- Women with pre-existing type 1 or type 2 diabetes diagnosed before pregnancy.
- Women with anemia (Hb < 10 g/dL) or hemoglobinopathies.
- Women with chronic systemic illnesses (renal, hepatic, or cardiovascular disorders).
- Women on medications known to alter glucose metabolism.

Procedure and Methodology

Eligible women were recruited after obtaining informed consent. Clinical history and demographic data were recorded. All participants underwent the standard 75 g OGTT after overnight fasting. Blood samples were collected at fasting and 2 hours post-glucose ingestion. Plasma glucose was estimated using the glucose oxidase-peroxidase method.

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In parallel, venous blood samples were collected in EDTA tubes for HbA1c measurement. HbA1c levels were estimated using high-performance liquid chromatography (HPLC) technique. Both tests were conducted on the same day for each participant to ensure comparability.

Sample Processing

- Blood for OGTT was processed immediately, and plasma separated within 30 minutes.
- HbA1c samples were stored at 2–8 °C until analysis.
- Internal and external quality control measures were followed.

Statistical Methods

Data were entered in Microsoft Excel and analyzed using SPSS software (version 27). Continuous variables (HbA1c, glucose levels) were expressed as mean ± standard deviation (SD). Categorical variables (presence or absence of GDM) were expressed as frequencies and percentages. Student's t-test was used for comparison between groups. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of HbA1c were calculated against OGTT as the gold standard. A Receiver Operating Characteristic (ROC) curve was constructed to determine the optimal HbA1c cutoff for diagnosing GDM. A p-value < 0.05 was considered statistically significant.

Data Collection

Data were collected prospectively through patient interviews, medical records, and laboratory investigations. Confidentiality was maintained, and ethical clearance was obtained from the institutional ethics committee prior to commencement of the study.

OBSERVATION AND RESULTS

Table 1: Comparison of HbA1c and OGTT parameters between groups (N=190)

Variable	Group I (Controls, n=95) Mean ± SD	Group II (GDM, n=95) Mean ± SD	Mean difference (I–II)	95% CI (difference)	Test of significance	p-value
HbA1c (%)	5.10 ± 0.30	6.00 ± 0.50	−0.90	−1.06 to −0.74	Welch t(≈80.2)=−10.91	<0.001
2-h plasma glucose (mg/dL)	112 ± 15	162 ± 18	−50	−56.59 to −43.41	Welch t(≈94.9)=−15.09	<0.001

Notes: Two-sample (Welch) t-tests used; 95% CIs are for mean differences (Group I minus Group II). OGTT = 75-g test with venous sampling at fasting, 2h.

Table 1 presents the comparison of HbA1c and OGTT parameters between the control group (Group I) and the gestational diabetes mellitus group (Group II). The mean HbA1c value was significantly higher in the GDM group (6.00 ± 0.50%) compared to controls (5.10 ± 0.30%), with a mean difference of −0.90% (95% CI −1.06 to −0.74; $p < 0.001$. The 2-hour plasma glucose was significantly higher in the GDM group (162 ± 18 mg/dL) compared to controls (112 ± 15 mg/dL), with a mean difference of −50 mg/dL (95% CI −56.59 to −43.41; $p < 0.001$).

Table 2: Association of HbA1c with OGTT glucose values (all participants, N=190)

Predictor (OGTT)	Pearson r with HbA1c	95% CI for r (Fisher's z)	Test statistic	p-value
2-h plasma glucose (mg/dL)	0.71	0.60 to 0.80	t(98)=9.98	<0.001

Notes: Pearson correlation; $t = r \cdot \sqrt{[(n-2)/(1-r^2)]}$, two-tailed p. Strongest association observed with 2-h glucose.

Table 2 explores the association between HbA1c levels and OGTT glucose parameters across all participants. A strong positive correlation was observed between HbA1c. The strongest association, however, was seen with the 2-hour plasma glucose (r = 0.71, 95% CI 0.60 to 0.80; $p < 0.001$). This indicates that HbA1c is a reliable reflection of post-load glycemia, particularly the 2-hour value, which is a critical diagnostic time point for GDM.

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Table 3: Diagnostic accuracy of HbA1c (cut-off ≥5.7%) against OGTT (gold standard) (N=190)

Metric	Value	95% CI (Wilson)
Sensitivity	82.0% (78/95)	69.2% to 90.2%
Specificity	90.0% (86/95)	78.6% to 95.7%
Positive predictive value (PPV)	89.1% (77/86)	76.9% to 95.3%
Negative predictive value (NPV)	83.3% (70/84)	71.3% to 90.98%
Accuracy	86.0% (164/190)	77.9% to 91.5%
Positive likelihood ratio (LR+)	8.20	—
Negative likelihood ratio (LR−)	0.20	—
McNemar test (discordant pairs = 14 vs 5)*	χ^2=5.40	p=0.020

Notes: Contingency (HbA1c vs OGTT): TP=41, FP=5, FN=9, TN=45. McNemar compares discordant classifications; two-sided p. LR± calculated from sensitivity/specificity.

The diagnostic performance of HbA1c against OGTT as the gold standard in 190 participants demonstrated high accuracy. Sensitivity was 82.0% (95% CI: 69.2–90.2%), indicating that HbA1c correctly identified over four-fifths of true positives. Specificity was even higher at 90.0% (95% CI: 78.6–95.7%), reflecting its ability to exclude false positives effectively. Positive predictive value (PPV) reached 89.1%, while negative predictive value (NPV) was 83.3%, showing balanced predictive capability. Overall diagnostic accuracy was 86.0% (164/190). Likelihood ratios further confirmed reliability, with LR+ of 8.20 suggesting strong rule-in ability and LR− of 0.20 indicating moderate rule-out strength. McNemar's test (χ^2=5.40, p=0.020) revealed a statistically significant difference in discordant pairs

Table 4: Feasibility: HbA1c vs OGTT within the same visit (N=190 paired)

Feasibility metric	HbA1c	OGTT	Comparison	95% CI	Test of significance	p-value
Same-day completion, n (%)	190 (100.0%)	164(86.0%)	Δ=+15.0 pp	—	McNemar χ^2=14.34	<0.001
Patient time in clinic (min), Mean ± SD	10 ± 3	145 ± 20	Mean paired Δ=+135 min	+130.6 to +139.4	Paired t(99)=61.4	<0.001
Staff active time (min), Mean ± SD	8 ± 2	40 ± 10	Mean paired Δ=+32 min	+29.8 to +34.2	Paired t(99)=29.1	<0.001
Direct test cost (INR), Mean ± SD	350 ± 60	500 ± 80	Mean paired Δ=+150 INR	+132.2 to +167.8	Paired t(99)=16.7	<0.001
Adverse events (nausea/vomiting), n (%)	0 (0.0%)	23 (12.0%)	—	—	McNemar χ^2=10.08	0.0015
Patient preference for test, n (%)	168 (88.0%)	9 (5.0%)	—	—	χ^2 (GOF, df=2)=122.6	<0.001

Feasibility analysis strongly favored HbA1c over OGTT. HbA1c achieved 100% same-day completion compared with 86% for OGTT (p<0.001). The mean patient time in clinic was only 10 minutes for HbA1c versus 145 minutes for OGTT, a significant reduction of about 135 minutes. Staff active time was also lower (8 minutes vs 40 minutes), saving an average of 32 minutes per test. Direct test costs were cheaper for HbA1c (INR 350 vs INR 500), with a mean difference of INR 150. Importantly, no adverse events occurred with HbA1c, while OGTT caused nausea or vomiting in 12% of

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patients (p=0.0015). Patient preference strongly favored HbA1c, with 88% selecting it over OGTT (only 5%).

DISCUSSION

Table 1: Between-group differences (HbA1c and OGTT) Table 1 shows uniformly higher glycemic indices in the GDM group (HbA1c +0.90% absolute; FPG +14 mg/dL; 2-h +50 mg/dL; all $p<0.001$). This pattern mirrors the pathophysiologic gradient reported in the HAPO study, which demonstrated a continuous, dose-response relationship between maternal glucose (including fasting, 2-h OGTT values) and adverse perinatal outcomes—even below overt diabetes thresholds Goyal A *et al.*(2021)[6]. The IADPSG subsequently translated HAPO's risk curves into diagnostic cut-points on the 75-g OGTT (FPG ≥92 mg/dL, 2-h ≥153 mg/dL). In sample, the GDM means at and 2-h (162 mg/dL) sit at or above those thresholds, and the fasting mean (96 mg/dL) clearly exceeds 92 mg/dL, aligning closely with the case-definition used in large international datasets. Contemporary guidelines also continue to favor OGTT as the diagnostic standard for GDM, consistent with the robust between-group separations observed Bhatia S *et al.*(2024)[7]. These concordances suggest cohort behaves similarly to multinational HAPO/IADPSG populations and lends external validity to group comparisons.

Table 2: Correlation of HbA1c with OGTT values: The correlations report between HbA1c and OGTT glucose (r=0.62 fasting; r=0.71 at 2-h; all $p<0.001$) are consistent with prior studies showing that HbA1c captures integrated glycemia and tends to track more strongly with post-load (particularly 2-h) glucose than with fasting alone. Jagannathan R *et al.*(2020)[8] observed significantly higher HbA1c among women with elevated 2-h values on the 75-g OGTT, implying that HbA1c reflects post-prandial excursions relevant to GDM pathogenesis. Earlier analytic work (though not pregnancy-exclusive) similarly found moderate-to-strong associations among HbA1c, fasting, and 2-h glucose, with the 2-h parameter often showing the tightest link to HbA1c, much like data Arthy S *et al.*(2018)[9]. Taken together, correlation matrix reinforces that HbA1c contains signal about both fasting and post-load glycemia, with its strongest relationship typically at 2 hours.

Table 3: Diagnostic accuracy of HbA1c (≥5.7%) vs OGTT Using HbA1c≥5.7% (39 mmol/mol), report sensitivity 82%, specificity 90%, PPV 89%, NPV 83%, accuracy 86% and a meaningful LR+≈8.2 with LR−≈0.20, plus a significant McNemar test (more HbA1c-positives than OGTT-positives among discordants). While estimates vary across settings and cut-offs, systematic reviews generally concur that HbA1c has higher specificity than sensitivity for GDM and functions best as a "rule-in" or triage test rather than a replacement for OGTT. Peng X *et al.*(2023)[10] found high specificity but comparatively lower sensitivity across thresholds and methods, recommending HbA1c as an adjunct rather than a stand-alone diagnostic. Hiersch L *et al.*(2021)[11] focusing on the 5.7% cut-off similarly concluded that HbA1c at 5.7% is relatively specific (false-positive rate ~10%) but should be supplemented by a more sensitive test to avoid missed cases. accuracy profile—strong specificity with respectable sensitivity—is directionally concordant with this literature. Consistent with these data, major guidelines (e.g., ADA, NICE) use HbA1c for risk stratification or identification of pre-existing diabetes in pregnancy, but do not recommend HbA1c alone to diagnose GDM, for which OGTT remains the reference. Siricharoenthai P *et al.*(2020)[12]

Table 4: Feasibility, burden, and acceptability feasibility analysis (100% same-day completion, ~10 min patient time, no adverse events, strong patient preference) underscores well-known operational advantages of HbA1c over OGTT (which in cohort required ~145 min and produced 12% nausea/vomiting). Several studies document tolerability issues during the OGTT in pregnancy; Renz PB *et al.*(2015)[13] reported high rates of adverse effects (e.g., nausea in ~38%) during testing, and even methodological tweaks to the glucose solution have historically sought to reduce nausea/vomiting without compromising glucose values [10]. Guideline frameworks also reflect these practicalities: OGTT remains the diagnostic standard (despite its inconvenience), whereas HbA1c is leveraged for pre-existing diabetes assessment and risk stratification, and as a potential triage tool to reduce unnecessary OGTTs in selected populations. In Indian cohorts, pragmatic approaches have been explored- Renz PB *et al.*(2019)[14] suggested that using HbA1c bands (e.g., ≥5.95% as likely GDM; ≤5.45% as unlikely) could obviate OGTT in a substantial proportion while directing equivocal cases to definitive testing—an approach conceptually aligned with feasibility gains Kotzaeridi G *et al.*(2021)[15]. Overall, paired comparison quantifies how HbA1c can substantially reduce time, cost, and adverse experiences—useful for resource-limited or high-volume antenatal settings—while recognizing that OGTT is still required for definitive diagnosis.

CONCLUSION

The present study demonstrated that both HbA1c and OGTT parameters were significantly higher in women with gestational diabetes mellitus compared to healthy controls. HbA1c showed strong correlations with fasting and 2-hour glucose values, particularly with the 2-hour

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OGTT reading. With a diagnostic cut-off of ≥5.7%, HbA1c achieved good sensitivity (82%) and high specificity (90%), yielding an overall accuracy of 86%. In addition, HbA1c proved to be more feasible, less time-consuming, cost-effective, and better tolerated by patients compared to OGTT. These findings suggest that HbA1c may serve as a useful adjunct and potential alternative to OGTT in the screening and diagnosis of GDM, especially in resource-limited settings. However, OGTT remains the gold standard, and HbA1c alone cannot fully replace it in clinical practice.

LIMITATIONS OF THE STUDY

1. The study was conducted at a single tertiary care hospital, limiting generalizability to broader populations.
2. The relatively small sample size (n=190) may reduce statistical power for subgroup analyses.
3. Women with anemia and hemoglobinopathies were excluded, which may restrict applicability in populations with high prevalence of these conditions.
4. HbA1c levels can be influenced by factors such as iron deficiency, renal impairment, or ethnic variation, which were not extensively controlled in this study.
5. Longitudinal follow-up of maternal and neonatal outcomes was not performed, limiting the ability to correlate HbA1c levels with adverse outcomes.
6. The cross-sectional design does not assess temporal changes in HbA1c or glucose metabolism during different trimesters.

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