

Comparative Diagnostic Performance of First-Trimester HbA1c and DIPSI For Early Screening of Gestational Diabetes Mellitus: A Prospective Study At A Tertiary Care Centre in Telangana, India

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Abstract

Background: Detecting gestational diabetes mellitus (GDM) early in pregnancy may allow earlier risk assessment and management. Although routine screening is commonly performed at 24–28 weeks, glucose abnormalities can be present much earlier. HbA1c is a convenient biomarker that does not require fasting, while the Diabetes in Pregnancy Study Group India (DIPSI) approach is a simple non-fasting test used widely in India. This study assessed and compared the performance of first-trimester HbA1c and DIPSI using the 75-g oral glucose tolerance test (OGTT) as the reference method.

Methods: This prospective observational comparative study included pregnant women attending a tertiary teaching hospital in Telangana during the first trimester. Eligible participants underwent HbA1c measurement, DIPSI testing, and a 75-g OGTT. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall diagnostic accuracy, and agreement between the screening tests were evaluated.

Results: One hundred women were enrolled. The mean HbA1c was $5.42 \pm 0.62\%$, and the mean 2-hour plasma glucose was 126.8 ± 28.5 mg/dL. The reference OGTT diagnosed GDM in 16% of participants. HbA1c classified 19% as screen-positive and had a sensitivity of 81.3% and specificity of 92.9%. DIPSI classified 15% as screen-positive and showed a sensitivity of 75.0% and specificity of 96.4%. Overall diagnostic accuracy was 91.0% for HbA1c and 93.0% for DIPSI. Agreement between the two screening methods was substantial ($\kappa = 0.68$, $p < 0.001$).

Conclusion: In this study population, both first-trimester HbA1c and DIPSI showed useful diagnostic performance compared with OGTT. HbA1c detected a larger proportion of OGTT-positive cases, while DIPSI showed greater specificity and slightly higher overall accuracy. HbA1c may therefore be useful as an early adjunct to glucose-based screening, while DIPSI remains a practical option in routine antenatal services.

Introduction

Gestational diabetes mellitus is a frequent metabolic complication of pregnancy and is associated with adverse maternal, fetal, and neonatal outcomes. Hyperglycaemia first detected during pregnancy has been linked with hypertensive disorders, operative delivery, fetal overgrowth, neonatal hypoglycaemia, shoulder dystocia, and an increased later-life risk of type 2 diabetes in both mothers and their offspring. The burden is particularly important in South Asian populations, where insulin resistance may occur at lower body mass indices.

India has a substantial burden of diabetes, and reported rates of GDM vary across regions and populations. Telangana has also experienced increasing metabolic risk in the setting of urbanisation, sedentary lifestyles, changing dietary patterns, and genetic susceptibility. These trends support the need for practical approaches that can identify women at risk early in pregnancy.

Routine screening for GDM is generally performed during the second trimester, often between 24 and 28 weeks. However, metabolic abnormalities may already be present in the first trimester. Identifying such abnormalities earlier could provide an opportunity for timely nutritional counselling, lifestyle modification, glucose monitoring, and treatment when indicated.

The DIPSI method was developed as a convenient single-step, non-fasting 75-g glucose challenge that can be implemented in settings where resources are limited. Its simplicity and low cost have contributed to its use in India, although questions remain regarding its sensitivity in comparison with other diagnostic approaches.

HbA1c reflects average glycaemic exposure over the preceding several weeks and can be measured without fasting. Nevertheless, pregnancy-related changes such as haemodilution and altered red-cell

turnover can affect HbA1c interpretation. Evidence directly comparing first-trimester HbA1c with DIPSI remains limited, particularly in South Indian populations.

The present study was therefore designed to compare the diagnostic performance of first-trimester HbA1c and DIPSI for screening GDM, using a 75-g OGTT as the reference standard.

Materials and Methods

Study design and setting

A prospective observational comparative study was undertaken in the Department of Obstetrics and Gynaecology at a tertiary teaching hospital in Telangana, India. Institutional Ethics Committee approval was obtained, and written informed consent was collected from all participants.

Study population

Pregnant women attending the antenatal clinic during the first trimester were assessed for eligibility. Consecutive women meeting the study criteria were enrolled until the required sample size was reached.

Inclusion criteria

- Pregnancy at ≤ 13 weeks of gestation.
- Singleton pregnancy.
- Age 18 years or older.
- Willingness to participate and provide written informed consent.

Exclusion criteria

Women were excluded if they had established type 1 or type 2 diabetes, multiple pregnancy, systemic disorders known to affect glucose metabolism, haemoglobinopathies or severe anaemia likely to alter HbA1c results, current medication affecting carbohydrate metabolism such as corticosteroids, incomplete laboratory assessment, or loss to follow-up.

Study procedure

Baseline information included maternal age, parity, BMI, obstetric history, previous GDM, hypertension, and family history of diabetes. Each participant underwent HbA1c estimation, a DIPSI test using a 75-g oral glucose load irrespective of fasting status followed by 2-hour plasma glucose measurement, and a 75-g OGTT used as the reference diagnostic test. Laboratory staff were blinded to the alternative screening result.

Outcome measures

The main outcome was GDM diagnosed by the reference OGTT. Secondary measures included sensitivity, specificity, PPV, NPV, diagnostic accuracy, agreement between HbA1c and DIPSI using Cohen's kappa, and associations between maternal risk factors and GDM.

Laboratory and statistical methods

Venous blood was collected using standard aseptic procedures. HbA1c was measured in the institutional biochemistry laboratory using a standardized assay, while plasma glucose was assessed by an enzymatic glucose oxidase method with routine quality control.

Data were entered in Microsoft Excel and analysed using IBM SPSS Statistics version 26. Continuous variables were summarized as mean $\pm$ standard deviation and categorical variables as frequencies and percentages. Diagnostic indices were calculated against OGTT. Agreement was assessed with Cohen's kappa. Chi-square or Fisher's exact tests were used for categorical associations, and independent-samples Student's t-test was used for continuous variables. A two-sided p-value below 0.05 was considered statistically significant.

Results

A total of 100 pregnant women in the first trimester participated. Participants aged 25–29 years formed the largest age group (34%), followed by those aged 18–24 years (28%), 30–34 years (25%), and 35 years or older (13%).

By BMI, 37% had a normal BMI, 26% were overweight, 26% were obese, and 11% were underweight. Forty-six participants were primigravida and 54 were multigravida.

Obesity was the most frequently recorded maternal risk factor (26%). A family history of diabetes was present in 22%, hypertension in 15%, polycystic ovarian syndrome in 13%, previous GDM in 11%, and previous delivery of a macrosomic infant in 9%.

The mean HbA1c was $5.42 \pm 0.62\%$, while the mean 2-hour plasma glucose was 126.8 ± 28.5 mg/dL. Using the predefined screening thresholds, HbA1c $\geq 5.7\%$ classified 19 participants as positive, whereas DIPSI ≥ 140 mg/dL classified 15 participants as positive.

The reference OGTT diagnosed GDM in 16 participants. HbA1c correctly identified 13 of these 16 cases, giving a sensitivity of 81.3%, while DIPSI identified 12 cases, giving a sensitivity of 75.0%. HbA1c produced six false-positive results, compared with three with DIPSI.

HbA1c had a specificity of 92.9%, PPV of 68.4%, NPV of 96.3%, and overall diagnostic accuracy of 91.0%.

DIPSI had a specificity of 96.4%, PPV of 80.0%, NPV of 95.3%, and overall diagnostic accuracy of 93.0%.

The two screening methods showed 90% observed agreement. Cohen's kappa was 0.68 ($p < 0.001$), representing substantial agreement.

Maternal age of at least 30 years, BMI ≥ 25 kg/m², family history of diabetes, previous GDM, and hypertension were significantly associated with GDM diagnosed by OGTT. The reported p-values were 0.004, 0.001, 0.002, 0.001, and 0.009, respectively.

Discussion

This prospective study compared first-trimester HbA1c and DIPSI against a 75-g OGTT in women attending a tertiary care centre in Telangana. Both tests showed useful diagnostic performance, although their performance characteristics differed.

HbA1c demonstrated greater sensitivity in this study, identifying 13 of the 16 OGTT-positive cases. This may make it useful when the aim is to identify more women who may require further assessment. DIPSI, in contrast, showed higher specificity and PPV, meaning that fewer women without GDM were classified as positive.

The findings also suggest that the two approaches can provide complementary information. HbA1c has the practical advantage of not requiring fasting, while DIPSI is inexpensive and straightforward to implement in outpatient antenatal care. The substantial agreement between the tests supports their use as related screening approaches, although neither should be interpreted as replacing the reference diagnostic assessment on the basis of this study alone.

An approach in which HbA1c is obtained during the first antenatal visit and followed by appropriate glucose-based testing later in pregnancy could be considered for further evaluation. Larger studies are needed before such an integrated strategy can be established as a standard approach.

The principal strengths of the study were its prospective design, standardized laboratory procedures, use of OGTT as the reference standard, and direct comparison of both screening methods in the same participants. Important limitations include the single-centre setting, the relatively small sample of 100 women, absence of detailed pregnancy and neonatal outcome assessment, and the possibility that conditions affecting red-cell turnover could influence HbA1c.

Conclusion

In this cohort, both first-trimester HbA1c and DIPSI demonstrated useful performance when evaluated against the 75-g OGTT. HbA1c showed higher sensitivity (81.3%), whereas DIPSI had higher specificity (96.4%) and a slightly greater overall diagnostic accuracy (93.0% versus 91.0%). The substantial agreement between the two methods ($\kappa = 0.68$, $p < 0.001$) indicates that they identify many of the same women.

The findings support considering HbA1c as an adjunctive early screening measure rather than as a replacement for established glucose-based diagnostic testing. DIPSI remains a practical screening approach, particularly where simplicity and affordability are important. Larger multicentre studies with longitudinal maternal and neonatal follow-up are needed to assess the clinical and economic value of combining these approaches.

Future Research

Future prospective studies should include larger and more diverse populations and follow participants through pregnancy and the postpartum period. Evaluation of maternal and neonatal outcomes, together with cost-effectiveness analysis, may clarify the most appropriate role of first-trimester HbA1c. Studies of combined HbA1c and glucose-based screening strategies may also help determine whether earlier identification can improve clinically relevant outcomes.

Keywords Gestational diabetes mellitus; HbA1c; DIPSI; first-trimester screening; oral glucose tolerance test; pregnancy; India.

Declarations

Ethics approval: The study was approved by the Institutional Ethics Committee of Deccan College of Medical Sciences, Hyderabad.

Consent to participate: Written informed consent was obtained from all participants.

Consent for publication: Not applicable.

Data availability: The study reports that the datasets are available from the corresponding author upon reasonable request.

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Conflict of interest: The authors reported no competing interests.

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