

EVALUATION OF DIABETES IN PREGNANCY STUDY GROUP OF INDIA (DIPSI) AS A DIAGNOSTIC TOOL FOR GESTATIONAL DIABETES MELLITUS AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is increasingly common in India. The Diabetes in Pregnancy Study Group of India (DIPSI) proposed a single-step, non-fasting 75 g oral glucose challenge test to simplify screening. We evaluated the diagnostic accuracy of DIPSI criteria against the standard oral glucose tolerance test (OGTT) at a tertiary care hospital in Chennai. **Materials and Methods:** This prospective observational study, August 2022–January 2024, enrolled 186 pregnant women (18-40 years) at Sri Venkateshwara Medcity, Redhills, Chennai. All underwent DIPSI test (2-hour plasma glucose after 75 g glucose) and OGTT. Sensitivity, specificity, predictive values, and maternal/neonatal outcomes were assessed. Final analysis included 179 women. **Result:** GDM prevalence was 20.1 % by OGTT and 23.5 % by DIPSI. Using OGTT as reference, DIPSI showed sensitivity 89.5 % (95 % CI 78.5-95.3), specificity 94.6 % (89.7-97.3), PPV 81.0 %, NPV 97.2 %, accuracy 93.3 %, and AUC 0.963. Women with GDM had significantly higher rates of caesarean section (50.0 % vs 25.2 %, p=0.003), preeclampsia (19.4 % vs 5.6 %, p=0.007), macrosomia (19.4 % vs 4.2 %, p=0.002), NICU admission (25.0 % vs 11.2 %, p=0.028) and neonatal hypoglycaemia (22.2 % vs 4.9 %, p<0.001). **Conclusion:** The DIPSI single-step test has excellent diagnostic accuracy for GDM in Indian tertiary care. Its non-fasting, single-visit, low-cost design makes it highly suitable for widespread use.

INTRODUCTION

Gestational diabetes mellitus is one of the most frequent medical complications in pregnancy, contributing to both maternal and neonatal morbidity. In India, the prevalence of GDM varies widely from 10 % to 35 % depending on the diagnostic criteria and population studied. The traditional two-step approach (glucose challenge test followed by OGTT) has several drawbacks: it requires an overnight fast, at least two hospital visits, higher costs, and leads to substantial patient drop-out.[1-7]

To address these challenges, the Diabetes in Pregnancy Study Group of India developed a simplified, single-step screening strategy. The DIPSI test uses a non-fasting 75 g oral glucose load with a single plasma glucose measurement at 2 hours; a value ≥ 140 mg/dL is diagnostic. It can be performed at any time of day, irrespective of the last meal, making it practical for busy antenatal clinics. Previous studies have shown that DIPSI has

comparable diagnostic accuracy to fasting WHO criteria and good agreement with IADPSG criteria. However, most of these studies were limited by small sample sizes or specific geographic regions. Data from urban south Indian populations are scarce.[8-22] Therefore, we undertook this prospective study to evaluate the diagnostic accuracy of DIPSI criteria against the standard OGTT in a tertiary care hospital in Chennai, and to correlate DIPSI-based diagnosis with clinically important maternal and neonatal outcomes.

MATERIALS AND METHODS

Study Design and Setting: This was a prospective observational study conducted at Sri Venkateshwara Medcity, a tertiary care teaching hospital in Redhills, Chennai, Tamil Nadu, India. The Institutional Ethics Committee approved the study. All participants provided written informed consent.

Study Period and Sample Size: The study was carried out from August 2022 to January 2024 (18 months). Sample size was calculated assuming an expected sensitivity of DIPSI of 85 %, precision 7 %, 95 % confidence interval, and a GDM prevalence of 20 %. The minimum required sample was 162. To account for 15 % attrition, 186 women were enrolled; 179 completed the study (96.2 % completion rate).

Inclusion Criteria

1. Pregnant women aged 18–40 years
2. Gestational age between 24 and 28 weeks at the time of testing
3. Singleton pregnancy
4. Willingness to undergo both DIPSI test and standard oral glucose tolerance test (OGTT)
5. Provision of written informed consent

Exclusion Criteria

1. Pre-existing diabetes mellitus diagnosed before pregnancy
2. Multiple gestation (twins, triplets, or higher)
3. Chronic hypertension (pre-existing or diagnosed before 20 weeks of gestation)
4. Thyroid disorders requiring medication
5. Known renal disease or hepatic disease
6. Use of medications known to affect glucose metabolism (e.g., corticosteroids)
7. Any other significant medical or obstetric condition that, in the investigator’s judgment, would interfere with study participation or outcomes

Data Acquisition: Data collection was done using a structured proforma that covered the demographic and obstetric details of each participant. Socioeconomic status was determined using the modified Kuppuswamy scale. BMI was worked out for every participant from standard measurements taken during the study. Blood pressure was recorded only after the participant had taken rest for at least ten minutes, so as to get a reliable reading. Weight gain over the course of the pregnancy was noted down and tracked at every visit throughout the study period.

DIPSI Test Procedure: The DIPSI test was performed as per the standardised protocol,^[17] at any time of day regardless of the last meal. Each participant received 75 g anhydrous glucose dissolved in ~250 mL water. A venous blood sample was collected exactly 2 hours later. Plasma glucose was measured by the glucose oxidase-peroxidase

method in the NABL-accredited central laboratory. A 2-hour plasma glucose ≥ 140 mg/dL (7.8 mmol/L) was considered diagnostic for GDM.

Reference Standard: OGTT: Within one week of the DIPSI test, all participants underwent a 75 g OGTT after an overnight fast (≥ 8 hours). Fasting, 1-hour, and 2-hour venous samples were collected. The diagnosis of GDM was based on the IADPSG criteria (fasting ≥ 92 mg/dL, 1-hour ≥ 180 mg/dL, or 2-hour ≥ 153 mg/dL). Laboratory personnel performing the OGTT were blinded to the DIPSI results.

Other Laboratory Tests: Fasting blood sugar and HbA1c (by HPLC) were also measured.

Maternal and Neonatal Outcomes:

Maternal outcomes: Preeclampsia (BP $\geq 140/90$ mmHg with proteinuria), polyhydramnios (AFI ≥ 24 cm), mode of delivery, caesarean section rate, and preterm labour (< 37 weeks).

Neonatal outcomes: Birth weight, macrosomia (≥ 4000 g), low birth weight (< 2500 g), NICU admission, neonatal hypoglycaemia (blood glucose < 40 mg/dL in first 24 hours), and respiratory distress.

Statistical Analysis: Data was analyzed using SPSS version 26.0. While frequencies (%) are used to indicate categorical variables, mean \pm SD is utilized to represent continuous data. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were all calculated using 95% confidence intervals. The receiver operating characteristic curve's area under the curve (AUC) was computed. Group comparisons for continuous variables were conducted using the independent t-test or Mann-Whitney U test; for categorical variables, the chi-square or Fisher's exact test was utilized. Multivariate logistic regression was used to find independent predictors of GDM. A p-value of less than 0.05 was considered statistical significant.

RESULTS

Demographic and Clinical Characteristics: Our sample comprised 179 individuals aged 19–39 (mean = 27.4 ± 4.2 years), with the 25–34 bracket making up the largest share at 63.7%. [Table 1] summarizes their baseline demographic and clinical data.

Table 1: Demographic and clinical characteristics of study participants

Characteristic	Total (N=179)	GDM (n=36)	Non-GDM (n=143)	p-value
Age (years, mean \pm SD)	27.4 \pm 4.2	29.1 \pm 3.8	26.9 \pm 4.3	0.006
Age ≥ 35 years, n(%)	23 (12.8)	9 (25.0)	14 (9.8)	0.014
BMI (kg/m ² , mean \pm SD)	24.8 \pm 3.6	27.1 \pm 3.2	24.2 \pm 3.5	<0.001
Overweight/obese (BMI ≥ 25), n(%)	78 (43.6)	25 (69.4)	53 (37.1)	<0.001
Family history of diabetes, n(%)	52 (29.1)	18 (50.0)	34 (23.8)	0.002
Lower middle SES, n(%)	87 (48.6)	17 (47.2)	70 (49.0)	0.041*
Primigravida, n(%)	110 (61.5)	18 (50.0)	92 (64.3)	0.112
Previous GDM (multigravida), n(%)	9/69 (13.0)	6/18 (33.3)	3/51 (5.9)	0.003
Previous macrosomia, n(%)	6/69 (8.7)	4/18 (22.2)	2/51 (3.9)	0.019
Systolic BP (mmHg, mean \pm SD)	112.4 \pm 8.6	115.2 \pm 9.1	111.7 \pm 8.4	0.031
Weight gain in pregnancy (kg, mean \pm SD)	9.2 \pm 3.1	10.8 \pm 3.4	8.8 \pm 2.9	<0.001

For socioeconomic status distribution across three categories.

Prevalence of GDM: When researchers used the oral glucose tolerance test to diagnose gestational diabetes, they found it in about 20% of participants (that's 36 out of 179). If you look at the DIPSI criteria (where blood glucose readings of 140 mg/dL or higher signal GDM), it flagged 42 women, or roughly

24%. But, statistically speaking, this difference doesn't stand out a p-value of 0.432 shows there's no significant gap between the two ways of diagnosing.

Laboratory Parameters: All laboratory values were significantly higher in the GDM group [Table 2].

Table 2: Laboratory parameters

Parameter	GDM (n=36)	Non-GDM (n=143)	p-value
Fasting blood sugar (mg/dL)	96.8±7.6	85.1±6.9	<0.001
HbA1c (%)	5.9±0.4	5.3±0.4	<0.001
DIPSI 2-hour glucose (mg/dL)	162.4±18.7	120.3±19.2	<0.001
OGTT fasting glucose (mg/dL)	96.2±7.9	84.6±6.8	<0.001
OGTT 1-hour glucose (mg/dL)	186.4±24.1	139.2±27.8	<0.001
OGTT 2-hour glucose (mg/dL)	165.8±21.3	118.6±22.6	<0.001

Diagnostic Accuracy of DIPSI Criteria: The diagnostic performance of DIPSI is presented in

Table 3. The AUC was 0.963 (95 % CI 0.937-0.989), indicating excellent discrimination.

Table 3: Diagnostic accuracy of DIPSI criteria (OGTT as reference)

Parameter	Value (%)	95 % Confidence interval
Sensitivity	89.5	78.5 – 95.3
Specificity	94.6	89.7 – 97.3
Positive predictive value	81.0	69.6 – 88.7
Negative predictive value	97.2	93.0 – 98.9
Accuracy	93.3	88.8 – 96.1

Of the 36 women with GDM by OGTT, DIPSI correctly identified 32 (true positives). Four false-negative cases had DIPSI values between 132 and 138 mg/dL. Among the 143 non-GDM women, 135 were correctly negative; eight false-positive cases had DIPSI values of 141-156 mg/dL.

and overall accuracy (93.3%). Error bars represent 95% confidence intervals.

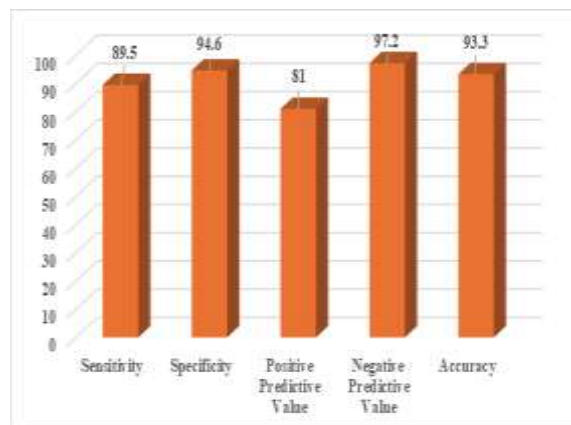


Figure 1: Diagnostic Accuracy of DIPSI Criteria

Diagnostic accuracy of DIPSI criteria using OGTT as reference standard. Bar chart showing sensitivity (89.5%), specificity (94.6%), positive predictive value (81.0%), negative predictive value (97.2%),

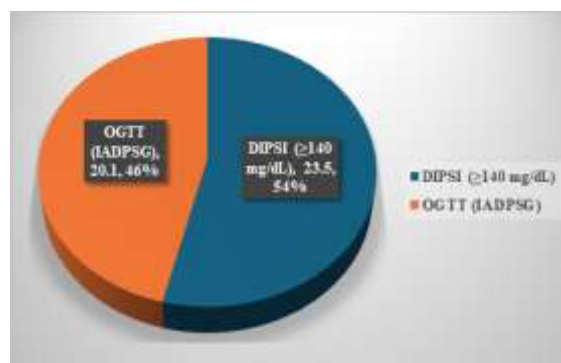


Figure 2: Prevalence of GDM by Diagnostic Criteria

Comparison of gestational diabetes mellitus prevalence by diagnostic criteria. DIPSI criteria (2-hour plasma glucose ≥140 mg/dL) diagnosed GDM in 23.5% of participants, while OGTT (IADPSG criteria) diagnosed GDM in 20.1% of participants (p=0.432).

Maternal Outcomes: Women with GDM had significantly higher rates of adverse maternal outcomes [Table 4]. The relative risk of caesarean section was nearly double (RR = 1.98, 95 % CI 1.33-2.96).

Table 4: Maternal outcomes

Outcome	GDM (n=36)	Non-GDM (n=143)	p-value	Relative risk (95 % CI)
Preeclampsia, n(%)	7 (19.4)	8 (5.6)	0.007	3.47 (1.35-8.92)
Polyhydramnios, n(%)	5 (13.9)	4 (2.8)	0.008	4.97 (1.40-17.61)
Caesarean section, n(%)	18 (50.0)	36 (25.2)	0.003	1.98 (1.33-2.96)
Preterm labour, n(%)	6 (16.7)	11 (7.7)	0.091	2.17 (0.85-5.50)

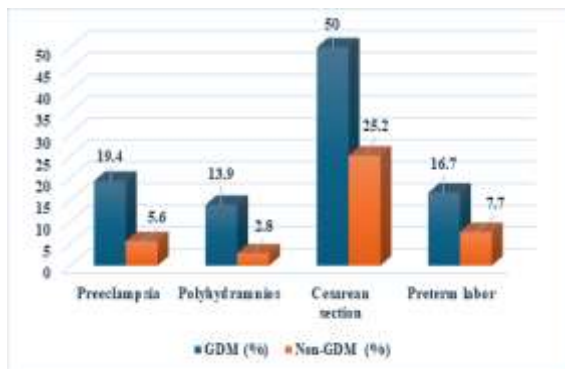


Figure 3: Maternal Outcomes in GDM vs Non-GDM

Maternal outcomes in women with GDM (n=36) versus non-GDM (n=143). Grouped bar chart comparing rates of preeclampsia (19.4% vs 5.6%, p=0.007), polyhydramnios (13.9% vs 2.8%, p=0.008), cesarean section (50.0% vs 25.2%, p=0.003), and preterm labor (16.7% vs 7.7%, p=0.091). p<0.05, p<0.01.

Neonatal Outcomes: Infants of mothers with GDM had significantly higher birth weight and more frequent complications [Table 5]. The risk of macrosomia was increased nearly five-fold (RR = 4.63) and neonatal hypoglycaemia more than four-fold (RR = 4.54).

Table 5: Neonatal outcomes

Outcome	GDM (n=36)	Non-GDM (n=143)	p-value	Relative risk (95 % CI)
Birth weight (g, mean±SD)	3184±486	2956±412	0.004	–
Macrosomia (≥4000 g), n(%)	7 (19.4)	6 (4.2)	0.002	4.63 (1.65-13.02)
Low birth weight (<2500 g), n(%)	3 (8.3)	14 (9.8)	0.787	0.85 (0.26-2.80)
NICU admission, n(%)	9 (25.0)	16 (11.2)	0.028	2.23 (1.07-4.66)
Neonatal hypoglycaemia, n(%)	8 (22.2)	7 (4.9)	<0.001	4.54 (1.76-11.71)
Respiratory distress, n(%)	5 (13.9)	9 (6.3)	0.116	2.21 (0.79-6.18)

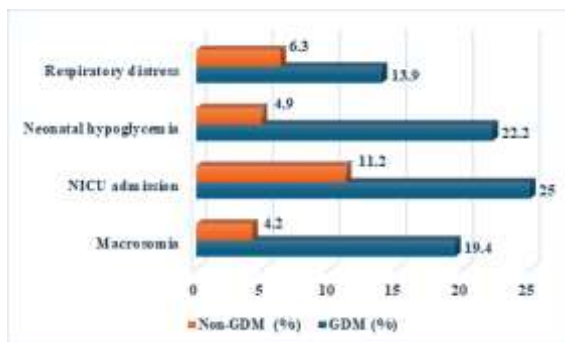


Figure 4: Neonatal Outcomes in GDM vs Non-GDM

Neonatal outcomes in GDM-exposed (n=36) versus unexposed (n=143) neonates. Grouped bar chart showing rates of macrosomia (19.4% vs 4.2%, p=0.002), NICU admission (25.0% vs 11.2%, p=0.028), neonatal hypoglycemia (22.2% vs 4.9%, p<0.001), and respiratory distress (13.9% vs 6.3%, p=0.116). p<0.05, p<0.01, p<0.001.

Predictors of GDM (Multivariate Logistic Regression)

After adjusting for confounders, the independent predictors of GDM were:

- Advancing age (aOR 1.12 per year, 95 % CI 1.03-1.22, p=0.008)
- Overweight/obesity (aOR 2.84, 95 % CI 1.31-6.15, p=0.008)
- Family history of diabetes (aOR 2.41, 95 % CI 1.12-5.18, p=0.024)
- Previous history of GDM (aOR 5.67, 95 % CI 1.48-21.73, p=0.011)

DISCUSSION

Our prospective study evaluated the DIPSII single-step, non-fasting glucose challenge test against the standard OGTT in 179 pregnant women in urban Chennai. DIPSII demonstrated excellent

diagnostic accuracy: sensitivity 89.5 %, specificity 94.6 %, NPV 97.2 %, and AUC 0.963. Importantly, women diagnosed with GDM (by OGTT) had significantly higher rates of cesarean section, preeclampsia, polyhydramnios, macrosomia, NICU admission, and neonatal hypoglycaemia – confirming that the DIPSII test identifies a group at true increased risk.

The GDM prevalence in our cohort was 20.1 % by OGTT, which is within the national range of 10-35 % reported by Mantri et al.^[23] and slightly higher than the 14.2 % reported from rural central India by Chebrolu et al.^[3] The DIPSII criteria gave a prevalence of 23.5 %, consistent with Vij et al., who noted that DIPSII identifies a slightly different but overlapping subset of women.^[18]

Our diagnostic accuracy findings are very similar to those of Balagopalan et al. (sensitivity 86.7 %, specificity 91.2 %) in a primary care setting,^[1] and to Saxena et al. (AUC 0.94).^[8,22] The high NPV of 97.2 % means that a negative DIPSII test effectively rules out GDM, which is valuable for avoiding unnecessary follow-up. The four false-negative cases had DIPSII values of 132-138 mg/dL. Some authors have proposed lowering the threshold to 132 mg/dL to improve sensitivity, but that would inevitably reduce specificity and increase false-positive diagnoses. The optimal threshold may depend on local resources and the prevalence of GDM.

Other simplified approaches, such as HbA1c, have shown lower sensitivity than DIPSII.^[8,22] The one-step versus two-step debate continues,^[7] DIPSII represents a pragmatic one-step method that avoids fasting and repeated visits. This is particularly important in India, where transportation costs, loss of daily wages, and family responsibilities can lead to high attrition rates.^[15] Our maternal outcome data align with earlier studies. The cesarean section rate was 50.0 % in GDM women versus 25.2 % in non-GDM women.

Bano et al. similarly reported that insulin resistance in pregnancy correlates with adverse obstetric outcomes.^[2] The elevated rates of preeclampsia (19.4 % vs 5.6 %) and polyhydramnios (13.9 % vs 2.8 %) are likely mediated by endothelial dysfunction and abnormal placentation in the setting of maternal hyperglycaemia.

Neonatal outcomes were also worse in the GDM group. The 19.4 % rate of macrosomia represents a nearly five-fold increased risk. This finding is consistent with Dwarakanath et al,^[12] and Sinha & Mayadeo,^[10] who reported increased neonatal morbidity in GDM diagnosed by DIPSI. Neonatal hypoglycaemia occurred in 22.2 % of GDM-exposed infants – more than four times the rate in non-GDM infants. These data underscore the clinical relevance of GDM diagnosis, regardless of which criteria are used.

The independent predictors of GDM in our study (advancing age, overweight/obesity, family history, and previous GDM) are well-established risk factors. However, Chebrolu et al. noted an absence of typical risk factors in rural central India,^[3] which supports universal rather than risk-based screening – especially given the low cost and simplicity of the DIPSI test. Interestingly, women in the upper-lower socioeconomic class had a higher GDM prevalence (38.9 %) than those in the upper-middle class (13.9 %), reflecting the nutrition transition in urban India. From a clinical perspective, the DIPSI test has several advantages: it requires no fasting, only one blood sample, and can be completed during a routine antenatal visit. The cost is very low (approximately ₹50-100 for glucose and laboratory processing). Magon and Chauhan have strongly advocated for DIPSI as a simple, cost-effective and sensitive screening strategy.^[24] Our results support that position, and provide contemporary data from an urban south Indian tertiary care centre.

Strengths and Limitations

Strengths: Prospective design, standardised protocols, blinding of laboratory personnel to DIPSI results, comprehensive maternal and neonatal outcomes, and a high completion rate (96.2 %).

Limitations: Single-centre study at a tertiary care hospital in urban Chennai – results may not be fully generalisable to primary care or rural settings. Sample size, while adequate for the primary objective, is modest for subgroup analyses. Follow-up was limited to delivery; long-term metabolic outcomes were not assessed. Pre-pregnancy weight was self-reported, though cross-checked with antenatal records when available.

Future Directions: Multicentre validation studies across diverse Indian populations are needed. Randomised controlled trials comparing DIPSI-based management with OGTT-based management would provide higher-level evidence. Cost-effectiveness analyses should be performed. The potential use of DIPSI earlier in pregnancy (first or early second trimester) deserves exploration. Finally, continuous glucose monitoring [19] may

help identify women with the highest risk despite a normal DIPSI result.

CONCLUSION

The DIPSI single-step, non-fasting 75 g glucose challenge test has excellent diagnostic accuracy for GDM at a tertiary care hospital in Chennai, with a sensitivity of 89.5 %, specificity 94.6 %, and overall accuracy 93.3 % compared to the standard OGTT. Women diagnosed with GDM have significantly higher rates of caesarean section, preeclampsia, polyhydramnios, macrosomia, NICU admission, and neonatal hypoglycaemia. Independent predictors include advancing age, overweight/obesity, family history of diabetes, and previous GDM.

Because of its simplicity, low cost, non-fasting requirement, and single-visit protocol, the DIPSI test is a practical and reliable screening tool for GDM in Indian healthcare settings. Widespread adoption could improve GDM detection, allow earlier intervention, and reduce the burden of adverse pregnancy outcomes.

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