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Original Research Article

Validity of DIPSI criteria performed during early mid- and late-pregnancy for diagnosis of gestational diabetes

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ABSTRACT

Background: Gestational diabetes mellitus increases the risk of perinatal complications and chronic diabetes in the mother and child, and early detection and treatment could improve perinatal and long-term outcomes in GDM women and their offspring. Several criteria have been proposed for diagnosing GDM, but there is no universal consensus regarding the most accurate and feasible test acceptable to every sociodemographic region. This study was undertaken to evaluate the single-step non-fasting 75 gm Diabetes in Pregnancy Study Group of India (DIPSI) criteria of GDM performed during early (16-20 weeks) mid-(24-28 weeks) late-pregnancy (32-36 weeks), compared with the two-step fasting 100 gm glucose challenge through the ACOG recommended Carpenter Coustan criteria.

Methods: It was a prospective study analyzing a cohort of pregnant women from the 16th week of gestation till the 36th week, excluding previously known diabetic patients. All study participants were screened for GDM three times using the DIPSI criteria (between 16-20 weeks, 20-24 weeks and 32-36 weeks) and once using the 2-step ACOG criteria between 24-28 weeks.

Results: The study includes 200 participants with a mean age of 27.14% of women were diagnosed with GDM based on the 2-step ACOG recommended criteria. The sensitivity, specificity and accuracy of DIPSI criteria during 16-20 weeks were 25%, 99.4% and 78.6%, respectively; during 20-24 weeks, sensitivity was 96.4%, specificity was 95.9%, and accuracy was 96.07%. The sensitivity, specificity and accuracy of DIPSI criteria during 32-36 weeks were 96.4%, 94.8% and 95.2%, respectively.

Conclusions: DIPSI criteria is highly sensitive and specific and can accurately detect GDM between 24-28 weeks; it lacks sensitivity and is inaccurate in detecting GDM between 16-20 weeks of gestation. However, as these parameters are similar at 32-36 weeks, high-risk patients for GDM could be considered for rescreening during the third trimester.

Keywords: Carpenter coustan criteria, Diabetes in pregnancy study group of India criteria, Gestational diabetes mellitus, Glucose tolerance test, Pregnancy

INTRODUCTION

New-onset or newly recognised hyperglycaemia during pregnancy is defined as Gestational diabetes mellitus (GDM).¹ GDM with hyperglycaemia increases maternal and foetal risk in the perinatal period.² It is also related to an increased risk of diabetes and its complications in the mother and the risk of obesity, hypertension and diabetes

in offspring later in life.³⁻⁵ As per recent estimates, the worldwide prevalence of GDM has been reported to be nearly 14%.⁶ The highest incidence has been reported in southeast Asian countries such as India, where GDM may complicate every 1 in 5 pregnancies.⁶

The Hyperglycaemias and Adverse Pregnancy Outcomes (HAPO) study published in 2008 reported an increased

maternal and foetal complications risk at glycaemic thresholds lower than those of diabetes mellitus.⁷ Based on the findings of the HAPO study, the World Health Organisation (WHO) and the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) recommended universal screening between 24-28 weeks gestation with a single step, 75-g 2-hour OGTT.^{1,8} These revised recommendations were also endorsed by the American Diabetes Association (ADA) and the International Federation of Gynaecology and Obstetrics.^{9,10} However, The American College of Obstetricians and Gynaecologists (ACOG) did not endorse the IADPSG recommendations, citing the expected increase in the prevalence of GDM and associated costs. It recommends a 2-step testing approach, with the initial screening GCT that involves the administration of a 50-g oral glucose solution followed by a 1-hour venous glucose determination for all women. Those who screen positive (1-hour glucose level more than 130-140 mg/dl) proceed to the diagnostic 100-g 3-hour OGTT. GDM is diagnosed if the 1, 2 or 3-hour blood sugars meet the thresholds established for the 3-hour OGTT by the National Diabetes Data Group and by Carpenter and Coustan.¹¹

Compared to other demographic groups, there is a higher prevalence of GDM in Indian women, and a simple and inexpensive universal screening method for GDM is applicable in the Indian scenario.¹² Diabetes in Pregnancy Study Group India (DIPSI) recommended a single-step procedure irrespective of the last meal. Pregnant women attending the antenatal OPD were given 75g of anhydrous glucose in 250-300ml of water, and plasma glucose was estimated after 2 hours. 2-hour plasma glucose ≥ 140 mg/dl is considered diagnostic for GDM.¹³

Most current guidelines only consider GDM diagnosis after abnormal OGTT between 24-28 weeks.^{11,14,15} Therefore, data about GDM diagnosed by abnormal OGTT early in pregnancy are scarce in the literature and show conflicting results on the potential benefit of screening for GDM in early pregnancy.¹⁶ However, several authors have

suggested that a repeat OGTT at a later gestation in mothers whose initial OGTT values were normal may improve obstetric and neonatal outcomes.^{17,18}

The present study analysed the accuracy of one-step, non-fasting DIPSI criteria as a screening and diagnostic modality for GDM and assessed its validity at three different periods during gestation, done between 16-20, 24-28 and 32-36 weeks.

METHODS

This prospective comparative study was conducted with 200 pregnant women who presented to the antenatal clinic of a tertiary-care hospital in Northern India over two years, from July 2021 to June 2018, after obtaining informed consent and approval from the Institutional Ethics Committee. All pregnant women were recruited before or at the 16th week of gestation, and those with pre-existing diabetes were excluded.

All women underwent a non-fasting plasma glucose measurement two hours after giving a 75gm glucose load at 16-20 weeks, 24-28 weeks and again during 32-36 weeks of gestation. Per the DIPSI criteria (Table 1), the 75gm glucose load was given irrespective of the last meal's time, and the venous sample was drawn after two hours. The cut-off value of this 75 g non-fasting DIPSI test was >140 mg/dl. Patients on insulin therapy or oral hypoglycaemic agents were asked to continue therapy.

All the study participants were also screened using the ACOG recommendations (Table 1), between 24 to 28 weeks, by independent observers who did not know the results of previous screening tests. All the women, irrespective of their GDM status as adjudged by either of two DIPSI assessments, were subjected to ACOG recommended 2-step diagnostic approach, using a cut-off for an abnormal 1-hour screen of 140 mg/dL and 2 abnormal values on the 3-hour, 100gm oral glucose tolerance test that includes a fasting value as per the Carpenter-Coustan criteria.

Table 1: Details of criteria for screening and diagnosis of GDM.

	Glycaemic Load	Criteria
DIPSI criteria¹³	75 gm non-fasting OGTT	Plasma glucose level ≥ 140 mg/dl is GDM
ACOG step 1 GCT¹¹	50 gm fasting GCT	>140 mg/dl; proceed to step 2
ACOG step 2 OGTT (Carpenter-Coustan)¹¹	100 gm fasting OGTT	Fasting plasma glucose ≥ 95 mg/dl, 1 h ≥ 180 mg/dl, 2 h ≥ 155 mg/dl and 3 h ≥ 140 mg/dl after 100gm glucose load; GDM is diagnosed if ≥ 2 values are above the threshold

GDM: gestational diabetes mellitus; DIPSI: Diabetes in Pregnancy Study Group of India; ACOG: American College of Obstetricians and Gynaecologists; GCT: Glucose Challenge Test; OGTT: Oral Glucose Tolerance Test

Statistical analysis

Data were analysed using SPSS (version 21; IBM Corporation). The patients' clinicodemographic profiles and blood glucose levels were correlated for descriptive statistics, including frequency, percentages, and 95% confidence intervals.

RESULTS

Total 200 pregnant women were enrolled in this study, ranging from 19 to 37 years (mean age - 27 years). 14% of study participants were overweight (BMI 25-30 Kg/m²), 1.5% had obesity (BMI >30 Kg/m²), and 28.5% had a

history of diabetes in a close relative. 39.5% of patients were primigravidae, and 1% had a bad obstetric history.

Table 2: Patients diagnosed with GDM between 16-20 weeks by DIPSI vs ACOG criteria.

DIPSI	ACOG		Total
	Positive	Negative	
Positive	7	1	8
Negative	21	171	192
	28	172	200

Table 3: Patients diagnosed with GDM between 24-28 weeks by DIPSI vs ACOG criteria.

DIPSI	ACOG		Total
	Positive	Negative	
Positive	27	7	34
Negative	1	165	166
	28	172	200

Table 4: Patients diagnosed with GDM between 32-36 weeks by DIPSI vs ACOG criteria.

DIPSI	ACOG		Total
	Positive	Negative	
Positive	27		36
Negative	1	163	164
	28	172	200

On screening evaluation using the DIPSI criteria, 8 (4%) women during 16-20 weeks, 34 (17%) during 24-28 weeks, and 36 during 32-36 weeks were diagnosed with GDM. In comparison, 28 (14%) women were diagnosed with GDM based on the 2-step ACOG recommended criteria between 24-28 weeks of gestation. Compared with the ACOG criteria, the sensitivity, specificity and diagnostic accuracy of the 75gm non-fasting OGTT between 16-20 weeks was 25%, 99.4% and 78.6%, respectively. The sensitivity of screening by DIPSI criteria during 24-28 weeks was 96.4%, the specificity was 95.9%, and the diagnostic accuracy was 96.07%.

Table 5: Diagnostic statistics of DIPSI criteria in comparison with ACOG criteria.

Statistic	16-20 weeks (%)	24-28 weeks (%)	32-36 weeks (%)
Sensitivity	25	96.43	96.43
Specificity	99.42	95.93	94.77
Positive likelihood ratio	43	23.69	18.43
Negative likelihood ratio	0.75	0.04	0.04
Positive predictive value	94.36	90.21	87.76
Negative predictive value	77.32	98.57	98.56
Accuracy	78.58	96.07	95.23

Upon screening during 32-36 weeks, the sensitivity remained the same; however, the specificity and accuracy decreased marginally to 94.77% and 95.23%, respectively.

DISCUSSION

Early and accurate diagnosis of GDM is crucial to prevent its potential complications during gestation and to prevent delayed issues such as diabetes in later life for both the mother and child. ACOG recommends a two-step process for diagnosing GDM, which employs an initial screening with 50gm GCT, followed by 100gm fasting OGTT in patients with abnormal GCT.¹¹ The HAPO study and the following IADPSG criteria recommended the universal use of OGTT for diagnosing GDM.^{7,8} However, this seemed to be an impractical exercise, specifically in developing countries. Hence, the DIPSI suggested a 75 g non-fasting test as an uncomplicated, economical and viable single-step method for diagnosing GDM.¹³ The DIPSI method does not require fasting status and needs measuring blood sugars only once at 2 hours after intake of 75gm glucose solution, making it easier to implement in the antenatal clinic and improving patient compliance.

The efficacy of glucose-challenge tests in the non-fasting condition for screening and diagnosing GDM has long been disputed. The ADA recommends selective screening for GDM and, considering risk factors such as a woman's age, ethnicity, and BMI for screening, may miss some patients with GDM in the lower-risk category.¹⁴ The rationale for universal screening for GDM is to try and reduce the number of pregnant women undergoing OGTTs. A universal screening protocol requires the consideration of patient comfort, cost, and the risk of missing the diagnosis. The current ACOG recommendation of universal screening is a more practical approach, but it advocates universal screening using two-step methods.¹¹ Currently, the most used screening test is the oral glucose challenge test (OGCT) with 50 g of glucose, followed by an OGTT with 100 g of glucose.

Based on the observations of the present study, we could report high sensitivity, specificity and overall accuracy of the OGTT done between 24-28 weeks and 32-36 weeks as per the DIPSI recommendations.

Various researchers have studied the DIPSI criteria in the past with varying conclusions. Certain authors have shown

a low sensitivity of 'non-fasting OGTT as compared to the fasting OGTT in the Indian population.^{19,20} However, a study by Anjalakshi et al on the south Indian population demonstrated 100% sensitivity and specificity of the DIPSI test for the diagnosis of GDM.²⁰ Saxena et al and Khan et al also concluded that there was no significant difference between DIPSI and the Carpenter–Coustan criteria in identifying women with GDM.^{21,22}

We studied the ability of 75gm non-fasting OGTT performed at 16-20 weeks in Indian women to predict a diagnosis of GDM. While the specificity of the early OGTT, done as per DIPSI criteria, was high, it had very poor sensitivity and accuracy. The bulk of GDM women would be missed, limiting its effectiveness as a screening tool to identify women for later follow-up and select women who would benefit from early intervention. The clinical value of recognising early hyperglycemia, and the impact of treating it since early gestation, were the object of study for considerable research, although the outcomes have been inconsistent. Inferring the glycemic thresholds of OGTT for tests done before 24 weeks of the gestational period has been contentious, and currently, there is inadequate evidence to validate its use. The presently available literature also lacks strong evidence on the best management of cases of early-pregnancy hyperglycemia.²³

Previous studies have concluded that fasting glucose in early pregnancy is an inefficient screening test for GDM.^{24,25} Others have analysed glucose measurements at other time points during the OGTT to see whether these yield better diagnostic performance during early gestation. Phaloprakarn et al found that the 1 h glucose level with a threshold value of 155 mg/dl gave a reasonable diagnostic accuracy but a low specificity.²⁶ Previous studies assessing the capacity of early OGTT to predict GDM have focused on high-risk patients, and the non-fasting DIPSI criteria have yet to be studied in this context.

While the sensitivity, specificity and accuracy of screening tests for GDM during 24-28 and 32-36 weeks were equitable, the delayed screening will leave several patients with hyperglycemia undiagnosed and increase the likelihood of fetal and maternal complications associated with gestational diabetes. Therefore universal screening could be recommended during 24-28 weeks of gestation, and women with high-risk characteristics should be rescreened for GDM at 32 weeks. Utilising the uncomplicated and inexpensive DIPSI criterion can make rescreening more comfortable and practical.

This study was limited by its modest sample size and that it was conducted at an urban tertiary care hospital and was not a population-based study.

CONCLUSION

In conclusion, the present study evaluates the inexpensive and pragmatic non-fasting 75 gm OGTT as per the DIPSI criteria against the ACOG-recommended Carpenter–

Coustan criteria for screening pregnant women between 16-20 weeks, 24-28 weeks, and 32-36 weeks of gestation. The study shows high accuracy, sensitivity and specificity of the DIPSI criteria when utilised between 24-28 and 32-36 weeks. However, OGTT by the DIPSI criteria lacks sensitivity when used between 16-20 weeks and is, therefore, not an ideal screening test for early detection of GDM.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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