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Original Research Article

COMPARATIVE STUDY OF DIAGNOSTIC ACCURACY OF DIABETES IN PREGNANCY STUDY GROUP OF INDIA (DIPSI) CRITERIA WITH INTERNATIONAL ASSOCIATION OF DIABETES IN PREGNANCY STUDY GROUP (IADPSG) CRITERIA: - A TERTIARY CARE CENTRE BASED STUDY

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Abstract

Background: Gestational diabetes mellitus (GDM) is a communal complication of pregnancy. Accurate diagnosis is crucial for timely management and prevention of adverse outcomes. The aim is to evaluate the accuracy of the DIPSI criteria in diagnosing Gestational Diabetes Mellitus (GDM) in comparison to the IADPSG criteria. **Materials and Methods:** This comparative experimental cross-sectional study was conducted on 212 pregnant women with gestational age of 24-28 weeks; who underwent oral glucose tolerance tests (OGTT) using both DIPSI and IADPSG criteria. The diagnostic accuracy of DIPSI was evaluated and compared with IADPSG is considered gold standard. **Result:** Out of 212 pregnant women, 35 were diagnosed with GDM by DIPSI, of which 33 were also diagnosed as GDM-positive by IADPSG. However, 20 women who were diagnosed as GDM-negative by DIPSI were actually GDM-positive by IADPSG, indicating a discrepancy between the two criteria. The sensitivity of DIPSI is found to be 62.26%, specificity is 98.74%, and diagnostic accuracy is 89.62%. When ROC curve was plotted for the validity of DIPSI against IADPSG, the area under curve was 0.862. **Conclusion:** The study compares the diagnostic accuracy of the Diabetes in Pregnancy Study Group of India (DIPSI) criteria and the International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria for identifying GDM in a tertiary care setting. Our results indicate that while both criteria are effective in diagnosing GDM, there are notable differences in their sensitivity, specificity, and practical applicability. The DIPSI criteria, being simpler and more accessible, may be better suited for resource-limited settings, while the IADPSG criteria provide a more rigorous diagnostic approach.

INTRODUCTION

GDM has become a significant global health concern,[1] particularly in India, where it affects approximately 4 million pregnancies annually.[1] If left inadequately managed, GDM poses a substantial risk of hostile perinatal consequences, compromising both maternal and fetal health.[2] Moreover, GDM marks the commencement of a vicious cycle, increasing the likelihood of long-term consequences, including the development of diabetes in both mothers and their offspring.[3] The "fetal origin of adult disease" hypothesis underscores the position of early identification and intervention to break this cycle and prevent unfavorable outcomes in future generations.[4] Given the varying prevalence of GDM across India, its timely detection has taken on national importance.[5]

Gestational diabetes (GD) can manifest with a range of clinical effects, from mild symptoms to severe hyperglycemia. The underlying cause of GD is believed to be insulin resistance triggered by pregnancy hormones, which the pancreatic β-cells are unable to counterbalance through increased insulin production. Although the exact mechanisms of GD are not yet fully understood, a genetic

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component is suspected, given the observed familial patterns and the identification of specific genes linked to an increased risk of developing the condition.[6] In addition to genetic factors, several nongenetic factors, including advanced maternal age, obesity, dietary habits, and lifestyle, have also been identified as contributing factors to the expansion of GDM.[7] The incidence of GDM in India varies widely, ranging from 4% to 18%, contempt a government directive to diagnosis all pregnant women.[8] However, the application and acceptance of diagnosis programs have been incomplete. Current studies on GDM in India are inadequate, primarily directed in urban, hospital-based settings, and national data on GDM are scarce.[8-10] In contrast, national data on type 2 diabetes prevalence in India are emerging,[11,12] showing an overall prevalence of approximately 7%, with higher rates in urban areas, older age groups, and higher socioeconomic status groups.[12] There is concern about a potential increase in diabetes and GD prevalence, but a comprehensive national assessment of GD and its associated socioeconomic, demographic, and geographic factors is lacking.[9]

In 1999, the WHO introduced new criteria for diagnosing GDM. According to these criteria, pregnant women who met the previous WHO criteria for impaired glucose tolerance (IGT) were reclassified as having GDM, effectively eliminating the term "GIGT". The WHO 1999 criteria, which involve a simple one-step procedure, require a 2-hour plasma glucose level ≥ 140 mg/dL after a 75g oral glucose load in a fasting state, and have become particularly relevant in developing countries due to their ease of implementation.[13] In 2010, based on hyperglycaemia and contrary pregnancy consequence study, IADPSG has introduced a new set of criteria in which the threshold for making a diagnosis of GDM were lowered and recommended that GDM can be diagnosed, if any one value of fasting PG, 1-hour and 2-hour PG values meet or exceed 92, 180, and 153 mg/dL, respectively, with 75 g oral glucose.[14] Hyperglycaemia and hostile pregnancy consequence study confirmed that adverse pregnancy outcome occurs with increasing maternal glucose in a continuous association even below the traditional cutoff value for screening of GDM. There is a widespread acceptance of IADPSG criteria including WHO.[15]

In 2006, Diabetic Association of India recommended DIPSI criteria to take 2-hour venous PG value after administrating 75 g of oral glucose in a non-fasting state, unlike 1999 WHO criteria in a fasting state.[13,16] This is a simple single-step procedure, as generally a pregnant woman visits the antenatal clinic in a non-fasting state. Many patients come from far-flung areas, and timing and frequency of their next visit is unreliable. Given the practical challenges in India, the one-step, cost-effective procedure recommended by the Diabetes in Pregnancy Study Group India (DIPSI), which allows for diagnostic testing in a non-fasting state, is a more convenient and pragmatic approach.[17] However, many workers have questioned the sensitivity and specificity of DIPSI criteria in diagnosing GDM in comparison with other well-established methods.[18-20] Hence, this study is carried out to compare detection rate of GDM through DIPSI over IADPSG criteria, IADPSG being most acceptable criteria internationally.

Aim: To study the accuracy of DIPSI criteria in contrast with IADPSG criteria for the screening of GDM.

MATERIALS AND METHODS

The present comparative experimental cross-sectional study was conducted on pregnant female with gestational age of 24-28 weeks attended the Obstetrics OPD for anti-natal care at tertiary health care centre, MVASMMC Basti, Uttar Pradesh. All Pregnant female who was visit in Obstetrics OPD with anti-natal pregnancy following the 1st March 2024 to 28 February 2025.

Sample Size Calculation:

$$n = \frac{z^2 * p * q}{d^2}$$

$$n = \frac{(1.96)^2 * 0.014 * 0.986}{(0.095)^2}$$

$$N = 212$$

Z =1.96
P = 0.014
Q =1-P=0.9 86
d =0.05

Therefore, required Sample size is approx. 212.

Inclusion Criteria

1. Pregnant Females who were registered to the Obstetrics department for anti-natal care with gestational age between 24–28 weeks.
2. Pregnant female with Age Group between 18-44 years

Exclusion Criteria

1. Patients with preexisting Diabetes, renal disorder, Pancreatic disorders, TB or any Endocrine disorders
2. Medications/Conditions affecting Glycemia etc

Sample Collection Procedure: After obtaining a history, examination, and informed consent, the patient was enquired for non-fasting state and non-fasting state,75-gram oral glucose load was given to her, after which 2 mL of a venous blood sample was taken. After 2 hours, blood sugar levels were estimated and analysed as per the DIPSI criteria.

The same women were called again after 3–4 days in a fasting state. First, 2 mL venous blood sample was taken in a fasting state fluoride vial under all aseptic precautions, and then an oral glucose load of 75 g was given. Samples were taken after 1 and 2 hours consecutively. Blood sugar levels were estimated by GOD-POD (glucose oxidase-peroxidase coupled) methods in biochemistry central lab by fully auto analyser and analysed as per the IADPSG criteria.

Statistical Analysis: Data was recorded on a predesigned Performa and managed in a Microsoft Excel spreadsheet. The data obtained were analysed

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using SPSS software version 23.0 for Windows (SPSS, Chicago, IL). Categorical data are presented as the percent frequency occurrence. To test the association / difference in proportions between the variables, Chi-square test / Fisher exact test was used. A cross-tabulation analysis was performed to compare the results of the index test (DIPSI) with the reference test (IADPSG). To evaluate the diagnostic accuracy of the DIPSI test, a receiver operating characteristic (ROC) curve was plotted, using sensitivity and specificity values for venous plasma glucose levels, and compared against the IADPSG values, providing a precise estimate of diagnostic accuracy. P value <0.05 was considered as statistically significant.

RESULTS

Initially, 245 pregnant women were enrolled in the study. However, 24 women failed to return in a fasting state after 3 days, 7 were diagnosed with overt diabetes mellitus, and 2 experienced excessive vomiting after consuming the glucose solution for the DIPSI test and were subsequently withdrawn. As a result, the final study cohort consisted of 212 pregnant women. Out of 212 women, 53 (25.0%) were GDM positive in IADPSG test; but only 35 (16.5%) were GDM positive with DIPSI test [Figure 1].

Women with GDM (n=53) were more expected to had as the study has been completed and now we are making observation a higher BMI (≥25 kg/m2) (45.3% vs 21.4%, p<0.001), reside in rural areas (47.2% vs 23.3%, p=0.001), had a history of polycystic ovary syndrome (PCOS) (26.4% vs 6.3%, p<0.001), and has a GDM history in a previous pregnancy (17.0% vs 5.0%, p=0.008). Additionally, women with GDM were more likely to have a diabetes mellitus family history of (7.5% vs 1.3%, p=0.037). These factors were suggestively related with an bigger risk of evolving GDM, with odds ratios ranging from 3.861 to 6.280. [Table 1].

Women with GDM had significantly higher mean blood sugar levels associated to those lacking GDM, regardless of the criteria used. Specifically, the mean DIPSI value was 136.42±15.99 mg/dl in GDM-positive women versus 112.00±15.30 mg/dl in GDM-negative women (p<0.001). Similarly, the mean IADPSG FBS and 2-hour postprandial blood sugar levels were also significantly higher in GDM-positive women (112.56±11.36 mg/dl and 142.81±10.71 mg/dl, respectively) compared to GDM-negative women (86.88±12.34 mg/dl and 94.96±13.08 mg/dl, respectively) (p<0.001 for both) [Table 2].

Out of 212 pregnant women, 35 were identified with GDM by DIPSI, of which 33 were also diagnosed as GDM-positive by IADPSG. However, 20 women who were diagnosed as GDM-negative by DIPSI were actually GDM-positive by IADPSG, indicating a discrepancy between the two criteria. Overall, the IADPSG criteria identified 53 GDM-positive cases, while the DIPSI criteria identified 35 GDM-positive cases [Table 3].

On analysing the investigative accurateness of DIPSI in contrast to IADPSG, the sensitivity of DIPSI is noted to be 62.26%, specificity is 98.74%, and diagnostic accuracy is 89.62%. The positive predictive value (PPV) is 94.29% and negative predictive value is 88.70% [Table 4]. When ROC curve was plotted for the validity of DIPSI against IADPSG, the area under the curve was 0.862 [Figure 2].

IADPSG had a sensitivity of 94.29% (95% CI: 80.84-99.30%), specificity of 88.70% (95% CI: 83.09-92.96%), and accuracy of 89.62% (95% CI: 84.71-93.38%) when compared to DIPSI as the gold standard. The positive predictive value was 62.26% (95% CI: 52.00-71.54%), and the negative predictive value was 98.74% (95% CI: 95.33-99.69%). The positive likelihood ratio was 8.34 (95% CI: 5.48-12.71), and the negative likelihood ratio was 0.06 (95% CI: 0.02-0.25). The area under the curve (AUC) was 0.959, indicating excellent diagnostic accuracy of the IADPSG criteria in identifying GDM [Figure 3].

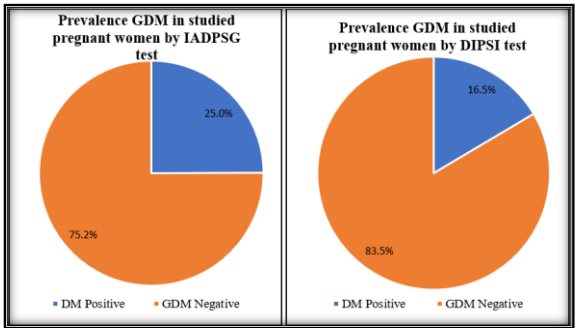

Figure 1: Prevalence GDM in studied pregnant women by IADPSG & DIPSI test

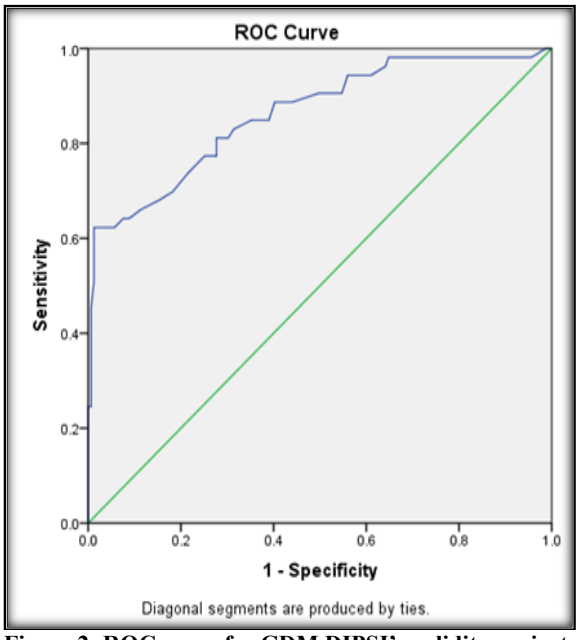

Figure 2: ROC curve for GDM DIPSI's validity against GDM IADPSG (gold standard) criteria.

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Table 1: Risk factors of GDM in studied pregnant women.

Variables	Category	GDM (IADPSG test)		Odds ratio	P value
		Positive (n=53)	Negative (n=159)		
Age Group (Years)	≤ 30	39 (73.6%)	111 (69.8%)	1.205	0.601
	>30	14 (26.4%)	48 (30.2%)		
	Mean±SD	27.12 ± 3.36	27.52 ± 3.64	0.706	0.481
Socioeconomic status	Upper middle	16 (30.2%)	61 (38.4%)	0.695	0.285
	Lower middle	37 (69.8%)	98 (61.6%)		
Occupation	Teaching	11 (20.8%)	22 (13.8%)	1.631	0.232
	Homemakers	42 (79.2%)	137 (86.2%)		
Residence	Urban	28 (52.8%)	122 (76.7%)	0.330	0.001
	Rural	25 (47.2%)	36 (23.3%)		
BMI (kg/m2)	≤ 24.9	29 (54.7%)	125 (78.6%)	0.270	<0.001
	≥25	24 (45.3%)	34 (21.4%)		
	Mean±SD	27.06±3.55	24.02±2.98	6.122	<,0.001
Gravida	Primi	12 (22.6%)	56 (35.2%)	0.538	0.092
	Multi	41 (77.4%)	103 (64.8%)		
Family history of diabetes mellitus	Yes	4 (7.5%)	2 (1.3%)	6.280	0.037
	No	49 (92.5%)	157 (98.7%)		
History of PCOS	Yes	14 (26.4%)	10 (6.3%)	5.349	<0.001
	No	39 (73.6%)	149 (93.7%)		
History of GDM in previous pregnancy	Yes	9 (17.0%)	8 (5.0%)	3.861	0.008
	No	44 (83.0%)	151 (95.0%)		

Table 2: Comparison of mean DIPSI, IADPSG FBS and IADPSG FBS 2 h in GDM positive and negative groups

	GDM (IADPSG test)		t value	p value
	Positive (n=53)	Negative (n=159)		
DIPSI	136.42±15.99	112.00±15.30	9.946	<0.001
IADPSG FBS	112.56±11.36	86.88±12.34	13.375	<0.001
IADPSG FBS 2 h	142.81±10.71	94.96±13.08	24.058	<0.001

Table 3: Cross tabulation of results of DIPSI versus IADPSG

		IADPSG FBS		Total
		Positive	Negative	
DIPSI	Positive	33	2	35
	Negative	20	157	177
Total		53	159	212

Table 4: Sensitivity, Specificity and accuracy of measures of DIPSI with respect to IADPSG (gold standard) criteria

Indicators	Values	95% CI
Sensitivity	62.26%	47.89% to 75.21%
Specificity	98.74%	95.53% to 99.85%
Positive Predictive Value	94.29%	80.38% to 98.52%
Negative Predictive Value	88.70%	84.74% to 91.73%
Accuracy	89.62%	84.71% to 93.38%
Positive Likelihood Ratio	49.50	12.29 to 199.34
Negative Likelihood Ratio	0.38	0.27 to 0.53
AUC	0.862	

Table 5: Cross tabulation of results of IADPSG versus DIPSI

		IADPSG FBS		Total
		Positive	Negative	
DIPSI	Positive	33	20	53
	Negative	2	157	159
Total		35	177	212

Table 6: Sensitivity, Specificity and accuracy of measures of IADPSG with respect to DIPSI (gold standard) criteria

Indicators	Values	95% CI
Sensitivity	94.29%	80.84% to 99.30%
Specificity	88.70%	83.09% to 92.96%
Positive Predictive Value	62.26%	52.00% to 71.54%
Negative Predictive Value	98.74%	95.33% to 99.69%
Accuracy	89.62%	84.71% to 93.38%
Positive Likelihood Ratio	8.34	5.48 to 12.71
Negative Likelihood Ratio	0.06	0.02 to 0.25
AUC	0.959	

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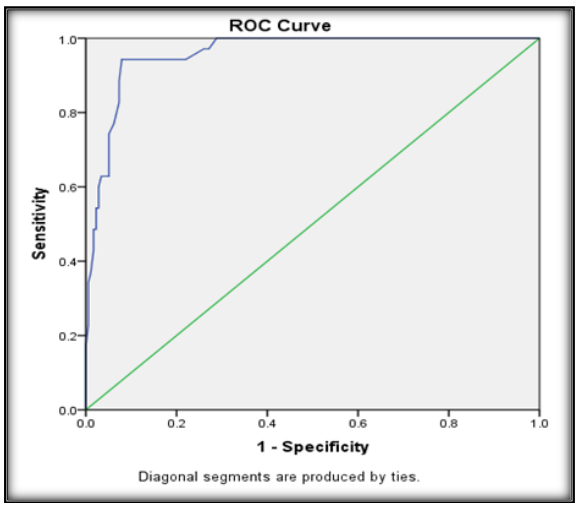

Figure 3: ROC curve for GDM DPSG (gold standard) validity against GDM DIPSI's criteria.

DISCUSSION

Universal diagnosis of all pregnant women for GDM in India is a well-accepted strategy. However, controversy arises on choosing the method of screening. IADPSG has a widespread acceptance including WHO.[15] It has been observed that many pregnant women do not visit healthcare centers in a fasting state for testing, often due to misconceptions. This can result in missed screening opportunities. To address this issue, the Government of India, through the Ministry of Health and Family Welfare, commends a universal diagnosis test grounded on the DIPSI guidelines, which can be conducted in a non-fasting state, ensuring that all pregnant women receive necessary screening.[21]

Our study identified several high-risk factors associated with GDM in pregnant women. Women with GDM were more expected to have a higher BMI, reside in rural areas, have a history of PCOS, and have a DM family history. These factors were significantly connected with an amplified risk of progressing GDM, with odds ratios ranging from 3.861 to 6.280. Reliable with our results, previous studies have also described those women through a PCOS history, diabetes family history, and previous GDM are at advanced risk of rising GDM. A meta-analysis study conducted by Toulis et al,[22] found that women suffering with PCOS are at higher danger to progressing GDM (OR: 2.89). Other studies Rajput R et al,[10] and Gowda SH et al,[23] have also reported that a GDM history in a previous pregnancy and a diabetes family history may disrupt glucose levels in succeeding pregnancies. In comparison to other studies, our study found that 80.5% of women had one or more risky issues for GDM, which is consistent with the findings of Chaudhary VP & Dixit P. However, our study found that women with a PCOS history had the highest odds of progressing GDM (OR: 13.51), shadowed by a DM family history (OR: 7.02), GDM (OR: 5.8), and perinatal mortality (OR: 4.27). Overall, our study highlights the consequences of detecting high-risk factors for GDM in pregnant women to provide early intervention and prevent adverse outcomes.

The present study noted that out of 212 women, 35 (16.5%) were identified with GDM by DIPSI, while 53 (25.0%) were diagnosed by IADPSG. This discrepancy is consistent with other studies, which have reported varying frequencies of GDM using the two criteria. Some studies have reported a higher frequency of GDM using the IADPSG criteria, such as Chaudhary VP & Dixit P (23.5% vs 7.5%) and Mohan et al,[19] (10.1% vs 4.2%). In contrast, Geetha DN & Sangeetha DK,[24] found a higher occurrence of GDM using the DIPSI criteria (14% vs 9%). Other studies Srinivasan S & Rani P,[25] and Dahiya V et al,[26] have reported similar frequencies of GDM using both criteria. The variability in GDM prevalence across different studies can be attributed to regional differences in food habits and lifestyles across India. This highlights the need for standardized criteria and screening methods for GDM to ensure accurate diagnosis and management.

This study compared the diagnostic accuracy of the DIPSI criteria with the IADPSG criteria for GDM. Our findings revealed that DIPSI had a sensitivity of 62.26%, specificity of 98.74%, and diagnostic accuracy of 89.62% when compared to IADPSG. Similar studies have reported varying results. Rudra S & Ashu A found DIPSI to have a sensitivity of 71.4% and specificity of 95.4% compared to IADPSG. Tripathi et al,[18] reported a sensitivity of 74.1% and specificity of 96.9%, but noted that DIPSI missed some cases and over diagnosed others. Mohan et al,[19] found DIPSI to have poor sensitivity compared to both WHO 1999 and IADPSG criteria. Vij et al,[20] also reported that DIPSI was not a satisfactory method, despite diagnosing 74.34% of cases.

Despite these variations, several studies have found DIPSI to be a useful criterion for detecting GDM, particularly in the Indian setting. Nallaperumal et al,[17] argued that IADPSG criteria may over diagnose or miss cases of GDM in Indian women, while Polur et al,[15] found DIPSI to be a useful method compared to WHO criteria. Magon et al,[27] and Sharma et al,[28] also recommended the use of DIPSI in India. These studies demonstrate the inconsistency in diagnostic accuracy of DIPSI compared to IADPSG and other criteria. While DIPSI shows promise, its sensitivity and specificity vary across studies, indicating the need for further research to establish its reliability and validity in diagnosing GDM. Furthermore, it has been found out by Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study that higher isolated fasting glucose levels have higher incidence of a poor maternal and fetal outcome.[29]

CONCLUSION

This study revealed that women with gestational diabetes mellitus (GDM) were more likely to have

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higher BMI, reside in rural areas, have a history of PCOS, and a family history of diabetes mellitus. Study highlights the comparative diagnostic accuracy of the Diabetes in Pregnancy Study Group of India (DIPSI) criteria and the International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria for identifying Gestational Diabetes Mellitus (GDM) in a tertiary care setting. Our findings suggest that while both criteria effectively diagnose GDM, there are notable differences in sensitivity, specificity, and practical applicability. The DIPSI criteria, with its simpler and more accessible approach, may be more suitable for resource-limited settings, while the IADPSG criteria offer a more rigorous diagnostic framework.

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