

Diagnostic efficacy of DIPSI criteria for diagnosis of gestational diabetes mellitus in comparison with WHO 2013 criteria

Sumaiya Yasmin^{1*}, Begum Nasrin², Tripti Rani Das², Sharmeen Mahmood², Maliha Parvin³

¹Medical Officer, Upazila Health Complex, Homna, Cumilla, Bangladesh

²Department of Obstetrics and Gynecology, Bangabandhu Sheikh Mujib Medical University, Shahbag, Dhaka, Bangladesh

³Department of Obstetrics and Gynecology, Dhaka Medical College Hospital, Dhaka, Bangladesh

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***Correspondence:**

Dr. Sumaiya Yasmin,

E-mail: dr.sharmeenmahmood30@gmail.com

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a global health issue due to its increasing prevalence and negative effects on maternal and fetal health. The standard screening method is the 75 g glucose tolerance test (OGTT), which requires fasting. The Diabetes in Pregnancy Study Group of India (DIPSI) suggests a one-stage, non-fasting test as an alternative, which could be more patient-friendly and aligns with international recommendations. This study aimed to assess the diagnostic efficacy of the DIPSI method compared to the WHO criteria for GDM screening.

Methods: This cross-sectional study was conducted from October 2021 to September 2022 at the Department of Obstetrics and Gynecology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka. One hundred and thirty-three singleton pregnant women who provided informed consent were included.

Results: Among 133 participants, 34 (25.6%) were diagnosed with GDM according to WHO criteria, while 26 (19.5%) were diagnosed with DIPSI. The DIPSI method showed high specificity (96.97%) but lower sensitivity (67.65%) compared to the WHO criteria. The positive and negative likelihood ratios were 22.32 and 0.33, respectively, with an overall accuracy of 89.46%. Lowering the DIPSI cutoff to 7.3 mmol/L improved sensitivity to 82.4% and specificity to 92.9% and increased overall accuracy to 90.2%.

Conclusions: The non-fasting DIPSI method demonstrated reasonable diagnostic accuracy compared to the WHO criteria. It is recommended for use in low-resource settings but should not replace the gold standard OGTT for comprehensive GDM screening.

Keywords: DIPSI, Gestational diabetes mellitus, Glucose tolerance test

INTRODUCTION

Gestational diabetes mellitus (GDM) is a common pregnancy-related disease characterized by high blood glucose levels with thresholds below those of overt diabetes.¹ This condition often has several adverse consequences for both mother and child. Mothers with GDM are at an increased risk of cesarean sections, hypertension, preeclampsia, excessive weight gain, and future type 2 diabetes and cardiovascular disease. Meanwhile, their children face risks such as high birth

weight, neonatal hypoglycemia, jaundice, birth trauma, stillbirths, and long-term problems including obesity and diabetes.² Early screening and diagnosis are crucial to preventing these complications.³

The lack of universal screening standards has led to varying practices for identifying GDM, which in turn impacts prevalence estimates.⁴ Globally, GDM prevalence ranges from 1% to 28%, depending on the population, screening methods, and diagnostic criteria.⁵ Genetic factors also influence the prevalence of GDM.⁶ GDM is

more common in low- and upper-middle-income countries, where it is approximately 64% higher than in high-income countries due to limited access to healthcare.⁷ In the United States, GDM affects 7.6% of pregnancies, with 19.7% of these women later developing diabetes.⁸ In the UK, GDM affects approximately one in 23 pregnancies.⁹ South Asians, particularly Indians, have higher rates of GDM, with a prevalence ranging from 16.55% to 22%.¹⁰ In Bangladesh, GDM prevalence is 9.7% according to WHO criteria and 12.9% according to ADA criteria.¹¹

Assessing the risk of GDM at the first prenatal visit is crucial. The risk level can be categorized as low, average, or high. Low-risk women usually do not need routine screening, while women at average risk should be screened between 24 and 28 weeks of pregnancy. Average risk factors include age over 25 years, pre-pregnancy obesity (BMI 25 kg/m²), high birth weight, first-degree relatives with diabetes, and belonging to certain ethnic/racial groups (South Asia, Middle East, Caribbean). On the other hand, high-risk factors include a history of GDM, impaired glucose tolerance, significant obesity (BMI 30 kg/m²), and a strong family history of type 2 diabetes.¹² Maternal insulin resistance during pregnancy is linked to glucose transfer to the fetus. Insulin sensitivity increases initially and then gradually decreases during pregnancy, allowing for the storage of essential energy for later stages.¹³ Rising levels of estrogen, progesterone, and placental hormones decrease insulin sensitivity and lead to elevated blood sugar and free fatty acids. This shift in energy from the mother to the fetus is facilitated by these hormonal changes.¹⁴⁻¹⁵

In GDM, metabolic disorders include impaired insulin response in tissues, decreased glucose suppression in the liver, and decreased glucose uptake in muscles.¹⁶ Inadequate insulin secretion cannot counteract insulin resistance, resulting in detectable hyperglycemia on routine examinations.¹⁷ GDM further triggers oxidative stress, increases free radical formation, and undermines antioxidant defenses. These reactive oxygen species (ROS) impede insulin-mediated glucose uptake and attenuate glycogen synthesis, worsening hyperglycemia. Furthermore, proinflammatory cytokines such as TNF can enhance ROS generation, thereby contributing the metabolic dysregulation characteristic of GDM.¹⁸

The diagnostic criteria for GDM vary across regions and are influenced by population characteristics, screening costs, methods, and thresholds. Multiple associations have developed their own criteria, including ADA, ADIPS, Carpenter-Coustan, IADPSG, ICD, JSOG, NDDG, and WHO. Despite the widespread adoption of the World Health Organization (WHO) criteria, debates remain regarding the appropriate criteria for diagnosis, timing of testing, and target population for screening.^{7, 19}

The WHO criteria utilize a 75g oral glucose tolerance test (OGTT) with specific plasma glucose level thresholds.

These include a fasting plasma glucose level of 5.1-6.9 mmol/L (92-125 mg/dL), 1-hour plasma glucose level ≥ 10.0 mmol/L (180 mg/dL), and 2-hour plasma glucose level of 8.5-11.0 mmol/L (153-199 mg/dL).¹ ADA, WHO, and IADPSG guidelines recommend fasting and multiple blood tests for diagnosis. However, the Diabetes in Pregnancy Study Group India (DIPSI) suggests a simpler non-fasting OGTT with a glucose load of 75 g and a 2-hour cutoff of 140 mg/dL (7.8 mmol/L) for community-level screening. This approach is particularly practical in resource-limited settings.²⁰ The DIPSI approach has demonstrated high sensitivity, specificity, negative predictive value, and diagnostic accuracy.^{10, 21-22} The WHO fasting glucose threshold from 2013 identifies women at increased risk of adverse outcomes, while higher 2-hour post-exercise thresholds exclude women who may benefit from GDM treatment.²³

The prevalence of GDM is on the rise globally due to increasing rates of overweight and obesity.²⁴ Early detection and intervention are vital in order to restore maternal health and prevent fetal complications, ultimately improving perinatal outcomes.²⁵ There is an increasing demand for an internationally standardized, cost-effective, and practical screening test for GDM that offers high sensitivity and ensures good patient compliance. The objective of this study was to assess the diagnostic effectiveness of the DIPSI fasting criteria in comparison to the WHO criteria for diagnosing GDM.

METHODS

This cross-sectional analytical study was conducted from October 2021 to September 2022 in the Department of Obstetrics and Gynecology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbagh, Dhaka. The study involved 133 pregnant women of varying ages and gestational stages who attended the outpatient and inpatient departments. After obtaining informed written consent, participants were enrolled based on specific inclusion criteria. Participants with multiple pregnancies, overt diabetes mellitus, acute critical illnesses (e.g., preeclampsia), chronic diseases (e.g., chronic renal failure, chronic liver disease, ischemic heart disease, chronic hypertension), PCOS, or those on glucocorticoids, diuretics, and metformin were excluded. Detailed medical histories and thorough clinical examinations were conducted. Initially, study subjects underwent a 75g glucose challenge test regardless of meal timing to screen for glycemic status according to DIPSI criteria. GDM was diagnosed if the 2-hour plasma glucose level was ≥ 7.8 mmol/L. Participants then returned 2-3 days later for a comprehensive OGTT as per WHO 2013 guidelines. They fasted for 8-12 hours overnight before testing. Blood samples were collected aseptically from the antecubital vein before and 2 hours after consuming 75g of anhydrous glucose dissolved in water. Samples were processed in the Biochemistry Laboratory at BSMMU, and plasma glucose levels were assayed using the hexokinase/G-6-PDH

method on an ARCHITECT cSystems automated analyzer.

Statistical analyses were conducted using SPSS version 26.0. Results were presented in tables and figures. The sensitivity and specificity of the DIPSI method were evaluated compared to the standard fasting WHO criteria. A p-value of <0.05 was considered statistically significant. Confidentiality was strictly maintained by assigning unique identification numbers to participants, ensuring privacy during blood collection and examinations, and securing data at all stages. Ethical aspects were strictly followed, with ethical clearance from BSMMU, informed consent from participants, and assurance of minimal risk during the study. The study did not involve any experimental drugs, placebos, or additional interventions beyond standard care.

RESULTS

Table 1 shows the demographic and obstetric characteristics of the respondents. The average age of the respondents was 25.50 ± 4.96 years, and 57.1% of them were aged 25 years or younger. The majority (68.4%) of participants resided in urban areas. In terms of occupation, 61.7% were housewives. Regarding educational qualifications, 47.4% had up to an HSC/equivalent level of education. The average monthly income was 24240.60 ± 10148.26 Taka. Additionally, 51.1% of the respondents were multigravida, with 56.4% being in the second trimester of pregnancy. The mean gestational age was 19.80 ± 7.78 weeks. Furthermore, the majority of study participants (67.7%) were overweight, followed by 30.8% with a normal BMI. Only 1.5% were classified as obese, with a mean BMI of 25.95 ± 2.24 kg/m².

Table 1: Distribution of the respondents according to demographic and obstetrics characteristics (n=133).

Parameters	Frequency (N)	Percentage (%)
Maternal age (in years)		
Up to 25	76	57.1
26 - 35	52	39.1
>35	5	3.8
Mean±SD (min-max)	25.50 ± 4.96 (15-40)	
Residence		
Rural	42	31.6
Urban	91	68.4
Educational qualifications		
Up to primary level	17	12.8
Secondary/equivalent	25	18.8
HSC/equivalent	63	47.4
Graduate/post-graduate	28	21.1
Occupation		
Housewife	82	61.7
Service holder	22	16.5
Student	29	21.8
Monthly income status (in Taka)		
≤ 10000	11	8.3
10,001-25,000	78	58.6
>25,000	44	33.1
Mean±SD (min-max)	24240.60 ± 10148.26 (2000-50000)	
Gravida		
Primigravida	65	48.9
Multigravida	68	51.1
Trimester		
First trimester	35	26.3
Second trimester	75	56.4
Third trimester	23	17.3
Gestational age (in weeks)		
Mean±SD (min-max)	19.80 ± 7.78 (6-35)	
Body mass index (kg/m²)		
Normal (18.5-24.9)	41	30.8
Overweight (25.0-29.9)	90	67.7
Obese (≥30)	2	1.5
Mean±SD (min-max)	25.95 ± 2.24 (18.5-31.1)	

Table 2 demonstrates the distribution of respondents based on their family history of type 2 diabetes mellitus. It was observed that a significant proportion (31.6%) of patients had a positive family history of T2DM.

Table 2: Distribution of the study subjects according to family history of T2DM (n=133).

Family history of type 2 DM	Frequency (N)	Percentage (%)
Present	42	31.6
Absent	91	68.4

Table 3 and Figure 1 depicts the comparable nature of the DIPSI criteria to the WHO 2013 criteria. The true positive cases amount to 23 (67.6%), while the true negatives account for 96 (97.0%). The false positives stand at 3 (3.0%), and the false negatives are 11 (32.4%). In total, 19.5% of the respondents were identified as having GDM using the DIPSI criteria, in contrast to 25.6% with the WHO criteria.

Table 3: Comparison of respondents diagnosed as GDM/NGT by DIPSI and WHO 2013 criteria (n=133).

DIPSI	WHO 2013		Total N (%)	χ^2 - value	P value
	GDM N (%)	NGT N (%)			
GDM	23 (67.6)	3 (3.0)	26 (19.5)	67.19	<0.001 ^a
NGT	11 (32.4)	96 (97.0)	107 (80.5)		
Total	34 (25.6)	99 (74.4)	133 (100.0)		

^a = chi-square test, GDM = Gestational diabetes mellitus, NGT = Normal glucose tolerance. Figure within the parenthesis () indicate percentage out of column total

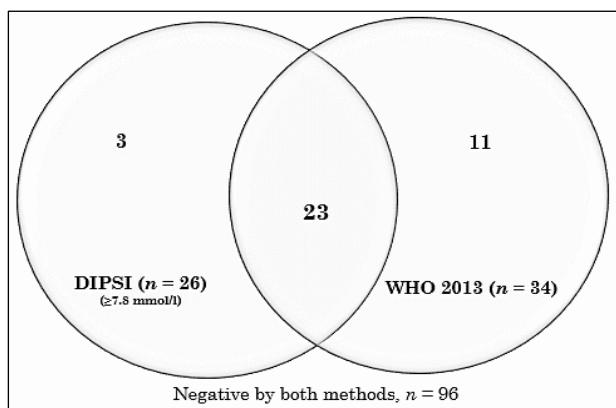


Figure 1: Venn diagram showing detailed breakup of patients diagnosed as GDM by DIPSI and WHO 2013 methods along with their concordance/discordance.

The sensitivity of DIPSI in comparison to WHO 2013 was 67.65%, specificity 96.97%, positive likelihood ratio 22.32, negative likelihood ratio 0.33, positive predictive

value 88.48%, negative predictive value 89.70% and accuracy 89.46%, demonstrated in table 4.

Table 4: Diagnostic efficacy of DIPSI criterion in comparison with WHO 2013 criteria (n=133).

Diagnostic efficacy	Value with 95% CI
Sensitivity	67.65 (49.47-82.61)
Specificity	96.97 (91.40-99.37)
Positive likelihood ratio (LR+)	22.32 (7.15-69.68)
Negative likelihood ratio (LR-)	0.33 (0.20-0.54)
Positive predictive value (PPV)	88.48 (71.10-96.00)
Negative predictive value (NPV)	89.70 (84.25-93.41)
Accuracy	89.46 (82.96-94.12)

Receiver operating characteristic curve (ROC) of blood sugar tests according to DIPSI criteria for prediction of GDM

The ROC for the blood glucose tests according to DIPSI criteria compared to the reference value of the OGTT estimates according to WHO criteria 2013 is shown in Figure 2, which gave a cutoff value of 7.30 mmol/L. The area under the curve was 0.932 (0.884-0.980), with a standard error of 0.024 and a significance level of <0.001, categorizing it as an excellent test compared to the gold standard (i.e., WHO 2013 criteria).

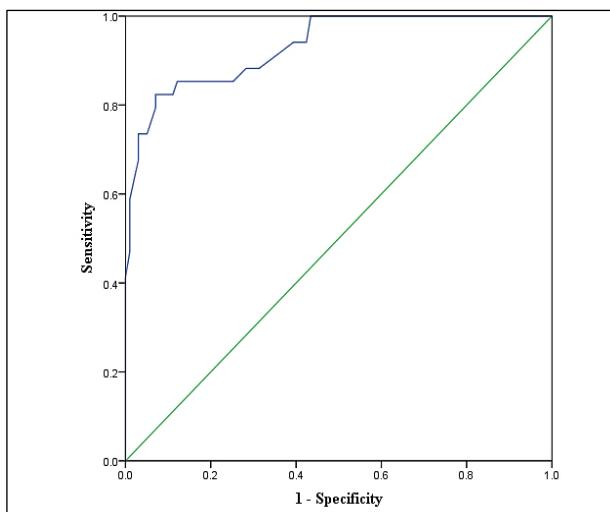


Figure 2: Receiver operating characteristic (ROC) curves of DIPSI test levels for prediction of GDM (area = 0.932, SE = 0.024, asymptomatic significance = 0.000, 95% CI: lower bound = 0.884, upper bound = 0.980).

Table 5 and figure 3 illustrates that among the respondents, using 7.30 mmol/L as the cut-off value of blood sugar for detecting GDM in the non-fasting state, there were 28

(82.4%) true positives, 92 (92.9%) true negatives, 7 (7.1%) false positives, and 6 (17.6%) false negatives. Overall,

26.3% of the respondents were identified as having GDM, compared to 25.6% using the WHO criteria.

Table 5: Categorization of non-fasting blood sugar levels in DIPSI compared to WHO 2013 criteria considering the cut-off value of 7.30 mmol/l (n=133).

Blood sugar (non-fasting) (mmol/l)	WHO 2013		Total N (%)	χ^2 -value	P value
	GDM N (%)	NGT N (%)			
≥ 7.30	28 (82.4)	7 (7.1)	35 (26.3)		
< 7.30	6 (17.6)	92 (92.9)	98 (73.7)	73.970	<0.001 ^a
Total	34 (25.6)	99 (74.4)	133 (100.0)		

^a = chi-square test. Figure within the parenthesis () indicate percentage out of column total

Table 6: Diagnostic efficacy of non-fasting state blood sugar level (cut-off 7.3 mmol/l) in comparison with WHO 2013 criteria (n=133).

Diagnostic efficacy	Value with 95% CI
Sensitivity	82.4 (65.47-93.24)
Specificity	92.9 (85.97-97.11)
Positive likelihood ratio (LR+)	11.7 (5.61-24.19)
Negative likelihood ratio (LR-)	0.19 (0.09-0.39)
Positive predictive value (PPV)	80.0 (65.87-89.27)
Negative predictive value (NPV)	93.9 (88.08-96.94)
Accuracy	90.2 (83.86-94.69)

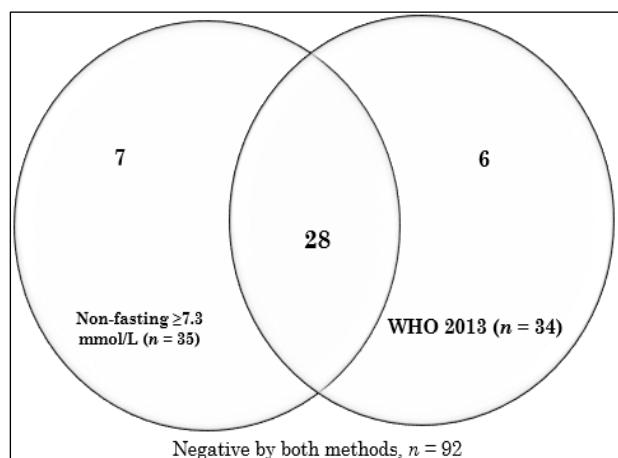


Figure 3: Venn diagram showing detailed breakup of patients diagnosed as GDM by non-fasting state blood sugar level (cut-off 7.30 mmol/l) and WHO 2013 methods along with their concordance/discordance.

The sensitivity of DIPSI compared to WHO 2013 at the cut-off value of ≥ 7.30 mmol/L was 82.4%, specificity 92.9%, positive likelihood ratio 11.7, negative likelihood ratio 0.19, positive predictive value 80.0% and negative predictive value 93.9%.

DISCUSSION

The aim of this cross-sectional study was to assess the diagnostic effectiveness of the DIPSI criteria in comparison with the WHO criteria for screening of GDM.

The study enrolled 133 pregnant women regardless of age and gestational age to evaluate the performance of the DIPSI criteria in detecting GDM.

Establishing standardized criteria for diagnosing gestational diabetes mellitus is critical to ensuring consistency and accuracy in clinical practice. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria, endorsed by the World Health Organization in 2013, have emerged as the gold standard for GDM diagnosis due to their improved sensitivity, specificity and accuracy.²² The DIPSI criteria offer the advantage of a one-step, non-fasting glucose challenge test, eliminating the need for a second visit and enabling cost-effective screening.²⁶

The results showed a discrepancy between the prevalence of GDM diagnosed according to the 2013 WHO criteria (25.6%) and the DIPSI criteria (19.5%). High frequency of GDM was also observed by some other tertiary care hospital-based studies of Bangladesh in recent years.²⁷⁻²⁸ The inconsistency underscores the importance of evaluating different screening methods to identify the most effective approach for GDM detection.

The DIPSI criteria demonstrated limitations in detecting GDM cases in the present study. Notably, the DIPSI criteria failed to identify a substantial proportion (32.35%) of women with GDM, and a small percentage (8.82%) of pregnant women tested positive by DIPSI but were not confirmed by fasting oral glucose tolerance test (OGTT). While the DIPSI criteria exhibited high specificity

(96.97%), its sensitivity was relatively low (67.65%), indicating its potential to miss GDM cases.

The diagnostic performance of the DIPSI criteria, as evidenced by the positive and negative predictive values, positive and negative likelihood ratios, and diagnostic accuracy, was consistent with previous studies. Anjalakshi et al.²⁹ reported 100% sensitivity and specificity for the two-hour non-fasting DIPSI test compared to the WHO-recommended OGTT, while Sharma et al emphasized the cost-effectiveness and patient-friendly nature of the DIPSI test.³⁰ However, studies by Mohan et al, Vij et al, Junnare et al and Tripathi et al highlighted the limitations of the DIPSI criteria in terms of sensitivity and specificity, suggesting its reduced effectiveness in certain populations.³¹⁻³⁴ The study corroborates these findings, emphasizing the need for careful consideration when utilizing the DIPSI criteria for GDM screening.

Furthermore, in the present study, the area under the ROC curve reached 0.932 when the non-fasting glucose level (DIPSI) cutoff point for GDM screening was set at 7.30 mmol/L, indicating high performance. Significant improvements were observed in the predictive values of DIPSI, with a sensitivity of 82.4%, specificity of 92.9%, PPV of 80.0%, NPV of 93.9%, and diagnostic accuracy of 90.2%. Basnet et al.³⁵ showed that a glucose threshold of >140 mg/dL (7.8 mmol/L) identified approximately 80% of GDM cases, with further increases to 90% using a threshold of >130 mg/L dl (7.2 mmol/l). Rudra and Yadav also emphasized that lowering the blood glucose threshold from 140 mg/dL to 136 mg/dL improved the sensitivity and specificity of the DIPSI criteria.³⁶

Therefore, DIPSI is not an exact alternative for traditional OGTT, its properties could make it valuable, especially in low-resource settings. Limitations of the current study include the small sample size and its single-centre design, which may limit the generalizability of the results. Additionally, the study did not account for certain confounding factors such as pre-test food intake, which may have influenced the accuracy of the DIPSI criteria. To address these limitations, future research should include larger, multicentre studies with diverse populations and include comprehensive assessments of confounding variables. In addition, efforts to standardize testing procedures and establish optimal cutoff points for DIPSI criteria would improve diagnostic accuracy and utility in clinical practice.

This study was limited to a single center with a small sample size, which may influence the applicability of the findings.

CONCLUSION

This study concluded that the Diabetes in Pregnancy Study Group of India (DIPSI) criterion is a useful method for diagnosing gestational diabetes mellitus (GDM), although it has a relatively low sensitivity compared to the 2013

WHO criteria. Adjusting the cut-off value to 7.3 mmol/L for a glucose load of 75g in the non-fasting state increases the diagnostic effectiveness of the DIPSI criterion. This adaptation may improve its utility in clinical practice, particularly in low-resource settings.

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