Original Article

Diagnostic accuracy of DIPSI criteria for diagnosing gestational diabetes mellitus in Puducherry

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Abstract

Context: Gestational diabetes mellitus (GDM) is a major concern in recent years. During pregnancy, it is difficult to consume 75 g of glucose in the fasting state as pregnant women may experience symptoms such as vomiting. The Diabetes in Pregnancy Study Group India (DIPSI) criterion requires a single prick in the non-fasting state to collect the sample for diagnosing GDM. **Aims:** This study aimed to assess the diagnostic accuracy of DIPSI criteria compared to the WHO criteria for GDM diagnosis. **Settings and Design:** A community-based cross-sectional study was conducted among pregnant mothers attending the primary health centers in Puducherry from August 2022 to November 2022. **Methods and Material:** A total of 384 samples were selected, and 75 g of anhydrous glucose was given after 8 hours of overnight fasting. Both fasting and postprandial venous blood sugar levels were measured to determine the prevalence of GDM as per the WHO 2013 criteria. After 2 days, GDM was diagnosed among all study participants based on the DIPSI criteria. Further analysis was done. **Results:** The prevalence of GDM was 14.1% and 12.8% per the WHO 2013 and DIPSI criteria, respectively. In comparison to the WHO 2013 criteria, DIPSI had 79.63% sensitivity, 98.18% specificity, 87.76% positive predictive value, and 96.72% negative predictive value. The results of kappa statistics showed that there was almost perfect agreement between the WHO 2013 criteria and DIPSI criteria. **Conclusions:** The present study shows that the DIPSI criteria can be used to screen and diagnose GDM as there is no need for overnight fasting. The blood glucose value can be measured easily with a single prick, which is comfortable for both pregnant women and treating doctors.

Keywords: Diabetes in pregnancy, diagnostic accuracy, DIPSI, GDM, gestational diabetes mellitus, OGTT

Introduction

Gestational diabetes mellitus (GDM) is defined as any level of glucose intolerance that develops or manifests during pregnancy.[1] The prevalence of GDM was 3.8% in Kashmir, 6.2% in Mysore, 9.5% in Western India, and 22% in Tamil Nadu.[2]

Pregnancy hormones are the primary cause of insulin resistance and GDM. The exact pathogenesis of GDM is unclear; a familial predisposition is widely accepted. Nongenetic factors such as maternal age, obesity, diet, and lifestyle are also associated with GDM.[3]

Pregnant women with GDM are at higher risk of developing type 2 diabetes mellitus in the future.[4] GDM can cause adverse maternal outcomes, including preeclampsia, stillbirths, macrosomia, and cesarean delivery, and cause neonatal complications such as hypoglycemia and respiratory distress. Hence, screening of GDM is essential.

There are several methods to detect GDM. According to the WHO 1999 criteria, fasting glucose ≥7.0 mmol/L and/or 2-hour glucose ≥7.8 mmol/L were classified as GDM.[5] The

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International Association of Diabetes and Pregnancy Study Group (IADPSG) criteria are also used.[6] The American Diabetic Association proposed two methods for diagnosing GDM in pregnant women. The "one step" strategy uses 75 g of glucose, and the "two steps" strategy uses 50 g of glucose, followed by 100 g of glucose, for diagnosing GDM.[7]

Diabetes in Pregnancy Study Group India (DIPSI) developed a one-step process to detect GDM, irrespective of their last meal. After administering 75 g of anhydrous glucose dissolved in 250–300 mL of water, the plasma glucose level in pregnant women will be measured 2 hours after consumption. Plasma glucose levels of ≥140 mg/dL are taken as GDM.[8]

Physicians and other healthcare providers in India disagree on how to diagnose and manage GDM. An integrated approach is the key to GDM management as patient compliance and outcomes will be better.[9]

Though numerous methods of screening tests are available to detect GDM, the prevalence is exhibiting a rising trend. Patients with GDM are at high risk of developing diabetes mellitus after delivery.[10] Hence, there is a need for screening and diagnostic tests that should be accurate, reliable, cheap, easy to do, and widely accepted by pregnant women. Thus, the current study was conducted to compare the diagnostic accuracy of the DIPSI criteria to the WHO criteria for diagnosing GDM.

Aims and Objectives

Aim

- To assess the diagnostic accuracy of the DIPSI criteria compared to the WHO criteria for GDM diagnosis.

Objectives

- To estimate the prevalence of GDM among pregnant women attending primary health centers (PHCs) in Puducherry
- To evaluate the sensitivity, specificity, positive predictive value, and negative predictive value of the DIPSI criteria in comparison to the WHO criteria for diagnosing GDM
- To determine the agreement between the results of the DIPSI and WHO 2013 criteria among pregnant mothers attending PHCs.

Materials and Methods

A community-based cross-sectional study was conducted among pregnant mothers who were attending PHCs for their regular antenatal checkups. A total of five PHCs were chosen from all over Puducherry. The study was conducted for 4 months, from August 2022 to November 2022. All pregnant women who were attending PHCs for regular antenatal checkups during the start of the study were included. Pregnant women with already existing diabetes mellitus, chronic illnesses (such as involvement of the kidney and pancreas), and pregnant women who were on drugs such as corticosteroids or antipsychotic drugs were excluded from the study.

Sample size

Assuming a 50% prevalence of GDM with a 95% confidence interval and 5% error, the sample size was 384. The sample size was calculated using Open Epi 3.01.

Study design

A multistage sampling technique was used to obtain the desired sample size. There were 27 PHCs in Puducherry. Assuming that 80 pregnant women will attend antenatal checkups in one PHC in a month (based on previous data from PHCs), five PHCs were selected to obtain a total of 384 samples. After obtaining permission from the respective department head, PHCs were selected using a simple random method.

Among those five PHCs, 77 pregnant mothers were recruited from each PHC to get 384 samples. After 8 hours of overnight fasting, 75 g of anhydrous glucose was given to all study participants. Both fasting and postprandial venous blood sugar levels were measured, and the prevalence of GDM was found as per the WHO 2013 criteria. After 2 days, the same study participants were recruited once again, and 75 g of anhydrous glucose was given in the non-fasting state. After exactly 2 hours, the venous blood glucose level was measured, and the prevalence of GDM was assessed according to the DIPSI criteria.

Definitions of GDM

Guidelines	Fasting blood sugar (mg/dL)	1-hour blood glucose level after 75 g glucose administration (mg/dL)	2-hour blood glucose level after 75 g glucose administration (mg/dL)
WHO criteria (2013)[11]	92–125 mg/dL (5.1–6.9 mmol/L)	≥180 mg/dL (10.0 mmol/L)	≥153–199 mg/dL (8.5–11.0 mmol/L)
DIPSI criteria[12]	Not required	Not required	≥140 mg/dL

Data collection

After explaining the procedure, consent was obtained from each study participant. Data were collected using a pretested, semi-structured, validated questionnaire that included demographic details such as age, period of gestation, history of diabetes in the past, family history of diabetes, anthropometric measurements, and blood sugar according to the WHO criteria and DISPI criteria. Data were collected, entered in Microsoft Excel, and analyzed in IBM SPSS Statistics for Windows, Version 21.

The diagnostic accuracy of the DIPSI criteria was evaluated by calculating sensitivity, specificity, and predictive values, with the WHO 2013 criteria as the gold standard. The kappa statistic was calculated to find out the level of agreement between the WHO 2013 criteria and DIPSI criteria.

The ethical approval for this study was obtained from the institutional ethical review committee. The study project was funded by the Indian Council of Medical Research **(ICMR STS project Reference ID: 2022-07296).**

Results

The basic characteristics of the study participants are shown in Table 1. The mean age of the study participants was 28.07 years, with a standard deviation (SD) of 4.22. The mean gestation period of the participants was 6.23 months, with an SD of 1.56. The mean postprandial blood sugar (PPBS) level according to the WHO 2013 criteria was 130.10 mg/dL, with an SD of 17.29. The mean blood sugar level according to the DIPSI criteria was 127.54 mg/dL, with an SD of 24.30.

The prevalence of GDM based on the WHO 2013 and DIPSI criteria is shown in Table 2. According to the WHO 2013 criteria, the prevalence of GDM was 14.1%, while the DIPSI criteria showed 12.8%. The above difference was statistically nonsignificant (Z = 0.5294 and *P* = 0.596).

The association between GDM (as per the WHO 2013 criteria) and selected variables is shown in Table 3a. There was a statistically significant association between GDM and age group (*P* = 0.001). GDM was significantly associated with the period of gestation (*P* = 0.001).

The association between GDM (as per the DIPSI criteria) and selected variables is shown in Table 3b. There was a statistically significant association between GDM and age group (*P* = 0.001). GDM was significantly associated with the gestational period (*P* = 0.001).

The statistical parameters of the DIPSI criteria compared to the WHO 2013 criteria are shown in Table 4. The sensitivity of DIPSI in comparison with the WHO 2013 criteria was 79.63%, specificity was 98.18%, positive predictive value was 87.76%, negative predictive value was 96.72%, with a positive likelihood ratio of 43.8, a negative likelihood ratio of 0.21, and accuracy was 95.57%.

Figure 1: The ROC curve and the corresponding area under the curve (AUC = 0.863; 95% CI: 0.812–0.914) indicate that the DIPSI criteria have 'good' diagnostic accuracy.

Table 5: shows the result of GDM by using the DIPSI and WHO 2013 criteria. The kappa value between the DIPSI and WHO 2013 criteria was 0.809, and the *P* value was 0.001. The result shows that there is "almost perfect agreement" between the WHO 2013 criteria and DIPSI criteria, which was statistically significant.

Table 1: Basic characteristics of study participants

Basic characteristics	Mean±Standard Deviation
Age (in years)	28.07±4.22
Gestational age (in months)	6.23±1.56
Fasting blood sugar as per the WHO 2013 criteria (in mg/dL)	84.69±4.34
Postprandial blood sugar as per the WHO 2013 criteria (in mg/dL)	130.10±17.29
Blood sugar as per the DIPSI criteria (in mg/dL)	127.54±24.30

Table 2: Prevalence of GDM by the WHO 2013 and DIPSI criteria

GDM	WHO 2013 criteria *n* (%)	DIPSI criteria *n* (%)	*Z*	*P*
Positive	54 (14.1)	49 (12.8)	0.5294	0.596
Negative	330 (85.9)	335 (87.2)		
Total	384 (100)	384 (100)		

Table 3a: Association between GDM (as per the WHO 2013 criteria) and selected variables

Variables	GDM (WHO 2013 Criteria)		Chi-square	*P*
	Positive *n*=54 (%)	Negative *n*=330 (%)		
Age (in years)				
18–20	9 (16.7)	9 (2.7)	38.67	0.001
21–25	0 (0.0)	78 (23.6)		
26–30	36 (66.7)	157 (47.6)		
31–35	9 (16.7)	68 (20.6)		
36–40	0 (0.0)	9 (2.7)		
>40	0 (0.0)	9 (2.7)		
Period of Gestation				
8 weeks	0 (0.0)	8 (2.4)	117.123	0.001
12 weeks	0 (0.0)	16 (4.8)		
16 weeks	9 (16.7)	1 (0.3)		
20 weeks	10 (18.5)	98 (29.7)		
24 weeks	21 (38.9)	113 (34.2)		
28 weeks	0 (0.0)	41 (12.4)		
32 weeks	5 (9.3)	53 (16.1)		
36 weeks	9 (16.7)	0 (0.0)		

Discussion

The current study was conducted to compare the DIPSI criteria with the WHO 2013 criteria for diagnosing GDM. A total of 384 pregnant mothers were included in the study, with a mean age of 28.07 years. The mean gestation age was 6.23 months. Both WHO criteria and DIPSI criteria had almost similar mean glucose levels after administering 75 g of glucose over two hours.

According to the WHO 2013 criteria, GDM prevalence was 14.1%, while the DIPSI criteria showed 12.8%. A study conducted by Singh *et al.*[13] showed that the prevalence of GDM was 20.1% according to the WHO 2013 criteria method and 16.8% according to the DIPSI criteria. Another study conducted by Shrestha *et al.*[14] showed a 5.88% prevalence of GDM (1.4% by DIPSI, 1.8% by WHO criteria, and 3.29 by both methods). The prevalence of GDM differed between the DIPSI and WHO 2013 criteria in the present study, but it was not statistically

Table 3b: Association between GDM (as per the DIPSI criteria) and selected variables

Variables	GDM (DIPSI criteria)		Chi-square	*P*
	Positive *n*=49 (%)	Negative *n*=335 (%)		
Age				
18–20	9 (18.4)	9 (2.7)	39.384	0.001
21–25	0 (0.0)	78 (23.3)		
26–30	32 (65.3)	161 (48.1)		
31–35	8 (16.3)	69 (20.6)		
36–40	0 (0.0)	9 (2.7)		
>40	0 (0.0)	9 (2.7)		
Period of Gestation				
8 weeks	0 (0.0)	8 (2.4)	80.552	0.001
12 weeks	0 (0.0)	16 (4.8)		
16 weeks	9 (18.4)	1 (0.3)		
20 weeks	10 (20.4)	98 (29.3)		
24 weeks	20 (40.8)	114 (34.0)		
28 weeks	0 (0.0)	41 (12.2)		
32 weeks	5 (10.2)	53 (15.8)		
36 weeks	5 (10.2)	4 (1.2)		

Table 4: Statistical parameters of the DIPSI criteria with the WHO 2013 criteria

Statistics	Value	95% CI
Sensitivity	79.63%	66.47%–89.37%
Specificity	98.18%	96.08%–99.33%
Positive likelihood ratio	43.8	19.60–97.89
Negative likelihood ratio	0.21	0.12–0.35
Disease prevalence	14.06%	10.74%–17.95%
Positive predictive value	87.76%	76.23%–94.12%
Negative predictive value	96.72%	94.56%–98.04%
Accuracy	95.57%	93.01%–97.40%

Table 5: Result of GDM by the DIPSI and WHO 2013 criteria (Kappa statistics applied)

	WHO 2013 criteria			Kappa	*P*
	Positive	Negative	Total		
DIPSI criteria					
Positive	43	6	49	0.809	0.001
Negative	11	324	335		
Total	54	330	384		

significant, as shown in Table 2. Similar findings were observed in the Shrestha *et al.*[14] study.

In this study, age and period of gestation were significantly associated with GDM by both the DIPSI and WHO 2013 criteria, and the distribution found in the DIPSI and WHO 2013 criteria was almost similar.

The sensitivity, specificity, positive predictive value, and negative predictive value of the DIPSI criteria compared to the WHO 2013 criteria were 79.63%, 98.18%, 87.76%, and 96.72%, respectively.

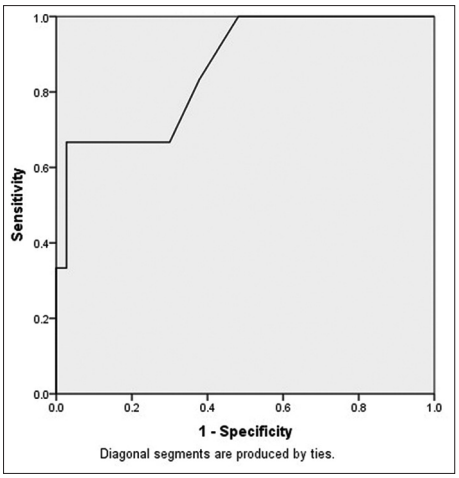

Figure 1: ROC curve of the DIPSI criteria

The specificity and sensitivity of the DIPSI criteria indicate that they are suitable for screening for GDM. The DIPSI criteria are simple to perform as there is no need to fast overnight and no need to take two samples, making it an easily acceptable method for pregnant mothers. In our study, DIPSI had a positive likelihood ratio of 43.8 and a negative likelihood ratio of 0.21. A study conducted by Saxena *et al.*[15] showed that the sensitivity and specificity of the DIPSI criteria in comparison to the WHO criteria were satisfactory. They concluded that the DIPSI criteria can be used as an alternative to the conventional WHO criteria and also reported that DIPSI had high diagnostic accuracy.

A similar finding was reported in the Shrestha *et al.*[14] study, which concluded that the DIPSI criteria can be used for screening. Another study conducted by Desai *et al.*[16] showed high sensitivity and specificity. Overall, diagnostic accuracy was high, and they concluded that conducting the DIPSI criteria is simple, economical, and convenient for screening GDM.

The kappa statistic was used in this study to determine the agreement between the DIPSI and WHO 2013 criteria. The result showed almost perfect agreement between the DIPSI criteria and WHO 2013 criteria, and it was statistically significant. The kappa value for this study was 0.809, and the *P* value was 0.001. Saxena *et al.*[15] also reported similar findings concerning agreement between the two studies.

Conclusion

A pregnant woman may face multiple health issues during her pregnancy. The most common symptoms include nausea and vomiting. The majority of the tests available for diagnosing GDM require overnight fasting. Conducting a test in the fasting state is uncomfortable for all pregnant mothers. DIPSI criteria can detect GDM in the non-fasting state. Our study reveals that the DIPSI criteria can serve as an alternative for screening GDM in the Indian population. This simple, single-prick test holds promise for widespread implementation in healthcare settings and research.

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Conflicts of interest

There are no conflicts of interest.

References

1. ACOG Practice Bulletin No. 190: Gestational diabetes mellitus. Obstet Gynecol 2018;131:e49e64.
2. Siddiqui S, Waghdhare S, Panda M, Sinha S, Singh P, Dubey S, *et al.* Regional prevalence of gestational diabetes mellitus in North India. J Diabetol 2019;10:25-8.
3. Swaminathan G, Swaminathan A, Corsi DJ. Prevalence of gestational diabetes in India by individual socioeconomic, demographic, and clinical factors. JAMA Netw Open 2020;3:e2025074. doi: 10.1001/jamanetworkopen.2020.25074.
4. Diaz-Santana MV, O'Brien KM, Park YM, Sandler DP, Weinberg CR. Persistence of risk for type 2 diabetes after gestational diabetes mellitus. Diabetes Care 2022;45:864-70.
5. World Health Organization. Definition, diagnosis and classification of diabetes mellitus and its complications: Report of a WHO consultation. Part 1, Diagnosis and classification of diabetes mellitus. World Health Organization; 1999. Available from: https://apps.who.int/iris/handle/10665/66040. [Updated on 2012 Jun 17; Last accessed on 2022 Dec 22].
6. Wendland EM, Torloni MR, Falavigna M, Trujillo J, Dode MA, Campos MA, *et al.* Gestational diabetes and pregnancy outcomes--A systematic review of the World Health Organization (WHO) and the International Association of Diabetes in Pregnancy Study Groups (IADPSG) diagnostic criteria. BMC Pregnancy Childbirth 2012;12:23. doi: 10.1186/1471-2393-12-23.
7. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes-2020. Diabetes Care 2020;43(Suppl 1):S14-31.
8. Tripathi R, Verma D, Gupta VK, Tyagi S, Kalaivani M, Ramji S, *et al.* Evaluation of 75 g glucose load in non-fasting state [Diabetes in Pregnancy Study group of India (DIPSI) criteria] as a diagnostic test for gestational diabetes mellitus. Indian J Med Res 2017;145:209-14.
9. Morampudi S, Balasubramanian G, Gowda A, Zomorodi B, Patil AS. The challenges and recommendations for gestational diabetes mellitus care in India: A review. Front Endocrinol (Lausanne) 2017;8:56. doi: 10.3389/fendo.2017.00056.
10. Eades CE, Styles M, Leese GP, Cheyne H, Evans JM. Progression from gestational diabetes to type 2 diabetes in one region of Scotland: An observational follow-up study. BMC Pregnancy Childbirth 2015;15:1-6.
11. World Health Organization. Diagnostic Criteria and Classification of Hyperglycaemia First Detected in Pregnancy. World Health Organization; 2013 Available from: https://www.who.int/publications/i/item/WHO-NMH-MND-13.2. [Updated on 2013 Jan 1; Last accessed on 2022 Dec 22].
12. Rani PR, Begum J. Screening and diagnosis of gestational diabetes mellitus, where do we stand. J Clin Diagn Res 2016;10:QE01-4.
13. Singh A, Singh RK, Aditya V, Singh P. Evaluation of "diabetes in pregnancy study group of India" (DIPSI) criterion as a diagnostic test for gestational diabetes mellitus. Int J Health Sci Res 2021;11:1-5.
14. Shrestha B, Pokhrel L. Comparative study of DIPSI and WHO 2018 criteria for diagnosis of GDM. Nepal Med College J 2020;22:13-7.
15. Saxena P, Verma P, Goswami B. Comparison of diagnostic accuracy of non-fasting DIPSI and HbA1c with fasting WHO criteria for diagnosis of gestational diabetes mellitus. J Obstet Gynaecol India 2017;67:337-42.
16. Desai GG, Sonawane P. Comparison of DIPSI guidelines versus conventional OGTT for diagnosis of gestational diabetes mellitus. Int J Reprod Contracept Obstet Gynecol 2018;7:3168-73.