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ORIGINAL ARTICLE

A Study on Diagnostic Accuracy of Dipsi Method Over Traditional Oral Glucose Tolerance Test Among Antenatal Women

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Abstract

Introduction: Gestational diabetes mellitus (GDM) is a condition of glucose intolerance during pregnancy, with potential adverse effects on both maternal and neonatal outcomes. Detecting and treating GDM early is crucial to prevent complications. Various diagnostic criteria and methods, such as the Diabetes in Pregnancy Study Group of India (DIPSI) criteria, IADPSG (International Association of the Diabetes and Pregnancy Study Groups) have been debated for GDM screening. This study is aimed to compare the DIPSI and IADSP criteria which is widely used in India with the World Health Organization (WHO) criteria and assess their diagnostic accuracy. **Methods:** A cross-sectional study involving 100 antenatal mothers was conducted in a tertiary care hospital. Sociodemographic data, risk assessments, gestational age, and clinical measurements (height, weight) were collected. Participants underwent both OGTT (using WHO criteria) and DIPSI tests. The blood sugar values were classified, and diagnostic accuracy was measured using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The correlation between the two methods was also examined. **Results:** The study demonstrated a lower sensitivity, and a high specificity compared to OGTT (WHO criteria). A new cutoff of 120 mg/dl for DIPSI was obtained by ROC curve analysis for our study which had a specificity and sensitivity of 78.02% and 77.78% respectively. The correlation between OGTT fasting/postprandial and DIPSI measurements was weak. **Conclusion:** The study assessed the diagnostic accuracy of the DIPSI method compared to the OGTT, particularly in resource-constrained settings like India. Given the DIPSI method's observed low sensitivity, relying solely on it for GDM diagnosis is ill-advised. Failure to identify true positive cases could have significant clinical implications, impacting maternal and neonatal outcomes and overburdening healthcare systems. Further research with larger and diverse populations is needed to establish more accurate diagnostic thresholds for GDM using the DIPSI method or alternative criteria.

Keywords: Gestational Diabetes Mellitus, Diagnostic Accuracy, DIPSI method, Fasting and Postprandial Blood sugar

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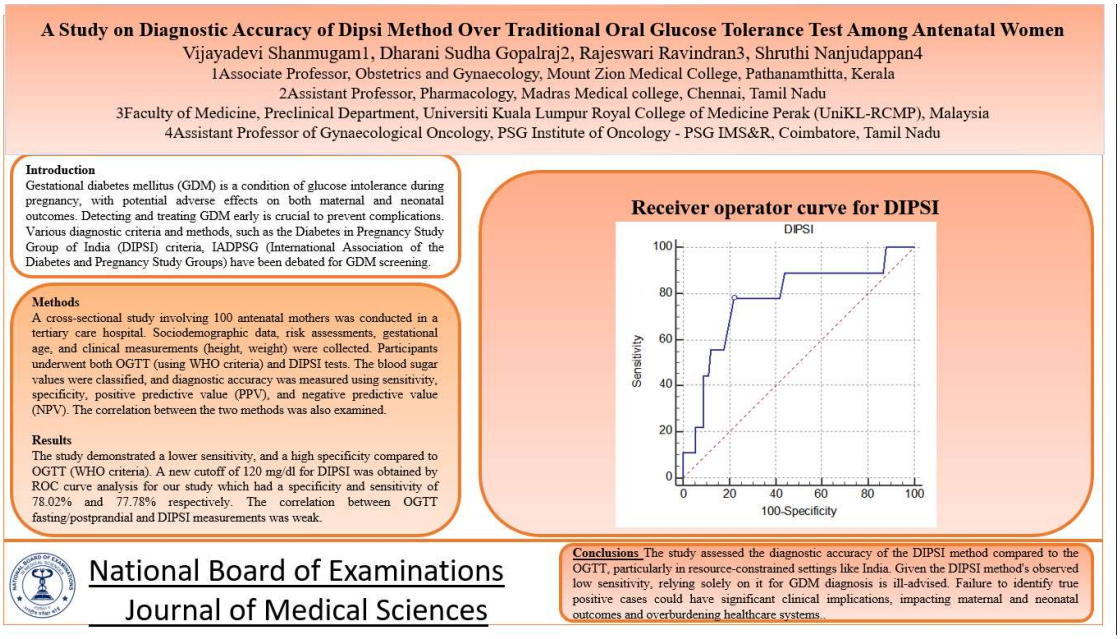
Graphical Abstract



Introduction

Gestational diabetes mellitus (GDM) is a general term for any degree of glucose intolerance that manifests or first noticed during pregnancy. Women with a history of GDM are more likely to experience unfavourable maternal and neonatal outcomes. They are also more likely to develop future Type II diabetes, which includes their children, putting two generations at risk [1,2]. The unfavourable maternal complications include hydramnios, preeclampsia, hypertension, urinary tract infection, increased surgical intervention, and future diabetes. It is linked to macrosomia, congenital malformations, metabolic abnormalities, respiratory distress syndrome, etc. in foetuses and newborns, as well as to later childhood and adolescent obesity [2]. Therefore, in order to avoid complications, it is crucial to detect early and treat this condition quickly. When it comes to screening and diagnosis of GDM, the precise glucose level to pick up glucose intolerance that characterises GDM is highly on debate.

Asian women are more likely to acquire GDM and associated complications due to the high incidence of familial DM and genetic vulnerability to metabolic syndrome, notably in Indian women [1]. In India, GDM affects 5 to 8 million women annually, accounting for one-third to two-thirds of births [3]. In India, it ranges from 6 to 9% in rural areas and 12 to 21% in urban areas, and it affects 7% of all pregnancies worldwide [4]. The high rate suggests that Indians are more likely to have GDM and have a higher incidence of diabetes and impaired glucose tolerance. Diagnoses are made at 16.3% within the first 16 weeks of gestation, 22.4% between 17 and 23 weeks, and 61.3% beyond 23 weeks [2]. The diagnostic criteria for diabetes outside of pregnancy have changed over time and are now broadly agreed by the world's leading diabetic organisations. However, there is still debate related to the screening and diagnosis of gestational diabetes mellitus (GDM). Despite years of research and numerous international conferences devoted to GDM, there is still no agreement among international organisations on a standard global strategy for GDM screening and diagnosis. There are different screening and diagnosis standards for GDM in different nations and among the world's main societies [4].

In India, where the prevalence of GDM is as high as 16.55% and the risk of developing the disease is 11 times higher for Indians than for Caucasians, more sensitive tests are needed to diagnose GDM. As a result, the test to be used depends on the ethnic group being researched.(5) Therefore, a universal, affordable screening and diagnostic procedure is required. The HAPO study shows that maternal hyperglycaemia, even at a level below that indicative of DM, is linked to macrosomia and higher birth weight. This continues to be a risk factor for having DM in the future and directly affects the foetal pancreas as it develops [2]. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria are based on the results of the large-scale hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study and are therefore well-known throughout the world. However, it is argued that this has the disadvantage of producing a high number of false-positive cases because the fasting cutoffs are too low, increasing the burden of GDM [6]. Additionally, the 2-hour cutoff is higher at 153 mg/dl, and it is debatable whether the blood glucose levels between 140 and 153 mg/dl can be left untreated without risk [5]. Additionally, the HAPO study's lack of Indian representativeness in its findings, diagnosing the Indian population by means of overseas studies can be inconclusive [6]. While WHO (1999) advises a fasting OGTT 126 mg/dl and/or after 75g of glucose with a cut-off plasma glucose of 140 mg/dl after 2-hours, DIPSI recommends non-fasting oral glucose tolerance testing (OGTT) with 75g of glucose with a cut- off of 140 mg/dl after 2-hours [7].

The Government of India guidelines propose using the Diabetes in Pregnancy Study Group of India (DIPSI) criteria, which is a variation of the previous WHO criteria, and it is utilized in epidemiological research all over India [7]. However, the test has also been shown to have a low positive predictive value and inadequate sensitivity. The WHO 1999 criteria of 2-h plasma glucose of 140 mg/dl was proved to be sufficient to diagnose GDM based on a sizable retrospective analysis comparing the IADPSG and WHO criteria. It was intended to compare the diagnostic accuracies of DIPSI criteria to WHO and IADPSG criteria for the diagnosis of GDM as both of these tests are widely used and acknowledged on a global scale [6].

Patients must visit the antenatal clinic in a fasted state and must then submit to several blood samplings for testing, as recommended by the ADA, WHO, and IADPSG. In contrast, the DIPSI proposes a two-hour plasma glucose measurement following the administration of a 75 g glucose load in a non-fasting state, regardless of the time since the last meal, as a straightforward, affordable, and practical single-step approach for the diagnosis of GDM. According to the DIPSI's recommendations, GDM is identified if the venous plasma glucose level is more than 140 mg/dl. It is extensively utilized since it is undoubtedly a simpler test, more patient-friendly, and it minimizes the discomfort for pregnant women. It is believed that this test can be used for both screening and diagnosis. In order to validate the use of a 75 g glucose load in a non-fasting state as a single step in the diagnosis of GDM, we decided to undertake this study [8]. With this background our study was undertaken to assess diagnostic utility of DIPSI compared to WHO criteria. Also secondarily the diagnostic utility of IADPSG classification was also assessed.

Materials and Methods

This cross-sectional study was commenced among 100 antenatal mothers who attended Obstetrics OPD in a tertiary care hospital, after IHEC approval. All antenatal women who attended the OPD were explained about the rationale and objective of the study, rights of the participants and other ethical issues concerned. The participant information sheet was given to them, and ample time

was given to the participant to understand the contents and make an informed decision. Written informed consent was obtained once they have consented to participate in the study. Those on steroids for auto immune disorders, obstructive lung disease, overt diabetes mellitus, Type 1 Diabetes mellitus were excluded from the study. A structured questionnaire was used to measure the socio demographic variables, basic risk assessment, gestational age, and clinical measurements (height, weight).

All those who accepted to participate were subjected to DIPSI test. The test was redone after few hours on the same day or was requested to come next day if the participant has vomited after glucose ingestion. If the patient has vomited the second time also, then she may be excluded from the study. After ingestion of the glucose, the participant was requested not to have meals for two hours. Two hours later, two ml of venous blood was drawn into sterile vials containing lithium heparin. For the OGTT, the individual was instructed to arrive after an 8 to 14-hour fast. All these samples were centrifuged before being processed in 1 hour on an automated Randox Daytonal clinical chemistry analyser utilising the Glucose Oxidase Peroxidase (GOD-POD) method to analyse for glucose. The internal quality control samples were tested following standardisation. The participant was asked to come for the OGTT within a week. After an overnight fast of 8 to 14-hours, a standard OGTT was conducted using 75g of anhydrous glucose in 250–300ml of water. It was determined that pregnant women who met the requirements for diabetes mellitus (DM) or impaired glucose tolerance (IGT) had gestational diabetes mellitus (GDM) after fasting and two hours.(9) DIPSI was a one-step process regardless of the most recent meal. In order to determine plasma glucose levels, pregnant women who were present at the prenatal OPD were given 75g of anhydrous glucose in 250–300ml of water [10]. The diagnosis cut offs of various guidelines are provided in Table 1.

Table 1. Diagnostic Criteria of various guidelines for GDM

Guideline	Fasting (mg/dl)	2 hour PPBS
WHO 1999	≥126	≥140
ACOG	≥95	≥155
Canadian Diabetes Association	≥95	≥160
IADPSG	≥92	≥153
DIPSI	NA	≥140

The results observed were entered in Microsoft Excel and analysed using SPSS software 20. The basic descriptive variables were expressed as frequency and percentages. The blood sugar values were classified according to the criteria mentioned and was expressed as frequency and percentages. The agreement between IADPSG criteria classification of GDM and DIPSI criteria was measured using kappa statistics.. Diagnostic accuracy specificity, sensitivity, Positive Predictive value (PPV) and Negative Predictive Value (NPV) were calculated for DIPSI and IADPSG classification considering WHO criteria as gold standard. Pearson correlation was done to measure the correlation between OGTT measurement and DIPSI measurements. $P<0.05$ was considered statistically significant.

Results

The prevalence of GDM with WHO criteria, IADPSG criteria and DIPSI method was 9%, 17% and 6% respectively. (Table 2). There was a poor agreement

between DIPSI and IADPSG Criteria (Table 3). The specificity and sensitivity of IADPSG Criteria was better compared to DIPSI classification (Table 4). There was a poor correlation between OGTT and DIPSI (Figure 1). Receiver operator characteristics Curve (ROC Curve) was drawn for GDM cutoff for Indian standards (Figure 2). The area under the curve was 0.773 with a significant P Value of 0.0037 for a DIPSI cut off of 120mg/dl at which the specificity was 78% and sensitivity was 77.78%. The specificity and sensitivity for various cut off is given in Table 5. At the usual cutoff of 140, though the specificity is more than 94.5%, the sensitivity is compromised to 11.1%.

Table 2. Distribution of study population according to diabetic status in each category

Method	**Normal**		**GDM**	
	F	**%**	**F**	**%**
WHO criteria	91	91.0	9	9.0
IADSP	83	83	17	17
DIPSI method	94	94.0	6	6.0

Table 3. Agreement between OGTT fasting, OGTT post prandial, Combine Fasting postprandial (WHO Criteria) with IADSP

Parameter	**Classification**	**IADSP**				**Agreement (Kappa)**	**P VALUE**
		NORMAL		**GDM**			
		F	**%**	**F**	**%**		
DIPSI	NORMAL	**79**		**15**		0.094	0.272
	GDM	**4**		**2**			

Table 4. Diagnostic accuracy of DIPSI/IADSP method over WHO OGTT classification

Criteria	**TP**	**TN**	**FP**	**FN**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
DIPSI	**1**	**86**	**5**	**8**	**11.1**	**94.5**	**16.7**	**91.5**
IADSP	**7**	**81**	**10**	**2**	**77.8**	**89**	**41.2**	**97.6**

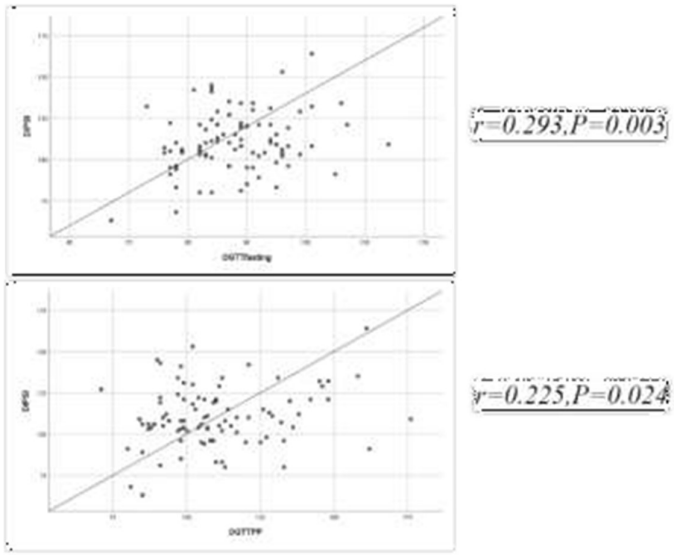
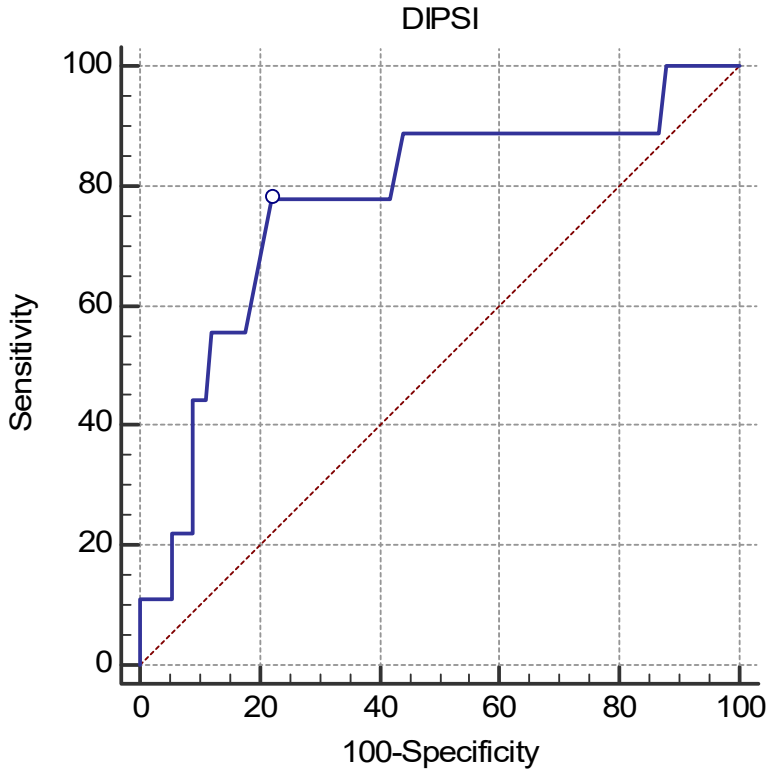


Figure 1. Correlation between OGTT and DIPSI



Area under the ROC curve (AUC)	0.773
Standard Error[a]	0.0939
95% Confidence interval[b]	0.678 to 0.851
z statistic	2.906
Significance level P (Area=0.5)	0.0037

Figure 2. Receiver operator curve for DIPSI

Table 5. Specificity and sensitivity for various DIPSI cutoff

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	95% CI	-LR	95% CI
≥63	100.00	66.4 - 100.0	0.00	0.0 - 4.0	1.00	1.0 - 1.0		
>89	100.00	66.4 - 100.0	12.09	6.2 - 20.6	1.14	1.1 - 1.2	0.00	
>91	88.89	51.8 - 99.7	13.19	7.0 - 21.9	1.02	0.8 - 1.3	0.84	0.1 - 5.8
>108	88.89	51.8 - 99.7	56.04	45.2 - 66.4	2.02	1.5 - 2.8	0.20	0.03 - 1.3
>109	77.78	40.0 - 97.2	58.24	47.4 - 68.5	1.86	1.2 - 2.8	0.38	0.1 - 1.3
>120	77.78	40.0 - 97.2	78.02	68.1 - 86.0	3.54	2.1 - 6.0	0.28	0.08 - 1.0
>121	55.56	21.2 - 86.3	82.42	73.0 - 89.6	3.16	1.5 - 6.6	0.54	0.3 - 1.1
>127	55.56	21.2 - 86.3	87.91	79.4 - 93.8	4.60	2.1 - 10.3	0.51	0.2 - 1.1
>129	44.44	13.7 - 78.8	89.01	80.7 - 94.6	4.04	1.6 - 10.3	0.62	0.3 - 1.1
>131	44.44	13.7 - 78.8	91.21	83.4 - 96.1	5.06	1.9 - 13.5	0.61	0.3 - 1.1
>132	22.22	2.8 - 60.0	91.21	83.4 - 96.1	2.53	0.6 - 10.1	0.85	0.6 - 1.2
>134	22.22	2.8 - 60.0	94.51	87.6 - 98.2	4.04	0.9 - 17.9	0.82	0.6 - 1.2
>135	11.11	0.3 - 48.2	94.51	87.6 - 98.2	2.02	0.3 - 15.5	0.94	0.7 - 1.2
>153	11.11	0.3 - 48.2	100.00	96.0 - 100.0			0.89	0.7 - 1.1
>164	0.00	0.0 - 33.6	100.00	96.0 - 100.0			1.00	1.0 - 1.0

Discussion

This cross-sectional analytical study was done to understand the diagnostic accuracy of DIPSI method over traditional OGTT method. Our result revealed that DIPSI is specific but not sensitive. Similar results were observed by other authors [1,8,11-16]. Many of the women who are mistakenly classified as normal have deranged fasting sugar readings, which may influence obstetrical outcomes [8].

Anjalakshi et al. [17] investigation on a population of South Indians revealed that the 75 g, two-hour non-fasting DIPSI test has 100% sensitivity and 100% specificity when compared to the WHO-recommended 75g OGTT for the diagnosis of GDM. They concluded that there was no discernible difference between the two tests for detecting GDM in women. Similar findings from another study on the Indian population were obtained [18]. The DIPSI test had been endorsed for widespread usage in India by Magon et al. [19]. Even though it involved fewer participants, a different study (20) found that 22.36 percent of instances of GDM were not identified using the DIPSI criteria. GCT with a two-hour cut-off value of less than 140 mg/dl is not sensitive enough to identify GDM recognised by GTT, according to a study done on Sri Lankan women. The main cause of the increased false positives is the DIPSI single cut off [22,23]. The 75 g, two-hour non-fasting DIPSI test's low positive predictive value (PPV) when compared to different OGTT types further emphasises the issue with accuracy. Low PPV suggests that many of the women diagnosed with GDM using this approach are unlikely to have the condition. Given that the test has a very high negative predictive value, a woman is not likely to have GDM if her values do not fall within the acceptable range.

A significant flaw in the DIPSI test is the substantial percentage of false positives and the very low number of false negatives. It is impossible to ignore the effects of clinical procedures brought on by

a false diagnosis of GDM. We attempted to determine if there was a likely cutoff with the highest level of specificity and sensitivity that could be utilised or advised in a South Indian scenario. The cutoff point that we were able to achieve with a balanced specificity (55%) and sensitivity (76%) was 107 mg/dl. The specificity and sensitivity were insufficient for the DIPSI Method to be employed as a diagnostic or screening method, as the estimated cutoff is extremely low. The present study is not without limitations.

In our study, the optimal cutoff for the DIPSI method was identified as **120 mg/dL** using ROC curve analysis, which showed better diagnostic performance compared to the standard DIPSI cutoff of **140 mg/dL**. This lower threshold demonstrated higher sensitivity and specificity, making it more suitable for our population. Similar findings have been reported in studies conducted in Indian and Asian subpopulations, where metabolic and glucose tolerance variations justify the need for region-specific cutoffs [10,24]. Adopting a cutoff of 120 mg/dL could facilitate earlier detection and timely management of gestational diabetes, potentially reducing adverse maternal and neonatal outcomes. However, further large-scale studies are needed to validate this threshold across diverse populations.

Conclusion

The primary objective of this study was to assess the diagnostic precision of the DIPSI method in comparison to the OGTT. In a developing nation like India, where expectant mothers continue to work until their anticipated delivery date, and where transportation options are limited, resulting in significant travel distances to prenatal appointments, often leading to inconvenience. Consequently, the non-fasting oral glucose tolerance test (OGTT) has garnered considerable attention in less developed countries. Given the observed low sensitivity of the DIPSI criteria in the current evaluation, it is unwise to rely solely on it for the diagnosis of gestational diabetes mellitus (GDM). It is crucial to recognize that failing to detect genuine positive cases could have significant clinical ramifications, potentially adversely affecting both maternal and neonatal outcomes, and further straining our healthcare system. Further research employing the DIPSI method or alternative criteria with larger sample sizes across diverse populations is warranted to establish more precise diagnostic thresholds for GDM.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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