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### **Original Research Article**

# Comparative study of DIPSI and IADPSG criteria for diagnosis of GDM

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### ABSTRACT

**Background:** GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. The prevalence of GDM varies, widely based on the diagnostic criteria used and the ethnic group studied. It is associated with adverse maternal and perinatal outcome. Incidence of GDM in India is 1-14%. There are several screening and diagnostic tests for GDM. It is important to diagnose early and treat to prevent these complications. The present study was done to compare Diabetes in Pregnancy Study Group India (DIPSI) with International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria for diagnosis of GDM and to assess the validity of these methods.

**Methods:** It was a cross sectional study done in 144 pregnant women who fulfilled the inclusion criteria. They underwent non - fasting OGTT with 75 grams glucose which was given irrespective of the last meal. A venous blood sample was drawn two hours after glucose administration. They were advised to come two to three days later and repeated with 75 grams OGTT after an overnight fast of atleast 8 hours. Venous blood sample was drawn at fasting, one hour and two hours after load with 75 grams of glucose. Plasma glucose was measured by using an autoanalyzer by glucose - oxidase peroxidase (GOD - POD) technique.

**Results:** The epidemiological parameters like Age, BMI, Parity and Gestational age did not have any difference between two groups. 17.4% was diagnosed by DIPSI criteria and 15.3% was diagnosed by IADPSG criteria and 6.9% was diagnosed by both. Sensitivity and specificity of DIPSI was 45% and87% and sensitivity and specificity of IADPSG was 40% and89% respectively. According to kappa statistics, the p-value is 0.000.

**Conclusions:** In present study it was concluded that screening is very essential in all pregnant women due to high prevalence of GDM in India. By comparing these two criteria, sensitivity of DIPSI was found better than IADPSG criteria in diagnosing GDM. Though IADPSG is universally accepted for diagnosis, DIPSI has still got a place in low resource countries as it is easy, cost effective and non fasting test.

Keywords: DIPSI, GDM, IADPSG

#### INTRODUCTION

GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy.<sup>1</sup> The prevalence of GDM varies, widely based on the diagnostic criteria used and the ethnic group studied.<sup>2</sup> It is associated with adverse maternal and perinatal outcome. Therefore, screening is essential in all pregnant women in Asia as they are at 11 fold increased risk of developing glucose intolerance during pregnancy as compared to caucasian women.<sup>3</sup>

GDM has been found to be more common in women living in urban areas as compared to women living in

rural areas.<sup>4</sup> So it is important to diagnose early and treat to prevent the morbidity. There are different types of screening methods viz. universal or risk based, one step or two step and different thresholds for diagnosis.

In India most centres do one step screening and diagnostic method with Diabetes in Pregnancy Study Group India (DIPSI) as it is simple, easy, feasible in non fasting state but it has low sensitivity and diurnal variation causing controversy.<sup>5,6</sup> It has been observed by Hyperglycemia and Pregnancy Outcome (HAPO) study that The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria has more sensitivity, universally accepted and even an isolated fasting glucose levels have higher incidence of poor maternal and fetal outcome. The present study was done to compare DIPSI (non-fasting OGTT) with IADPSG criteria for diagnosis of GDM and to assess the validity of these methods.

### METHODS

This is a cross sectional study of 144 pregnant women who were fulfilling the inclusion criteria and willing to participate in the study were included. Informed and written consent were taken before study and ethical committee approval was obtained. A standardized questionnaire was used to collect demographic details. family history of diabetes, previous history of Gestational Diabetes Mellitus, previous obstetric history. Height was measured by stadiometer in centimeter, weight by electronic weighting machine in kilograms. The BMI was calculated by weight (in kg) divided by height in meter (squared) and any other associated risk factors was also noted. They underwent non - fasting OGTT with 75 grams glucose which was given irrespective of the last meal. A venous blood sample was drawn two hours after glucose administration. They were advised to come two to three days later and repeated with 75 grams OGTT after an overnight fast of atleast 8 hours. Venous blood sample was drawn at fasting, one hour and two hours after load with 75 grams of glucose. Plasma glucose was measured by using an autoanalyzer by glucose - oxidase peroxidase (GOD - POD) technique.

### Inclusion criteria

All pregnant women attending antenatal OPD of Mahatma Gandhi Medical College and Research Institute over a period of 18 months with the gestation of 20-32 weeks.

### Exclusion criteria

- Pregnant women with known pregestational diabetes mellitus
- Pregnant women with chronic illness (renal, pancreatic etc.)
- Pregnant women on drugs like corticosteroids, hydrochlorothiazide and antipsychotic drugs.

#### Statistical analysis

All data was entered into Microsoft excel 2007. It was analysed by using SPSS Windows (Version 16). Descriptive data was expressed by using number and simple percentage. Sensitivity and Specificity was calculated and compared between DIPSI and IADPSG criteria.

### RESULTS

The epidemiological parameters like Age, BMI, Parity, Gestational age did not have any difference between two groups. 68% of women were primigravida and 31% of women were multigravida among 144 patients screened.

Age	Positive	Mean	Median	Standard deviation	t-test	p-value
DIPSI	25	25.96	26	4.04	1.2826	0.2062
IADPSG	22	27.36	27.5	3.35		

Table 1: Comparison of mean age between positive cases of DIPSI and IADPSG criteria.

Among the 25 positive women in DIPSI the mean age was 25.96, median was 26 and standard deviation was 4

and among the 22 IADPSG positive women the mean age was 27.36, median was 27 and standard deviation was 3. P-value was not significant between the two groups.

Table 2: Comparison of BMI between positive cases of DIPSI and IADPSG criteria.

BMI				Standard deviation	4 4004	
	Positive Mean Median		Median	Stanuaru ueviation	t-test	p-value
DIPSI	25	27.38	27.5	3.29	1.0556	0.2069
IADPSG	22	28.48	28.6	3.04	1.0556	0.2968

By comparing the BMI among the 25 DIPSI positive the mean was 27.38, median was 27.5 and standard deviation was 3.

In IADPSG criteria among the 22 positive the mean was 28.48, median was 28 and standard deviation was 3. P-value was not significant between the two groups.

### Table 3: Distribution of patients according to gestational age in all screened patients.

Gestational age (weeks)	No. of cases	Percentage
20-25	80	55.6
26-32	64	44.4
Total	144	100

About 56% of women were within 20-25 weeks of gestational age and 44% of women were within 26-32 weeks of gestational age.

### Table 4: Total number of positive and negative casesby DIPSI criteria.

DIPSI	No. of cases	Percentage
Positive	25	17.4
Negative	119	82.6
Total	144	100

Total number of positive cases by DIPSI was 25 and their percentage is 17.4% and total number negative cases of DIPSI was 119 and their percentage is 82%.

## Table 5: Total number of positive and negative casesby IADPSG criteria.

IADPSG	No. of cases	Percentage
Positive	22	15.3
Negative	122	84.7
Total	144	100

### Table 6: Statistical parameters between positive and negative cases of DIPSI and IADPSG criteria.

	Positi	Positive		Negative		Chi aguana	n voluo
	Ν	%	Ν	%	Total	Chi-square	p-value
DIPSI	25	17.4	119	82.6	144	0.2288	0 6224
IADPSG	22	15.3	122	84.7	144	0.2288	0.6324

Total number of positive cases of IADPSG was 22 and their percentage is 15.3% and total number of negative cases of IADPSG was 122 and their percentage is 84.7%.

In parameters between both positive and negative cases of DIPSI and IADPSG criteria the chi-square was 0.2288 and p-value was 0.6 and was not statistically significant.

#### Table 7: Comparison of DIPSI with IADPSG criteria.

		IADPSG		Total
		Positive	Negative	Total
DIDGI	Positive	10	15	25
DIPSI	Negative	12	107	119
Total		22	122	144

Number of both DIPSI and IADPSG positive in 10 cases, both negative in 107, DIPSI positive with IADPSG negative has 15, DIPSI negative with IADPSG positive has 12.

The sensitivity of DIPSI with IADPSG was 45.45%, specificity 87.70%, Positive predictive value 40.00% and Negative predictive value 89.92%.

Number of both IADPSG and DIPSI positive was 10 cases, both negative were 107, IADPSG positive with

DIPSI negative was 12, IADPSG negative with DIPSI positive was 15 cases.

### Table 8: Statistical parameters of DIPSI with<br/>IADPSG criteria.

Statistical parameters	Value	95% CI
Sensitivity	45.45%	24.39% to 67.79%
Specificity	87.70%	80.53% to 92.95%
Positive likelihood ratio	3.70	1.91 to 7.15
Negative likelihood ratio	0.62	0.42 to 0.92
Disease prevalence	15.28%	9.83% to 22.21%
Positive predictive value	40.00%	25.65% to 56.30%
Negative predictive value	89.92%	85.82% to 92.92%

### Table 9: Comparison between IADPSG and DIPSIcriteria.

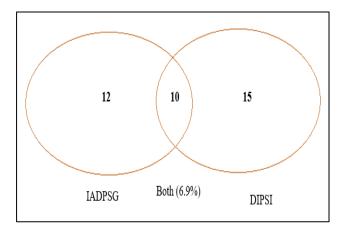
		DIPSI		Total
		Positive	Negative	Total
IADPSG	Positive	10	12	22
IADPSG	Negative	15	107	122
Total		25	119	144

According to kappa statistic (Kappa value 0.314, P-value 0.000), there is disagreement in diagnosing GDM between DIPSI and IADPSG criteria.

## Table 10: Statistical parameters between IADPSGwith DIPSI criteria.

51.33%
94.68%
15
92
0 24.55%
0 63.13%
o 90.81%

The sensitivity of IADPSG is 40.00%, specificity is 89.92%, positive predictive value is 45.45% and negative predictive value is 87.70% when compared to DIPSI. Therefore, by comparing tables 17 and 19 DIPSI has got higher sensitivity and is found comparatively better than IADPSG in diagnosing GDM.



### Figure 1: Total number of DIPSI and IADPSG positive.

Both were positive in 10 cases. DIPSI diagnosed higher number of GDM cases than IADPSG.

### DISCUSSION

This was a cross sectional study carried out over a period of 18 months from March 2016 to August 2017 in antenatal women who were attending MGMCRI OG OPD, who were within the gestational age of 20 to 32 weeks, who fulfilled the inclusion criteria and were willing to participate in the study.

Gestational diabetes mellitus remains as one of the major public health problem associated with adverse maternal and perinatal outcome. The prevalence is completely based on the diagnostic criteria and the ethnic group studied. There is a lack of uniformity in screening and diagnostic tests for GDM and there is a need for universal screening for GDM in high risk population like Indians. A simple, easier, cost effective, non fasting test DIPSI is being followed widely in India.

Recently based on HAPO study IADPSG consensus panel recommended that GDM should be diagnosed based on IADPSG criteria which has more sensitivity and specificity, more precise and accurate for diagnosing GDM and to have uniform diagnosing method all over the world. India was not included in HAPO study inspite of being highly populous and high risk ethnic group. The present study was conducted with the aim of comparing the sensitivity and specificity of DIPSI and IADPSG criteria for diagnosis of GDM and to evaluate the maternal and perinatal complications.

In the present study, the epidemiological parameters like age, BMI, parity, family history of Diabetes Mellitus and Gestational age at screening did not have any difference in both groups and not statistically significant. 68% were primigravida and 40% had family history of Diabetes Mellitus. Similar findings were observed in studies by Mohan et al, Geetha et al and Pulkit et al.<sup>5,7,8</sup>

In the present study, out of 25 women identified as GDM by DIPSI criteria, only 10 women were diagnosed by IADPSG. Of the 22 women diagnosed by IADPSG, 12 women were not detected by DIPSI criteria. The prevalence of GDM in the present study was 17.4% (25) with DIPSI and 15.3% (22) based on IADPSG criteria. Both tests were positive in only 6.9% (10). The sensitivity of DIPSI was 45.45%, specificity was 87.70%, positive predictive value was 40.00% and negative predictive value was 89.92%.

The sensitivity of IADPSG was 40.00%, specificity was 89.92%, positive predictive value was 45.45% and negative predictive value was 87.70%. In the present study the sensitivity of DIPSI was slightly higher and was found to be comparatively better than IADPSG criteria for diagnosis of GDM. According to Kappa statistic the p-value was 0.000.

Geetha et al in their prospective study of 100 women found prevalence rates of GDM were 14% and 9% with DIPSI and IADPSG criteria respectively and 4% were diagnosed by both leaving 5% undiagnosed by IADPSG criteria which could have been easily detected by DIPSI.<sup>7</sup> Though DIPSI criteria detected more number of cases than IADPSG criteria the difference was not statistically significant. They concluded that DIPSI was better than IADPSG criteria as it was easier to do and tolerance of patient to glucose load was much better in non fasting state whereas IADPSG needed more blood samplings, fasting state, more laboratory support with extra cost. In low resource settings, DIPSI is better than IADPSG for diagnosis of GDM. The observations of this study were similar to present study. In a mini review on diagnostic criteria for GDM the authors emphasized DIPSI as cost effective and evidence based procedure in the low resource countries and with high risk ethnic population like Indians who require universal screening as a single step definitive glucose test.<sup>9</sup>

Pulkit et al in their retrospective study of 152 women comparing DIPSI and IADPSG criteria and also evaluating the isolated fasting glucose in diagnosis of GDM found that IADPSG criteria found better than DIPSI as it left 23.36% undiagnosed which were easily detected by IADPSG criteria and they found prevalence rate of GDM was 74.34% by DIPSI and 88.15% by IADPSG using both fasting and 2 hours plasma glucose values and by fasting value of  $\geq 92 \text{mg/dl} 22.365\%$  were diagnosed.<sup>8</sup> They claimed that higher rates were due to prevalence of high risk factors in their subjects of study like advanced age, BMI, family history etc and also associated with poor maternal and fetal outcome and justified that IADPSG criteria was better as it picked up more number of women with GDM than DIPSI and also by analyzing the complications associated with GDM patients IADPSG criteria serves better than DIPSI.

Bhavadharini et al highlighted the GDM diagnosis strategy based on women in India with GDM Strategy (WINGS) project carried out in Chennai suggested that despite the constraints of low resource, fasting state, three blood samples in IADPSG criteria, it appears to be the best which will help to bring out a uniform criteria for screening and diagnosis of GDM.<sup>10</sup>

DIPSI criteria which is used widely in many parts of India due to its simplicity, but it is not able to reproduce ideal sensitivity and specificity. WINGS project results found DIPSI has very low sensitivity of 22.6% and specificity of 97.8% whereas IADPSG criteria has sensitivity of 27.7% and specificity of 97.7%.

The lower sensitivity of DIPSI is believed to be due to non fasting state when women consumes a carbohydrate meal, insulin level rises due to increased blood glucose levels and when a glucose load of 75 grams given at this point, blood glucose levels are fluctuated since insulin levels are already elevated. The sensitivity of the test drops. Therefore, WINGS project supports the international guidelines where test should be done after over night fast.

### Table 11: Prevalence of GDM in various studies.

Studies	No. of cases	DIPSI	IADPSG
Geetha et al <sup>7</sup>	100	14%	9%
Pulkit et al <sup>8</sup>	152	74.34%	88.15%
Present study	144	17.4%	15.3%

In another study of 1031 pregnant women from Chennai comparing DIPSI non fasting with IADPSG criteria for

diagnosis of GDM found 10.3% (106) women were diagnosed by IADPSG criteria. Out of them only 22.65% (24) women were diagnosed by DIPSI leaving behind 77.4% (82) women undiagnosed by DIPSI and they concluded that DIPSI has very low sensitivity compared to IADPSG criteria.<sup>5</sup> Wide variation in GDM prevalence rates may be attributed to the use of different criteria for diagnosis, variation in geographical region and lifestyle with lack of physical activity.

#### CONCLUSION

DIPSI is practically simple, easier, non fasting single test procedure, suitable in low resource countries. Though IADPSG criteria, is uniform criteria for screening and diagnosis of GDM worldwide the sensitivity of IADPSG criteria was found to be slightly lesser when compared with DIPSI criteria in present study.

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