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## Original Research Article

# Can single plasma glucose value 2 hours after 75g glucose (DIPSI criteria) replace the gold standard OGTT for the diagnosis of gestational diabetes mellitus?

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### ABSTRACT

**Background:** Gestational diabetes mellitus is a common medical complication of pregnancy associated with several fetal and maternal complications. There are several screening tools for detecting gestational diabetes mellitus including recent DIPSI criteria of non-fasting single plasma 2-hour value after 75 grams glucose (single step test). The present study was aimed at calculating prevalence of GDM, sensitivity and specificity using non-fasting single plasma 2-hour value after 75 grams glucose for screening and diagnosis of gestational diabetes mellitus and to study the high-risk characteristics for GDM in this study population.

**Methods:** This was a prospective study conducted for a period of one year. 750 antenatal women attending Antenatal outpatient department(OPD) with period of gestation 24-28 weeks were enrolled in the study. All women were first tested by 75 gm glucose and then by OGTT for confirmation. Prevalence rates, sensitivity, specificity, positive predictive value and negative predictive value were studied. History based questionnaire was used to study the risk characteristics for GDM.

**Results:** Prevalence rate, sensitivity, specificity, positive predictive value and negative predictive value for patients were 14.13%, 73.58%, 95.03%, 70.90% and 95.67%. Among the risk factors 7.2% patients were more than 30 years in age. 0.93% had GDM in previous pregnancy. 4.21% had GCA in previous pregnancy, 12.4% had SB/IUD/NND in previous pregnancy. 1.17% had previous pregnancy with birth weight more than 3.5 kg and 9.73% had family history of diabetes mellitus. Past history of GDM (50%) was the most common risk factor in GDM group followed by age > 30 years (29.6%), and family history (24.6%).

**Conclusions:** Screening using DIPSI criteria has good sensitivity and negative predictive values. It can serve as both screening and diagnostic test besides being simple, user friendly, cost effective and evidence-based test in less resource countries like India.

**Keywords:** DIPSI, GDM, IADPSG, OGTT, OPD

### INTRODUCTION

Globally, gestational diabetes mellitus (GDM) is emerging as a major health concern for pregnant women. This trend is visible in India too, with much risk of adverse outcomes for the pregnant women and the newborn, if not managed appropriately.<sup>1</sup> It is defined as

“carbohydrate intolerance of variable severity with the onset or first recognition during pregnancy”.<sup>2</sup> It has been estimated that 6% to 7% pregnancies are complicated with diabetes and that 90% of these cases represent women with GDM.<sup>3</sup> Various International organisations have proposed different diagnostic criteria to diagnose GDM, however a single diagnostic criterion remains

elusive. International Federation of Obstetrics and Gynaecology endorses IADPSG criteria and recommended its use in all nations.<sup>4</sup>

Indian women have higher tendency to develop diabetes in pregnancy possibly due to genetic predisposition. A community-based study conducted in India showed a prevalence of 13.9%.<sup>5</sup>

This led to the adoption of Diabetes in Pregnancy Study Group in India (DIPSI criteria) as a widely recommended guideline to diagnose GDM, especially in community setting. The recent National Institute of Clinical excellence (NICE) also recommends 2hr plasma glucose > 140 mg/dl to diagnose GDM which is very similar to DIPSI guidelines.<sup>6</sup>

On 14th March 2007, Government of India issued the instructions that universal screening of glucose intolerance during pregnancy should be mandatory. The order recommends that all women should be screened between 24 and 28 weeks of gestation with 2 h 75 g oral glucose.

This study was conducted to assess the prevalence, sensitivity and specificity, positive and negative predictive value of DIPSI criteria for GDM. Aims and objectives were 1. To study sensitivity and specificity of 75-gram single plasma 2-hour value (DIPSI criteria) which was then confirmed by 75 grams oral glucose tolerance test (OGTT) done at 0, 1 and 2 hours. 2. To study high risk characteristics of GDM in this study group.

## METHODS

Present study was prospective study conducted over a period of one year at Dr. Baba Saheb Ambedkar Hospital, Rohini, New Delhi [Department of obstetrics and gynaecology]. 750 antenatal women attending OPD were enrolled in the study after satisfying the inclusion and exclusion criteria. This sample size was chosen based on the prevalence rate of 3% to 21% in previous study, the margin of error and the level of significance. Formula used was:  $me = z \cdot \sqrt{p(1-p)/n}$  where  $z$  is value of  $z$  at two-sided alpha error of 5%,  $me$  is margin of error and  $p$  is prevalence rate. Prior to our study ethical committee clearance was taken. Written informed consent was taken from the subjects.

### Inclusion criteria

- Pregnant women with period of gestation between 24-28 weeks.

### Exclusion criteria

- Known case of diabetes mellitus, patient on steroids, patient not willing to be a part of study.

A detailed history to assess maternal high-risk factors if any followed by general clinical, systemic and obstetric examination was done in all subjects. Routine antenatal investigations were done, and patients were kept on ANC follow up. Study population underwent glucose challenge test with 75 grams glucose dissolved in 250-300ml of water irrespective of last meal and 2-hour plasma glucose value was taken (DIPSI criteria). Within a week of GCT subjects were advised to come for OGTT which was used as a gold standard in our study. They had to report after an overnight fasting of 8-10 hours but not more than 14 hours and after 3 days of unrestricted diet ( $\geq 150$  gm of carbohydrate) and physical activity. Fasting venous sample was taken, then 75 gm of glucose solution was given and 1 hour and 2 hours venous blood sample was taken.

The cut off value for screening of GDM using 75 grams, 2 hours GCT was  $\geq 140$  mg/dl. In Glucose tolerance test the cut off plasma glucose values used for the diagnosis of GDM are as follows; Fasting  $\geq 92$  mg/dl; 1 hour  $\geq 180$  mg/dl and 2 hour  $\geq 153$  mg/dl. If any one of the values was met or exceeded, then OGTT was taken as positive and patient was diagnosed as GDM as per the International Association of the Diabetes and Pregnancy Study Group (IADPSG) 2010 criteria. Primary outcomes were prevalence rate, sensitivity and specificity, positive and negative predictive value of DIPSI criteria.

### Statistical analysis

Categorical variables were presented in Number and Percentage (%) and continuous variables were presented as Mean  $\pm$  SD and Median. The data was entered in MS-Excel spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

## RESULTS

Present study assessed age, parity, socio economic condition, high risk factors of the study population. It was seen that 82.26% of the study sample was in 20-30 years of age group. The minimum age was 18 and maximum age 37. The mean age was  $24.63 \pm 3.56$  years. The inter quartile range was 22-26 years (Figure 1).

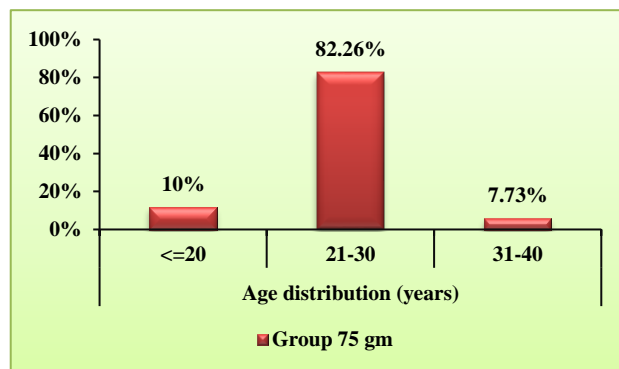


Figure 1: Age distribution of the study group.

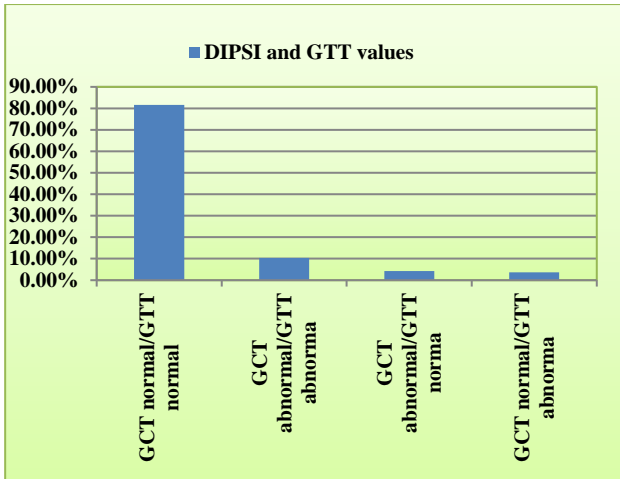


Figure 2: DIPSI and GTT values of the study group.

The prevalence of GDM using DIPSI criteria is 14.13% (106/750). 81.6% (612/750) had both normal GCT and OGTT, 3.73% (28/750) had normal GCT but abnormal OGTT, 4.26% (32/750) had abnormal GCT but normal OGTT and 10.4% (78/750) had both GCT and OGTT abnormal (Figure 2).

Table 1: Plasma glucose values of DIPSI and OGTT.

DIPSI and GTT values	Frequency	%
DIPSI normal/ OGTT normal	612	81.6
DIPSI abnormal/ OGTT abnormal	78	10.4
DIPSI abnormal / OGTT normal	32	4.26
DIPSI normal/ OGTT abnormal	28	3.73

Thus, the sensitivity, specificity, positive predictive and negative predictive value using 75gm 2-hour GCT (DIPSI) is 73.58%, 95.03%, 70.90%, 95.64% respectively. 106 patients had deranged GTT and thus diagnosed as GDM (Table 1, Figure 3).

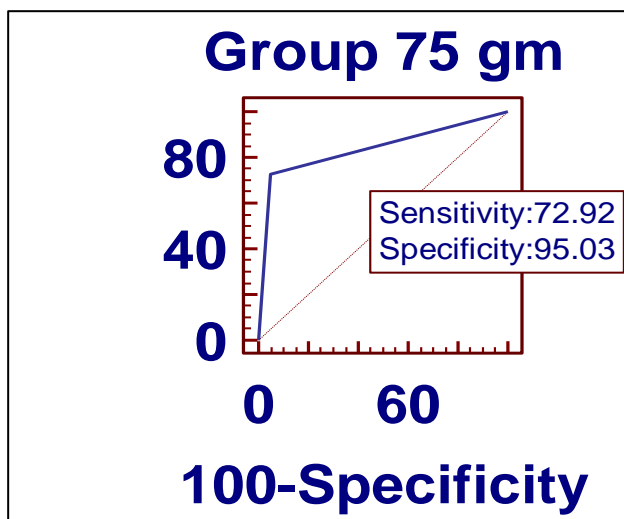


Figure 3: ROC curve of sensitivity and specificity.

The high-risk factors studied were age >30 years, history of GDM, GCA, SB/IUD/NND/, birth weight more than 3.5 kg in previous pregnancy and family history of diabetes mellitus. It was seen that 7.2% (54/750) were more than 30 years in age. 0.93% (4/427) had GDM in previous pregnancy. 4.21% (18/427) had GCA in previous pregnancy, 12.4% (53/427) had SB/IUD/NND in previous pregnancy. 1.17% (5/427) had previous pregnancy with birth weight more than 3.5 kg and 9.73% (73/750) had family history of diabetes mellitus. Of all the GDM women identified 50% had past history of GDM, 29.6% had age >30 years, 24.6% had family history of diabetes mellitus, 27.2% had history of gross congenital anomaly of previous child, 22.64% had history of still birth, IUD, neonatal death, and 20% had previous pregnancy with birth weight more than 20% (Table 2).

Table 2: Risk factors in GDM population.

Risk factors	Total in study population	GDM	%
Age>30 years	54	16	29.6
Family history	73	18	24.5
Previous GDM	4	2	50
H/O GCA	18	5	27.7
H/O SB/IUD/NND	53	12	22.64
Birth Weight >3.5kg	5	1	20

DISCUSSION

Gestational Diabetes Mellitus is one of the most important metabolic disorders during pregnancy. It occurs quite often during pregnancy even in unsuspected cases with prevalence of 1.1-14.3% depending on the ethnic and clinical characteristics.<sup>7</sup> traditional tests require fasting which may be inconvenient to the pregnant women travelling long distances specially in low resource countries, a single step non-fasting procedure seems a reasonable approach. Diabetes in Pregnancy Study group India (DIPSI) recommended a “single test procedure” for diagnosing GDM with a 2 hour PG cut off of  $\geq 7.8$  mmol/L (140 mg/dl) after 75 gm oral glucose irrespective of the last meal.<sup>8</sup> Thus, performing a non-fasting 75gm glucose challenge test emerged as a logical option and this has become very popular in India. Our study recommends the use of single plasma 2-hour value after 75-g glucose as screening and diagnostic criteria for gestational diabetes mellitus. The mean age of our study population was comparable to recommendations of the American Diabetes Association.<sup>9</sup> The mean age of patients was  $24.63 \pm 3.56$  years, Similar results were shown by Rajesh Rajput et al in 2013 where the mean age of participants was  $23.62 \pm 3.42$  year (range 18-38). Their prevalence rate was higher in women aged 26-30 and >30 year (11.57 and 34.8%, respectively) compared to women aged 16-20 and 21-25 year (4.54 and 4.53%, respectively) and this observation was found to be statistically significant ( $P < 0.001$ ).<sup>10</sup>

The prevalence of relatively younger population in this study probably reflects the trend of early marriages in India, especially in the socioeconomic group of patients coming to this hospital. In this study, 106 patients were diagnosed as GDM and thus the prevalence was 14.13% (106/750). The prevalence of GDM was 16.2% in Chennai, 15% in Thiruvananthapuram, 21% in Alwaye, 12% in Bangalore, 18.8% in Erode and 17.5% in Ludhiana in a random survey performed in various cities in India in 2002-2003.<sup>11</sup>

An overall GDM prevalence of 16.55% was observed. Study by Vinita Das et al showed that out of 300 women 20.3% had positive screening for GDM.<sup>12</sup> In a study in Tamil Nadu (2005-2007), a total of 4151, 3960 and 3945 pregnant women were screened in urban, semi urban and rural areas respectively and GDM was detected in 17.8, 13.8 and 9.9% women respectively.<sup>13</sup>

In this study Patients were screened with 75 g 2-hour GCT using 140 mg/dl as cut off (DIPSI criteria) and was followed by OGTT with 75 g glucose irrespective of GCT value. Sensitivity of 75 g 2-hour GCT was 73.58%, specificity was 95.03%, positive predictive value was

70.90%, negative predictive value was 95.64% (Table 1). A similar study done in India by Seshiah V et al to find out whether DIPSI guidelines could still be continued to diagnose GDM in our country showed the prevalence of GDM using DIPSI criteria as 14.6% (N=214) and by IADPSG criteria 13.4% (N=196). The discordant pair between the two criteria examined by McNemar's test indicated that there was no statistical significance (P = 0.21) and thereby implying a close agreement between these two procedures.<sup>14</sup>

Another study done by Anjalakshi et al on South Indian population showed 100% sensitivity and 100% specificity of 75 g 2-hour GCT when compared with the WHO recommended 75 g 2-hour OGTT for the diagnosis of GDM. They concluded that there was no statistically significant difference the two tests in identifying women with GDM (p=1).<sup>15</sup>

A retrospective study in Italy by Lapolla et al reclassified patients using IADPSG 2010 criteria. This reanalysis showed that 2.8% of women who were initially classified as normal by the Fourth international Conference criteria on gestational diabetes needed to be labeled as GDM.

**Table 3: Risk factors in study group patients.**

Risk factors	Dixon et al <sup>18</sup>	Jindal et al <sup>19</sup>	Sesiah et al <sup>14</sup>	Anand et al <sup>20</sup>	Present study
Age > 30 years	82.2%	22.2%	47.3%	40.8%	7.7%
Family history of diabetes mellitus	7.7%	10%	32.3%	8.3%	10.4%
Past history of congenital anomalies	-	2.3%	-	1.9%	4.2%
Past history of GDM	2.1%	2.3%	-	0.4%	0.94%
Past h/o SB/IUD/NND	0.5%	14.6%	-	13.59%	12.4%
Birth weight >3.5 kg	14.5%	5.3%	-	1.9%	1.17%

**Table 4: Risk factors in GDM patients.**

Risk factors	Dixon et al <sup>18</sup>	Jindal et al <sup>19</sup>	Sesiah et al <sup>14</sup>	Anand et al <sup>20</sup>	Present study
Age >30 years	90.4%	44.4%	-	63.6%	29.6%
Family history of diabetes mellitus	22.7%	22.2%	19.4%	27.3%	24.65%
Past history of congenital anomalies	-	3.7%	-	18.2%	27.7%
Past history of GDM	19.4%	22.2%	-	9%	50%
Past h/o SB/IUD/NND	2.7%	44.4%	-	36.3%	22.6%
Birth weight >3.5 kg	29.2%	29.6%	-	9.1%	20%

The study showed an increase in the prevalence of GDM in population of developed countries when defined by the IADPSG 2010 criteria.<sup>16</sup>

Study performed by Wer E et al to evaluate the impact of the new IADPSG thresholds on gestational diabetes mellitus (GDM) prevalence was done by doing a universal screening for GDM on 200 consecutive patients at 24 to 28 weeks with 75 g oral glucose tolerance test. The prevalence of GDM was 14.0%.

The study concluded an increased rate of GDM with the new IADPSG criteria compared to previous published data.<sup>17</sup> The purpose of our study was to show that DIPSI can be used as both screening and diagnostic test for GDM.

It labels only 4.26% of patients as false positive. High specificity (95.03%) is its strength as it will decrease the burden of false positive labelled GDM patients.



In our study, past history of GDM (50%) was the most common risk factor in GDM group followed by age > 30 years (29.6%), and family history (24.6%) (Table 1). The risk factors were almost comparable with Dixon et al and Jindal et al. study.

In the study by Seshiah et al, family history of diabetes (19.4%) was more significant.<sup>13,18,19</sup> Age was the most common risk factor in Western countries. Our study has more patients with risk age group than Jindal et al study (Table 3) (Table 4). Its increasing trend is comparable to that of Western countries. Past history of SB/IUD/NND and macrosomia were the least common risk factors among patients diagnosed with GDM, as comparable with study by Anand et al.<sup>20</sup>

The limitation of present study was that the women diagnosed as diabetic were not followed up and the outcome was not studied. Also, large multicentric studies are needed to validate this test before using it as a diagnostic criterion.

## CONCLUSION

Diabetes in practice study group in India offers a single step test (DIPSI criteria) to diagnose GDM. This universal screening is simple, feasible, convenient, economical and acceptable in Indian scenario as Indian women have an eleven-fold increased risk of developing glucose intolerance during pregnancy.

In India, women have to travel long distances for check-up, hence this non-fasting single test becomes more acceptable to the pregnant women and is also economical as only a single blood test is sufficient to diagnose GDM,

Also, the timely recognition of the disease helps to achieve euglycemia and prevent maternal and fetal complications. Single step 75 g 2-hour test has high specificity (95.03%) and negative predictive value (95.64%) and thus decreases the false positive rate. It serves both as screening and diagnostic criteria besides being a simple, user friendly and evidence-based test.

Though universal screening has been recommended by the Government of India a simple detailed history can help us identify the high-risk women who are at increased risk of developing GDM and thus prevent adverse maternal and perinatal outcome.

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