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Original Research Article

Screening and Diagnosis of Gestational Diabetes Mellitus with Diabetes in Pregnancy Study Group of India Criteria - A Prospective Study in South Indian Population

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is one of the most common metabolic complications of pregnancy. There is no consensus regarding optimal standard for diagnosis of gestational diabetes mellitus.
Aims and Objectives: To assess and compare 75 gm glucose load in non-fasting state DIPSI criteria for GDM in pregnant women with different oral glucose tolerance tests (OGTS).
Materials and Methods: This prospective study was done on 600 pregnant women. Plasma glucose was evaluated two hours after 75 gm glucose load (DIPSI criteria for GDM). After three days, standard 75 gm OGTT was also done i.e. World Health Organization (WHO) and International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria. All the results were tabulated and compared.
Results: Plasma glucose value ≥140 mg/dl two hours after glucose load was seen in 45 (7.5%) patients. When compared to WHO and IADPSG criteria, the sensitivity values were 63.3 and 72.4 % respectively and the specificity was 96.3 and 96.9 % respectively.
Conclusion: DIPSI criteria for diagnosing GDM is recommended as it is a one step procedure that is less time consuming, economical and feasible. But it should be used with caution till further validation.

Key words: Diabetes mellitus, Gestational diabetes, Oral glucose tolerance tests, Pregnancy, Screening.

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as glucose intolerance of variable severity with onset or first recognition during pregnancy. The screening and diagnosis of gestational diabetes mellitus (GDM) continues to be a contentious issue. [1]

Diabetes in Pregnancy Study Group India (DIPSI) diagnostic criterion of 2 hour venous plasma glucose with 75 gm oral glucose load is a modified version of WHO, in which the procedure is performed in the fasting/nonfasting state irrespective of the last meal timing. [2,3]

GDM predisposes to future risk of type-2 DM in both the mother and her offspring. GDM occurs in up to 14% of all pregnancies in the United States of America (USA), whereas Asians have an 11.3 higher

relative risk of GDM. [6] Indian women with GDM have a higher risk of diabetes and metabolic syndrome. [7] Early detection of glucose intolerance during pregnancy has tri-pronged implications. One, GDM offers a timely opportunity for screening, management, and prevention of GDM and type-2 DM in pregnant women. Secondly, it prevents fetal complications thereby improving neonatal outcomes. [8] Thirdly, it offers the development, testing, and implementation of clinical and epidemiologic strategies for diabetes prevention in the population. [4-7]

The terms "screening" and "diagnosis" are often used interchangeably. A screening test for GDM identifies women at greater or lower risk of GDM depending on a particular glucose threshold. Those exceeding the threshold in the screening test should then proceed to a definitive diagnostic test, which provides a definitive answer to the presence or absence of GDM. The lack of consensus regarding the screening and diagnostic criteria for GDM means that different sets of women would be identified as having GDM by the different criteria. [7, 8]

This prospective study was undertaken to ascertain the validity of DIPSI criterion to diagnose GDM based on pregnancy outcome in South Indian population.

MATERIALS AND METHODS

We did our study on 600 consecutive pregnant women who reported to the antenatal clinic of the department of Obstetrics and gynaecology, Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar, Telangana state, India. The study had institutional ethical clearance and informed consent from all the patients was obtained.

Inclusion Criteria:

Pregnant women before 28 completed weeks of gestation

Exclusion Criteria:

1. Known diabetics.
2. Pregnant women after 28 completed weeks of gestation

Procedure:

All women underwent a non-fasting plasma glucose evaluation two hours after giving 75 gm of glucose load between 24 and 28 weeks of gestation. The recommended cut-off value according to DIPSI criteria is >140 mg/dl. [2] After 3 days, all the subjects underwent standard OGTT with 75 g of glucose. A venous blood sample (3 ml) was taken after overnight fasting of 8-14 hours. A solution containing 75 g of glucose was then given orally to all women and two venous blood samples were subsequently collected at hourly intervals. Plasma glucose estimation was done by hexokinase method on an autoanalyzer. Later 75 gm non-fasting DIPSI criteria were compared with the WHO 1999 and IADPSG criteria. [9-11]

Statistical Analysis:

The categorical variables were expressed as number and percentage. Chi Square test was used for the comparison of groups. *P* value <0.05 was considered significant. Data was analyzed by software SPSS Version 20 (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY: USA).

RESULTS

This study included 650 consecutive patients, out of which 600 could be successfully followed for final analysis. Of the total 600 pregnant women, 535 women (89.16%) tested negative for GDM by all methods. The remaining 65 women had one or other tests for GDM positive and hence could be labelled as GDM. Using the DIPSI criteria, 45 women (7.5%) had a two-hour plasma glucose value ≥140 mg/dl and were therefore labelled as having GDM (Table 1). However when the IADPSG criteria were used, only 40 (6.67%) women were diagnosed as GDM. Whereas using the WHO criteria, 42 (7%) women had abnormal OGTT. Only 20 women (3.33) could be labelled as having GDM by all the three methods (DIPSI, IADPSG and WHO).

Majority of the cases were between 26-30 years (43.67%) (Table 2, Graph 1).

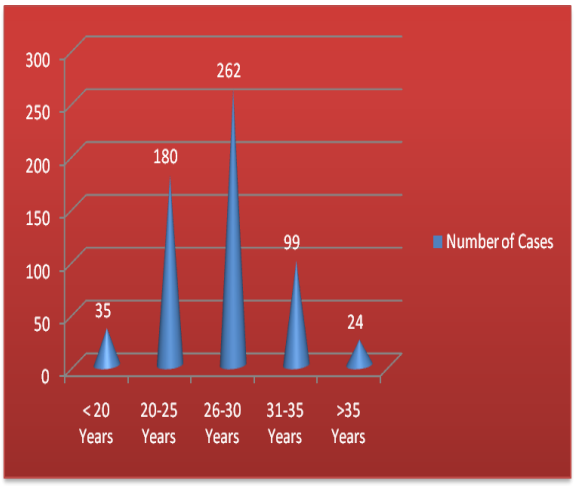
Majority of the pregnant women were primi (44.17%: Table 3). 88.33% women had positive family history of diabetes (Table 4).

Table 1: Incidence of Gestational diabetes mellitus

Category	Number of cases	Percentage of cases
Total no of cases screened	600	100%
Number of cases detected having GDM (Incidence)	65	10.83%

Table 2: Age distribution of the sample

Age Range	Number of Cases	Percentage of cases
< 20 Years	35	5.83%
20-25 Years	180	30 %
26-30 Years	262	43.67%
31-35 Years	99	16.5%
>35 Years	24	4%
Total	600	100%



Graph 1: Age distribution of the sample

Table 3: Obstetric score among tested cases

Obstetric score	Number of Cases	Percentage of cases
PRIMI	265	44.17%
GRAVIDA 2	215	35.83%
GRAVIDA 3	80	13.33%
GRAVIDA >3	40	6.67%
Total	600	100%

Table 4: Family history of Diabetes among tested cases

Family History	Number of Cases	Percentage of cases	P Value
Positive	530	88.33%	
Negative	70	11.67%	
Total	600	100%	<0.001*

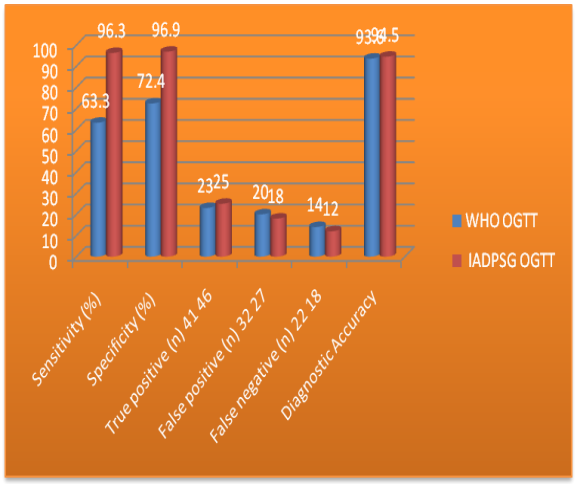
*=Significant

We observed that the DIPSI test was positive in 8 women with normal OGTT by both other criteria (WHO and IADPSG). This suggests the possibility of false-positive cases diagnosed by the DIPSI criteria. When DIPSI criteria was compared with other 2 criteria, i.e. WHO and IADPSG, it was found to have sensitivity values of 63.3 and 72.4 % respectively and specificity values of 96.3 and 96.9 % respectively (Table 5: Graph 2).

Table 5: Comparison of DIPSI test with WHO and IADPSG tests

Statistical parameters	WHO OGTT	IADPSG OGTT	P VALUE
Sensitivity (%)	63.3	96.3	<0.001*
Specificity (%)	72.4	96.9	0.001*
True positive (n)	23	25	0.7903
False positive (n)	20	18	0.7722
False negative (n)	14	12	0.7356
True negative (n)	543	545	0.9818
Diagnostic Accuracy	93.6	94.5	0.829

*=Significant



Graph 2: Comparison of DIPSI test with WHO and IADPSG tests

DISCUSSION

"DIPSI - A modified version of WHO criteria is a one step procedure with a single glycemic value". The effectiveness of glucose-challenge tests in the non-fasting state for screening and diagnosing GDM has long been a matter of debate. The ADA recommends only selective screening for GDM. [1-3]

Seshiah V et al reported an incidence of 13.4% of GDM in antenatal women. The incidence in the present study is 7.5%. [12] Maternal age is an established risk factor for gestational diabetes mellitus. Studies have shown that the risk of GDM becomes significantly and progressively increased from 25 years onwards. [10-12]

A study done by Anjalakshi et al on south Indian population showed 100 per cent sensitivity and 100 per cent specificity

of 75 gm, two hour non-fasting DIPSI test when compared with the WHO-recommended 75 gm OGTT for the diagnosis of GDM. They concluded that there was no significant difference between the two tests in identifying women with GDM. Another study conducted on Indian population had shown similar results. [2]

However Mohan et al have shown a very low sensitivity of non-fasting OGTT as compared to the fasting OGTT'. These authors further reported that DIPSI test when compared to the WHO criteria had sensitivity of 27.7 per cent and specificity of 97.7 per cent and when compared to the IADPSG criteria had sensitivity of 22.6 per cent and specificity of 97.8 per cent. [13]

In another Indian study conducted in the State of Maharashtra18, GDM was reported in only 6.52 per cent cases and they suggested that this low prevalence might be due to 'less sensitivity of DIPSI criteria'. [14]

Another study, though conducted in smaller numbers19 had stated that 22.36 per cent of cases of GDM were not diagnosed by the DIPSI criteria. [15] A study on Srilankan women has also concluded that 'GCT with two-hour cut-off value ≥140 mg/dl is not sensitive enough to diagnose GDM recognized by GTT. This study analyzed only 274 women, but prevalence rate of GDM in Srilanka study20 was 22 per cent and therefore, their results should be considered significant. [16]

However, Magon et al had recommended the DIPSI test for universal use in India. The problem of accuracy of the 75 gm, two-hour non-fasting DIPSI test is further highlighted by showing low positive predictive value (PPV) in comparison with various types of OGTT. [17]

The large extent of false positives, together with a smaller number of false negatives, is a major limitation of DIPSI test. The consequences of clinical interventions due to the erroneous diagnosis of GDM cannot be overlooked. Hence, use of this test for diagnostic purposes needs to be further investigated in large, multicentre studies before utilizing for universal implementation in India.

Study Limitations

The study is limited by sample size and unaccounted fasting hyperglycemia.

CONCLUSION

Indian women are more prone to gestational diabetes during pregnancy; hence there is a need for universal screening. For universal screening, DIPSI TEST with 75 grams as a one step screening and diagnostic procedure is recommended. One step procedure is less time consuming, economical and feasible.

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