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"Effectiveness of Diabetes in Pregnancy Study Group India (DIPSI) Diagnostic Criterion in Detecting Gestational Diabetes Mellitus – a Pilot Study in a Rural Population."

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Abstract:

Background: Gestational diabetes mellitus (GDM) increases the risk of adverse maternal and neonatal outcome if untreated. Diabetes in Pregnancy Study Group India (DIPSI) has recommended a modified 75 g oral glucose tolerance test (OGTT) to diagnose GDM. There are very few studies on the effectiveness of the DIPSI recommended OGTT in diagnosing GDM. The present study was planned to assess the effectiveness of DIPSI recommended OGTT in diagnosing GDM.

Materials and Methods: 200 healthy pregnant women from a rural population attending the antenatal clinic of a teaching hospital at Chinnaoutapalli underwent the DIPSI recommended 75 g OGTT between 24-28 weeks of pregnancy. Three days later all of them were made to undergo the American Diabetic Association (ADA) recommended 75 g OGTT.

Results: Of the 200 women 22 had an abnormal 75 g OGTT. Out of the 22 women only 5 had an abnormal ADA recommended OGTT value. Seventeen of the women were wrongly categorised as GDM based on the DIPSI criteria. The 2 hr plasma glucose value in the non GDM group was 105±18mg/dl and in the GDM group was 162±24.3 mg/dl ('p' value <0.0001).

Conclusion: Our study has demonstrated that the DIPSI recommended 75 g OGTT was able to accurately detect GDM and has a higher sensitivity when compared to the 50 g OGCT though the specificity is almost the same. Further studies are needed to determine the effect of the timing of the OGTT on the plasma glucose value, in order to reduce the false positives.

Key words: DIPSI, 75g OGTT, false positives

Introduction:

Gestational diabetes mellitus (GDM) is defined as glucose intolerance with onset or first recognition during pregnancy. [1] Pregnancy is associated with increasing insulin resistance that begins in mid-pregnancy and progresses through the third trimester to levels that approximate insulin resistance seen in type 2 diabetes mellitus (T2DM). The insulin resistance of pregnancy is due to maternal adiposity and the insulin - desensitising effects of placental hormones. GDM is associated with adverse maternal and neonatal outcome. GDM is thought to represent diabetes in evolution and the increasing prevalence of GDM along with DM confirms this supposition.[1] The International Association of Diabetes in Pregnancy Study Groups (IADPSG) consensus panel recommends universal early testing in populations with a high prevalence of type 2 diabetes and also recommended that all pregnant women irrespective of risk of GDM should be screened for GDM between 24-28 weeks of pregnancy using the 75 g oral glucose tolerance test (OGTT). [2] This procedure requires the pregnant woman to be in a fasting state. It is difficult for the pregnant woman to get up possibly with morning sickness, travel to

a clinic and wait an additional two hours before eating. Diabetes In Pregnancy Study Group India (DIPSI) diagnostic criterion of 2-h plasma glucose ≥7.8 mmol/l or ≥ 140 mg/dl is a modified version of the World Health Organization (WHO) criteria in that, this procedure is performed irrespective of the last meal timing [3]. This prospective study was undertaken to ascertain the validity of the DIPSI criterion in diagnosing GDM.

Materials and methods:

The study was initiated after informed consent was taken from the participants and with the approval of the institutional ethical committee of Dr Pinnamaneni Siddhartha Institute of Medical Sciences and Research Foundation (Dr PSIMS & RF) Chinnaoutapalli , Krishna district A.P. The prevalence of GDM based on the 50 g oral glucose challenge test (OGCT) and 75 g OGTT criteria recommended by the American Diabetic Association (ADA) was 1% in this rural population. Two hundred healthy pregnant women aged between 19 – 35 years from a rural population attending the antenatal clinic at Dr PSIMS & RF was followed up till delivery. Details of their pregnancy, anthropometric measurements, family history of DM, prior history of GDM and other relevant history were recorded at their first visit. The participants of gestational age between 24-28 weeks of pregnancy were given 75 g oral glucose load irrespective of their last meal timing and venous blood samples were collected two hours later. Two ml venous samples were collected in vacutainers containing lithium heparin. The samples were centrifuged immediately and analysed for glucose by the glucose oxidase peroxidase (GOD-POD) method using commercial kits supplied by Randox diagnostics on a fully automated Randox Daytona clinical chemistry analyser within an hour. After standardization, internal quality control samples were run (Randox kits). A 2 hr plasma glucose value of ≥140 mg/dl was considered diagnostic of GDM (DIPSI criteria). [3] After three days of unrestricted carbohydrate diet all the pregnant women were subjected to ADA stipulated 75 g OGTT. Three venous blood samples from each of the pregnant women was collected and processed in a similar manner and analysed for plasma glucose values. Fasting plasma glucose of ≥ 95 mg/dl, 1 hr value of ≥180 mg/dl or a 2hr value of ≥155 mg/dl were considered abnormal.Two or more values equalling or exceeding the above mentioned values were considered diagnostic of GDM [4]. The women with plasma glucose less than any 2 of the above values were considered as normal glucose tolerant (NGT) women. Women diagnosed as GDM were managed appropriately. All of them were followed up till delivery.

Statistical Analysis:

Descriptive statistics was used to calculate the mean and standard deviation. Z test was used on the results obtained and a 'p' value <0.05 was considered statistically significant.

Results:

A total of 200 healthy pregnant women comprising of 109 primi and 91 multigravid women, aged between 19-35 years and attending the antenatal clinic of Dr PSIMS & RF hospital, Chinnaoutapalli were followed up until delivery. The mean age of the pregnant women was 22.8 ± 3.2yrs. The clinical and biochemical characteristics of the study participants are given in Table 1. Of the 200 women 22 (11%) tested positive for the DIPSI recommended 75 g OGTT. The ADA recommended 75g OGTT revealed only 5 positive (2.5%) cases. This indicated a prevalence of 2.5% in the population. The specificity of the test was 89% and sensitivity was 100%. Of the 5 who were true positives all had a 1 hr post load plasma glucose value ≥180 mg/dl, 2 also had a fasting plasma glucose ≥ 95 mg/dl

and the remaining 3 women who had a normal fasting value had a 2 hr plasma glucose value ≥ 155 mg/dl.

Discussion:

Among the 200 healthy pregnant women followed up during pregnancy 22(11%) tested positive when they were screened with the DIPSI recommended 75 g OGTT irrespective of the last meal taken. According to the DIPSI group the rationale of performing this type of OGTT is that after a meal, a normal glucose tolerant woman would be able to maintain euglycemia despite the glucose challenge due to a brisk and adequate insulin release. [5]In the case of a pregnant woman who has impaired insulin secretion, she will not be able to maintain euglycemia after a meal and there will be a further increase in plasma glucose value after an OGTT. This cascading effect is advantageous and would not result in false positive diagnosis of GDM.[5] Out of the 22 only 5 tested positive by the ADA recommended 75 g OGTT. There were no false negatives observed in the present study on performing the DIPSI 75 g OGTT unlike the 50 g OGCT which studies have shown is associated with a higher number of false negatives (6.25 – 14%)[6]. The reason could be that the present study population is small compared to other studies and comprises of a younger age group all of whom are from a rural background where the prevalence of GDM is low. Table 2 shows the sensitivity and specificity of the 75 g OGTT. Several studies have shown that the sensitivity and specificity of 50 g OGCT as 85% and 86% respectively. [6] Out of the 22 women who tested positive on the DIPSI 75 g OGTT, 17 had a normal ADA 75 g OGTT in our study. Lee et al in a study have observed that glucose tolerance decreases in the afternoon and evening as detected by the oral and intravenous GTT.[7] Reduced insulin sensitivity and β-cell responsivity to glucose both account for this deterioration of glucose tolerance later in the day. [7] The DIPSI OGTT in our study was performed without regard to the time of the day and this could be the cause of the false positive OGTT obtained. A study done by Goldberg et al reveals this anomaly. [8] They have demonstrated that women with positive OGCT in the afternoon were less likely to have GDM than those with a positive OGCT in the morning. This suggests that the time of performance of the OGCT will influence the results and give rise to false positive OGCT.[8] McElduff and Hitchman demonstrated that the percentage of women with a positive GCT screening test was higher in the afternoon when compared to the morning (31.1% vs 17.0%).[9] Another study also showed that the positive predictive value of the OGCT was consistently lower when performed in the afternoon. [10] The same holds true in our study as the time of the day when the DIPSI 75 g OGTT was administered was not recorded, and this could be the cause of the false positives observed.

Conclusion:

These findings hold significant import for GDM screening. As of now there is no gold standard test to diagnose GDM.[6] On 14th March 2007, a government of India order issued the instructions that universal screening for glucose intolerance during pregnancy should be mandatory. [11] The order recommends that all women should be screened between 24 and 28 weeks of gestation with 2 h 75 g oral glucose irrespective of the last meal taken. Plasma glucose value of ≥140 mg/dl is suggestive of GDM and meal plans without compromising the nutrition of the mother are advised to GDM mothers. Though compliance is enhanced by performing the DIPSI recommended 75 g OGTT, it may lead to unnecessary dietary control and regular follow up in women who are wrongly categorised as GDM based on the screening test performed later in the day. This may lead to anxiety in the mother and low birth weight in the

newborn.[6] Therefore DIPSI recommended 75 g OGTT can be administered during pregnancy to diagnose GDM, provided further studies are done to see the effect of time of the day on the test results of the OGTT. This will prevent false positives and increase the specificity of the test.

TABLE I: CLINICAL AND METABOLIC CHARACTERISTICS OF THE STUDY PARTICIPANTS.

Ante partum characteristics	Non GDM women	GDM women	p value
Age in years	22.8±2.5	22.7±3.5	>0.05 NS
Weeks gestation at OGCT	24±2.5	24±2.9	>0.05 NS
Mean plasma glucose value after 75g OGCT in mg/dl	105±18	162±24.3	<0.0001 HS
Birth weight of newborn in kg	2.79±0.3	2.71±0.3	>0.05 NS
Proportion of Lower Segment Caesarean Section	0.4	0.8	
NS = nil significant, HS= highly significant, p = probability, OGCT= oral glucose challenge test. 'p' value <0.05 is considered significant			

TABLE II: TEST CHARACTERISTICS OF DIABETES IN PREGNANCY STUDY GROUP INDIA (DIPSI) RECOMMENDED ORAL GLUCOSE TOLERANCE TEST(OGTT)

Test characteristics	75 g OGTT (DIPSI)
Specificity %	89
Sensitivity %	100
False positives %	1.6

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