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Research Article

Comparison of diagnostic accuracy of two one step procedures for screening of gestational diabetes mellitus

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ABSTRACT

Background: Single test procedures for screening GDM in Indian women will help in its management.This study was aimed to compare the accuracy measures of the random glucose test and the Diabetes In Pregnancy Study group India (DIPSI) recommended glucose challenge test as screening tests for Gestational Diabetes Mellitus (GDM) between 24 and 28 weeks of pregnancy and to study the prevalence of GDM and associated risk factors.
Methods: In this prospective cohort study, all pregnant women without pre-existing diabetes underwent a random glucose test first followed by DIPSI recommended method (2 hours after a 75 g oral glucose load, without regard to the time of the last meal). All the pregnant women were subjected to 2-h 75-g oral glucose tolerance test for diagnosis of GDM within one week. Receiver Operating Characteristic (ROC) analysis was used to evaluate the discriminatory power of the two screening tests.
Results: The OGTT was performed in 576 women. The area under the ROC curve was larger for the DIPSI test [0.97 (95% CI 0.95-0.98)] than for the random glucose test [0.76 (95% CI 0.72-0.79)]. There was a significant difference in the areas under the curve of the two tests of 0.21 (0.14 to 0.28) (P <0.0001) in favour of the DIPSI recommended method. GDM was present in 8.9% women confirmed by 75 g 2 hour OGTT using the WHO criteria. Age ≥30 years, BMI ≥25 and family history of diabetes were found to be risk factors for GDM.
Conclusions: In screening for GDM, the DIPSI procedure test was more useful than the random glucose test.

Keywords: GDM, Random glucose test, DIPSI

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is commonly defined as glucose intolerance first recognized during pregnancy. The prevalence of GDM is increasing, fuelled by advancing maternal age, racial/ethnic shifts in childbearing, and obesity. As a result of the global trend of increased maternal obesity, it is estimated that approximately 15% of all pregnant women worldwide develop GDM.[1] Comprising around 90% of all cases of diabetes in pregnancy, GDM left undetected or uncontrolled is a formidable threat to the health of the mother and her unborn child. Estimates of the prevalence for GDM in India vary greatly; from low figures in the northern region of Jammu,[2] to higher figures reported in the southern state of Tamil Nadu.[3] These widely ranging statistics may reflect a true variation in GDM prevalence throughout the subcontinent, but may also be partially accounted for by discrepancies in protocols for screening and diagnosis, and access to care or changes in risk factors in different geographic regions.

The Diabetes In Pregnancy Study group India (DIPSI) guidelines for screening & diagnosis GDM recommends that a pregnant woman after undergoing preliminary clinical examination, has to be given a 75g oral glucose load, without regard to time of last meal. A venous blood sample is collected at 2 hours for estimating plasma glucose by the GOD-POD method. GDM is diagnosed if 2 hour plasma glucose is ≥140 mg/dl.

Another screening test commonly performed for screening GDM is Random Glucose Test (RGT). The RGT is a simple, fast and inexpensive test, which measures plasma glucose at a random point in time, irrespective of the time of the last meal and without any specific preparation and is very often performed in European countries and in India for screening GDM.

The data regarding prevalence of GDM and the number of women affected are important to allow for rational planning and allocation of resources and the preventive strategies that may be undertaken in future. Because widely different prevalence rates have been observed in studies in different regions of India, multiple regional studies in different subtypes of populations are needed for quantifying prevalence data as well as risk factors associated with it. Single test procedures for screening GDM will help in its management.

The objective of the present prospective cohort study was to compare the accuracy of DIPSI method and random plasma glucose testing (single test procedures) as screening tests for GDM between 24 and 28 weeks of pregnancy and to study the prevalence of GDM and associated risk factors in women attending a tertiary care hospital in Uttar Pradesh.

METHODS

Consecutive pregnant women with singleton pregnancy at 24^{th} to 28^{th} week of gestation coming for routine antenatal check-up in the department of gynaecology and obstetrics, Santosh hospital, Ghaziabad, from January 2012 to June 2013 were selected for the study. Ethical clearance was taken from Santosh University. Informed consent was taken from all women. Women known to have pre-existing diabetes were excluded from the studies.

At intake, a detailed history and clinical examination was taken which included, general information on demographic characteristics, socio-economic status, education level, obstetric history, family history of diabetes, height, and self-reported weight (before pregnancy). BMI was calculated as weight in kilograms divided by the square of height in meters.

In all women, the random glucose test was performed first followed by DIPSI recommended method (2 hours after a 75 g oral glucose load, without regard to the time of the last meal). Venous blood sample were collected for estimating plasma glucose by the glucose oxidase method. If the random plasma glucose measured between 24 and 28 weeks of gestation was 110 mg/dl (6.1 mmol/L), the random glucose test was considered abnormal. There seem to be only few studies on the accuracy of the RGT as a screening test for GDM. We used the 110 mg/dl cut off as abnormal for RGT as was taken by Leeuwen et al.[4] in their study. By DIPSI method if 2 hour plasma glucose was ≥140 mg/dl (7.8 mmol/L) it was considered abnormal.

After three days of unrestricted carbohydrate diet all the pregnant women were subjected to 2-h 75-g Oral Glucose Tolerance Test (OGTT). The OGTT was performed in the morning after a 12-h overnight fast. Plasma glucose was determined before and 2 h after administration of a 75-g glucose-containing solution. GDM was considered present if venous plasma glucose equalled or exceeded the threshold values according to World Health Organization criteria (fasting ≥7 mmol/l or ≥126 mg/dl; 2 h plasma glucose ≥7.8 mmol/l or 140 mg/dl).

Statistical analysis

We constructed two-by-two tables for abnormal and normal test results on the random glucose test and the DIPSI screening test against the OGTT. These tables reflect true-positive, false-positive, true-negative, or false-negative test results for both the random glucose test and the DIPSI test. Diagnostic accuracy (sensitivity, specificity, predictive values, and likelihood ratios) and 95% CIs were calculated. Receiver Operating Characteristic (ROC) analysis was used to evaluate the discriminatory power of the two screening tests. Using the receiver operating characteristic technique, comparison of sensitivity with specificity was made over the entire range of diagnostic test cut points, and areas under the curve were plotted. By interpolation from the area under the curve, the point closest to the upper-left corner, which maximized sensitivity and specificity, was selected; this identified the highest number of subjects with or without a GDM. Categorical data were compared by using Fisher's exact test to get two-sided (two-tailed) P value and P value <0.05 was considered significant. Data were analyzed using Medcalc (Version 12.6.0).

RESULTS

Out of the 700 women recruited for the study, only 576 women returned for 2-h 75-g Oral Glucose Tolerance Test (OGTT) and completed the study. Data from 576 women were used for further analysis. The age (mean ± SD) of the participants was 25.3 ± 3.9. The age (mean ± SD) of women diagnosed having GDM was 27.1 ± 4.1. Out of 576 women in study population GDM was present in 51 women (8.9%) confirmed by OGTT.

In the age group of ≥30 years; 14 women (27.4%) had GDM as compared to 37 women (7.1%) in the age group ≤30 years. Prevalence of GDM was significantly high in the age group of ≥30 years (P <0.05). Significant difference was noted among those with normal BMI compared to those who were overweight or obese (P <0.01). In our study, a significantly higher per cent of women with GDM had positive family history of diabetes mellitus (P <0.02). Seshiah et al.[3] observed a significant association between family history of diabetes mellitus and the occurrence of GDM among pregnant women.

No statistically significant association was found between education and GDM (P <0.07), parity and GDM (P <0.06), class and GDM (P <0.12) and, between history of previous spontaneous abortions and GDM (P <0.11) (Table 1a, Table 1b and Figure 1).

Table 1a: Demographics summary.

	GDM present	GDM not present	Total
n (Number of cases)	51	525	576
Age (mean ± SD)	27.1 ± 4.1	25.1 ± 3.8	25.3 ± 3.9
BMI before pregnancy, mean (kg/m^2) ± SD	24.6 ± 2.7	22.8 ± 2.0	22.9 ± 2.1
Family history of diabetes			
Yes n (%)	14 (27.5)	74 (14.1)	88 (15.3)
No n (%)	37 (72.5)	451 (85.9)	488 (84.7)
Obstetric history 1			
Previous spontaneous abortion n (%)	16 (31.4)	111 (21.1)	127 (22.0)
No previous spontaneous abortion n (%)	35 (68.6)	414 (78.9)	449 (77.9)
Obstetric history 2			
Nullipara n (%)	15 (29.4)	196 (37.3)	211 (36.6)
Multipara with history of GDM n (%)	2 (3.9)	4 (0.8)	6 (1.0)
Multipara without history of GDM n (%)	34 (66.7)	325 (61.9)	359 (62.3)

Table 1b: Demographics summary.

	GDM present	GDM not present	Total
n (No. of cases)	51	525	576
Education			
12 plus n (%)	13 (25.5)	74 (14.1)	70 87 (15.1)
9-12 n (%)	19 (37.3)	171 (32.6)	190 (33)
1-8 n (%)	13 (25.5)	175 (34.3)	188 (32.6)
Illiterate n (%)	6 (11.8)	105 (20)	111 (19.3)
Class			
Upper n (%)	9(17.6)	58 (11)	67 (11.6)
Upper middle n (%)	9 (17.6)	180 (34.3)	189 (32.8)
Lower middle n (%)	12 (23.5)	106 (20.2)	118 (20.5)
Upper lower n (%)	5 (9.8)	31 (5.9)	36 (6.3)
Lower	16 (31.4)	150 (28.6)	166 (28.8)

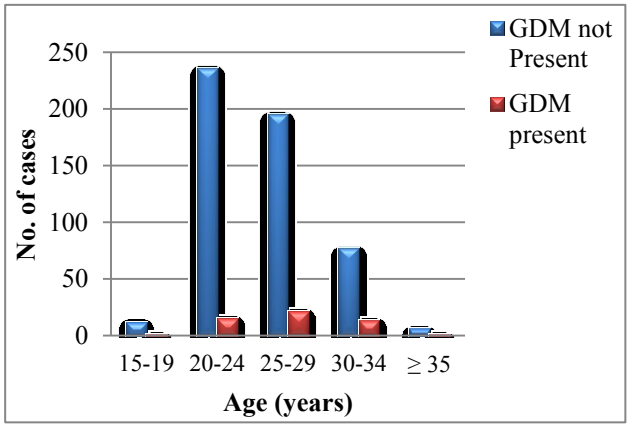

Figure 1: Prevalence of GDM according to age.

Comparison of accuracy measures resulted in higher sensitivity in favour of the DIPSI screening test compared with the random glucose test [90.2% (95% CI 78.6-96.7) vs. 15.7% (7.1-28.6)]. The DIPSI test also had less false-positive test results and was therefore more specific [97.5% (95.8-98.7) vs. 95.4% (93.3-97.1)]. Positive predictive values for DIPSI tests were high as compared to Random Glucose test. Negative predictive values for both tests were comparable (Table 2 and Figure 2). The likelihood ratio of an abnormal test result was larger for the DIPSI test than for the random glucose test. The likelihood ratio of a normal test was smaller for the DIPSI test.

The area under the ROC curve was larger for the DIPSI test [0.97 (0.95-0.98)] than for the random glucose test [0.76 (0.72-0.79)]. There was a significant difference in the areas under the curve of the two tests of 0.21 (0.14 to 0.28) (P <0.0001) (ROC comparative curve).

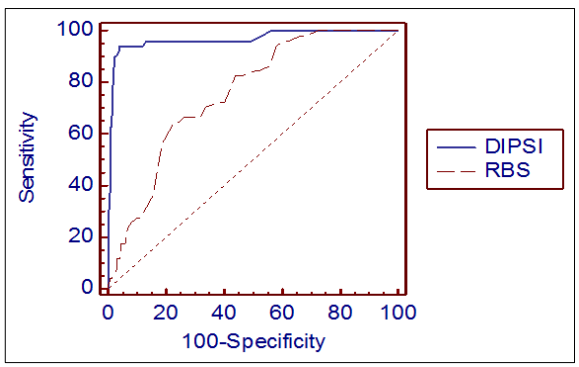

Figure 2: Comparison of roc curve analysis of random plasma glucose test and DIPSI test for GDM.

Table 2: Comparison of accuracy measures between the screening tests.

Accuracy measures	Random glucose test	DIPSI Test
Sensitivity	15.7 (7.1 to 28.6)	90.2 (78.6 to 96.7)
Specificity	95.4 (93.3 to 97.1)	97.5 (95.8 to 98.7)
Positive predictive value	25.00 (11.49 to 43.41)	77.97 (65.27 to 87.70)
Negative predictive value	92.10 (89.50 to 94.22)	99.03 (97.76 to 99.68)
Positive likelihood ratio	3.43 (1.63 to 7.24)	36.43 (21.13 to 62.78)
Negative likelihood ratio	0.88 (0.78 to 1.00)	0.10 (0.04 to 0.23)
Area under the ROC curve (AUC)	0.76 (0.72 to 0.79)	0.97 (0.95 to 0.98)
All accuracy measures are displayed with 95% CIs.		

DISCUSSION

GDM was present in 8.9% women confirmed by 75 g 2 hour OGTT using the WHO criteria. We calculated the prevalence of GDM using DIPSI recommendation as a diagnostic test also in the study population and GDM was present in 59(10.2%) women. In a study by Balaji et al.[5] using DIPSI criterion 13.4% of women were identified as GDM .Anjalakshi et al.[6] evaluated, whether a 2-h 75 g oral glucose test done in a non-fasting state, irrespective of last meal timing, is as efficacious as 2-h 75 g oral glucose test done in the fasting state recommended by WHO in detecting GDM. The study showed all women diagnosed as GDM by 75 g glucose non fasting test also satisfied the diagnostic criteria of 75-g oral glucose test performed in the fasting state recommended by WHO. No difference in the plasma glucose levels of the 75 g glucose test in fasting and non-fasting state was noted, in GDM and Normal Glucose Tolerant (NGT) pregnant women (P >0.05). The rationale is that, normal glucose tolerant women are able to maintain euglycaemia despite glucose challenge due to adequate insulin response, whereas in women with GDM, impaired insulin secretion increases glycaemic level with a meal and the glucose challenge is expected to exaggerate the glycaemic excursion. This cascading effect is advantageous as it increases specificity and eliminates false positive diagnosis of GDM. The specificity of DIPSI method of screening was very high in our study also. Philips et al.[7] also observed that plasma glucose value with a glucose challenge test was unaffected by the time after a meal or time of the day in normal glucose tolerant non pregnant subjects.

In a recent study, Seshiah et al.[8] done on 1463 consecutive pregnant women with no previous history of GDM/pre GDM showed no significant difference (P >0.05) in the discordant pair of diagnosing GDM by the two criteria - DIPSI criterion, 196 (13.4%), applying IADPSG recommendation the cumulative prevalence of GDM was 14.6% (n=214). And concluded that the disagreement in diagnosing GDM by both criteria was not significant (P = 0.21, by Mc Nemar test). Thus DIPSI method is a suitable test for screening and diagnosing GDM in Indian population.

In the present study the random plasma glucose revealed a very low sensitivity of 15.7% (95% CI 7.1-28.6) and a high specificity of 95.4% (95% CI 93.3-97.1) using a threshold value of ≥110 mg/dl (6.1 mmol/L). Using this threshold GDM was present in 32 (5.6%) women only. The sensitivity of the RGT in the study by Jowett et al.[9] ranged from 25 to 47% for random blood glucose measurement in the same women at different times of day. In our study the sensitivity was low. As pregnancy progresses plasma glucose levels under fasting conditions drop whereas plasma glucose levels after a meal become higher. As the RGT is performed at a random point in time, peak values after a meal might remain undetected.

As high sensitivity is key to any screening test, random glucose testing is not an accurate method to screen women for GDM because five of six women with GDM would still be missed. In our study, sensitivity and specificity of the RGT seem to be not sufficient to be used as a screening test. In screening for GDM, the DIPSI procedure test is more useful. This single-step procedure has also been approved by Ministry of Health, Government of India[10] and recommended by WHO.

CONCLUSION

In screening for GDM, the DIPSI procedure test was found to be more useful than the random glucose test. DIPSI procedure for screening GDM requires little preparation, without requiring the patient in fasting test and it could be applied to the entire obstetric population. Thus, DIPSI procedure would serve the purpose of implementing public health program to screen as well as diagnose GDM in the community.

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