One step oral glucose challenge test as screening and diagnostic test for Gestational Diabetes Mellitus

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ABSTRACT

Aim: The Diabetes in Pregnancy Study Group of India (DIPSI, 2010) guidelines recommend the non-fasting 75-g oral glucose challenge test (OGCT) as a single-step screening and diagnostic test for gestational diabetes mellitus (GDM). The aim of this study was to assess the validity of DIPSI criteria by comparing with the World Health Organization (WHO) 1999 criteria of diagnosing GDM.

Methods: This study was a hospital based prospective comparative study conducted among 282 pregnant women, of gestational age of 24-28 weeks attending antenatal OPD of Patan hospital. The OGCT was performed on them irrespective of fasting state and without any dietary preparation and they were again asked to come after 3 days of unrestricted carbohydrate diet in fasting state for WHO 2-hour oral glucose tolerance test (OGTT) with 75 gram of glucose load. The value of OGCT >140 mg/dl is diagnostic of GDM (DIPSI 2010). For the reliability of this test, it was compared with WHO 2-hour OGTT.

Results: Among the study population, the mean age and BMI was 26.04±4.50 and 24.08±3.30 respectively. Out of 282 patients, 8 cases (2.83%) were found to have abnormal non-fasting 75-g OGCT and 4 cases (1.41%) had abnormal WHO 2-hour OGTT. Paired t test was employed to examine the difference of blood glucose level of the tests. There was statistically significant difference ($p<0.001$) between the tests. The Sensitivity, specificity, positive predictive value and negative predictive value of oral glucose challenge test was 25%, 97.48%, 12.5% and 98.90% respectively. The non-fasting 75-g OGCT was able to detect only 25% of the cases.

Conclusions: Though the non-fasting 75-g OGCT test is cost effective and more compliant to pregnant women, the present report suggests that it cannot be used as a single step screening and diagnostic test because of its low sensitivity. However, it is an adequate alternative for screening test in resources limited areas.

Keywords: Gestational Diabetes Mellitus (GDM), Oral Glucose Challenge test (OGCT), Oral glucose tolerance test (OGTT)

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INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance on recognition of pregnancy, whether or not the condition persisted after pregnancy and not excluding the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy.[1,2]

A state of insulin resistance is seen during the pregnancy which is mainly due to antagonistic action of human placental lactogen and accelerated insulin catabolism by renal, placental insulinases. The anti-insulin effects of other hormones like cortisol, estriol, and progesterone also contribute to insulin resistance. The presence of these stimuli triggers hyperinsulinemia, insulin resistance, fasting hypoglycemia and postprandial hyperglycemia. Consequently, there is a reduction in peripheral sensitivity to insulin and an increase in demand. As a compensatory mechanism, an increase in pancreatic secretion of insulin occurs. As pregnancy advances, these compensatory mechanisms may be insufficient in susceptible women, resulting in an imbalance between insulin production and insulin requirements in pregnancy and thus, GDM occurs.

Gestational diabetes is associated with poor maternal outcomes such as pre-eclampsia, polyhydramnios, fetal macrosomia, birth trauma, postpartum hemorrhage and primary cesarean delivery. The fetus is also exposed to high level of glucose which results in excess fetal growth, impaired insulin secretion and decreased insulin sensitivity which can lead to neonatal

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hypoglycemia, hyperbilirubinemia, hypocalcemia and erythema, and an increase in neonatal intensive care unit (NICU) admissions. Long-term maternal complications of GDM include a greater risk for type 2 diabetes, with an estimated annual incidence of 10% per year.[3] Long-term adverse neonatal outcomes include increased risk of childhood obesity, type 2 diabetes, impaired neurological functions.[3] Risk factors for recurrence are older maternal age, greater parity and weight gain between pregnancies.[4,5] One-third of women with GDM may have recurrence in the subsequent pregnancies.[6]

Diabetes in Pregnancy Study group India (DIPSI) in 2010[7], have come up with "A one step procedure with a single glycemic value", to diagnose GDM in the community. In the antenatal clinic, a pregnant woman after undergoing preliminary clinical examination is given a 75-g oral glucose load, irrespective of whether she is in the fasting or non-fasting state, without regard to the time of the last meal. A venous blood sample is collected at 2-hours for estimating plasma glucose by the glucose oxidase - peroxidase method. GDM is diagnosed if 2-hour plasma glucose is >140 mg/dl. Previously, in 2005 DIPSI recommended 75 gram OCGT in fasting state.[8]

This procedure assumes clinical relevance with WHO criteria[9] as it is also based on glucose level > 140 mg/dl at 2 hours after 75 gm oral glucose load. This test serves as both screening and diagnostic procedure and causes least disturbance in a pregnant woman's routine activities.

The aim of this study was to assess the validity of DIPSI criteria by comparing with the World Health Organization (WHO) 1999 criteria of diagnosing GDM.

METHODS

This is a hospital based prospective comparative study of pregnant women of 24-28 weeks of gestation irrespective of maternal age, parity or any risk factors for gestational diabetes mellitus attending antenatal OPD of Patan Hospital from March to June 2015. Total 282 patients were randomly selected with exclusion of pregestational diabetic women, diagnosed case of GDM and those who were under medications like steroids, beta agonists were excluded. The study population (n=282) underwent both the tests. They were given a 75-g of glucose load (OGCT) irrespective of last meal taken and venous blood sample was collected after 2 hours according to DIPSI Criteria. They were again asked to come after 3 days with unrestricted carbohydrate diet (minimum of 150gms of carbohydrate per day and activity) in fasting state for WHO 2-hour Oral Glucose Tolerance Test (OGTT). Plasma glucose (PG) was estimated by Glucose oxidase – Peroxidase (GOD–POD) method.

Paired t-test was applied to examine the difference of blood glucose values between the 75-g OGCT and WHO 2-hr OGTT values in all study population. Diagnostic statistics like sensitivity, specificity, PPV, NPV and accuracy have been computed to find the correlation of 75-g OGCT and WHO 2-hr OGTT. The p-value of <0.05 was considered as statistical significant. The Statistical Package for Social Science version 20 (SPSS-20) was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, charts and tables.

RESULTS

Among the study population, the mean age and BMI was 26.04 ± 4.50 and 24.08 ± 3.30 respectively. The study population includes 145 (51.42%) primigravida and 137 (48.58%) multigravida. Among them 36 (12.77%) women gave the history of diabetes mellitus in their family, whereas 246 (87.23%) had no history of Diabetes Mellitus in their family. The majority of women, 79 (28.01%) were near to 24 weeks of gestational age and only 18 (6.38%) were near to 28 weeks of gestation [Table-1].

Table-1: Distribution by age, Parity, BMI and Family history of Diabetes

Clinical variables	Number of women	Number of women with GDM		
Age in Years		OGCT	OGTT	Both test
16 - 20	27	0	0	0
21 - 25	105	4	0	0
26 - 30	109	1	1	1
31 – 35	34	2	2	0
36 - 40	7	0	0	0
41 - 45	0	0	0	0
Parity				
Primigravida	145	3	1	0
Multigravida	137	4	2	1
Family History				
Yes	36	0	2	1
NO	246	7	1	0
BMI (Kg/m2)				
15-20	16	1	0	0
>20- 25	173	3	3	0

>25 - 30	77	2	0	0
>30 - 35	15	1	0	1
>35 – 40	1	0	0	0

Out of 282 patients, 8 cases (2.83%) were found to have abnormal non-fasting 75-g OGCT and 4 cases (1.41%) had abnormal WHO 2-hour OGTT. There was statistically significant difference ($p \leq 0.001$) between the tests [Table-2].

Table -2: Pick up rate of OGCT and OGTT in GDM

Age	GDM	Percentage	p-value
OGCT	8	2.83%	
WHO Fasting OGTT	1	0.35%	0.001
OGCT	8	2.83%	
WHO 2-hour OGTT	4	1.41%	0.001

The Sensitivity, specificity, positive predictive value and negative predictive value of oral glucose challenge test was 25%, 97.48%, 12.5% and 98.90% respectively [Table-3].

Table-3: Ability of detection of GDM at OGCT threshold >140 mg/dl

		GDM (Diagnosed by WHO 2-hr OGTT)		
		Present	Absent	Total
OGCT >140 mg/dl	Yes	1	7	8
	No	3	271	274
		4	278	282
Sensitivity = 1/ (1+3) = 25% Specificity = 271/ (271+7) = 97.48% Positive predictive value = 1/ (1+7) = 12.5% Negative predictive value = 271/ (3+271) = 98.9%				

The non-fasting 75-g OGCT was able to detect only 25% of the cases. Hence, the observation in this study was that only 1 woman diagnosed as GDM by 75-g OGCT irrespective of the last meal timings satisfied the diagnostic criteria of WHO 2-hr OGTT.

DISCUSSION

Gestational diabetes is the commonest medical condition accounting 3-18 % of all pregnancies depending on the population and diagnostic criteria.[3] The prevalence of GDM is increasing with the increase in prevalence of maternal obesity, older age at pregnancy, and sedentary lifestyle.[3] The study done in Nepal by Bajracharya A et al[10] and Yadav S et al[11] observed the prevalence of gestational diabetes mellitus 1.58 % and 1.58% respectively, of the prevalence of gestational diabetes mellitus. Similarly, in our study the prevalence of GDM were 2.83% as per 75-g OGCT criteria and 1.41% as per WHO 2-hr OGTT criteria. Low incidence of Gestational diabetes mellitus in our study could be due to random selection of patients in short period of time with low incidence of diabetes mellitus among selected cases coming for antenatal checkup in this hospital. The additional cause could be due to low socioeconomic status as diabetes mellitus is associated with sedentary lifestyle, obesity and increasing age as mentioned earlier. Whilst, the present study included predominantly of young women, who often had either no risk factor for diabetes mellitus or a single factor that presented with relatively low incidence of diabetes mellitus.

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study have advocated screening of gestational diabetes in 24 to 32 weeks of gestation, which will increase more number of GDM cases as it has already been mentioned that insulin resistance begins in the second trimester and progresses throughout the remainder of the pregnancy.[12] In our study, the incidence of gestational diabetes is low as we have included women with gestational age 24 to 28 weeks as it is currently recommended, though there are reports that claim much of women with GDM can be detected early during pregnancy.[13]

The DIPSI guidelines (2010) have been widely accepted all over India. They propose that the non-fasting 75-g OGCT using a 2-hour venous plasma glucose value of 140 mg/dl (7.8 mmol/l) can be used as a single-step, definitive, screening and diagnostic test for GDM. This guidelines were based on a single-center study from southern India which reported 100 % sensitivity and 100 % specificity for this cut point compared to the WHO 1999 criteria which also uses the same cut point of 140 mg/dl (7.8 mmol/l).[7] 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 glycemic level with a meal and the glucose challenge is expected to exaggerate the glycemic excursion. This cascading effect is advantageous as it increases specificity and eliminates false positive diagnosis of GDM.

The simplicity of non-fasting OGCT is the main reason for the recommendation over WHO 2-hr OGTT as it is believed that WHO 2-hr OGTT is too complex to perform in the antenatal clinic setting and also would result in significant low turnover as it require pregnant women to be overnight fast. Another presumed advantage of the non-fasting OGCT over fasting state is that the frequency of women who would vomit would be lower as the glucose drink is

not consumed on an empty stomach. In a developing country like ours, a woman has to travel a long distance to attend antenatal clinics. Hence, it has been felt by many obstetricians and physicians that getting all pregnant women to come in a fasting state would be a great challenge in our set up.

The studies done by Anjalakshi C et al,[14] Balaji V et al,[15] and Dash S et al[16] assessed the validity of DIPSI guideline. They all concluded that DIPSI criterion is cost effective and evidence based procedure to diagnose GDM in any socio-economic situation.

In our study the sensitivity of OGCT was low (25%), similarly the study done by Viswanathan M et al[17] as a part of Women in India with GDM strategy (WINGS) programme showed that the non-fasting OGCT has poor sensitivity compared to both the WHO 1999 criteria (27.7 %) and the IADPSG criteria (22.6 %) and concluded that the current DIPSI guidelines as screening and diagnostic test for GDM may need to be revised.

Our study does not seem to agree with current DIPSI guideline. Ideally, and whenever feasible, a single-step 75-g OGTT using the WHO criteria should be done in the fasting state as this is being increasingly accepted worldwide and would help to bring about international standardization. However, in resource-limited settings, especially in the rural areas of developing countries, where getting all pregnant women to come in a fasting state may be difficult, the non-fasting OGCT is an adequate alternative for screening test.

CONCLUSIONS

The 75-gram oral glucose challenge test is cost effective and more compliant to pregnant women; the present report suggests that it cannot be used as a single step screening and diagnostic test because of its low sensitivity. However, it is an adequate alternative for screening test in resources limited areas.

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