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The Validity of One Step 75 Grams Oral Glucose Challenge Test for Universal Screening of Gestational Diabetes Mellitus: A Prospective Study

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ABSTRACT

Background- Diabetes mellitus (GDM) is the most common metabolic disorder in pregnant women and is characterized by carbohydrate intolerance of variable severity with onset or first recognition during pregnancy regardless of glycemic status after delivery .There has been a recent trend in increase in Type 2 diabetes mellitus in Asia which is well documented. The increase seems to be greater in South Asian region as compared to East and South East Asia. The validity of 75 gram 2 hours Glucose Challenge Test as a diagnostic tool is not well established. Therefore, present study was undertaken to evaluate the validity of 75 gram 2 hours Glucose Challenge Test as a diagnostic test.

Methodology- This study included 100 women with gestational age between 24th and 28th weeks, attending antenatal care (ANC) clinic at a tertiary care hospital in Delhi. Women who had given the consent to participate were given a standardized 2-h 75 g oral glucose tolerance test (OGTT). Then they were asked to come after a week on an empty stomach for 100g oral glucose tolerance test recommended by Carpenter Couston. Venous blood will be drawn in the fasting state, 1hr, 2hr & 3hr.

Results- Prevalence of GDM was found 19% and 75 gram Glucose Challenge Test is a highly sensitive (100%) and specific (98.7%) test which has a very high positive (95%) and negative (100%) predictive value.

Conclusion- Country like India, where antenatal visits and follow-ups are not very regular, this test is an important single step screening for gestational diabetes mellitus (GDM). The present study concludes that 75-gms GCT is an easy, economical as well as less cumbersome procedure. It is a patient-friendly approach because it is performed irrespective of the last meal and patient need not to come fasting. Patient needs to come once for this test. So this test can be utilized for screening purpose.

Keywords- *ANC, Blood glucose, Delhi, GDM, OGTT*

INTRODUCTION

Gestational diabetes mellitus (GDM) is the most common metabolic disorder in pregnant women and is characterized by carbohydrate intolerance of variable severity with onset or first recognition during pregnancy regardless of glycemic status after delivery[1].There has been a recent trend in increase in Type 2 diabetes mellitus in Asia which is well documented[2]. The increase seems to be greater in South Asian region as compared to East and South East Asia[3]. This increase in prevalence is related to increasing urbanization, decrease level of physical activity, changes in dietary patterns and increasing prevalence of obesity and can also be attributed to genetic mutations/polymorphisms in the mother and

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neonates[4]. Several studies from various parts of India have reported the prevalence of GDM ranging from 3.8% to 17.8% using different criteria[5].Thus gestational diabetes is a major health problem in pregnant females in India.

Hyperglycaemia during pregnancy is found to be associated with various maternal and perinatal adverse outcomes[6,7]. The short term outcomes in mothers include risk of pre-eclampsia, increased operative delivery, premature delivery and shoulder dystocia. There is increased risk of macrosomia, neonatal hypoglycemia, birth injuries and hyperbilirubinemia. Mothers have a higher risk of metabolic syndrome and diabetes in the future whereas their offspring have a life-long increase risk of glucose intolerance, obesity and metabolic syndrome[8] Up to 50% of women with a history of gestational diabetes develop type 2 diabetes in the decade following their GDM diagnosis[9] There is also increased risk of poor pregnancy outcome with maternal glucose levels demonstrating positive correlation with the risk of poor fetal development[6].

As early diagnosis and appropriate treatment has favourable effect on pregnancy outcome[10]. There is still controversy regarding optimal strategy for detection and diagnosis of diabetes in pregnancy, There is much debate whether universal or high risk screening should be done. Other issue in contention is strategy to use either "one step" or a "two step" approach to screen. However, recently American College of Obstetricians and Gynecologist (ACOG)[11], American Diabetes Association (ADA)[12] and Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG)[13] recommend universal screening because of the beneficial effect from screening, diagnosis and subsequent treatment. ACOG recommends "two steps", American Diabetes Association (ADA) recommends "one step" and RANZCOG recommends either approach. The validity of 75 gram 2 hours Glucose Challenge Test as a diagnostic tool is not well established. Therefore, we aim to evaluate the validity of 75 gram 2 hours Glucose Challenge Test as a diagnostic test.

METHODOLOGY

The Present Prospective study was conducted in antenatal clinic of the Department of Obstetrics and Gynaecology at Tirath Ram Shah Hospital, Delhi- 54 between May 2014 to April 2015. Considering 7% prevalence of gestational diabetes and 5% of error, sample size is calculated by using $4pq/l^2$ and 100 obstetrics patients between 24-28 weeks attending antenatal clinic were included in study after taking their consent. Patients attending regularly to the antenatal clinic of the hospital with 24- 28 weeks of gestation, ready for follow up and having singleton pregnancy were included in the study. Subjects with multiple pregnancy, diagnosed case of Diabetes mellitus and patients on drugs altering glucose metabolism were excluded. After taking the detailed history of diabetes, clinical examination was conducted then patients underwent glucose challenge test (GCT) and 75 grams of glucose was dissolved in 300 ml of water and the patients were asked to drink it over five minutes period irrespective of time of the day and her last meal. After 2 hours of ingestion of glucose, venous blood was drawn. The plasma glucose was estimated by enzyme hexokinase reference method using COBAS c311 auto-analyser.

The results were analyzed as per WHO and Diabetes in Pregnancy Study group India (DIPSI) recommendations considering positive GCT with glucose value ≥ 140 mg/dl after 2 hrs. These patients were asked to come after a week on an empty stomach for 100 gram oral glucose tolerance test (OGTT) and advised to take normal unrestricted diet three days prior to OGTT, After the fasting of 8-14 hours, a fasting blood sample was drawn and following which 100gm of glucose dissolved in 300-400ml of water was given orally and then venous blood was drawn at 1 hr , 2hr, 3hr apart. Gestational Diabetes was diagnosed as per Carpentar and Coustan values. Two or more of the following criteria must be met or exceed for the diagnosis of Gestational Diabetes Mellitus.

Carpentar and Couston Conversion levels

Status	Glucose level(mg/dl)	Glucose level (mmol/dl)
Fasting	95	5.3
1 Hr	180	10
2Hr	155	8.6
3 Hr	140	7.8

These patients were followed till the termination of pregnancy and record for outcome, mode of delivery, maternal complications and babies.Collected data was entered in Microsoft excel sheet and analysed in SPSS

21.0 version using chi-square test and regression. Sensitivity, Specificity, Positive Predictive value of test were also calculated.

RESULTS

Table 1 depicts that majority of participants were in the age group of 26-30 yrs and association of age with OGTT + was not found significantly associated. Out of 100 participants 71% were housewife and 29% working, 19.7% of house wife were found OGTT positive as compared to working women that to 15.2% and this difference was not found significant. 84% of participants were from class ll of socioeconomic status and the association between socioeconomic status and OGTT were not found significant. For the validity of Glucose challenge test taking Oral Glucose Tolerance Test as the standard test, we assessed the sensitivity, specificity, Positive and Negative Predictive value of GCT using and Thus we found that GCT is highly sensitive, specific and has a very high positive and negative predictive value. (Table 2). 90% of participants were having BMI within the range of 25-29.9kg/cm^2.(fig 1). Babies born to mothers with GDM (OGTT +ve group) had higher birth weight than non GDM (OGTT -ve group) but the difference was not found significant.

Table 1- Association between Socio-demographic profile and OGTT of the Participants

Age	**OGTT +Ve**	**OGTT -Ve**	**Chi square**	**P Value**
21-25	3(15.8%)	17(21%)	4.7	0.19
26-30	10(52.6%)	43(53.1%)		
30-35	4(21.1%)	20(24.7%)		
>35	2(10.5%)	1(1.2%)		
Total	19	81		
Mean+SD	29.31 ± 4.23	28.53 ± 3.52	100	
Occupation	OGTT +ve	OGTT -ve		
Housewife	14(73.7%)	57(70.4%)	.08	0.77
Working	5(26.3%)	24(29.6%)		
Total	19	81	100	
Socio-economic Class	OGTT +ve	OGTT -ve		
I	1(5.3%)	1(1.2%)	2.37	0.30
II	14(73.7%)	70(86.4%)		
III	4(21.0%)	10(12.4%)		

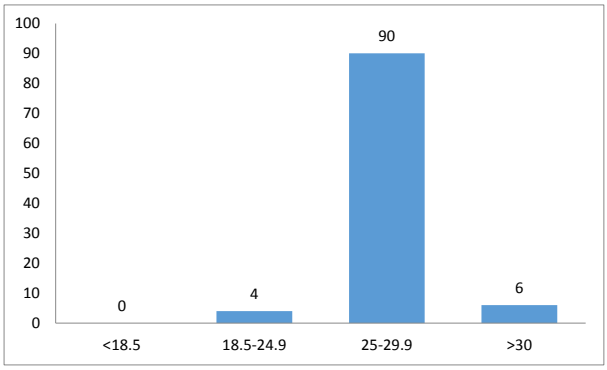
Table-2 Distribution of cases according to GCT & OGTT

Tests Positive		**OGTT**		**Total**
		Negative		
GCT	Positive	19(a)	1 (b)	20
	Negative	0 (c)	80 (d)	80
Total		19	81	100

Sensitivity =100% , **Specificity** = 98.76% ,**Positive predictive value**= 95 % ,**Negative predictive value**= 100

%

Above table shows that out of 100 participants 19 participants were screed positive by OGTT on the other



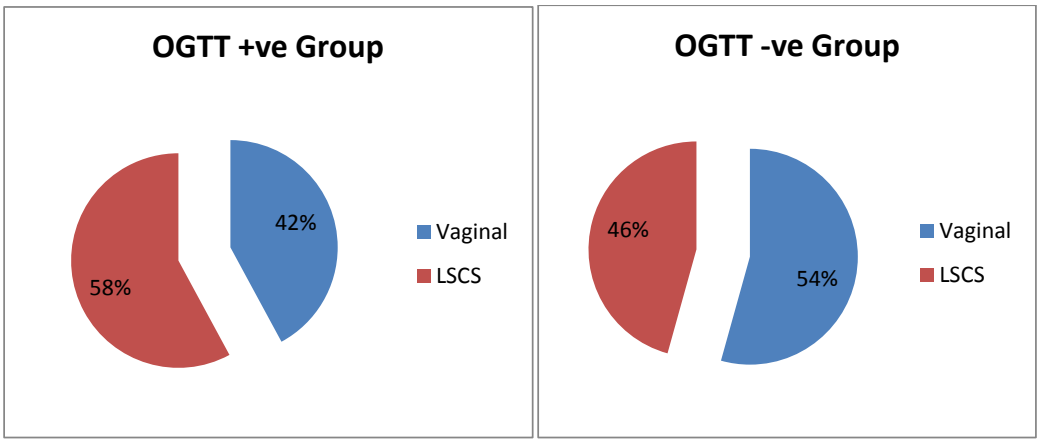
hand 20 participants was screened positive by OGCT.

Figure 1- Distribution of Participants according to BMI

Above figure depicts that out of 100 participants 90%participants had BMI between 25-29.9 kg/m^2

Table 3- Association of BMI with the OGTT

BMI	OGTT +ve	OGTT -ve
<18.5	0(0%)	0(0%)
18.6-24.9	1(0%)	4(4.9%)
25-29.9	18(73.7%)	71(93.8%)
>30	5(26.3%)	1(1.3%)
Total	24	76



Chi-square value-12.3, p=,0.005

Figure 2- Mode of delivery in the study population

42% of vaginal delivery was conducted in participants with +OGTT and it was 54% among –ve OGTT .

Table 4: Distribution of study population according to birth weight

Gestation	OGTT +ve	OGTT -ve
<2500	1(5.3%)	3(3.7%)
2500-2999	6(31.6%)	26(32.1%)
3000-3499	8(42.1%)	49(60.5%)
3500-3999	2(10.5%)	3(3.7%)
>=4000	2(10.5%)	0(0%)
Mean ± SD (grams)	3200±518	3049±292
Total	**19**	**81**

t value- -1.3, p=0.22

Babies born to mothers with GDM (OGTT +ve group) had higher birth weight than non GDM (OGTT -ve group) but the difference was not found significant.

DISCUSSION

In this prospective study 100 gram Oral Glucose Tolerance Test (OGTT) is used as the standard test and the validity of 75 gram glucose challenge test done as per DIPSI guidelines as a screening test for gestational diabetes mellitus (GDM) is assesed. Balaji V et al assessed the validity of Diabetes in Pregnancy Study Group India (DIPSI) guidelines to diagnose gestational diabetes mellitus (GDM). They concluded that DIPSI criterion is a one step, cost effective and evidence based

procedure to diagnose GDM in any socioeconomic setting [14]. Seshiah V et al (2012) studied the usefulness of DIPSI guidelines to diagnose GDM in resource limited country like India in view of recent International Association of Diabetes in Pregnancy Study Group (IADPSG) recommendations and observed that there was no statistical significance (P = 0.21) between the prevalence of GDM by IADPSG criteria (14.6%) and by DIPSI criteria (13.4%).

They concluded that DIPSI procedure is cost-effective, without compromising the clinical equipoise and can be continued to diagnose GDM in India, as well as other less resource countries[15]. In the present study, we observed very high sensitivity (100%), specificity (98.76%), positive predictive value (95%) and negative predictive value (100%). Similar findings was obserbed in a study conducted by Balaji and Seshiah .

Mohan V conducted a study to compare the DIPSI criteria with the World Health Organization (WHO) 1999 and the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria for GDM and observed very low sensitivity of DIPSI non-fasting OGTT 2-h VPG cut point of 140 mg/dl when compared to the WHO 1999 criteria (sensitivity 27.7 %, specificity 97.7 %) and IADPSG criteria (sensitivity 22.6 %, specificity 97.8 %). Therefore they concluded that DIPSI non-fasting OGTT criteria cannot be recommended for diagnosis of GDM due to its low sensitivity [16].

In the present study, the prevalence of GDM was 19%. Thus, in various studies done in India, variable prevalence of GDM has been reported. Arora G et al determined the prevalence and risk factors of GDM using the WHO 1999 versus WHO 2013 criteria in North India. The observed prevalence of GDM was 35% using WHO 2013 criteria versus 9% using WHO 1999 criteria[17]. Thus, in various studies done in India, variable prevalence of GDM has been reported. This can be attributed to various factors like hospital or community based study, type of diagnostic criteria used, geographic area, study population being rural or urban and socio-economic class of the study population.

Tripathi R et al studied the relevance of universal screening for gestational diabetes mellitus (GDM) in the patients attending the antenatal clinic of a tertiary institute of North India. They observed the prevalence of GDM to be 10.8% in their study population of 687, in a tertiary care hospital of New Delhi[18]. This can be attributed to various factors like hospital or community based study, type of diagnostic criteria used, geographic area, study population being rural or urban and socio-economic class of the study population. In present study 19% of participants had OGTT positive and out of which52.6% were in the age group of 26-30 yrs but that was found insignificant. In this study increasing trend of positive OGTT was found with increasing BMI and this was found significant. Study conducted by Bhatt concluded that significantly higher frequency of induction of labor than spontaneous labor in GDM mothers. Operative delivery occurred in 40.1 % GDM mothers and 35.8 % of non-GDM mothers[19]. These findings were similar in present study but the difference in operative delivery was not significant (p=0.337). Kösüs N carried out a study to find the effect of number of abnormal oral glucose tolerance test (OGTT) values on birth weight in women with gestational diabetes and observed that infant birth weight of GDM cases were higher than the other groups. Infants of women with GDM weighted 200 g more than infants of non-GDM cases despite of adequate treatment[20]. These findings were in concordance with present study.

Conflict of Interest: Nil

Funding: Self

Ethical Approval: Etihcal Committee of Tirathram Shah Hospital, Delhi

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