

Efficacy of 50g Glucose Challenge Test as a Screening Tool for Gestational Diabetes Mellitus

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ABSTRACT:

Objective: To evaluate the validity of 50 g oral Glucose Challenge Test as a screening tool for GDM in our population.

Materials and Methods: This cross sectional study was carried out in Obstetrical clinic, Combine Military Hospital (CMH) Lahore. 100 women carrying singleton pregnancy between 20-35 years of age, booked in first trimester were included while patients with risk factor of GDM or with established type I or II DM were excluded from study. 50 g GCT was administered to patients between 24-28 weeks of gestation after informed consent. Venous plasma glucose levels after 1 hour of glucose load, were taken, using 140 mg/dl as a cut off value. Regardless of results of screening, all patients were tested with 100 g OGTT as a "gold standard" of diagnosis of GDM.. Validity of 50g GCT was calculated for sensitivity, specificity, positive and negative predictive value. Data was analysed by SPSS version 16.

Results: Out of 100 patients, 19% were screen positive and 81% screened negative with 50g GCT. With 100 g OGTT, true positive were 10 out of 19(52.6%) screen positive, and false positive were 9 out of 19(47.4%) screen positive. False negative were 3 out of 81(3.7%) screen negative, whereas true negative were 78 out of 81(96.3%) screen negative. Validity of 50 g GCT has been calculated to be having sensitivity of 76.92%, specificity of 89.6%, positive predictive value of 52.6% and negative predictive value of 96.2%.

Conclusion: 50 g GCT is an effective screening tool for GDM between 24-28 weeks of gestation with adequate sensitivity and specificity.

Key words: GDM, OGTT, 50 g GCT, Screening tool

INTRODUCTION:

Gestational Diabetes Mellitus (GDM) is defined as glucose intolerance with onset or first detection during pregnancy.^{1,2} It usually disappears immediately after delivery or upto 6 weeks postpartum. Prevalence of GDM varies among different racial, ethnic groups³ and with prevalence of type II diabetes mellitus (DM). It is more common in African, Latino, Hispanics and Asian (Indian subcontinent) women. Risk factors for GDM are family history,⁴ body mass index (BMI) > 25,^{5,6} age >35 yrs, grand multi parity, macrosomia in previous pregnancy, intra uterine demise (IUD),⁷ foetal anomaly⁸ and black race.⁹ But 12% of patients with GDM have no risk factors.¹⁰ Overall worldwide its prevalence is 1-14% depending upon the population studied and diagnostic tools applied. Overall GDM affects 2-5% of pregnancies in USA and 4-5% in UK.¹¹ Reported incidence in Asian population is 2-10%. In Pakistan prevalence of type II DM is around 10-14%¹² and even younger population is getting afflicted with it.¹³ A study conducted at Karachi

observed 8% prevalence of GDM.¹⁴ Other studies conducted in different cities of Pakistan showed a range of 15.7% to 24%.^{15,16} Early detection and treatment of GDM is of utmost importance to prevent obstetrical and perinatal implications like miscarriages, birth defects, macrosomia, unexplained IUDs, shoulder dystocia, polycythemia, respiratory distress syndrome (RDS), hypoglycaemia, hypocalcaemia, hyperbilirubinemia; childhood risks like dyslipidemias and adiposity.¹⁷ Maternal risk factors include preeclampsia, repeated urinary tract infections (UTIs),¹⁸ vaginal infections, polyhydramnios, instrumental deliveries, perineal tears and increased chances of C sections. One third of women develop type II DM later in life.

For early detection of GDM screening is required as it is an asymptomatic metabolic syndrome. Screening recommendations about tests applied and timing of screening and whether to do universal or selective screening vary among different organizations due to lack of properly conducted randomised controlled trials (RCTs).¹⁹ Screening methods include risk factors based screening, fasting plasma glucose, timed random blood sugar (RBG), HbA1C and 50 g GCT. Yet no screening test is validated.

American Diabetes Association (ADA) and American college of obstetricians and gynaecologists (ACOG) recommend screening by 50 g GCT (threshold 7.2mmol/l or 7.8mmol/l can be used).^{20,21} Either of the thresholds can be used. Even for diagnostic, there is lack of universally accepted "gold standard". ADA and ACOG recommend 100 g oral glucose tolerance test (OGTT) while WHO recommends 75 g OGTT as diagnostic test. The question whether selective or universal screening is better is still unanswered. In Canada and USA, universal screening is done as recommended by ACOG and in UK risk factor based screening is practised. ADA recommends universal screening. Australasian Carbohydrate Intolerance Study (ACHOIS) demonstrated

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improved perinatal outcome by formal screening of whole obstetrical population. A commentary on this trial published in BJOG 2006, also supports this recommendation.²² Canadian task force on preventive health care does not support for or against universal screening for GDM. General recommendation is to conduct risk assessment and then glucose testing for high risk women on 1st antenatal visit followed by retesting at 24-28 weeks of gestation. Average risk women should be screened at 24-28 weeks of gestation as recommended by ACOG. In short a single approach to testing of GDM cannot be recommended at present because of lack of evidence based data.

Purpose of this study was to establish efficacy of 50 g GCT as a screening test of GDM in our population as very few local studies are available to guide us in this regard.

MATERIALS AND METHODS:

This cross sectional study was conducted from 1st Aug 2012 to 30th July 2013 at the obstetrical outpatient clinic of Combined Military Hospital, Lahore. Patients were selected through non probability convenient sampling. 100 patients carrying singleton pregnancy either primigravida or multigravida within age group of 20-35 yrs, booked in 1st trimester were included in this study. Patients with history of type I or II DM, history of glucose intolerance in the past, with bad obstetrical history, family history of DM, IUDs, still births or early neonatal deaths, congenital anomalies, macrosomic babies and patients with polyhydramnios were excluded. After taking the consent, patients between 24-28 weeks of gestation were tested with 50 g GCT, regardless of previous state of fasting. Venous plasma glucose levels were measured by taking sample of blood one hour after administering the glucose drink using glucose oxidase hexokinase method. A glucose value of 140 mg/dl was taken as cut off. Regardless of the results, all patients were further evaluated with 3 hours 100 g OGTT. Patients with two or more values of blood glucose equal to or exceeding the proposed values were labelled as having GDM and those with one abnormal value were labelled to have impaired glucose tolerance. Values proposed by Carpenter and Coustan and adapted by 4th international workshop conference on GDM were used, which are: fasting- 95 mg/dl, 1 hour after glucose load- 180 mg/dl, 2 hours after glucose load - 155 mg/dl and 3 hours after glucose load - 140 mg/dl. Data was collected on a pre designed proforma and was analysed using computer software (SPSS 10). Validity of 50 g GCT was measured in terms of sensitivity, specificity, positive and negative

predictive value.

RESULTS:

Total of one hundred patients were evaluated in this study. 19 were screen positive, whereas 81 were screen negative (Table 1). Among screen positive, majority were of greater than 28 years of age i.e. 57% (11 out of 19) and multi or grand multi gravidas i.e. 78.9 % (15 out of 19). Screening was negative mostly in primigravidas i.e. 69.1% (56 out of 81) and in patients with age of less than 28 years i.e. 71.6 % (58 out of 81). All the patients were put to 100 g 3 hrs OGTT as gold standard diagnostic test. Out of these, 13 (13%) were labelled to have GDM due to either one impaired glucose tolerance (IGT) or two abnormal values (frank DM) according to Carpenter and Coustan's criteria. 76.9% of patients labelled with GDM on 100 g OGTT were screen positive initially, while 23 % of these patients were not picked up on initial screening alone. Out of 13 patients with GDM on OGTT, 69.2% had only impaired glucose tolerance while 30.7% had frank Diabetes (Table 2). Out of 19 screen positive patients, 10(52.6%) had abnormal OGTT as well; so were labelled as true positive. 9 out 19 (47.3%) had normal OGTT; so were labelled as false positive. Out of 81 screen negative patients, 78 (96.3%) came out to be true negative. They had normal OGTT as well. Whereas 3 out of 81(3.7%) had abnormal OGTT, so were labelled as false negative.

According to this study, sensitivity of 50 g GCT was calculated to be 76.92%, specificity of 89.6%, positive predictive value of 52.6% and negative predictive value of 96.2%. (Table 3).

Table: 1
Results of 50 g GCT

Results of screening	No of patients	%
Screen positive	19	19%
Screen negative	81	81%

Table: 2
Patients with GDM on OGTT

Total no of patients labelled as Gestational Diabetics	Screen positive	Screen negative	GDM	IGT
13(13%)	10 (76.9%)	3 (23.07%)	4/13 (30.7%)	9/13 (69.2%)

Table: 3
Validity of 50 g GCT

	Formula	Result	Percentage
Sensitivity	$TP/(TP+FN)*100$	$10/(10+3)*100$	76.92%
Specificity	$TN/(TN+FP)*100$	$78/(78+9)*100$	89.6%
Positive Predictive Value	$TP/(TN+FP)*100$	$10/(10+9)*100$	52.6%
Negative Predictive Value	$TN/(FN+TN)*100$	$78/(3+78)*100$	96.2%

DISCUSSION:

The high frequency of GDM in Asian (Pakistani population)^{14,15,16} and its foetal and maternal implication emphasize the significance of timely diagnosis and management of GDM. As it is an asymptomatic metabolic syndrome so for detection of preclinical disease, screening is required. There is no consensus about time of screening, test to be applied, various thresholds for screening tests and which population should be screened (universal or selective).²³ Systematic screening of pregnant population is still not common in Pakistan despite of the fact that subcontinent is included in high risk population for GDM by most of authorities. There is a need to conduct study about how to screen, which population to screen in Pakistan and to develop a country wide protocol.

In this study, we have evaluated the validity of 50 g GCT as a screening tool for GDM. This was a small study and on low risk patients. Although this study showed very encouraging results to apply GCT as a screening tool between 24-28 weeks of gestation but a larger scale study is still required for on average high risk patients to validate its results. In this study, 19% came out to be screen positive and 81% were negative. This is consistent with many international studies which show that 14 -18% of patients were screen positive if threshold of GCT was taken as = 140mg/dl and 20 - 25% with 130 mg/dl. Most of the screen positive patients were multigravidas (47.3%) in patients with age >28 years, whereas screen was negative in primigravidas. This is consistent with the study of Maresh.²⁴ All the patients were put to 100 g OGTT regardless of results of screening and 13 patients were labelled as having GDM. It is important to note that all the 3 patients who were screen negative initially but had abnormal 100 g OGTT results had only IGT (Impaired Glucose Tolerance) and none had frank DM. Among the patients who were screen positive, 6 out of 10 had impaired glucose tolerance and 4 had two abnormal values (criteria for GDM). The validity of 50 g GCT was calculated in term of sensitivity, specificity, positive predictive value and negative predictive value which came out to be 76.9%, 89.6% 52.6% and 96.2% respectively. This is in consistence with a study that showed sensitivity of 80% and specificity of 90%.²⁵ According to these results, we recommend that 50 g GCT, as a screening test for GDM, should be applied to all pregnant ladies between 24-28 weeks of gestation with a threshold of 140 mg/dl, with high sensitivity and specificity and also as a simple method, suitable for all pregnant women. Difficulties encountered were to convince the ladies for these special tests, extra financial burden, and nausea/vomiting associated with glucose intake. Some of large hospitals have instituted this test as an essential part of antenatal clinic services. But still a lot of work is required in this regard to create a nationwide strategy. This study was a small effort to develop a fixed framework of screening of GDM for Pakistani population.

CONCLUSION:

50 g GCT is an effective screening tool for GDM between 24-28 weeks of gestation with high sensitivity and specificity. It picked up almost all the cases with GDM or IGT between 24-28 weeks of gestation. This can not only help us to improve perinatal outcome, but also to identify ladies who are at high risk of developing type II DM in future. A large scale population based study is recommended to further validate the findings of this study.

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