

COMPARATIVE STUDY OF 50 GRAM GLUCOSE CHALLENGE TEST AND 75 GRAM ORAL GLUCOSE TOLERANCE TEST IN DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS IN HIGH RISK GROUP

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ABSTRACT

Background: Pregnancy is a complex endocrine-metabolic adaptation and diabetogenic condition involving impaired cellular insulin sensitivity, increased β -cell function, and moderate elevation of blood glucose level. The threshold for a positive glucose challenge test (GCT) necessitating further diagnostic testing remains controversial in gestational diabetes mellitus (GDM).

Aims & Objective: To find the association of risk factors with GDM, to evaluate the diagnostic value of GCT as compared to oral glucose tolerance test (OGTT) in GDM, and also to determine the optimal cut-off value of GCT with best sensitivity and specificity for the prediction of GDM and also to find the association of GCT between FBS and 2nd hour OGTT glucose level.

Material and Methods: The study was conducted at Hanagal Shri Kumareshwara Hospital, Bagalkot, Karnataka, India, from June 2009 to February 2010. 247 pregnant women were selected for the study. Selected women were subjected to screening by GCT. If the blood glucose level was greater than 140 mg/dl, the GCT was considered as positive and these patients were subjected to 75 gm OGTT to confirm the diagnosis of GDM. The diagnosis of GDM was based on WHO criteria.

Results: In the present study out of 247 pregnant women selected, 199 women participated, of which 26(13.06%) of the pregnant women were diagnosed to have GDM. Mean age of the study subjects was 24.7 $\pm$ 3.51 years. There was a positive association of GDM with age, BMI, glucosuria, polyhydramnios, obstetrics score, previous GDM, past history of unexplained IUD, family history of DM, recurrent vaginal infection. Area under the curve is 0.994 ($p > 0.0001$) which has best diagnostic accuracy at glucose level of 128 mg/dl, as the best cut off value. Second hour OGTT is more correlated with GCT than FBS.

Conclusion: In this ethnic group, the high risk pregnant women for GDM should undergo initial 50 gm. GCT. If GCT value is more than 128 mg/dl, it should be followed by second hour 75 gram OGTT, for the diagnosis of GDM and it reduces the FBS estimation of blood sugar level and an extra prick too.

Key-Words: Gestational Diabetes Mellitus; Glucose Challenge Test; Glucose Tolerance Test

Introduction

Pregnancy is a physiological stress. Many changes occur in the milieu interior of the body, more and more stress is being laid on the biochemical changes, which occur in the blood during normal pregnancy.^[1] Pregnancy is a complex endocrine-metabolic adaptation and diabetogenic condition involving impaired cellular insulin sensitivity, increased β -cell function, and moderate elevation of blood glucose levels, particularly following the ingestion of a meal.^[2] Hormones like oestrogen, progesterone, human placental lactogen, cortisone and growth hormone are anti insulinogenic. These changes do not reflect a pathological condition; rather, they represent a necessary and

indispensable adaptation to meet the energy demand of the foetus and to prepare the maternal organs for delivery and lactation. These changes are increased in mid pregnancy period and cause abnormal glucose tolerance in some women (3–5%) rendering them prone for gestational diabetes mellitus (GDM).^[2–4] Diabetes mellitus is a common medical condition complicating pregnancy.^[5–7]

The incidence of GDM varies between 1–16%.^[8] Prevalence rates of GDM vary widely by ethnicity^[6]; South Asian countries and Indian women have the highest frequency of GDM.^[6,9] The prevalence of GDM in India varies from 3.8 to 21% in different parts of the country, depending

on the geographical locations and diagnostic methods used. GDM has been found to be more prevalent in urban areas than in rural areas.^[4]

GDM is a controversial clinical entity^[10], represents progressive changes in glucose intolerance, either first onset or discovered during pregnancy, regardless of whether insulin or only diet modification is used for treatment or whether the condition persists after pregnancy. Most likely the development of gestational diabetes reflects individual predisposition.^[2] Clinical risk factors for GDM^[8], which are, age of ≥ 30 , family history of DM, previous history of GDM, previous history of macrosomia (Child birth weight $\geq 4,000$ grams), previous history of unexplained intrauterine foetal death, obesity (Body Mass Index: BMI ≥ 27 kg/m²), and glucosuria were identified at the first prenatal visit.^[8] GDM is considered the first clinical manifestation of permanent diabetes early in its course.^[11,12] Maternal acute complications like ketoacidosis, toxemia during pregnancy, hypertension can occur.^[13] GDM predisposes to GDM in subsequent pregnancies.^[2,14,15]

It has been related with, at birth, intermediate and long term adverse effects; a common complication - pancreatic hyperplasia and hyperinsulinemia, resulting in fetal macrosomia, malformation, polyhydramnios, hypoglycemia, hypocalcemia, plethora, hyperbilirubinemia, hypertrophic cardiomyopathy, and infantile respiratory distress syndrome, which increases the risk for obstetric problems and birth injury, adult obesity and glucose intolerance in late adolescence and young adulthood.^[13]

Two generations are at risk of developing diabetes in the future. Mothers with a history of GDM are at 17% to 26% risk of developing predominantly Type 2 diabetes mellitus at around 15-years after pregnancy, and their children are also affected.^[2,9,14,15]

Perinatal morbidity and mortality rates can be reduced if adequate treatment is offered resulting in the view that GDM is a treatable disorder.^[11,12] Timely action taken in screening all pregnant women for glucose intolerance, achieving euglycemia in them and ensuring adequate nutrition may prevent the complication of GDM, in

all probability.^[4] However, the long-term prognosis of the mother with glucose intolerance including impaired glucose tolerance (IGT) and diabetes is not good.^[13]

The screening method of 50-g GCT using a cut-off value at 140 mg/dL, according to data from the National Diabetes Data Group (NDDG), seemed to be effective in identifying pregnant women with GDM, but the false positive rate was quite high and variable in the general population.^[8]

Performing GCT during midpregnancy is a useful screening method for GDM.^[13] The threshold for a positive GCT necessitating further diagnostic testing remains controversial. GCT cut-off level range is 130-140 mg/dL for screening of GDM between 24 and 28 weeks of gestation. However, in later studies, most of the cut-off values were different from those in the previous reports. These findings may have been due to the differences in ethnicity and nutrition of the population.^[6]

While a higher threshold gives better specificity and lowers the likelihood of a false-positive test result, the disadvantage is that a number of women who may have gestational diabetes will remain undiagnosed and untreated. In contrast, a lower threshold yields a higher sensitivity, but more women will undergo unnecessary diagnostic testing, which can be expensive, time-consuming, and leads to unnecessary intervention. Racial differences regarding the glucose screening test findings have been demonstrated. Nahum and Huffaker^[6] suggested race-specific criteria for GCT because of the heterogeneity of glucose intolerance between ethnic groups.

The oral glucose tolerance test (OGTT) is considered as the gold standard for diagnosis of diabetes mellitus.^[16] Since OGTT is a very time consuming method, needs preparation of the patient like three days normal diet intake prior to the testing day, overnight fasting, and repeated pricking, glucose challenge test (GCT) can be used as an alternative in patients with high risk factors.^[17]

As per WHO criteria, GDM is diagnosed as the FBS more than 126 mg/dl or 2nd hour blood glucose level of 140 mg/dl after 75 gm. of glucose, which

needs estimation of blood glucose two times. Hence the present study was undertaken to find the association of risk factors with GDM, to evaluate the diagnostic value of GCT as compared to OGTT in GDM, to determine the optimal cut-off value of GCT with best sensitivity and specificity for the prediction of GDM and also to find the association of GCT with FBS and 2nd hour OGTT.

Materials and Methods

The study was conducted on pregnant women from Hanagal Shri Kumareshwara Hospital, Bagalkot, Karnataka, India. The study was approved by S Nijalingappa Medical College ethical committee (Ref No: SNMC/09-10/602). The study was conducted from Jun 2009 to February 2010. Informed consent was obtained. A total number of 247 pregnant women were selected for the study based on the presence of risk factors but 17 women refused for investigation and 31 subjects did not turn up for further evaluation and finally 199 pregnant women were studied. Pregnant women with DM, hypertension, renal diseases and any other known chronic disease patients were excluded from the study. Detailed history and clinical examination of the selected women was carried out. The demographic details included age, sex, body weight, and body mass index (BMI). Both systolic blood pressure and diastolic blood pressure were recorded. The selected women were subjected to the screening by GCT. GCT was performed as an out-patient department procedure. 50 gm. of glucose was dissolved in 200 ml of water and the patient was asked to drink it within 5 minutes. The time was noted and the patient was asked to take rest for one hour, after which venous blood specimen was collected and tested for blood glucose level. If the blood glucose level was greater than 140 mg/dl, the screening test was considered as positive and these patients were subjected to OGTT to confirm the diagnosis of GDM.^[18] For OGTT initial blood sample was taken after 8-12 hours of fasting and the patient was asked to drink 75gm glucose dissolved in 200-400 ml water within 5 minutes. Blood sample was taken at 2nd hour. The blood glucose was estimated by glucose oxidase peroxidase method using Stat-fax 3300 semiautoanalyser, the kit was supplied by Transia Biomedicals Limited. The

fasting glucose values of 110mg/dl or below, and 2 hour glucose values of 140 mg/dl or below was considered as normal.^[18] The diagnosis of GDM was based on WHO criteria.^[17]

Statistical Analysis

Data collected was tabulated in Microsoft excel sheet. Statistical package for social science (SPSS for window version; SPSS, 19.0 Inc, Chicago IL) software was used for statistical analysis. Bivariate logistic regression and multinomial logistic regression were done to see the association of risk factors with GDM. Pearson's correlation coefficient was used to show the correlation between GCT and FBS and 2nd hour OGTT. Sensitivity, specificity, predictive values of GCT various cut-off values were evaluated using OGTT as the gold standard. The "p" value less than 0.05 was considered as statistically significant. Receiver operator characteristic curve (ROC curve) was constructed to identify the best cut-off value of GCT for screening of GDM. All the values were expressed in mean $\pm$ SD.

Results

In the present study, 199 women participated, out of which 26 (13.06%) of the pregnant women were diagnosed to have GDM. Mean age of the study subjects was 24.7 ± 3.51 years, Mean obstetric score was 1.7 ± 1.1 and mean body mass index was 24.4 ± 2.5 kg/m².

Bivariate logistic regression analysis was done to know the association of GDM with Age, BMI, glucosuria, polyhydramnios, obstetric score, previous GDM, past history of unexplained IUD, family history of DM, recurrent vaginal infection. There is a positive association between the GDM and above mentioned risk factors (Table 1). Multinomial logistic regression analysis for age intervals and BMI was done. Age less than 15 years and BMI less than 20 was considered as reference. As age and BMI increases the association / risk of GDM also increases (Table 2). Odd's ratio and 95% confidence intervals are as mentioned in respective tables.

In the ROC curve (Figure 1) area under the curve is 0.994 ($P > 0.0001$) which has best diagnostic

Table-1: Odd's Ratio and 95% Confidence Intervals for Various Risk Factors Using Bivariate Logistic Regression Analysis

Variable	OR	95% CI
Age	1.1075	0.9679 to 1.2673
BMI	1.1170	0.9318 to 1.3390
Glucosuria	0.2428	0.0234 to 2.5161
Polyhydramnios	1.6134	0.1516 to 17.1756
Obstetrics Score	0.9782	0.6050 to 1.5817
Previous GDM	9.1221	1.4038 to 59.2773
IUD	1.7553	0.1531 to 20.1188
Family History of DM	1.6635	0.1666 to 16.6121
Recurrent Vaginal Infection	11.6521	0.4609 to 294.5847

OR: Odd's Ratio; CI: Confidence Interval; BMI: Body Mass Index; IUD: Intrauterine Death

Table-2: Multinomial Logistic Regression Analysis for Age and Body Mass Index and the Risk of Development of GDM

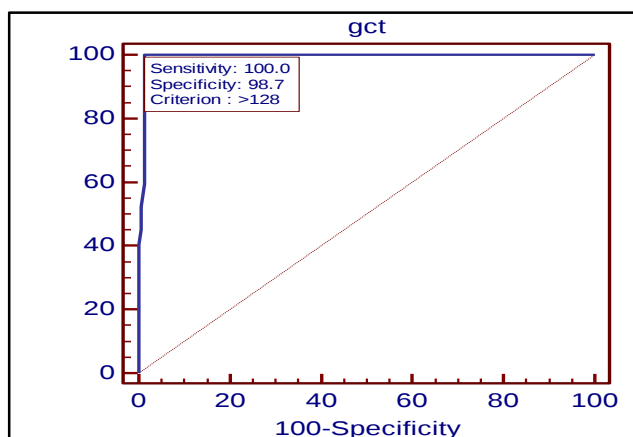
	β - Coefficient	SE	Wald	OR	95% CI
Age (Years)					
15-25	-17.936	0.000	0.000	Ref	-
21-25	-0.708	1.100	0.414	0.493	0.057 - 4.256
25-30	-0.596	0.865	0.475	0.551	0.101 - 3.001
30-35	0.168	0.870	0.037	1.183	0.215 - 6.503
BMI (Kg/m²)					
<20	-16.607	0.000	0.000	Ref	-
20-25	0.123	1.131	0.012	1.131	0.123 - 10.384
26-30	0.732	1.142	0.412	2.080	0.222 - 19.495

OR: Odd's Ratio; CI: Confidence Interval; SE: Standard Error

Table 3: Sensitivity and Specificity of Various Cut-Off Values of GCT

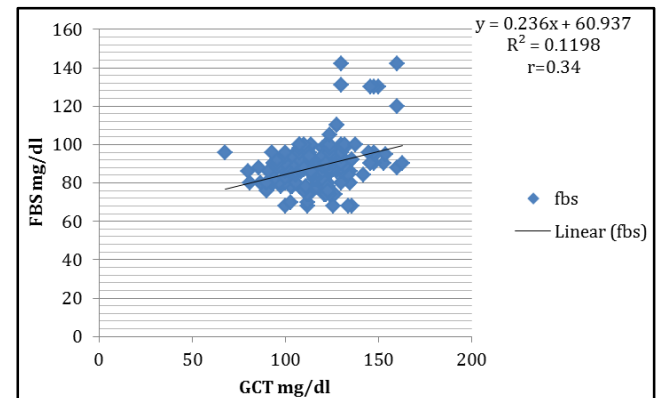
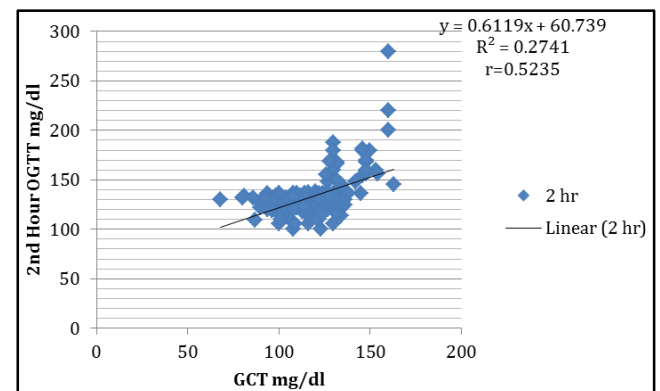
Criterion	Sensitivity	95% CI	Specificity	95% CI
≥68	100.00	91.6 - 100.0	0.00	0.0 - 2.3
>128	100.00	91.6 - 100.0	98.73	95.5 - 99.8
>132	59.52	43.3 - 74.4	98.73	95.5 - 99.8
>134	52.38	36.4 - 68.0	99.36	96.5 - 100.0
>135	45.24	29.8 - 61.3	99.36	96.5 - 100.0
>136	40.48	25.6 - 56.7	100.00	97.7 - 100.0
>163	0.00	0.0 - 8.4	100.00	97.7 - 100.0

GCT: Glucose Challenge Test; CI: Confidence Interval

**Figure-1: Diagnostic Accuracy of GCT** [Area under curve: 0.994; Z Statistic: 105.66; $p < 0.0001$ (Highly significant); GCT: Glucose Challenge Test]

accuracy at glucose level of 128 mg/dl, has the best cut off value, at which the sensitivity (95%

CI) and specificity (95% CI) were 100% (91.6-100) and 98.73(95.5-99.8) respectively (Table 3). The correlation coefficient for GCT and FBS was 0.34 (Figure 2). The correlation coefficient for GCT and 2nd hour OGTT was 0.52 (Figure 3). Second hour OGTT is more correlated with GCT than FBS.

**Figure-2: The Correlation between GCT and FBS** [GCT: Glucose Challenge Test; FBS: Fasting Blood Sugar]**Figure-3: The correlation between GCT and 2nd hour OGTT** [GCT: Glucose Challenge Test; OGTT: Oral Glucose Tolerance Test]

Discussion

In the present study, the proportion of GDM was 13.06% in high risk group. Ethnically, Indian subcontinent women have high prevalence of diabetes mellitus and the relative risk of developing GDM is 11.3 times more compared to White women.^[9,18] Few studies conducted in India, have shown increasing trends in prevalence from 2% in 1982, 7.62% in 1991 to 16.55% in 2001^[19,20,21], hence necessitating universal screening for GDM in India.^[9] There is general consensus that the prevalence of GDM is increasing globally. The prevalence of GDM is reported to be 1.2% to 14.3% in the available literature.^[22,23] The American college of obstetrician and gynecologists and American Diabetes Association have recommended that all pregnant women should be screened for

GDM.^[24,25] The increased prevalence could be due to change in the life style, environmental factors and increased age at pregnancy.

In this study, the study group over 31 years were at risk of developing GDM with odd's ratio of 1.18 (0.215-6.50), similarly it was found in population based cohort study done in India, that there was a significant association with increasing age and development of GDM.^[26] The confluence conditions like pregnancy induced hypertension, increase in BMI, dyslipidemia, increased risk of diabetes mellitus are more common in older age than in younger age, hence even GDM is more prevalent in older age than below 20 years of age.^[16,27,28] Wahi P et al. in a study done in Jammu found that, women with GDM were older, mean age in GDM group was 27.2 ± 2.3 years, while in control group it was 26.2 ± 2.3 years. Similarly Seshaiyah V et al.^[21] showed age more than 25 years as a risk factor for GDM. Even history of more number of pregnancies is associated with GDM.^[16] This finding is in agreement with the other studies conducted in Indian subcontinent.^[21,29,30]

P et al showed a significant proportion of subjects with GDM were overweight [19 (30.65%)] and obese [16 (25.8%)].^[29] Study of prevalence of GDM in Southern Iran (Bander Aban City) showed that BMI of 25 kg/m² or more were significantly more prevalent in GDM subjects^[31], which is in accordance with the present study. Lueprasitsakul K et al found that significant clinical risk factor for GDM was obesity (defined as BMI >27 kg/m²) with a risk ratio of 2.32. This was similar to previous study by Khine ML et al.^[32] and one study of GDM in adolescence, which found that body mass index (BMI), was an important risk factor for development of GDM in teenage pregnancies. GDM was seen to be least prevalent (3.23%) in underweight subjects (BMI <18.5 kg/m²).^[29]

In the current study, polyhydramnios was risk factor associated with GDM; the odd's ratio was 1.6134. The mechanism of polyhydramnios in GDM is unclear and an increased glucose concentration in the amniotic fluid may play a role. However, Biggio et al. demonstrated that polyhydramnios caused by diabetes is generally

mild and does not considerably increase the risk of an adverse outcome.^[33]

In the present study, previous history of GDM and recurrence in subsequent pregnancy was found to be associated with odd's ratio of 1.75. In Asian women, history of GDM in previous pregnancies was the most significant clinical risk factor (with an odds ratio of 14.5).^[8] Similarly, significant association was found in the study conducted in Turkey.^[34] Previous history of IUD as one of the risk factors for GDM, was observed by Nilofer AR et al.^[27]

The family history of DM was found to be an associated risk factor for development of GDM in the study subjects with odd's ratio of 1.66. Wahi P et al observed family history of diabetes mellitus in significant proportion of cases i.e. 15 (24.19%).^[29] A study from Tamil Nadu, India also concluded that family history of diabetes was significant risk factor for GDM. This finding is in accordance with studies in Europe that showed positive family history of type-2 diabetes subjects with GDM.^[35]

The threshold for a positive GCT necessitating further diagnostic testing in the previous studies were varying from 130-140 mg/dl^[36,37], but in our study cut-off of GCT was found to be 128mg/dl. The method to identify the best cut-off value of the test is the Receiver-operator characteristic curve (ROC curve).^[8] Area under ROC curve was 0.994 ($p < 0.0001$) (Figure 1). The GCT threshold values best correlated with 2nd hour OGTT with correlation co-efficient 0.34 (Figure 2). A study conducted in Turkey identified GCT value more than 132 mg/dl as best cut-off value with area under ROC curve 0.903 ($p < 0.0001$).^[6] In another study conducted in Iran best threshold for GCT was found to be more than 135 mg/dl.^[38]

An important limitation regarding GCT results is low reproducibility, because it relies on the timing since the last meal and diurnal variation is not taken in to account. Only 8.3% of the abnormal results were reproducible the next day in a study.^[39] Other limitations of the study were the small sample size and the follow up of the cases was not done. Hence further follow up studies are required with large sample size, so that the cut-off

value and direct 2nd hour blood sugar level after 75 grams of OGTT, without FBS can be substantiated strongly.

Conclusion

In this ethnic group the high risk pregnant women for GDM, should undergo initial 50 gm. GCT screening test. If GCT value is more than 128 mg/dl, it should be followed by diagnostic second hour 75 gram OGTT. It is more valuable for diagnosis of GDM and it reduces the FBS estimation and an extra prick.

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