

Comparative Study of Non Fasting Single Plasma 1 Hour Value After 50 Grams Vs Non Fasting Single Plasma 2 Hour Value After 75 Grams Glucose for Screening of Gestational Diabetes Mellitus

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Abstract: *Introduction:* Gestational diabetes mellitus is a common medical complication of pregnancy with several fetal and maternal complications. There are several screening tools for detecting gestational diabetes mellitus including recent DIPSI criteria of non-fasting single plasma 2 hour value after 75 grams glucose. *Aims:* present study was aimed at comparing sensitivity and specificity of non fasting single plasma 1 hour value after 50 grams vs non fasting single plasma 2 hour value after 75 grams glucose for screening of gestational diabetes mellitus. *Materials and methods:* This was a prospective comparative randomized study conducted from December 2013 to July 2015. Women with period of gestation 24-28 weeks were included. Both groups i.e. Group A (50 g) and Group B (75 g) were tested by OGTT for confirmation. Prevalence rates, sensitivity, specificity, positive predictive value and negative predictive value of both groups were studied. *Results:* Prevalence rate, sensitivity, specificity, positive predictive value and negative predictive value for Group A were 16.57%, 68.97%, 75.34%, 35.71% and 92.44%. Prevalence rate, sensitivity, specificity, positive predictive value and negative predictive value for Group B were 13.71%, 72.92%, 95.03%, 70.00% and 95.67%. Group B showed better strength of agreement with kappa value of 0.668 where as Group A showed kappa value of 0.323. *Conclusions:* Screening using DIPSI criteria has better sensitivity and negative predictive values. It can serve as both screening and diagnostic test besides being simple, user friendly, cost effective and evidence based test in less resource countries like India.

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I. Introduction

Gestational Diabetes Mellitus is a common medical complication of pregnancy and is defined as “carbohydrate intolerance of variable severity with the onset or first recognition during pregnancy”.^[1] WHO defines diabetes under two subcategories: diabetes (2-h plasma glucose \geq 200 mg/dl) and impaired glucose tolerance (2-h plasma glucose \geq 140 mg/dl and $<$ 200 mg/dl).^[2] In 2010, the IADPSG recommended change in terminology. In this, diabetes diagnosed during pregnancy is classified as either overt or gestational. This recognizes that an increasing number of women have unrecognized type 2 diabetes at the time of conception, which is associated with a higher risk of adverse pregnancy outcomes including congenital anomalies, as well as diabetic complications.^[3] Hence is a dire need to screen antenatal women for diabetes. NICE^[4] recommends screening to women with any risk factor. The ADA^[5] recommends selective screening for women who fulfill all of the low risk factors. The *Australasian Diabetes in Pregnancy society (ADIPS)* recommends universal screening for GDM; however it advises that where resources are limited, or in areas of low incidence, selective screening based on risk factors may be appropriate^[6] *Despite of more than 40 years of research, whether is no consensus regarding the optimal approach to screening for gestational diabetes, whether screening should be done universally or selectively.* The WHO recommends universal screening.^[2] ADA subsequently recommend selective screening as stated above.^[7] The Fifth International Workshop-Conference on GDM also recommends selective screening based on risk assessment at first prenatal visit and to be repeated at 24-28 weeks of gestation in average and high risk women.^[8] U.S. Preventive Services Task Force concludes that the current evidence is insufficient to assess the balance between the benefits and harms of screening women for gestational diabetes either before or after 24 weeks of gestation.^[9] IADPSG recommended two phase strategy for detecting hyperglycemia in pregnancy by measuring fasting or random plasma glucose or HbA1c at first antenatal visit in all high risk women and 2-hour 75 g OGTT in all women at 24 to 28 weeks of gestation.^[3] *Despite of large studies on GDM ,screening test for diagnosing diabetes in pregnancy, there is still no consensus . On 14th March 2007, Government of India issued the instructions that universal screening of glucose intolerance during*

pregnancy should be mandatory. The order recommends that all women should be screened between 24 and 28 weeks of gestation with 2 h 75 g oral glucose. Hence this study was conducted to assess the sensitivity and specificity of two screening tests for GDM and come up with a better approach towards screening procedure for gestational diabetes mellitus. Aims and objectives were 1. To study and compare sensitivity and specificity of 50 grams glucose challenge test and 75 gram single plasma 2 hour value (DIPSI criteria) with 75 grams oral glucose tolerance test (OGTT) done at 0, 1 and 2 hours. 2. To compare 50 grams glucose challenge test and 75 grams single plasma 2 hour value (DIPSI criteria) as a screening procedure for gestational diabetes mellitus.

II. Material And Methods

The study was conducted in the department of obstetrics and gynaecology at dr. Baba saheb ambedkar hospital, rohini, new delhi – 110085. Study population comprised of patients attending the outpatient department. Study design was prospective comparative randomized study. On the basis of previous study, prevalence of disclosure was 3% to 21%. taking this value as reference, the minimum required sample size with 3% margin of error and 5% level of significance is 709 patients.

To reduce margin of error, total sample size taken is 750. Formula used is:- $me = z \cdot \sqrt{p(1-p)/n}$ where z is value of z at two sided alpha error of 5%, me is margin of error and p is prevalence rate. The study included 750 patients, randomized to group a consisting of 375 patients undergoing glucose challenge test with 50 grams of glucose and group b consisting of 375 patients undergoing glucose challenge test with 75 grams glucose. Time frame was december 2013 to july 2015. Inclusion criteria was all women with period of gestation between 24 – 28 weeks. Exclusion criteria were known case of diabetes mellitus, patient on steroids, patient not willing to be a part of study. Randomization was done using computer generated random sequence of numbers 1 and 2 using ms-excel. All subjects were informed of the aim to ensure best possible compliance throughout the study. An ethical committee clearance was attained before the start of the study.

Written informed consent was taken from subjects eligible for the study. After randomization, the subject was positioned in either of the two groups. A detailed history followed by general clinical examination and systemic examination was done. Routine obstetric examination was done in all subjects.

The enrolled subjects were divided into two groups; GROUP A [n=375]: All women received 50 grams of glucose dissolved in 250-300 ml water irrespective of previous meal. GROUP B [n=375]: All women received 75 grams of glucose dissolved in 250-300 ml water irrespective of last meal.

OGTT was used as a gold standard test in this study. All subjects irrespective of GCT values underwent a OGTT with 75 grams glucose. The subjects were advised to follow up within a week in morning after an overnight fasting of 8-10 hours but not more than 14 hours and after atleast three days of unrestricted diet (more than or equal to 150 grams of carbohydrate) and physical activity. A fasting venous sample was taken and a solution containing 75 grams of glucose was given to all subjects and two samples were taken at 1 hour and 2 hour. In Glucose challenge test Group A: the cut off value for 50 grams, 1 hour GCT is ≥ 130 mg/dl and in Glucose challenge test Group B: the cut off value for 75 grams, 2 hour GCT is ≥ 140 mg/dl. In Glucose tolerance test the cut off plasma glucose values used for the diagnosis of GDM are as follows; Fasting ≥ 92 mg/dl; 1 hr ≥ 180 mg/dl and 2 hr ≥ 153 mg/dl. If any one of the value was met or exceeded, then OGTT was taken as positive and patient was diagnosed as GDM as per IADPSG 2010 criteria.

Glucose values were entered on a MS-Excel spreadsheet and analyzed. The patients who failed to return for follow up were excluded from the statistical analysis. The patients diagnosed as GDM were managed as per standard protocol. Primary outcomes were prevalence rate, sensitivity and specificity of each test, positive and negative predictive value of each test. Categorical variables were presented in Number and Percentage (%) and continuous variables were presented as Mean \pm SD and Median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used. Quantitative variables were compared using Unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups. Qualitative variables were compared using Chi-Square test /Fisher's exact test. Receiver operating characteristics curve was used to assess the sensitivity and specificity. Kappa statistic for agreement: inter rater agreement statistic (Kappa) to evaluate the agreement between two classifications on ordinal or nominal scale. Agreement is quantified by the kappa (k) or weighed kappa (Kw) statistic. The data was entered in MS-Excel spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. A p value of <0.05 was considered statistically significant.

III. Result

More than 80% of the study sample belongs to the age group of 20-30 years. The mean age in 50 grams group is 25.63 ± 3.82 with minimum age of 19 years and maximum age of 40 years. The interquartile range was 23-28 years. The mean age in 75 grams glucose group was 24.63 ± 3.56 years with minimum age of 18 years and maximum age of 37 years. The inter quartile range was 22-26 years. Hence the age distribution between the two groups was not significant ($p=0.058$) indicating similar age distribution between the two groups. Majority of

cases 292/350 (83.43%) in 50 g group and 280/350 (80.00%) in 75 g group were Hindus by religion. The difference between the two groups was statistically not significant (p value=0.282). Socioeconomic status was classified according to modified Kuppaswamy scale taking into consideration education, occupation of head of family and total family income. Maximum number of cases i.e. 186 (53.14%) in Group A and 164 (46.86%) in Group B belonged to lower middle class. The distribution of population was similar between the two groups (p value=0.453). Majority 140 (40.00%) in 50 grams group and 133 (38.00%) in 75 grams group were primigravidas. The p value of 0.352 implies that distribution of population according to gravida is similar for both the groups.

Out of total patients in 50 grams group, 62.8% had normal GCT and GTT, 51.4% had normal GCT and abnormal GTT, 20.6% had abnormal GCT and normal GTT whereas 11.4% had both abnormal GCT and GTT. Prevalence of GDM using GCT with 50 grams glucose is 16.57%. Out of total patients in 75 grams group, 82.00% had normal GCT and GTT, 42.86% had abnormal GCT and normal GTT, 37.14% had normal GCT and abnormal GTT whereas 10.00% had both abnormal GCT and GTT. Prevalence of GDM using GCT with 75 grams glucose is 13.71%

Total 223 number of patients had deranged GTT, out of which 79 (11.29%) had only fasting deranged whereas 35 (5.00%), 37 (5.29%) had only 1 and 2 hour value deranged respectively. Only 12 (1.71%) had all the three values deranged. Maximum number of patients had fasting value of GTT deranged.

The mean age in 50 g glucose challenge test group [Group A] was 25.63±3.82 years and in 75 g glucose challenge test [Group B] was 24.63±3.56 years. The overall prevalence in Group A was found to be 16.57%. The overall prevalence in Group B was found to be 13.71%. Sensitivity, specificity, positive predictive and negative predictive value of 50 g GCT using IADPSG recommended GTT was 68.97%, 75.34%, 35.71% and 92.44%. Sensitivity, specificity, positive predictive and negative predictive value of 75 g 2 hour GCT using IADPSG recommended GTT was 72.92%, 95.03%, 70.00% and 95.67%. 58 women in 50 g glucose challenge test group whereas 48 women in 75 g 2 hour glucose challenge test were diagnosed GDM. 75 g single 2 hour plasma glucose challenge test showed better strength of agreement between the two tests using kappa values.

IV. Discussion

In 2009, Diabetes in Pregnancy Study group India (DIPSI) recommended a “single test procedure” for diagnosing GDM with a 2 hr PG cut off of ≥ 7.8 mmol/L (140 mg/dl) after 75 gm oral glucose administered in the fasting and non-fasting states irrespective of the last meal.^[10] In developing countries like India, women have to travel long distances 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. Thus, performing a non-fasting OGTT emerged as a logical option and this has become very popular in India. This led to conduct of this study to validate use of single plasma 2 hour value after 75-g glucose as screening and diagnostic criteria for gestational diabetes mellitus comparing with the traditional 50-g glucose challenge test.

The mean age of the overall study population was between 21-30 years. The mean age in Group 1 was 25.63±3.82 and mean age in Group 2 was 24.63±3.56 years with p value of 0.058 suggesting that distribution of population according to age was similar for both the groups.

The results of our study were comparable to recommendations of the American Diabetes Association^[11], where the lowest cutoff is ≥ 25 years but there are little data to support this recommendation. Similar results were shown by Rajesh Rajput et al in 2013 where the mean age of participants was 23.62 ± 3.42 yr (range 18-38). The prevalence rate was higher in women aged 26-30 and >30 yr (11.57 and 34.8%, respectively) compared to women aged 16-20 and 21-25 yr (4.54 and 4.53%, respectively) and this observation was found to be statistically significant (P<0.001).^[12] The prevalence of relatively younger population in this study probably reflects the trend of early marriages in India, especially in the socioeconomic group of patients coming to this hospital.

India is a country of diversified religious backgrounds, this study constitutes more of Hindus (502/700) probably because more number of Hindu population attending the hospital. 292 out of 350 (83.43%) were Hindus in Group 1 whereas 280 out of 350 (80.00%) were Hindus in Group 2, the remaining in both the groups were Muslims. The p value of less 0.282 implies that distribution of population according to religion is similar in both the groups.

In the present study, patients are divided into different socioeconomic classes according to modified Kuppaswamy scale taking into consideration education and occupation of the head of the family and family total income. Maximum number of cases i.e. 186 (53.14%) in Group A and 164 (46.86%) in Group B belonged to lower middle class. The most common group for occurrence of diabetes becomes lower middle class probably because they form the majority of study population. The p value of 0.453 suggests that distribution of population according to socioeconomic class was similar for both the groups. Yang et al did not find any association of gestational diabetes with socio-economic status in Chinese pregnant women in his study.^[13]

In the present study, 273 out of 700 (39%) were primigravidas, 31.14% (218/700) were gravid 2, 20.71% (145/700) were gravid 3 whereas only 9.1% (64 out of 700) were gravid 4 and more. 140 out of 350 (40.00%) from Group 1 and 133 out of 350 (38.00%) from Group 2 were primigravidas. The p value of 0.352 suggests that distribution of population according to gravid is same for both the groups. Jang et al found greater ratio of women with GDM in the group with parity > 2, in comparison with primigravidas but the association was not significant.^[14] In our study majority population being primigravidas this association could not be elicited.

In this study, 106 patients were diagnosed as GDM and thus the prevalence was 15.14% (106/700). The prevalence of GDM using 50-g as glucose challenge test was 16.57% [TP+FN/350 i.e. 40+18/350]. The prevalence of GDM using 75-g as glucose challenge test was 13.71% [35+13/350]. In a random survey performed in various cities in India in 2002-2003, the prevalence of GDM was 16.2% in Chennai, 15% in Thiruvananthapuram, 21% in Alwaye, 12% in Bangalore, 18.8% in Erode and 17.5% in Ludhiana.^[15] An overall GDM prevalence of 16.55% was observed. Similar results were shown by Vinita Das et al, out of 300 women 20.3% were found to have positive screening for GDM.^[16] In another study in Tamil Nadu (2005-2007), a total of 4151, 3960 and 3945 pregnant women were screened in urban, semi urban and rural areas respectively and GDM was detected in 17.8, 13.8 and 9.9% women respectively.^[17]

Group A was screened with 50 g GCT and sensitivity, specificity, positive predictive value and negative predictive value were 68.57%, 75.34%, 35.71% and 92.44% respectively. Positive likelihood ratio was 2.8 and negative likelihood ratio was 0.41 (table 1).

TABLE 1: Comparison Of Sensitivity And Specificity Between Two Groups

	GROUP A [50 GRAMS]	GROUP B [75 GRAMS]
SENSITIVITY	68.97%	72.92%
SPECIFICITY	75.34%	95.03%
POSITIVE PREDICTIVE VALUE	35.71%	70.00%
NEGATIVE PREDICTIVE VALUE	92.44%	95.67%
POSITIVE LIKELIHOOD RATIO	2.8	14.68
NEGATIVE LIKELIHOOD RATIO	0.41	0.28

Using 140 mg/dl as cut off for GCT the sensitivity was 53.45%, specificity was 80.82%. The results were comparable to study by V Seshiah et al (2004) in which 50 g oral glucose challenge test was compared with 75 g OGTT and sensitivity, specificity, positive predictive value and negative predictive value were 79.8%, 42.7%, 24.5% and 90.1% respectively.^[15] Group B was screened with 75 g 2 hour GCT using 140 mg/dl as cut off (DIPSI criteria) and was followed by OGTT with 75 g glucose irrespective of GCT value. Sensitivity of 75 g 2 hour GCT was 72.92%, specificity was 95.03%, positive predictive value was 70.00%, negative predictive value was 95.67%, positive likelihood ratio was 14.68 and negative likelihood ratio was 0.28 (table 1).

A study done in India by Seshiah V et al to find out whether DIPSI guidelines could still be continued to diagnose GDM in our country, as this requires one blood test compared to three tests of IADPSG, which is expensive. The prevalence of GDM was 14.6% (N = 214) by IADPSG criteria and 13.4% (n = 196) by DIPSI criteria. The discordant pair between the two criteria examined by McNemar's test indicated that there was no statistical significance (P = 0.21) and thereby implying a close agreement between these two procedures.^[104]

Another study done by Anjalakshi et al on South Indian population showed 100% sensitivity and 100% specificity of 75 g 2 hour GCT when compared with the WHO recommended 75 g 2 hour OGTT for the diagnosis of GDM. They concluded that there was no statistically significant difference the two tests in identifying women with GDM (p=1).^[18]

In our study the sensitivity and specificity with fasting as gold standard was 65.82% and 82.29%. the results were comparable with studies by Reichelt AJ et al, Daniele Perucchini et al and Sacks et al.^[19,20,21]

A recent retrospective study in Italy by Lapolla et al reclassified patients using IADPSG 2010 criteria. This reanalysis showed that 2.8% of women who were initially classified as normal by the Fourth international Conference criteria on gestational diabetes needed to be labeled as GDM. The above studies showed an increase in the prevalence of GDM in population of developed countries when defined by the IADPSG 2010 criteria.^[22]

Another study was performed by Wer E et al in 2014 to evaluate the impact of the new IADPSG thresholds on gestational diabetes mellitus (GDM) prevalence was done by doing a universal screening for GDM on 200 consecutive patients at 24 to 28 weeks with 75 g oral glucose tolerance test. The prevalence of GDM was 14.0%. The study concluded an increased rate of GDM with the new IADPSG criteria compared to previous published data.^[23]

In this study, 58 out of 106 were diagnosed GDM by using 50-g glucose challenge test whereas 48 out of 106 were diagnosed GDM using 75-g glucose challenge test. Analysis of strength of agreement and receiver operator curve between the two groups is shown in table2, table 3 and table4.

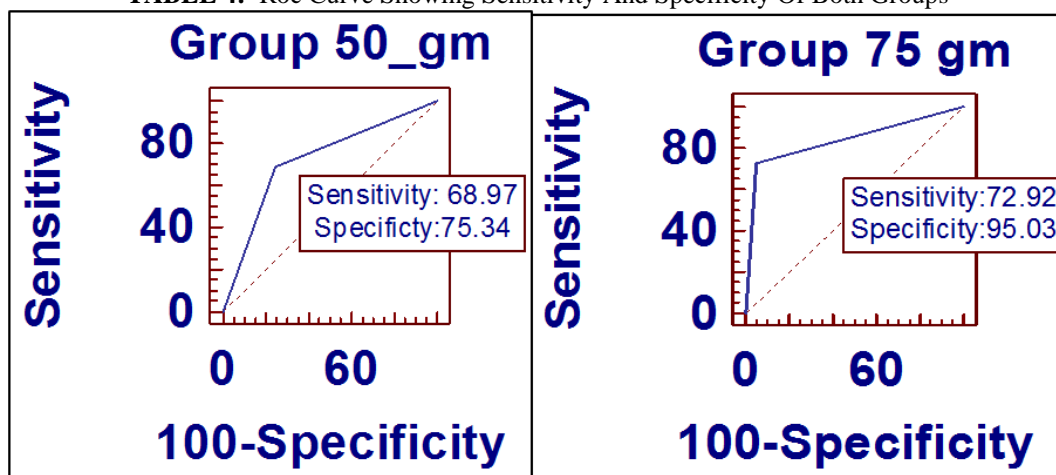
TABLE 2: RECEIVER OPERATOR CURVE OF TWO GROUPS WITH RESPECT TO 75g OGTT

ROC CURVE	50 gm	75 gm
Area under the ROC curve (AUC)	0.72154	0.839749
Standard error	0.0331	0.033
95% confidence interval	0.671408 to 0.767879	0.797040 to 0.876593
Sensitivity	68.97%	72.92%
Specificity	75.34%	95.03%
Difference	-0.118209	
Standard error	0.0467	
Significance level	0.0114	

TABLE 3: Analysis Of Strength Of Agreement Between Both Methods Using Kappa

75 gm	GDM		Total	P value	Kappa
	No	Yes			
No	287(82.00%)	13(3.71%)	302(86.29%)	<.0005	0.668
Yes	15(4.29%)	35(10.00%)	48(13.71%)		
50 gm	GDM		Total	P value	Kappa
	No	Yes			
No	220(62.86%)	18(5.14%)	292(83.43%)	<.0005	0.323
Yes	72(20.57%)	40(11.43%)	58(16.57%)		

TABLE 4: Roc Curve Showing Sensitivity And Specificity Of Both Groups



The purpose of our study was to bring out a better screening methodology for gestational diabetes. In our study, sensitivity of 72.92% suggests that 75 g 2 hour GCT is unable to detect 27.08% of GDM patients whereas sensitivity of 68.57% of 50 g GCT suggests that it cannot detect 31.43% of GDM patients. Moreover, specificity of 75.34% of 50 g GCT means it will label 24.66% as false positive patients whereas GCT with 75 g glucose labels only 4.97% of patients as false positive. Henceforth, 75 g 2 hour GCT is a better screening test of the two. Missing 27.08% of the patients is not acceptable as a screening test but on the other hand high specificity (95.03%) is its strength as it will decrease the burden of false positive labeled GDM patients.

V. Conclusion

The prevalence of diabetes is increasing globally and it occurs even in cases without risk factors during pregnancy. The timely recognition of the disease helps to achieve euglycemia and prevent complications for the mother and the baby and this demands for an universal screening approach. Single step 75 g 2 hour test is better test than 50 g glucose challenge test as it has high specificity (95.03%) and negative predictive value (95.67%) but the sensitivity (72.92%) is not very high, although every aspect is better than 50 g GCT. It serves both as screening and diagnostic criteria besides being a simple, user friendly and evidence based test. In developing countries like India ,getting all pregnant women to attend opd in a fasting state becomes a great challenge . thus performing a non fasting single step, highly specific glucose tolerance test decreases the drop out rates.DIPSI procedure is cost-effective, without compromising the clinical equipoise and can be used to diagnose GDM in our country, as it decreases the drop-out rates

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Limitations Of The Study

Larger sample size could have been analyzed. Maternal and fetal outcomes based on these recommendations are not available and these data are needed to predict outcomes. Thirdly, the study participants were not randomized with the non-fasting and fasting states which could have introduced a bias, but it is unlikely that this would have affected the conclusions drawn from the study.

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