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The Validity Of 75gms OGTT For Detection Of GDM Keeping 100gms OGTT As Gold Standard

Shazia Mehreen[1], Muhammad Usman[2], Kashif Rauf[3], Saima Naz[4], Muhammad Abdul Rab Faisal Sultan[5], Muhammad Akram Randhawa[6]

Abstract

Objective: To determine the validity of 75gms (Oral Glucose Tolerance Test) OGTT for the detection of GDM keeping 100gms OGTT as the gold standard.

Methodology: This was a Cross-sectional validation study done at **the** Mother and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad. The duration of the study was Six months from the approval of the synopsis. Data was collected from March 2019 to September 2019. Informed consent for participating in the study was taken from all 205 patients. The patients' bio data along with the hospital registration number was entered pro forma. The patients were assessed initially by History taking and examination. All pregnant women underwent a 75g oral glucose test in the 2nd trimester at 24-28 weeks of gestation. For this, the patients were sent to the MCH laboratory with overnight fasting where FBS was taken and they were given a 75 g glucose drink. Their blood sample was taken at 1-hour and 2-hour interval. Two or more elevated values out of the 3 blood samples were sufficient to diagnose GDM. Laboratory reports were reviewed and data was entered in the performa (attached) by the researcher. All the diagnosed patients were further evaluated for a 100g OGTT dose at the MCH laboratory with overnight fasting. Their FBS was studied and women were given a 100 g glucose drink and blood samples were drawn at an interval of 1, 2 and 3 hours respectively. Out of the 4 blood samples, two or more elevated values were sufficient to diagnose GDM. Lab reports were entered in the Performa.

Results: From a total of 205 patients, the sensitivity and specificity of OGTT-75 g for diagnosing GDM were 83.02% and 82.83%. However, positive predictive and negative predictive value for OGTT-75 g was 83.81% and 82% respectively. However, the overall diagnostic accuracy of OGTT-75 g was 82.93%.

Conclusion: Results of this study showed that 75 gms OGTT is highly sensitive (83.02%) and specific (82.83%) for the detection/diagnosis of gestational DM. Advanced screening and diagnosis of gestational DM, and its effective treatment not only inhibit adverse perinatal and maternal outcomes but also save the lives of both child and mother from diabetes in future.

Keywords: GDM, Validity, 75gms OGTT, 100gms OGTT, Gold standard

[1] Senior Registrar, Ayub Medical College, Abbottabad; [2] Assistant Professor, Paediatrics, Fatima Memorial Hospital, Lahore; [3] Consultant, Bio-Chemistry Department, Rawalpindi Medical University; [4] Professor of Anatomy, Rawalpindi Medical University; [5] Senior Lecturer, Post Graduate Department, Rawalpindi Medical University; [6] Professor at Post Graduate Department, Rawalpindi Medical University.

Correspondence: Dr. Shazia Mehreen, Senior Registrar, Ayub Medical College, Abbottabad. **Email:** shazi.mehreen@yahoo.com.

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1. Introduction

Gestational diabetes mellitus (DM) refers to the condition of impaired glucose tolerance that is initially identified during pregnancy.[1, 2]

There is an increase in insulin resistance during pregnancy, which begins from mid-pregnancy and progresses throughout the 3rd trimester.[1]

Gestation DM is linked to complications affecting both the mother and the fetus or newborn, but appropriate management of gestation DM can mitigate unfavourable results.[3]

Prevalence of gestational DM is 16.55%.[4] Variations regarding sex, age, urbanization & location have been noted. The prevalence of GDM in Pakistan falls between 3.2 to 3.5%, similar to that in Western populations. However, instances of maternal and neonatal complications were observed to be elevated, potentially attributed to inadequate management of blood sugar levels.[5]

Extensive discussions have arisen regarding the methods employed to screen for GDM.

Due to their ethnic background, Pakistani women are categorized as highly vulnerable individuals. Consequently, it is advisable to contemplate implementing universal GDM screening within the Pakistani population.

A novel guideline has been introduced by the International Association of Diabetes and Pregnancy Study Groups (IADPSG), advocating the utilization of a 75g OGTT between the 24th and 28th weeks of pregnancy for screening and diagnosis of diabetes. The process involves three tests: measuring fasting

plasma glucose levels, followed by repeated measurements at one and two hours after consuming 75g of glucose orally. A pregnant woman is diagnosed with GDM if any of the three test results exceed the prescribed threshold.

Conversely, the absence of GDM is indicated in a pregnant woman when all three test values fall within the normal range. According to IADPSG, the one-hour 75g test has 85.74% sensitivity & 99.68 % specificity.3 As per Diabetes in Pregnancy Study Group India (DIPSI), the 75g oral glucose tolerance test (OGTT) demonstrates a sensitivity of 100% and a specificity of 89%.[1] According to the American Diabetes Association for OGTT a criteria of sensitivity of 100% alongside an accuracy of 92%, while maintaining a specificity of 95.4%, is observed.[6]

Traditionally, we use Random Blood Sugar (RBS) as a screening test for GDM, which has a maximum sensitivity of 75.4% with a specificity of 77.9%. A single RBS value is an inadequate method to screen for GDM. A Screening procedure should have high accuracy especially high specificity, so RBS although simple and inexpensive is insufficient for GDM7. Contemporary studies increasingly suggest a universal recommendation for GDM screening between the 24th and 28th weeks of gestational age. This should be followed by definitive testing for women categorized as high-risk. Consequently, a rational strategy involves integrating the screening and GDM diagnosis processes through a single procedure, employing a 75g oral glucose tolerance test (OGTT) that warrants evaluation.8 This study aims to check the validity of 75g OGTT, so if it is found to be high we can use 75g OGTT as a universal screening test to identify a large no of patients with GDM so that with early diagnosis and treatment of maternal and fetal complications can be reduced.

2. Materials & Methods

This was a cross-sectional comparative study carried out at the Mother and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad from March 2019 to September 2019. A total of 205 pregnant patients in the second trimester aged 15 to 45 years were enrolled. The exclusion criteria were women with preexisting diabetes, while the inclusion criteria were all high-risk pregnant women having BMI>30kg/m^2, gestational diabetes in a previous pregnancy, family history of diabetes, previous history of large size baby &/or previous stillbirth of reproductive age (15-45 years) booking in the first trimester of pregnancy attending the mother-child health OPD.

Informed consent for participating in the study was taken from all 205 patients. The patients' bio data along with hospital registration number was entered on the performa. The patients were assessed initially by History taking and examination. All pregnant women underwent a 75g oral glucose test in the 2nd trimester at 24-28 weeks of gestation. For this, the patients were sent to the MCH laboratory with overnight fasting where FBS was taken and they were given a 75 g glucose drink. Their blood samples were taken at 1-hour and 2-hour intervals. Two or more elevated value out of the 3 blood samples was considered sufficient to diagnose GDM. Laboratory reports were reviewed and data was entered in the performa (attached) by the researcher. All the diagnosed patients were further evaluated for a 100g OGTT dose at the MCH laboratory with overnight fasting. Their FBS was studied and women were given a 100 g glucose drink and blood samples were drawn at an interval of 1, 2 and 3 hours respectively. Out of the 4 blood samples, two or more elevated values were sufficient to diagnose GDM. Lab reports were entered in the Performa.

Data Analysis Procedure:

The descriptive analysis of the collected data was done using SPSS version 10 (statistical software). Mean ±SD was calculated for age, BMI, gestational age and LMP. Frequency as a percentage was calculated for True positives. A 2x2 table was constructed to determine the diagnostic accuracy of 75gm OGTT.

75gm OGTT	100gm OGTT	
	GDM +	GDM -
GDM +	TP	FP
GDM -	FN	TN

TP – True positive; FP – False positive; FN – False negative; TN – True negative

Sn=TP/TP+FNx100; Sp=TN/TN+FPx100; PPV=TP/TP+FPx100; NPV=TN/TN+FNx100

DA= TP+TN/TP+TN+FP+FNx 100

Sen – Sensitivity; Spec – Specificity; PPV - positive predictive value

NPV - negative predictive value; DA – diagnostic accuracy

Effect modifiers like age, gestational age, and BMI were controlled through stratification. Post-stratification, the chi-square test was applied. P-value≤0.05 was considered as significant.

3. Results

A total of 205 patients with a mean age of 29.44 ± 8.75 years were considered in this study. Their gestational age ranged from 24 to 28 weeks with a mean value of 26.1 ± 1.352 wks. The mean value of BMI was 30 to 37 ± 33.377 kg/sq m and 1.9947 kg/sq m. The mean age of women was 29.44±8.75 years. The minimum and maximum age of women was 15 and 45 years respectively.

There were 74(36.10%) women whose gravida was 1, 47(22.93%) women's gravida was 2, 62(30.24%) women's gravida was 3 and 22(10.73%) women's gravida was 4. The mean gestational age of women was 26.01±1.35 weeks. The minimum and maximum gestational age of women was 24 and 28 weeks respectively. The mean BMI of women was 33.377±1.99. The minimum and maximum BMI of women was 30 and 37 respectively.

Table-1 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM stratified for age

Age	OGTT-75g	OGTT-100g		Total	Sen	Spec	PPV	NPV	DA	p-value
		Positive	Negative							
<30 years	Positive	41	8	49	75.9	84	83.7	76.4	79.8	<0.001
	Negative	13	42	55						
	Total	54	50	104						
≥30 years	Positive	47	9	56	90.4	81.6	83.9	88.9	86.1	<0.001
	Negative	5	40	45						
	Total	52	49	101						

BMI – body mass index; Sen – Sensitivity; Spec – Specificity; PPV - positive predictive value

NPV - negative predictive value; DA – diagnostic accuracy

Table-2 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM stratified for gestational age

GA	OGTT-75g	OGTT-100g		Total	Sen	Spec	PPV	NPV	DA	p-value
		Positive	Negative							
24-26 weeks	Positive	49	8	57	77.8	87.3	85.9	79.7	82.5	<0.001
	Negative	14	55	69						
	Total	63	63	126						
27-28 weeks	Positive	39	9	48	90.7	75	81.3	87.1	83.5	<0.001
	Negative	4	27	31						
	Total	43	36	79						

Table-3 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM stratified for BMI

BMI	OGTT-75g	OGTT-100g		Total	Sen	Spec	PPV	NPV	DA	p-value
		Positive	Negative							
<35 kg/m^2	Positive	64	14	78	83.1	81.6	82.1	82.7	82.4	<0.001
	Negative	13	62	75						
	Total	77	76	153						
≥35 kg/m^2	Positive	24	3	27	82.8	86.9	88.9	80	84.6	<0.001
	Negative	5	20	25						
	Total	29	23	52						

BMI – body mass index; Sen – Sensitivity; Spec – Specificity; PPV - positive predictive value
NPV - negative predictive value; DA – diagnostic accuracy

As per findings of OGTT-75 g test 105(51.2%) women were positive for GDM and as per findings of OGTT-100 g test 106(51.7%) women were positive for GDM. (Table-4)

Table-4 Results of OGTT Test

Results	OGTT-75 g	OGTT-100 g
Positive	105(51.2%)	106 (51.7%)
Negative	100(48.8%)	99(48.3%)
Total	205	205

The sensitivity and specificity of OGTT-75 g for diagnosing GDM were 83.02% and 82.83%. However, positive predictive and negative predictive value for OGTT-75 g was 83.81% and 82% respectively. However, the overall diagnostic accuracy of OGTT-75 g was 82.93%. (Table-5)

Table-5 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM

OGTT-75g	OGTT-100g		Total
	Positive	Negative	
Positive	88(83%)	17(17.2%)	105
Negative	18(17%)	82(82.8%)	100
Total	106	99	205

Sensitivity= 83.02% (74.75, 88.98); Specificity= 82.83% (74.21, 88.99); Positive Predictive Value= 83.81% (75.59, 89.64); Negative Predictive Value= 82% (73.33, 88.3); Diagnostic Accuracy = 82.93% (77.18, 87.46)

Data was stratified for the age of patients. In females with age<30 years, the specificity and sensitivity of OGTT-75 gram for diagnosing GDM were 84.0% and 75.9%. However, in females of age ≥ 30 years, the specificity and sensitivity of OGTT-75 gram were 81.6% and 90.4% respectively. (Table-6)

Table-6 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM stratified for age

Age	OGTT-75g	OGTT-100g		Total	Sen	Spec	PPV	NPV	DA	p-value
		Positive	Negative							
<30 years	Positive	41	8	49	75.9	84	83.7	76.4	79.8	0.000
	Negative	13	42	55						
	Total	54	50	104						
≥30 years	Positive	47	9	56	90.4	81.6	83.9	88.9	86.1	0.000
	Negative	5	40	45						
	Total	52	49	101						

Data was stratified for gestational age. In females at 24-26 weeks, the specificity and sensitivity of OGTT-75 gram for diagnosing GDM were 87.3% and 77.8%. However, in females at gestational age 27-28 weeks, the specificity and sensitivity of OGTT-75 gram were 75.0% and 90.7% respectively. (Table-7)

Table-7 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM stratified for gestational age

GA	OGTT-75g	OGTT-100g		Total	Sen	Spec	PPV	NPV	DA	p-value
		Positive	Negative							
24-26 weeks	Positive	49	8	57	77.8	87.3	85.9	79.7	82.5	0.000
	Negative	14	55	69						
	Total	63	63	126						
27-28 weeks	Positive	39	9	48	90.7	75	81.3	87.1	83.5	0.000
	Negative	4	27	31						
	Total	43	36	79						

Data was stratified for the BMI of patients. In females with BMI<35kg/m^2, the specificity and sensitivity of OGTT-75 gram for diagnosing GDM were 81.6% and 83.1%. However, in females with BMI≥35kg/m^2, the specificity and sensitivity of OGTT-75 gram were 86.9% and 82.8% respectively. (Table-8)

5. Discussion

There remains a lack of international consensus concerning the appropriate timing for GDM screening, as well as the ideal threshold values for diagnosis and intervention. DIPSI proposes a non-fasting OGTT involving 75g of glucose, with a diagnostic threshold of ≥140 mg/dl after 2 hours. In contrast, the WHO (1999) recommends a fasting OGTT using 75g glucose, with a cut-off plasma glucose level of ≥140 mg/dl after 2 hours. ADA/IADPSG's recommendations for screening women at diabetes risk are as follows: during the first and subsequent trimesters at 24-28 weeks, GDM diagnosis criteria involve a 75g OGTT and fasting glucose of 5.1mmol/l, 1-hour value of 10.0mmol/l, and 2-hour value of 8.5mmol/l through universal glucose tolerance testing. Detractors of these criteria argue that they lead to excessive GDM diagnoses and unnecessary

interventions, fueling an ongoing controversy. ACOG continues to favour a two-step process: initiating with a non-fasting GCT using 50g glucose, and if the value exceeds 7.8mmol/l, followed by a 3-hour OGTT for definitive confirmation of diagnosis.9 It is worth noting that the 75g glucose load has gained more prominence in pregnancy screenings compared to the traditional 100g load.

In the current study sensitivity and specificity of OGTT-75 g for diagnosing GDM were 83.02% and 82.83%. However, positive predictive and negative predictive value for OGTT-75 g was 83.81% and 82% respectively. However, the overall diagnostic accuracy of OGTT-75 g was 82.93%. In his study, Tarakeswari Surapaneni found that when used independently, the one-hour 75g test accurately categorized 85.74% of GDM cases. It exhibited a specificity of 99.68%, a clinically meaningful positive likelihood ratio (111.12), and resulted in a post-test probability of 96.87%.[4]

Table-8 Diagnostic accuracy of OGTT-75 g Test for diagnosing GDM stratified for BMI

BMI	OGTT-75g	OGTT-100g		Total	Sen	Spec	PPV	NPV	DA	p-value
		Positive	Negative							
<35 kg/m^2	Positive	64	14	78	83.1	81.6	82.1	82.7	82.4	0.000
	Negative	13	62	75						
	Total	77	76	153						
≥35 kg/m^2	Positive	24	3	27	82.8	86.9	88.9	80	84.6	0.000
	Negative	5	20	25						
	Total	29	23	52						

The results of this study reading the sensitivity and specificity of the 75-g OGTT test were consistent with the results reported by Tarakeswari Surapaneni. In this study sensitivity and specificity of the 75-g OGTT test was >80%.

Based on data from a Brazilian cohort of 4998 pregnant women, M.A.A. Campos10 findings indicate that the 1-hour 75g OGTT demonstrates similar diagnostic attributes for GDM as the conventional 2-hour 75g OGTT. The 1-hour test that yielded optimal balance between sensitivity and specificity in GDM detection (141 mg/dL) closely aligns with the threshold initially established by O'Sullivan et al.[11] for the 50g 1-hour test (blood glucose of 130 mg/dL), which continues to be widely employed for GDM screening. The attributes associated with the 1-hour test at the 141 mg/dL threshold (sensitivity and specificity of 83%) conform to the typical requirements for GDM screening, as does the proportion of women identified as positive (22%)—these being women warranting the subsequent diagnostic 2-hour test.

Pregnant females exhibiting elevated post-glucose load levels alongside normal fasting glucose levels demonstrated an increased likelihood of encountering preterm deliveries, hypertensive disorders during pregnancy, or neonates with hyperbilirubinemia.[12] On the other hand, pregnant females with elevated fasting glucose levels but normal post-glucose load levels were more prone to having a baby with a large size for their gestational age.12 Unfortunately, our study lacked sufficient statistical power to investigate and comment on these correlations. Furthermore, it is essential to consider the potential advantageous impacts of both non-pharmacological and pharmacological interventions administered to women with GDM on their associations with various outcomes.

5. Conclusion

Results of this study showed that 75gms OGTT is highly sensitive (83.02%) and specific (82.83%) for the detection/diagnosis of gestational DM. Efficiently screening, diagnosing, and managing gestational DM not only inhibits unfavourable outcomes for both the mother and newborn but also contributes to the prevention of future diabetes in both individuals.

CONFLICTS OF INTEREST- None

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Potential competing interests: None to report

Contributions:

S.M - Conception of study

S.M - Experimentation/Study Conduction

S.M, M.A.R.F.S - Analysis/Interpretation/Discussion

K.R, S.N, M.A.R - Manuscript Writing

K.R - Critical Review

M.U, S.N - Facilitation and Material analysis

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