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Original Research Article

How Reliable is the Screening Method for Gestational Diabetes Mellitus in Predicting Fetal Macrosomia?

Okunowo Bolanle,[1*] Odeniyi Ifedayo,[2,3] Olopade Oluwarotimi,[3] Okunowo Adeyemi,[4,5] Adegbola Omololu [4,5], Fasanmade Olufemi, [2,3] Ohwovoriole Augustine[2,3].

[1]Endocrinology, Diabetes and Metabolism division, Department of Medicine. Lagos State University Teaching Hospital, Lagos; Nigeria. [2]Endocrinology, Diabetes and Metabolism division, Department of Medicine, College of Medicine, University of Lagos (CMUL), Nigeria. [3]Endocrinology, Diabetes and Metabolism division, Department of Medicine, Lagos University Teaching Hospital, Lagos, Nigeria. [4]Obstetrics and Gynecology Department, College of Medicine, University of Lagos (CMUL), Nigeria. [5]Obstetrics and Gynaecology Department, Lagos University Teaching Hospital, Lagos, Nigeria.

[a]*Correspondence

[a]*Dr. Bolanle Okunowo
aboutbolanle@gmail.com.
+2347031188085. P.O BOX 21005,
Ikeja, Lagos; Nigeria
ORCID: 0000-0001-5471-6256

ABSTRACT

Background: Fetal macrosomia is a major complication of Gestational Diabetes Mellitus (GDM). Universal screening of all pregnant women has been advocated by WHO, however this remains a major challenge in low-income settings. The aim of this study is to audit the reliability of the universal screening method used for GDM on macrosomic delivery. **Methods:** This was a prospective study conducted over a period of nine months. All the pregnant women were screened for GDM. They had 75g Oral Glucose Tolerance test (OGTT) and glycated hemoglobin (HBA1C) done at 24 to 28 weeks' gestation and they were followed up till delivery. Their newborns had their weight measured at birth. **Results:** Ninety pregnant women were screened for GDM. The overall prevalence of GDM was 23.3%. One-hour plasma glucose correlated and independently predicted fetal macrosomia compared to fasting plasma, two-hour post-glucose load and HBA1c. Also, one hour post glucose load had the highest specificity (97.3%) and highest OR of 11 for predicting macrosomia delivery. However, the highest diagnosis for GDM (16.67%) was using the two-hour post glucose load. **Conclusion:** Our study demonstrated the importance of fasting glucose and one-hour post glucose load in the prediction of fetal macrosomia. However, one-hour post glucose load plasma glucose was the most significant parameter that independently predicted the occurrence of macrosomic birth weight in this study

Keywords: Audit, Macrosomia, Gestational Diabetes Mellitus, Fasting Plasma, One-Hour Post Glucose Load, Two-Hour Post Glucose Load

INTRODUCTION

Gestational Diabetes Mellitus (GDM) remains a major cause of maternal and fetal mortality [1.] It's being linked to both short and long term adverse fetal outcomes. [2-7] These short-term adverse outcomes include neonatal hypoglycemia, birth trauma and macrosomic birth weight amongst others.[2-4] Meanwhile, the long-term adverse outcomes include childhood obesity and risk of type 2 diabetes mellitus.[5-7] One of the major complications of GDM is the delivery of macrosomic baby with its attendant metabolic implications in future years such as childhood obesity and risk of type 2 diabetes mellitus. [5-7]

There are various screening methods employed for GDM. The method used in the screening for GDM is very important. [8] The screening method could be selective or universal screening. For selective screening for GDM, the risk factors for GDM are used to determine whether pregnant women should be screened for GDM or not. [8] Those with risk factors are subjected to either a 75g OGTT or to an initial 50g glucose challenge test, if positive they proceed to 100g OGTT. Meanwhile the universal screening method screens all pregnant women from 24 to 28 weeks gestations irrespective of their risk factors for GDM. [8]

The screening technique with 75g oral glucose tolerance test involves fasting plasma glucose, 1 hour post glucose load and 2-hour post glucose load. While another screening technique involves an initial 50g glucose challenge test, if positive, the patient proceeds to 100g OGTT using fasting plasma glucose, 1 hour post glucose load, 2-hour post glucose load and 3-hour post glucose load. Despite the various screening methods, there are also different diagnostic criteria and glucose thresholds for the diagnosis of GDM. [8]

Glycated hemoglobin is yet to be used as a screening tool for the diagnosis of GDM. Few studies have shown good sensitivity and specificity of glycated hemoglobin for the diagnosis of GDM and good predictive value for birth weight.[9,10] A similar study has demonstrated the use of 75g OGTT screening method in predicting macrosomia. [11] A similar study by N Chastang et al showed 'practical test' which consisted of glucose measurement in the fasting state and two hours after a usual breakfast was superior to 100g OGTT in predicting fetal macrosomia. [12] Yuting Z et al showed fasting blood glucose was positively associated with newborn birthweight compared to ultrasound Fetal Weight Gain (FWG) and Amniotic Fluid Index (AFI). [13] Among the major draw backs of OGTT are multiple prickings for sample collection, fasting state etc.

Using the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study which was conducted using the two hour-75g OGTT. In this study the effect of plasma glucose was measured on the both the maternal and fetal outcomes of pregnancy.[4] The findings in this study led to the diagnostic criteria employed by the International Association of Diabetes and Pregnancy Study Groups (IADPSG).[(4)] This was similarly adopted by the International Federation of Gynecology and Obstetrics (FIGO) guidelines where universal screening of all pregnant women for GDM using a 75g two-hour oral glucose tolerance test (OGTT) was recommended.[14]

The glucose threshold employed for diagnosing DM were the average glucose values at which the odds for birth weight were >90th percentile, cord C-peptide > 90th percentile and neonatal per cent body fat >90th percentile. [4] Due to these changes the prevalence of GDM increased using FIGO guidelines which now varies between 11.1% and 44.3%. [15,16] Wenlin B et al also demonstrated the use of 75g OGTT using the IADPSG criterion to demonstrate the risk of fetal macrosomia. [11] Hence, the huge demand on resources and cost of screening all pregnant women for GDM are enormous especially in resource challenged-settings. Do the benefits of universal screening outweigh the risk of adverse fetomaternal complications? Which screening method is better associated with fetal macrosomia? These are areas yet to be explored especially in resource-challenged settings. The aim of this study was to determine the component of 75g OGTT that predicts fetal macrosomia.

Most studies reported in the literature were mainly on the impact of the diagnosis of GDM and fetomaternal outcomes. [2,17,18] Hence the results of this study will assist the clinicians in predicting macrosomia in resource-challenged settings.

MATERIALS AND METHODS

Ethical Approval

Ethical approval was obtained from Health Research and Ethical Committee of the Lagos University Teaching Hospital (LUTH) with ethical approval number AM/DCST/HREC/APP/862. Written informed consent was obtained from all the participants before the commencement of the study. All the participants were fully informed about the aim of the study and that their personal and baby's information would be treated with strict confidentiality. They were also informed of their freedom to voluntarily withdrawal from the study without their care being compromised. No identifying information was collected from the participants. The study was conducted in accordance with the 1964 Declaration of Helsinki and its amendments.

Research Design: It was a prospective, cross-sectional study.

Study Population and Duration: The population was pregnant women who attended the antenatal clinics of LUTH during the period of September 2016 to May 2017.

Inclusion/Exclusion Criteria

Pregnant women within 24 to 28 weeks of gestation at the time of recruitment and those who gave written informed consent to participate in the study were included in the study. On the other hand, pregnant women with chronic medical conditions such as chronic kidney disease, hemoglobinopathies were excluded from

the study. Women with preexisting Diabetes Mellitus (DM), those on medications that could predispose to dysglycemia for example steroids etc were also excluded. Also, women who did not give informed consent to participate in the study were excluded.

Sample Size

The sample size was determined using a correlational formula for the objective and assuming a significance level of 0.05 in a two-tailed analysis, a moderate effect size (rho=3 according to Cohen) [19] and allowing for 20% attrition rate in view of the prospective nature of the study. A total of 90 pregnant women were recruited for the study.

$N = \{(Z_a + Z_B)/C\}^2 + 3$

Where type 1 error = $a=Z_a=0.05$

$_B = Z_B=0.20$

r or rho = 0.3 (using moderate r)[19]

$C = 0.5^a\text{In}(\{1+0.3\}/\{1-0.3\}$

$N = \{(0.05a +0.20)/C\}^2+3$

N = minimum sample size

Sampling Technique

A simple random sampling method was used to recruit the study participants over a nine months period from the antenatal clinics in LUTH. These pregnant women who met the inclusion criteria were randomly selected and were invited to participate in the study. The women who gave informed consent were enrolled in the study until the desired sample size was achieved.

Data Collection

The study data form was used to collect all the information of the study participants. This information included the sociodemographic, medical and obstetrics history. Women with risk factors for GDM such as previous delivery of macrosomic babies, previous GDM, family history of DM, previous Intrauterine Fetal Death (IUFD) amongst others were recorded. All the pregnant women had 75g OGTT and glycated hemoglobin (HBA1c) done between gestational age of 24 and 28 weeks. They were subsequently classified into the GDM group and Non GDM group based on the outcomes of the result of 75g OGTT. The diagnosis of GDM was based on the International Association of Diabetes in Pregnancy Study Group (IADPSG) using FBS ≥ 5.1mmol/L, one Hour post glucose load ≥ 10.0mmol/L, and two-Hour post glucose load ≥ 8.5mmol/L. Subsequently all the pregnant women were followed up till delivery and the weight of their newborns measured at birth.

Birth weight of the new borns were measured using an electronic baby weighing scale MBC 15K2DM after removal of the diaper with the newborns naked. Two measurements were taken and the average of the two measurement was used as the birth weight of the newborn. The electronic weighing scale was set at zero. The measurement was taken to the nearest grams. Two measurements were taken. However, ,if the measurement differ by at least 10g, a third measurement was done. The average of the two measurements was used unless a third was taken.

Data Analysis

The data generated was entered into Excel work sheet cleaned and analysis was done using Statistical Package for Social Sciences (SPSS) for window version 26. A p value < 0.05 was considered to be statistically significant. The descriptive statistics were presented as mean and standard deviation for normally distributed data. Chi square analysis was used to compare proportions between the groups of pregnant women diagnosed with GDM and those diagnosed without GDM. The 95% confidence interval and p values were used to determine clinical and statistical significances. Multiple linear regression was used to determine independent predictors of birth weight. The sensitivity and specificity of maternal plasma glucose and macrosomia were calculated.

RESULTS

Table 1 shows the sociodemographic characteristics of study participants. The mean age of the pregnant women was 32.6 ± 5.0 years. Women with GDM were 24 while those without GDM were 66 in a study

Table I: Socio-demographic Characteristics of Study Participants

Variable	Number (%)
Age (years)	**N=90**
20-29	19 (21.1)
30-39	66 (73.3)
40-49	5 (5.6)
Total	90 (100.0)
Socioeconomic class	
Upper class	32 (35.6)
Middle class	32 (35.6)
Lower class	26 (28.8)
Total	90 (100.0)

Table 2: Clinical and Biochemical Characteristics of GDM and Non GDM Group

Characteristics		GDM	Non GDM	Total	□	P value
			Number (%)			
Age group (years)						
	20-29	3(3.3)	16(17.8)	19 (21.1)	1.709	0.425
	30-39	20(22.2)	46(51.1)	66(73.3)		
	40-49	1(1.1)	4(4.4)	5(5.6)		
BMI (kg/m^2)	<30	16 (17.8)	60(66.7)	76(84.4)	7.874	0.005
	>30	8(3.7)	6(6.7)	14(15.6)		
			Mean (± SD)		F	CI
	P value					
FBS		4.78(0.72)	4.2(0.78)	0.03	0.20-0.90	0.003
1 Hour post glucose load		9.01(1.67)	6.31(1.46)	0.12	1.91-3.35	0.001
2 Hour post glucose load		8.86(0.88)	5.86(1.0)	1.98	2.54-3.46	0.001

BMI; body mass index, GDM: Gestational Diabetes Mellitus, DM : diabetes mellitus GDM : Gestational diabetes mellitus, IUFD; intrauterine fetal death

Table 3: Correlation between birth weight and the results of Oral Glucose Tolerance Test versus Glycated Hemoglobin

Birth weight versus Maternal variables N=90	Pearson's correlation (r)	P value	95 % C.I
FPG (mmol/L)	0.278	0.007	0.761-0.771
1HPG(mmol/L)	0.424	0.001	0.748- 0.765
2HPG(mmol/L)	0.398	0.001	0.931- 0.941
HBA1C (%)	0.383	0.001	0.012- 0.016

Multiple linear regression between birth weight and the results of oral glucose tolerance versus glycated haemoglobin

BW versus MG N=90	t	P value	95% C.I
FPG	-0.032	0.974	-0.003- 0.564
1HPG	3.262	0.002	0.067-0.174
2HPG	0.192	0.316	0.136- 0.446
HBA1C	2.580	0.011	0.080- 0.618

C.I; confidence interval, FPG; fasting plasma glucose, HBA1C; glycated hemoglobin, 1HPG; one hour plasma glucose; 2HPG; two-hour plasma glucose, MG; maternal glucose, t; t test

Table 4: Maternal Glycaemic Predictors of Macrosomia

	Macro	Normal BW	SN (%)	SP	ACC	PPV	NPV	LR+	LR-	OR
	N=9	**N=75**								
FPG										
≥5.1¥	4	6	44.4	92.0	86.9	40.-0	93.2	-0.49	-0.47	6.64
< 5.1	5	69								
1HPG										
≥10¥	4	2	44.4	97.3	91.7	66.7	93.6	-0.46	-0.45	11.0
<10	5	73								
2HPG										
≥8.5¥	5	7	45.5	90.7	87.0	41.7	94.4	-0.51	-0.49	6.55
< 8.5	4	68								

ACC: accuracy, FPG: Fasting plasma glucose, LR: Likelihood ratio, OR: odds ratio, NPV: negative predictive value, PPV: positive predictive value, SN: sensitivity, SP: specificity, 1HPG: one hour plasma glucose, 2HPG: two-hour plasma glucose.

¥*ADPSG criteria*

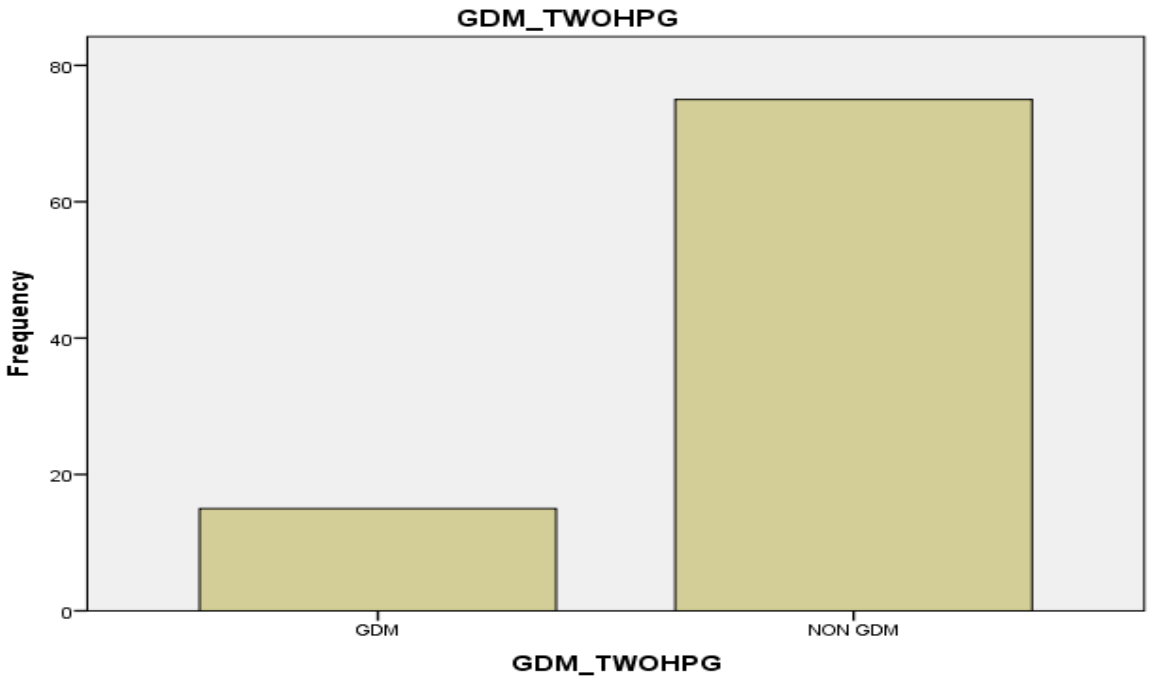

Figure 1 showing the prevalence of Gestational Diabetes Mellitus (GDM) using two-hour post glucose load.

population of 90 pregnant women. The study showed that the prevalence of GDM was 26.7%. The women with GDM had higher fasting plasma glucose, one hour post glucose load and two-hour post glucose values which were statistically significant (table 2).

Using the multiple linear regression, analysis the one-hour plasma glucose and glycated hemoglobin independently predicted birth weight. (table 3). However, one hour plasma glucose was a better predictor of fetal birth weight than glycated hemoglobin. The fasting plasma glucose and two-hour plasma glucose values were not predictive of birth weight.

Table 4 shows the maternal glycaemic predictors of macrosomia. The use of one hour post glucose load values ≥ 10.0mmol/L has the highest specificity (97.3%) and is associated with highest occurrence of macrosomia (OR= 11.0).

Figure 1 shows the incidence of GDM using two-hour post glucose load alone which was 16.67%. In this study using fasting plasma glucose alone 13.33% of the participants were diagnosed with GDM, while one hour post glucose load was 7.78%- and 2-hour post glucose load was 16.67%. Four women (8.7%) had GDM among those without traditional risk factors for GDM.

DISCUSSION

Using 75g OGTT as our screening method, two-hour post glucose load, one hour post glucose load and Fasting plasma glucose showed similar sensitive in the diagnosis of GDM but one hour post glucose load had highest specificity. This is similar to the study by Holt et al where they advocated for one hour post glucose load which was more specific in diagnosis of GDM. [20,21] A similar study by Chukwunyere et al compared fasting plasma glucose and random plasma glucose and demonstrated that FPG has a higher sensitivity and specificity. However, in the same study, the random plasma glucose used was not based on one hour or two post glucose loads.[22]

It is interesting to note that the fasting plasma glucose and post glucose load showed a significant correlation with weight. This is similar to the findings in some studies where fasting glucose correlated with occurrence of the macrosomia .[21,23] However, one hour post glucose load plasma glucose best independently predicted the occurrence of macrosomic birth weight in our study with the highest specificity. This is similar to the findings by Kim et al where one-hour plasma glucose best predicted birth weight. [25] Krstevska et al also demonstrated that fasting plasma glucose and one hour post load glucose from 75g OGTT were the strongest predictors of macrosomia.[26] Meanwhile, Seabra et al showed that women who had macrosomic babies had a higher second and third trimester fasting plasma glucose.[27]

Many of the studies have demonstrated the role of one hour plasma glucose predicting macrosomia compared to fasting plasma glucose as many factors can influence fasting plasma glucose including diet, maternal prepregnancy body mass index, gestational weight gain among others. [27,28]

Findings in our study showed that almost 20% of women with GDM were diagnosed using two-hour post glucose load. Considering the short and long term feto-maternal effects of undiagnosed and poorly managed GDM, universal screening using 75g OGTT is advocated. The American Diabetes Associated, World Health Organization and International Association of Diabetes in Pregnancy Study group guidelines recommend universal one step screening for all pregnant women between 24-28 weeks with or without risk factors for GDM. [4,29]

The role and timing of glycated hemoglobin in the diagnosis of GDM still remains unclear as most guidelines employs 75g OGTT as the gold standard for screening.[30,31] The increased hemoglobin turn over in pregnancy could affect the use of glycated hemoglobin as a monitoring tool for glycemic control in pregnancy.[32,33] Glycated hemoglobin is an irreversible, non-enzymatic reaction between plasma glucose and hemoglobulin in the last two to three months.[30,31] This is affected by many factors ranging from any cause of anemia to hemoglobinopathies in accurately diagnosing diabetes mellitus.[32,33] Hence the proposed use of glycated albumin which is a non-enzymatic reaction between glucose and albumin appears more stable and measures glycemia within a shorter period of one to three weeks compared to glycated hemoglobin of two to three months.[(34)] Some studies have advocated the use of glycated hemoglobin early in pregnancy to predict, monitor and possibly diagnose hyperglycemia first detected in pregnancy while other studies demonstrated its role in predicting birth weight.[35-42] In our study the glycated hemoglobin showed a good correlation with birth weight and this may be an independent tool in screening for the risk of macrosomic delivery. This is similar to the study by Jianing et al which showed glycated hemoglobin is an independent risk of macrosomic delivery, preterm delivery and large for gestation age.[43]

About 9% of women with GDM would have been missed if universal screening was not employed in screening for GDM in this study. Should all pregnant women be subjected to sampling plasma glucose for one hour post glucose load, two-hour post glucose load when 75 g OGTT method is employed? Considering the cost implication of universal screening especially in resource-constraint settings, we advocate from the findings in our study that women should have universal screening using the 75g OGTT screening method.

Strengths and Limitations

The study demonstrates the impact of the screening method used for the diagnosis of GDM on birth weight. Our study provides useful information to clinicians on the preferred screening method for Gestational Diabetes Mellitus in resource challenged settings. The prospective design of the study also represents the main strengths of this study as most studies done in our environment were retrospective in nature. A long-term follow-up study of the macrosomic babies to determine the impact of macrosomia on the newborn's well-being was not done which is a limitation of our study.

CONCLUSION

Our study showed the importance of fasting glucose and one hour post glucose load in the prediction of fetal macrosomia. However, one hour post glucose load plasma glucose was the most significant parameter that independently predicted the occurrence of macrosomic birth weight in this study.

Recommendations

There is a need for a large multi-center-based study to further evaluate the role of the screening method employed on delivery of macrosomic babies and diagnosis of GDM. This can be useful in designing a model for use in low resource settings.

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