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First Trimester Fasting Blood Glucose as a Screening Tool for Diabetes Mellitus in a Teaching Hospital Setting in Nigeria

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Authors' contributions

This work was carried out in collaboration between both authors. Author MA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author TK helped with the analyses of data and contributed towards writing the paper. Both authors read and approved the final manuscript.

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ABSTRACT

Aim: The study sought to ascertain the performance of first trimester fasting blood glucose as a screening tool for diabetes mellitus (gestational or pre-gestational), to justify its introduction as one of the booking blood tests in the first trimester and to determine the association of risk factors with gestational diabetes.
Study Design: This is an observational cross-sectional study.
Place and Duration of Study: The study took place at the University of Port Harcourt Teaching Hospital in Rivers State, Nigeria from June 2016 to January 2017.
Methodology: Venous blood was drawn for fasting blood glucose from 288 consented consecutive maternities attending the antenatal clinic in the first trimester. Demographic, obstetric, medical, social and family history was taken from the patients. Data was collected on excel spread sheet, cleaned and then analyzed with SPSS-19 software.
Results: The prevalence of gestational and overt diabetes was 21.2% and 2.4% respectively. There was no statistical significant difference in the prevalence of diabetes among women of various groups except "parity" where the difference was significant – 5.9%, 15.4%, 30.4% and

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50.0% in nulliparous, Para 1, multiparas and grand multiparas respectively (P = 0.03). There were however tendencies towards higher prevalence in women of age 40-49 years (42.86%), with secondary education (24%), maternal weight of ≥ 80 Kg (25.5%), BMI ≥ 30 (30%) and previous deliveries of babies ≥ 4.0 Kg (39.1%).

Conclusion: The prevalence of gestational diabetes was 21.2% while overt diabetes 2.4% when women were screened in the first trimester with fasting blood glucose. The findings underscore the urgent need for routinely doing fasting blood glucose for patients in the first trimester.

Keywords: First trimester; fasting blood glucose; diabetes; teaching hospital; Nigeria.

1. INTRODUCTION

Gestational diabetes is carbohydrate intolerance resulting in hyperglycemia of variable severity with onset or first recognition during pregnancy [1] but it is not clearly overt diabetes [2]. The diagnostic criteria for hyperglycemia in pregnancy were recommended by the World Health Organization (WHO) in 2013 [1] but unfortunately the WHO 1999 diagnostic criteria are still being used in most hospitals all over the world [3]. GDM is still diagnosed in the late second or early third trimester because its diagnostic difficulties still exist in the first trimester [4]. The diagnostic level of fasting blood Glucose ≥ 7.0 mmol/l is universally considered to be too high.

GDM is associated not only with adverse maternal and perinatal outcomes, such as large-for-date babies, shoulder dystocia, operative delivery, birth injury, preeclampsia, hemorrhage and preterm delivery [5–7], but also with a sevenfold higher risk of the mother developing type 2 diabetes mellitus (T2DM) after pregnancy [8]. In addition, the maternal metabolic milieu has been identified as a key determinant for susceptibility to obesity, metabolic syndrome and type 2 diabetes mellitus in the offspring [9].

The increasing number of women with undiagnosed type 2 diabetes mellitus (T2DM) in pregnancy has led to the recommendation of screening women with risk factors for preexisting diabetes at the first antenatal visit. The urgent need for introduction of diagnostic test in the first trimester has been intensified because we now know that most of the complications of GDM can be prevented if they are diagnosed in the first trimester and treatment initiated immediately. This is particularly so for low-income region of sub-Saharan Africa where Type II diabetes and GDM are becoming epidemic.

Some have proposed that an early oral glucose tolerant test OGTT combined with maternal history, maternal demographic features together with promising new biomarkers such as glycosylated fibronectin (glyFn) can diagnose GDM in the first trimester. A study protocol for international European collaboration in 2016 used oral glucose tolerant test and glycosylated fibronectin as screening tools for gestational diabetes at 12-15 weeks [10].

In 2008, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) sponsored an International Workshop-Conference on Gestational Diabetes Diagnosis and Classification, to review results of the 'Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study and other studies which examined associations of maternal glycaemia and perinatal and long-term outcomes in the offspring [6,11]. On the basis of the IADPSG recommendations, the WHO gave its recommendation for diagnosis of GDM [1,12].

The WHO recommendations are as follows: hyperglycemia first detected at any time during pregnancy should be classified as either diabetes mellitus in pregnancy or gestational diabetes mellitus (GDM). T-he diagnosis of GDM at any time during pregnancy should be based on any one of the following values: fasting plasma glucose = 5.1-6.9 mmol/l (92 -125 mg/dl), 1-h post 75 g oral glucose load ≥10.0 mmol/l (180 mg/dl), 2-h post 75 g oral glucose load 8.5 – 11.0 mmol/l (153-199 mg/dl) [12]. These cut-offs represent the average glucose values at which odds for birth weight > 90th percentile, cord C-peptide > 90th percentile, and neonatal percent body fat >90th percentile reached 1.75 times the estimated odds of these outcomes at the mean glucose values, based on fully adjusted logistic regression models [6].

The WHO criteria for diagnosis of diabetes in pregnancy which were based on the HAPO study and the IADPSG review resulted in a considerable increase in GDM prevalence of 17.8%, a detection rate of 83% for adverse

outcome and a positive predictive value of 16% [11]. One recent prevalent study in Nigeria gave prevalence of 21.5% and 16.2% using the IADPSG and the WHO criteria respectively [13]. What is common about all these studies is that the OGTT was performed at 24 to 32 weeks of pregnancy.

Other studies that diagnosed GDM using the OGTT and assessed the risk factors and complications of GDM in respective tertiary institutions in Nigeria gave lower prevalent levels of GDM - 0.69% [14] and 0.30% [15] respectively. These studies were retrospective and the 1999 WHO diagnostic criteria were used. The most recent prospective study in the same hospital that used the most recent WHO criteria with specimen collected in the third trimester of pregnancy or OGTT gave a high prevalence of 15.2% [16].

Two studies used the WHO 1999 criteria (after OGTT at 24-28 weeks) for patients who screened positive for gestational diabetes with 1-hour 50g glucose load. The prevalence of gestational diabetes in both studies was 8.3% [17] and 7.7% [18] respectively. In three other studies that used fasting or random blood glucose, the prevalence stood at 2.2%, 6.2% and 1.13% respectively [19–21]. Again, what is common about all these studies is that the patients were assessed in the late second and the third trimester of pregnancy.

The perceived prevalence of gestational diabetes in Nigeria was 1.13- 21.5% [22]. Common with all the studies is the fact that they were all performed from 24 to 32 weeks of pregnancy. The most recent WHO criteria for diagnosis of gestational diabetes have not been adopted in the country. Unfortunately elective screening for type II diabetes in the general population is not performed in Nigeria despite the fact diabetes is becoming epidemic in the country; worse still, women do not go for pre-pregnancy check-up. We therefore hypothesize that first trimester diagnostic test, in this case, fasting blood glucose with the use the 2013 WHO criteria should be able to identify significant number of patients with diabetes which may either be gestational or pre-gestational.

We have chosen only fasting blood glucose and not OGTT because of four reasons, the first is financial constraint, second is its simplicity, third - the ease of achieving informed consent, fourth – the urgent need for its introduction into clinical practice. Upon this we have planned to do the OGTT and glycosylated hemoglobin not in our tertiary center but as a multicenter community-based study which will be more representative of the true burden of the disease. The glycosylated hemoglobin will differentiate between current new disease (gestational diabetes) and preexisting diabetes.

The primary aim of the study was therefore to ascertain the performance of first trimester fasting blood glucose as a screening tool for diabetes mellitus (gestational or pre-gestational) and to justify the need for its introduction as one of the booking blood tests in the first trimester at the University of Port Harcourt Teaching hospital UPTH. The secondary goal was to determine the association of risk factors with gestational diabetes.

2. MATERIALS AND METHODS

2.1 Sample Size Determination

The most recent prospective study at the University of Port Harcourt Teaching Hospital in 2014 used the current WHO criteria for gestational diabetes mellitus (GDM) at 24-28 weeks of pregnancy. The prevalence of GDM in that study was 15.2% [16]. We used the result to calculate the sample size for our study. The sample size of 198 was calculated using sample size formula for cross-sectional study with a prevalence of 15.2%, precision of 5%, and standard normal deviation of 1.96 at 95% confidence intervals.

$$n = Z^2 \times PQ / d^2$$

Where,

n = sample size
Z = the proportion of normal distribution corresponding to the required significance level (5%) which is 1.96
P = the prevalence of gestational diabetes in pregnancy in the previous study in 2014 [16]
Q = (1.00 – P)
D = How close to the previous reported prevalence, the prevalence for the current study is desired to be (0.05).

$$n = 1.96^2 \times 0.152 \times 1- 0.152 / 0.05^2 = 3.8416 \times 0.152 \times 0.848 / 0.0025= 0.5839 \times 339.2 = 198.06 = 198$$

If the attrition rate was considered to be 10%, the study sample size of 218 (198+20) was

calculated. Although the sample size was determined to be 218, we collected venous blood samples for fasting blood glucose from 288 patients considering the peculiarities and the difficulties in collecting complete data in sub-Sahara Africa.

2.2 Setting

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2.3 Design

This is a prospective cross-sectional study.

2.4 Procedure

The study population included all pregnant women attending the antenatal clinics in the first trimester of pregnancy up till 14 weeks. All consecutive women that attended the clinic were counseled about the research project and verbal consent was obtained. The exclusion criteria were pregnant women with physical disabilities such as deafness and dumbness, critically ill patients, as well as those with a history of ongoing mental illness/retardation (because of the difficulties associated with taking history from the patients), an uncertain date of last menstrual period and no ultrasonographic estimation of gestational age between 11-14 weeks of gestational age, conception by means of gonadotropin ovulation induction or in vitro fertilization and a known diabetic.

Maternities that do not fully understand English language were provided with interpreters. Out of the 305 patients that were counseled about the study, 288 consented to partake in it while 17 declined. Data collection was conducted from June 2016 to January 2017. Demographic, obstetric, medical, social and family history was taken from the patients. Those that consented to the study were fasted for at least 12 hours and then venous blood was taken from their arm into the fluoride oxalate tube (to prevent glycolysis) and assayed immediately for glucose levels. The whole blood was centrifuged at 2000 revolutions per minute for ten minutes in other to separate plasma from other blood components. Glucose level was then determined from the plasma spectrophotometrically using glucose oxidase method with Randox kit.

2.5 Statistical Analysis

The collected data was entered and stored in a password-protected computer and analyzed with the SPSS-19 software. Data was collected on excel spread sheet, cleaned and then uploaded unto the SPSS-19 for analysis. Simple proportions were used in the descriptive analysis. Bivariate analysis was also carried out. Comparison of related variables was conducted, using the Chi-square (X^2) and the P-values. When the P-value was less than 0.05, the difference between two variables was said to be statistically significant. When an expected count was lower than 5 in a cell, Fisher Exact test was used.

3. RESULTS

Data on the demographic, social and obstetric characteristics of the patients were shown in Table 1. Out of the 288 patients that had their fasting blood glucose checked, demographic characteristics were available for 160 of them. The mean age of the patients was 31.18 ± 4.7years. There were 56 (35%) women between 20 and 29 years of age, 97 (60.63%) from 30-39 years and 7 patients (4.38%) at 40 years and above.

All the data were not available for each of the demographic characteristics because either the answer to a question was not clear some of the patients did not know the answers to given questions. Therefore the total for each of the characteristics in a group did not correspond to the total number of patients that were sampled. A hundred and nineteen patients (75.32%) were employed while 19 (12.03%) were unemployed and 20 (12.66%) were students. Data on educational qualifications was available for 137 patients; 110 (80.29%) had tertiary education, 18 (18.25%) – secondary while 2 (1.46%) had primary education. Out of the 145 women who had data for their weight at booking, 90 (62.07%) were less than 80 kg while 55 (37.93%) were above that threshold. 80 kg was chosen empirically with a view of determining any hidden association between increased weights (greater than 80 kg) and gestational diabetes; in our hospital, we have seen many cases of GDM at maternal weights of 80kg and more at booking. Seventy one (63.9%) patients had BMI below 30 while 40 (36.0%) of the total 111 had BMI of more than 30.

Table 1. Demographic, obstetric and general characteristics

Demographic obstetric and general characteristics		Frequency	Percentage %
Age group (yrs.)	20-29	56	35.0
	30-39	97	60.6
	40-49	7	4.4
	Total	160	100.0
Employment status	Employed	119	75.3
	Unemployed	19	12.0
	Student	20	12.7
	Total	158	100.0
Educational qualification	Primary	2	1.5
	Secondary	25	18.3
	Tertiary	110	80.3
	Total	137	100.0
Weight (kg)	< 80	90	62.1
	80 and above	55	37.9
	Total	145	100.0
BMI	< 30	71	64.0
	30 and above	40	36.0
	Total	111	100.0
	Primigravida	17	14.7
Parity	Para 1	39	33.6
	Multipara. Para 2– 4.	56	48.3
	Grand Multipara Para 5 and more	4	3.4
	Total	116	100
FBG (mmol/L)	< 5.1	220	76.4
	≥ 5.1	68	23.6
	Total	288	100.0
	5.1 – 6.9	61	21.2
	≥ 7	7	2.4
	Total	68	100.0
Prev. 2nd trimester m/c		6	
Previous PTD		19	
Previous Stillbirth		7	

Data on parity was available for 116 of the patients. Seventeen (14.66%) were nulliparas or primigravida, 39 (33.62%) were Para 1, 56 (48.23%) and 4 (3.45%) were grand multiparas. Data on the mode of previous deliveries was available for only 32 of the patients; 6 of them had previous second trimester miscarriage, 19 – previous preterm labor while 7 had stillbirth in the past.

It is important to note that out of the 288 patients who had fasting blood glucose test in the first trimester of pregnancy up until 14 weeks of pregnancy, 220 (76.39%) had levels of glucose less than 5.1 mmol/l, 68 (23.61%) of them had levels of 5.1mmol/l and above, 61(21.2%) - 5.1-6.9 mmol/l and 7 Patients had levels 7mmol/l and above.

We went on to conduct intergroup comparison for the risk of developing gestation diabetes in the first trimester of pregnancy. The groups under consideration were as indicated in Table 2 and they included the following: age group, employment, educational qualification, weight, body mass index (BMI), parity and previous fetal weight. Analysis showed that the risk of a patient being diagnosed with diabetes mellitus in the first trimester increases with maternal age, with the highest prevalence at the extreme of reproductive age 40-49 years of age. Three (3) out of 7 patients in that age group had blood glucose 5 mmol/l and more.

Regarding the level of educational qualification, there was no statistical significant difference in the prevalence of diabetes in women with

Table 2. Intergroup comparison for the risk of fasting blood glucose ≥ 5.1 (GDM)

Demographic, obstetric and general variables		FBG ≥ 5.1		Total	X^2	P-Value
		Yes	No			
		Frequency (%)	Frequency (%)			
Age group	20-29	10 (17.86%)	46 (82.14%)	56		
	30-39	24 (24.74%)	73 (75.26%)	97		0.254
	40-49	3(42.86%)	4 (57.14%)	7		
	Total	37	123	160		
Level of education	Primary	0	2 (100%)	2		1.000
	Secondary	6 (24.00%)	19 (76.00%)	25		
	Tertiary	25 (22.73%)	85 (77.27%)	110		
	Total	31	106	137		
Weight group.	< 80 Kg	18 (20.00%)	72 (80.00%)	90		
	≥ 80 Kg	14(25.45%)	41(74.55%)	55	0.316	0.574
	Total	32	113	145		
BMI	< 30	14 (19.72%)	57 (80.28%)	71	1.805	0.179
	≥ 30	12 (30.00%)	28 (70.00%)	40		
	Total	26	85	111		
Gravidity Parity	Primigravida (P0)	1 (5.88)	16 (94.12)	17		
	Primipara (P1)	6 (15.38%)	33 (84.62%)	39		
	Multipara (P2-4)	17 (30.36%)	39 (69.64%)	56		0.030
	Grand multipara (P5 and more)	2 (50.00%)	2 (50.00%)	4		
	Total	26	90	116		
Prev Fetal weight	< 4.0Kg	12 (17.14%)	58(82.86%)	70		0.087
	4.0 to <4.5Kg	3 (33.33%)	6 (66.67%)	9		
	≥ 4.5 Kg	6 (42.86%)	8 (57.14%)	14		
	Total	22	71	93		
Prev Fetal weight	< 4.0Kg	12 (17.14%)	58(82.86%)	70	3.612	0.057
	≥ 4.0 Kg	9 (39.13%)	14 (88.57%)	23		
	Total	22	71	93		

secondary and tertiary levels of education; none of the two patients with primary educational qualification had fasting blood glucose of 5.1 mmol/l or more (Table 2). The intergroup analysis of the weights of the study population showed that there was some difference between the prevalence of fasting blood glucose of 5.1 and more (FBG ≥ 5.1) in those less than 80 Kg and those who are 80 Kg and more with the later predominating (X^2 = 0.318; *P = 0.57*) but the difference was not statistically significant. Regarding the available data on the BMI of the study population, although there was tendency towards higher prevalence in those with BMI ≥ 30, it was not statistically significant.

The correlation of parity with the prevalence of FBG ≥ 5.1 was equally interesting (Table 2). The more the parity, the more the prevalence of diabetes and this disparity was statistically significant (*P = 0.03*). There were also some differences between the prevalence of FBG ≥ 5.1 in women with previous fetal weight < 4 Kg and those with previous weight ≥ 4 Kg (X^2 = 3.612; *P = 0.06*) with the prevalence for the later higher but not statistically significant (Table 2).

4. DISCUSSION

The study sought to ascertain the performance of first trimester fasting blood glucose as a screening tool for diabetes mellitus (gestational or pre-gestational), to justify the need for its introduction as a booking blood tests in the first trimester and to determine the association of risk factors with gestational diabetes.

The most striking finding of the study was the prevalence of gestational diabetes of 21.2% in the first trimester and that of overt diabetes of 2.4% in the same trimester. Both results were based on 2016 WHO classification of diabetes in pregnancy and the International Federation of Gynaecology and Obstetrics (FIGO) Initiative on gestational diabetes mellituscut off levels of 5.1-6.9 mmol/l for GDM while levels equals and more

than 7 mmol/l for overt diabetes respectively [1,2].

The results of the fasting blood glucose were conveyed to our patients and their respective consultants in the Teaching Hospital. Unfortunately, we did not have enough data on the follow-up management of these patients due to incessant strikes and closure of our hospital. With targeted early intervention, complications can be minimized.

One caveat that is worth noting is the fact that the IADPSG review of the HAPO study showed that FPG alone identified 8.3% of the cohort as having GDM. Adding measurement of the 1-h plasma glucose identified an additional 5.7%; adding the 2-h plasma glucose measurement identified another 2.1% of the cohort and 1.7% was overt diabetes [2,6,11].Thus, by these new criteria, the total incidence of GDM was 17.8%; the FPG plus 1-h plasma glucose levels identified a large majority of these individuals.

The results of the study therefore raise a lot of questions. Why is it that only fasting blood glucose in our study gave a prevalence of GDM of 21.2% and that of overt diabetes of 2.4% while OGTT gave GDM prevalence of 17.8% in the IADPSG review? If the HAPO study were carried out in Nigeria, would it have given a higher rate of GDM prevalence than 17.8%? Are there epidemics of diabetes in Nigeria? Is the result an overestimation of what the actual prevalence is? What is the reason for the high prevalence of diabetes? Is it genetic in nature, nutritional peculiarities (more of carbohydrates) or perpetual environmental degradation in the Niger Delta area of Nigeria where this study was carried out? These and many other questions are left unanswered, intensifying the need and urgency of further research. A universal coverage of maternity population with OGTT is not possible at the moment in sub-Sahara Africa due to financial constraints; it is not even done in many European countries even if it is recommended. So introduction of FBG as a screening test should be a welcome development.

Another important issue with the prevalence of gestational diabetes in the present study is the fact that when compared with the values in previous studies from the same University Teaching Hospital, the present value is far higher. Some of the studies were those by C.O. John et al. [14] F. and S. Wokoma et al. [15], which gave prevalence of 0.69% and 2.98% respectively. Both studies were retrospective. The most recent study that was carried out in 2015 used the 2013 WHO criteria for diagnosis of gestational diabetes and it gave a prevalence of 15.2% [16]. These findings also raise some questions. Is the low prevalence of diabetes in the studies due to the fact that they were carried out retrospectively? Can it be that the low level of fasting blood glucose that is used in the WHO recommendation is leading to over-diagnosis of the disease?

The secondary goal of this study was to confirm the risk factors or associations of gestational diabetes.

The HAPO study demonstrated that the association between gestational diabetes, adverse pregnancy outcomes and glycaemic levels is independent of other risk factors such as age, body mass index and weight gain during pregnancy. So each of the known risk factors can independently affect the prevalence of GDM. They can therefore form a part of future algorithm that can be used for diagnose GDM.

Our study also showed that there was no statistical significant difference in the prevalence of diabetes among women of various demographic, obstetric and general groups except parity where the difference was significant – 15.9% and 15.4% in nullipara and Para 1 respectively and 30.6% in Para 2 and more ($P = 0.03$). There were however tendencies towards higher prevalence in women of age 40-49 years (42.9%), with secondary education (24%), maternal weight of ≥ 80 Kg (25.45%), BMI ≥ 30 (30%) and previous baby's weight at birth of ≥ 4 Kg (39.1%).

5. LIMITATIONS

The main limitation of the study is the fact that OGTT was not performed. It probably would have increased the prevalence of gestational diabetes in the first trimester. Furthermore, although fasting blood glucose can be used to differentiate between GDM and overt diabetes, this differentiation would have been better if glycosylated hemoglobin levels were also done. Furthermore, the study was based in a tertiary center and may not therefore represent the true picture of gestational diabetes in remote communities of the Niger Delta. Also we did not have enough number of patients to illustrate some of the associations with gestational diabetes.

6. RECOMMENDATION

The results and the limitations of the study had thrown light unto many questions, which should stimulate future research projects in the same subject – diagnosis of diabetes in the first trimester of pregnancy. Furthermore, the results of the study have underscored the need for introduction of fasting blood glucose as a must-do blood test in the first trimester of pregnancy for every woman.

7. CONCLUSION

The study clearly demonstrated a very high first trimester prevalence of GDM of 21.2% and overt diabetes of 2.4%, using FBG as a screening tool. It therefore unveiled the possible risk that fetuses face in early pregnancy and therefore the need to introduce fasting blood glucose as a routine test in the first trimester. The study also confirmed some of the factors that are associated with high prevalence of GDM in pregnancy.

CONSENT

All authors declare that written informed consent was obtained from the participants.

ETHICAL APPROVAL

This study proposal was presented before the University of Port Harcourt ethical committee and was approved in June 2016. Participants had the right to accept or decline request to participate in the study and they were reassured that their decision would not affect their care. Written informed consent was obtained from the participants and their confidentiality was preserved.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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