

Glycated Haemoglobin Concentration correlation to Fasting Blood Glucose values of pregnant women in Port Harcourt Metropolis, Rivers State, Nigeria



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ABSTRACT

Background and Aim: *Gestational diabetes mellitus (GDM) is hyperglycaemia in pregnancy. Although HbA1c may be a better screening tool for GDM, its availability and accessibility is poor due to high cost compared to fasting blood glucose. The aim of this study was to determine the HbA1c concentration correlation to FBG values of pregnant women attending antenatal clinic in selected private hospitals in Port-Harcourt Metropolis, Rivers State, Nigeria. Materials and Methods:* *A Laboratory based descriptive cross-sectional study design was used with participants recruited using a convenience sampling technique. An ichroma machine for analysis of HbA1c data and*

a photocolorimetre for analysis of FBG data were used. Descriptive and inferential statistical were performed and significance level was set at ≤ 0.05 . Results: A total of 113 pregnant women were studied with a mean age of 32.38 ± 5.40 years. Prevalence of GDM with HbA1c was 5.3% while FBG was 6.2%. Socio-demographic (Age) and obstetric factors (Gravidity and Parity) were identified as risk factors for GDM. There was a strong linear positive correlation between participant's HbA1c concentration and FBG values ($r=0.775$). Conclusion and Recommendations: The HbA1c and FBG levels of participants in this study were found to be strongly correlated. It is therefore recommended that in facilities where HbA1c is not available, the regression equation formulated in this study can be used for inter-conversion of values between HbA1c and FBG. Additionally, there is the need to closely monitor the blood glucose level of pregnant women who are ≥ 40 years, multi-gravida and multi-para.

Keywords: Glycated haemoglobin, fasting blood glucose, pregnant women, Port-Harcourt.

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is one of the leading causes of maternal and infant mortality and morbidity (Ma et al., 2013). GDM is a condition in which a woman without diabetes develops high blood sugar levels during pregnancy which is associated with adverse obstetric and perinatal outcomes (Yu et al., 2014). GDM has become a public health burden and pregnant women with GDM are at a risk of developing gestational hypertension, pre-eclampsia, and having operative deliveries. Some babies born to GDM women are at risk of being big and may suffer some congenital anomalies, develop neonatal hyperglycaemia and even Type 2 DM later in life (Yu et al., 2014). Globally, about 15% of pregnant women are affected with GDM, about 87% of these women are found in low and middle-income countries (Mahtab & Bhowmk, 2016). In Africa, the prevalence of GDM was 13.61% (Niroomand et al., 2019). Studies in Nigeria showed an overall prevalence of gestational diabetes as 13.4% among pregnant women with unidentified risk factors (Nwaokoro et al., 2014)

while in Rivers State, the prevalence of gestational and overt diabetes was 21.2% and 2.4% respectively (Abbey & Kasso, 2018).

Fasting Blood Glucose (FBG) is a predictive index for GDM, It is easy to administer, inexpensive and reproducible (Mendez-Figueroa et al., 2014). Studies have shown that FBG can be used to predict risk for GDM (Hinkle et al., 2018). However, the value of FBG for GDM screening remains uncertain. Glycated haemoglobin (HbA1c) is a form of haemoglobin that is chemically linked to a sugar and can maintain in the whole lifespan

(120 days) of red blood cells, and shows the average level of blood glucose for the past three months (Yu et al., 2014). HbA1c has also been widely accepted as an indicator used to evaluate the blood glucose control in diabetes mellitus (DM) patients (Al-Rowaily et al., 2010). However, evidence on the application of HbA1c in the screening/diagnosis of GDM is very poor (Yu et al., 2014). HbA1c and FBG are screening tools for detection of GDM. FBG is cheap, available and it is faced with issues pertaining long fasting for at least 8 hours and shows the level of blood glucose at the time of testing, HbA1c does not entail fasting and shows the average level of glucose in blood for the past three months which is an added advantage over FBG tests, but its availability and accessibility is low due to high cost. The aim of this study was thus to determine the glycated haemoglobin concentration correlation in relation to fasting blood glucose values among pregnant women attending ANC in private hospitals. This was necessary in order to bridge the knowledge gap in this field of study, to identify more convenient method of GDM detection, as well as provide an alternative for addressing issues related to unavailability/inaccessibility of HbA1c testing which is essential for early glycaemic control.

MATERIALS AND METHODS

A laboratory based descriptive, cross sectional study design was employed for this study. The study was conducted among 113 pregnant women, aged between 15 and 49 years attending the antenatal clinics of four selected private hospitals in Port Harcourt Metropolis. Inclusion criteria for this study included all pregnant women attending antenatal clinics in the selected four private hospitals, with no known history of diabetes mellitus as well as pregnant women who came for the ante-natal clinics fasting. Those with a known history of haemoglobinopathies e.g. anaemia were excluded from the study. A sample size of 113 was calculated using the formula $n = Z\alpha^2pq/d^2$ (Lwanga & Lemeshow, 1991). Convenience sampling method was employed in the selection of participants for this study. Participants' socio-demographic (age) and obstetric characteristics (Gravidity and Parity) were collected after due permission had been sought from the authorities. The selected hospitals were visited earlier and the study participants informed about the research and encouraged them to come fasting for their next antenatal care clinic (ANC). Blood samples were collected from consenting participants between 7:00 am and 9:00 am while they were still in the fasting state in the phlebotomy room of the laboratory. A 5ml syringe and needle were used to withdraw blood from the median cubital vein in the cubital fossa and was dispensed into coded sample bottles. Two mls of the blood sample was dispensed into fluoride oxalate tube for analysis of fasting blood glucose using the enzymatic approach (Wiener, 2000). Another 2mls was dispensed into an ethylene diamine tetra-acetic acid (EDTA) tube for analysis of glycated haemoglobin using the fluorescence immunoassay method (Gupta et al., 2017). Collected blood samples were pooled and

stored in a sample box carrier (Synlab) at a temperature of 2 to 80c and transported to the reference laboratory for analysis. Ethical approval to carry out this study was obtained from the Research and Ethics Committee of the University of Port Harcourt. Permission was also sought from the Medical Directors of the selected hospitals. Informed consent was obtained from subjects and blood samples were collected in the phlebotomy room of the laboratories to ensure privacy. No harm came to any of the study participants by ensuring infection control practices. Sample bottles were coded and no unique identifier of the participants was collected in order to ensure confidentiality of their laboratory results. Collected data was coded and entered into the Microsoft Excel software (version 2010) and then exported to the Statistical Package for Social Sciences (SPSS version 20.0, IBM, Armonk, New York, United States of America). FBG & HbA1C values were tested for normality using the Anderson-Darling (AD) test, Jarque-Bera (JB) test and Shapiro-Wilk (W) test. Descriptive statistical operations were performed and categorical data were presented as frequencies and percentages while continuous data were presented as means and standard deviations. Inferential statistical analysis involved the use of the chi-square (χ^2) test for comparison of proportions, student t-test for difference in two means and analysis of variance (ANOVA) for difference in three means. Bivariate logistic regression was used to assess odds of association in selected variables and Pearson's correlation coefficient in assessing association for two continuous variables. A p-value of ≤ 0.05 was considered statistically significant. GDM diagnosis was made using the World Health Organization's diagnostic criteria. GDM was present if fasting blood glucose was ≥ 7.0 mmol/L and HbA1c $\geq 6.5\%$

RESULTS

Socio-Demographic and obstetric characteristics of participants.

In this study, those within the age range 30-39 years had the highest proportion of 65.49%, followed by those within the age range 20-29 years, with 27.43%. The least were those 40-49 years with 7.08%. Participants' mean age was 32.38

Table 1: Socio-demographic (age) and Obstetric factors (gravidity and parity) of participants

Characteristics	Frequency (n=113)
Age (Years)	31

20-29	
30-39	74
40-49	8
Mean age: 32.38 ± 5.40 years	
Gravidity	
	26
1	
	51
2	
3+	36
Mean gravidity: 2.30 ± 1.11	
Parity	35
0	43
1	
	15
2	
	20
3+	

Mean parity: 1.22 ± 1.16

- 5.40 years. The mean number of pregnancies (gravidity) of participants was 2.30 ± 1.11 , with 51 (45.13%) women having 2 pregnancies followed by 36 women that have had 3 or more pregnancies (31.86%) in the past. The least were those with only one pregnancy (23.01%). Furthermore, mean number of deliveries (parity) of participants was 1.22
- 1.16, with 38.05% of the women having only one delivery, followed by 30.97% for those with no delivery. Those with 2 children and 3 or more were 13.27% and 17.71% respectively. This data is shown in Table 1.

Prevalence of GDM

Table 2 shows that only 6 (5.31%) of the pregnant women had HbA1c levels of $\geq 6.5\%$ indicating GDM while 107 (94.69%) of them had values within the range of 4 – 6.4% which is non-GDM. The table additionally shows that mean glycated haemoglobin of participants was $4.92 \pm 0.66\%$. The prevalence of GDM from HbA1c parameters was therefore found to be 5.3%. Also, the mean Fasting Blood Glucose level of the participants was $4.78 \pm 0.77\text{mmol/L}$, with 106 (93.81%) of the women being Non-GDM, and 7 (6.19%) women having FBG level $\geq 7.0\text{ mmol/L}$, thus giving a prevalence of Gestational Diabetes Mellitus of 6.2%.

Table 2: Glycated Haemoglobin (HbA1c) and Fasting Blood Glucose (FBG) values of study participants

Variable	GDM	Non GDM
	($\geq 6.5\%$ or	(4 – 6.4% or
	$\geq 7.0\text{mmol/L}$)	$< 7.0\text{mmol/L}$)
	Freq (%)	Freq (%)
HBA1C	6 (5.31)	107 (94.69)
FBG	7 (6.19)	106 (93.81)

Association between FBG and HbA1c values

A statistically significant association was found to exist between the participants' glycated haemoglobin (HbA1c) and fasting blood glucose (FBG) values ($p=0.000$). From Table 3, 106 (93.81%) of the pregnant women were classified as non-GDM by both HbA1c and FBG. Similarly, 6 (5.31%) women were categorized as GDM cases by the two screening tools with only one (0.88%) woman that was classified as GDM by FBG which the HbA1c classified as non-GDM. Also, a statistically significant strong linear positive correlation was found between the participants' glycated haemoglobin (HbA1c) and fasting blood glucose (FBG) values. ($r=0.775$; $p=0.001$).

Table 3: Association between FBG and HbA1c among participants

FBG

	NON-GDM	GDM
	(<7.0mmol/L)	(≥7.0mmol/L)
	Freq (%)	Freq (%)
HbA1c	106 (99.07)	1(0.93)
NON-GDM (4-6.4%)		
GDM (≥6.5%)	0 (0.00)	6
Total	106 (93.81)	7
	Pearson's correlation coefficient (r)	
HbA1c vs. FBG	0.775	

Formulating a regression equation.

Assessment of the FBG & HbA1C levels for normality using the Anderson-Darling (AD) test, Jarque-Bera (JB) test and Shapiro-Wilk (W) test revealed a significant ($p = ? 0.05$) normal

distribution with values 5.442, 118.8 and 0.835 respectively for FBG, while for HbA1C the values were 3.935, 83.42 and 0.866 respectively. The assumption for regression analysis is not violated since the normality test is significant; it was therefore appropriate to determine the predictive relationship between FBG and HbA1C. From Fig 1, “Y” the dependent variable was the HbA1c levels while the independent variable was “X” which is FBG; “a” the

intercept on the “Y-axis was 1.716, while the slope “b” was 0.67. The regression equation to predict the value of HbA1c from a given value of FBG is therefore: $Y = 1.716 + 0.670X$.

Association between socio-demographic and obstetric factors with GDM

Assessment of the associations with the occurrence of GDM diagnosed using Glycated Haemoglobin (HbA1c) showed a statistically significant relationship between age and GDM. The proportion of participants with GDM increased with increasing age: 2.86% for those who are ≤ 39 years compared to 37.5% for those that are ≥ 40 years of age ($p = 0.000$). Additionally, logistic regression shows that participants who are ≥ 40 years are about 20.4 times more likely to have GDM compared to those who are younger (OR: 20.4; 95% CI: 0.01-0.49). Also a statistically significant association was found to exist between the number of pregnancies and the GDM status of the participants diagnosed using their HbA1c levels. The proportion of pregnant women with HbA1c level of $\geq 6.5\%$

increased with increasing number of pregnancies: 1.3% for those with ≥ 2 pregnancies compared to 13.89% for those with ≥ 3 pregnancies ($p = 0.005$). Logistic regression shows that participants with ≥ 3 pregnancies are about 12 times more likely to have HbA1c value of $\geq 6.5\%$ compared with those with ≥ 2 pregnancies (OR: 12.26; 95% CI: 1.27-587.13). Finally, a statistically significant relationship was found to exist between parity and HbA1c levels. Those who have had one or less previous delivery had a lower proportion for GDM (1.28%) compared to those with two or more previous deliveries (14.29%) and the difference was significant ($p = 0.02$). Logistic regression shows that those with two or more previous deliveries are almost 13 times more likely to have GDM compared to those with one or no previous delivery (OR:12.83; 95% CI: 1.43-114.45). These are shown on Table 4.

Table 4: Association between socio-demographic and obstetric factors with GDM diagnosed using Glycated Haemoglobin (HbA1c)

	HbA1c		Total

	GDM		NON-GDM	
	(≥6.5%)		(4 – 6.4%)	
	Freq (%)		Freq (%)	
Age				
≤39	3	(2.86)	102 (97.14)	105(100)
≥40	3	(37.50)	5 (62.50)	8 (100)
Total	6	(5.31)	107 (94.69)	113(100)
Number of				
Pregnancies				
≤2	1	(1.30)	76 (98.70)	77(100.0)
≥3	5	(13.89)	31 (86.11)	36(100.0)
Total	6(5.31)		107(94.69)	113(100)
Parity				
≤1	1	(1.28)	77 (98.72)	78(100.0)
≥2	5	(14.29)	30 (85.71)	35(100.0)

Total	6(5.31)	107(94.69)	113(100)

Assessment of the associations with the occurrence of GDM diagnosed using Fasting Blood Glucose (FBG) showed a statistically significant association between age and FBG level. The proportion of participants with GDM increased with increasing age; 3.81% for those who are ≤ 39 years of age compared with 37.50% for those who are ≥ 40 years of age ($p=0.000$). Also bivariate logistic regression shows that those who are ≥ 40 years of age are about 15 times at odds of having GDM compared to those who are younger (OR: 15.15; 95% CI: 0.01 – 0.60). Also, a statistically significant association was found between the number of pregnancies and the occurrence of GDM. Participants who have been pregnant three or more times have a higher proportion of GDM (16.67%) compared to those with two or less pregnancies (1.30%) with $p = 0.002$.

Logistic regression indicated that women who have had three or more pregnancies are about 15 times more likely to have FBG level of ≥ 7.0 mmol/L compared to those with two or less number of pregnancies (OR: 15.20; 95% CI: 0.00 to 0.59). Finally, a statistically significant association was found to exist between parity and GDM using the FBG values. The table shows that the ante-natal women who are para ≥ 2 have a higher proportion of those with GDM (17.14%) compared to those who are para ≤ 1 (1.28%) and the difference is statistically significant ($p \leq 0.05$). Logistic regression also shows that those who are para ≥ 2 are almost 16 times at odds of having GDM compared to those that are para ≤ 1 (OR= 15.93; 95% CI: 0.00-0.57). This data is shown on Table 5.

Table 5: Association between socio-demographic and obstetric factors with GDM diagnosed using Fasting Blood Glucose (FBG)

	HbA1c			Total
	GDM		NON-GDM	
	($\geq 6.5\%$)		(4 – 6.4%)	
	Freq (%)		Freq (%)	

Age				
≤39	4	(3.81)	101 (96.19)	105(100)
≥40	3	(37.50)	5 (62.50)	8 (100)
Total	7	(6.19)	106 (93.81)	113(100)
Number of				
Pregnancies				
≤2	1	(1.30)	76 (98.70)	77(100.0)
≥3	6	(16.67)	30 (83.33)	36(100.0)
Total	7	(6.19)	106(93.81)	113(100)
Parity				
≤1	1	(1.28)	77 (98.72)	78(100.0)
≥2	6	(17.14)	29 (82.86)	35(100.0)
Total	7(6.19)		106(93.81)	113(100)

DISCUSSION

Gestational diabetes mellitus is a public health burden resulting in increased morbidity and mortality of both mother and offspring (Veeraswamy et al., 2012). This study showed that the prevalence of GDM using HbA1c was 5.3% and FBG was 6.2%. This implies that the prevalence of GDM among this population was low. This finding is similar to that reported by Odsaeter et al., (2016); Yadav et al., (2012) in India; which revealed the prevalence of GDM to be 7.2% and 7.1% respectively. The results from this study are however slightly

higher than what was reported in the studies conducted by Ewenighi et al. (2013) in South-East Nigeria (4.8%) and Ogu et al. (2017) in South-South Nigeria (3.3%). In addition, a study conducted in Malaysia by Logakodie et al. (2017) gave a prevalence of 27.9%. and a study in South East Nigeria by Onyenekwe et al. (2019) using various criteria reported a prevalence of 38.0% using the IADPSG. These values are much higher than the findings from this study. The differences in the prevalence of GDM could be as a result in the usage of various diagnostic criteria. The situation in Nigeria is plagued with the same lack of definite consensus on criteria for diagnosis of GDM Onyenekwe et al. (2019). Also, it could be as a result of a large sample size (704) used by Logakodie et al., (2017) which enabled the identification of large number of pregnant women with GDM.

In this study, there was also strong positive correlation (0.775) between HbA1c and FBG which was statistically significant, implying that as the value of HbA1c increased so did the values of FBG. This therefore indicates that even though HbA1c may not replace FBG, it may still be a useful supportive tool to assess glycaemic status. This finding is similar to the results of the studies by Ahmed et

al. (2013) in Bangladesh and Ketema et al. (2015) in Ethiopia with moderate positive correlation coefficients of 0.507 and 0.61 respectively. The coefficient of determination (R^2) value in this study's analysis also showed that FBG explains 60.1% of the variation in HbA1C, indicating that the fitted model was appropriate. Based on the regression formula, $Y = a + bX$; where Y = dependent variable (HbA1C), X = independent variable (FBG); a = y-intercept = 1.716; b = slope = 0.670; the regression equation was given as $HbA1C = 1.716 + 0.670 (FBG)$. The independent variable, X (FBG) can thus be calculated using the formula: $Y - a/b$; which is $FBG = HbA1c - 1.716/0.670$.

The implication of this finding is that these equations could be utilized for inter-conversions between the levels of FBG and HbA1c thereby predicting their expected values in gestational diabetic patients. Applying the regression equation, as the HbA1c level increases, there will be a concomitant increase in fasting blood glucose level and vice versa. This finding is similar to findings in a study conducted by Khan et al. (2015) in Saudi Arabia where a regression equation was formulated for inter-conversion of HbA1c and FBS.

Regarding the association between certain factors and GDM (using HbA1c and FBG as diagnostic tools), it was found that a significant relationship existed between maternal age and GDM; implying that as maternal age increased, the risk of developing GDM also increased. Participants who were 40 years or more showed a 20 and 15 fold increase for GDM using HbA1c and FBG respectively compared to those with ages 39 years or younger. This is similar to findings from studies conducted by Afolayan and Tella (2009) in Yenagoa,

Nigeria; Elmugadam et al., (2019) in Sudan; Al-Rowaily & Abolfotouh (2010) and Alfadhli et al. (2015) both in Saudi Arabia as well as Basha

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et al. (2019) in Jordan. Also, a statistically significant association was observed between number of pregnancies and GDM. Participants that have had 3 or more pregnancies showed a 12 and 15 fold likelihood for developing GDM (using HbA1c and FBG respectively) compared to those that have had 2 pregnancies and less. This infers that an increase in the number of pregnancies (gravidity) increases the risk of having GDM using both screening tools. This is similar to findings by Elmugadam et al., (2019) in Sudan; Basha et al. (2019) in Jordan and Abualhamael et al. (2019) in Saudi Arabia. Similarly, a statistically significant association was found to exist between parity and GDM. Participants that have had 2 or more children showed a 13 and 16 fold likelihood for developing GDM (using HbA1c and FBG respectively) compared to those that have had 1 or no child. This suggests that with increasing number of children, there was also a concomitant increase in the risk of GDM using both FBG and HbA1c screening tools. This is similar to findings by Basha et al. (2019) in Jordan and Abu-Helja et al. (2017) in Oman; Abualhamael, et al. (2019) in Saudi Arabia.

CONCLUSION

Findings in this study undertaken to determine the glycated haemoglobin concentration correlation to fasting blood glucose values of pregnant women in Port Harcourt revealed a low prevalence of GDM and a positive strong correlation between HbA1c and FBG. Formulation of a regression equation for the prediction of HbA1c and FBG and vice versa was done and there was a significant relationship between socio-demographic and obstetric factors with GDM. The following recommendations were thus made:

1. Screening all pregnant women who are aged 40 years and above, multiparous and multigravida for GDM using FBG test on booking; for prompt detection of GDM and early intervention to be put in place to prevent any negative pregnancy outcomes.
- b. Clinicians who prefer HbA1c but cannot easily obtain it should adopt the regression equation formulated in this study to convert FBG values to HbA1c to meet their requirements for monitoring pregnant patients with diabetes mellitus.
- c. Further research should be conducted on a larger sample size among diabetic mellitus patients in the Nigerian environment to enable the generalization and applicability of the findings from such studies.

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