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Correlations between Glycated Hemoglobin (HbA1c) and Oral Glucose Tolerance test, OGTT (and Some Cardiovascular Risk Factors) in a Cohort Population of Patients at the University of Port Harcourt Teaching Hospital (UPTH), Niger Delta Region of Nigeria

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Abstract

Background: Diabetes mellitus (DM) is increasing in prevalence globally and in Nigeria today. Fasting blood glucose and oral glucose tolerance test (OGTT) have been the traditional gold standard tests for diagnosis of DM until recently when glycated hemoglobin (HbA1c) is being used. Is there a correlation between the two? **Objectives**: The aim of this study was to determine the level of correlation between HbA1c and OGTT and some cardiovascular risk factors in a certain population in UPTH, Nigeria. **Materials and Methods**: This was a cross-sectional study involving 400 consecutively attending patients at the medical and general outpatient clinics of UPTH. **Results**: The HbA1C had a strong positive correlation with the 2 h post-glucose load of the OGTT (r = 0.652, $P < 0.001$). The HbA1c also had a positive correlation with the body mass index, waist circumference, age, total cholesterol (TC), triglyceride levels, and low-density lipoprotein cholesterol levels, but it was most positively correlated with the TC (r = 0.582, $P < 0.001$). It was, however, negatively correlated with the high-density lipoprotein cholesterol (r = –0.166, $P = 0.001$).**Conclusion**: Glycated HbA1c had a positive correlation with OGTT, and most of the cardiovascular risk factors of DM studied.

Keywords: Cardiovascular risk factors, Correlations, Hemoglobin, Nigeria, Oral glucose tolerance test

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Introduction

Diabetes mellitus (DM) is considered to be a major cardiovascular disease risk factor.[1,2] The hyperglycemia that occurs in DM is a major cause of the vascular complications that frequently occur. These complications are mediated through multiple pathways.[2-4] DM has some risk factors that either directly cause diabetes or are associated with it.[5-8] The presence of a risk factor does not confer 100% certainty that an individual will develop a disease. However, the greater the number of risk factors present in an individual, the greater the chance of the individual developing the disease.[8,9] On the other hand, the chance of developing DM in an asymptomatic individual with no risk factors is relatively low.[9]

Some factors that are associated with an increased risk of DM include: a family history of diabetes in first-degree relatives; obesity; physical inactivity; a history of gestational diabetes; dyslipidemia; polycystic ovary syndrome; increasing age; hypertension; and impaired glucose tolerance or pre-diabetes.[8,10] Hypertension is a significant risk factor for developing DM, as hypertensive patients are 2.5 times more likely to develop diabetes than their normotensive counterparts.[11-13] When the two diseases coexist, there is a marked increase in the incidence of cardiovascular complications.[11-13]

Fasting plasma glucose (FPG) and 2-h plasma glucose following an oral glucose tolerance test (2-h OGTT) have been used as the gold standard tests for the diagnosis of DM.[14-17] However, these tests require individuals to fast, which is an inconvenience in the clinical setting and may result in lower testing rates. Furthermore, the tests are costly and time-consuming. More recently, the American Diabetes Association (ADA) has recommended that glycated hemoglobin (HbA1c) also be used to diagnose DM.[14,18]

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HbA1c is a stable indicator of chronic hyperglycemia and offers a potentially simpler, non-fasting, and, therefore, more acceptable test. Furthermore, HbA1c is associated with less intra-individual variability and is more reproducible than the FPG and 2-h OGTT.[19] The use of HbA1c for the diagnosis of DM was suggested in the mid-1980s.[20] In 2010, the ADA included HbA1c ≥6.5% (48 mmoL/L) as a diagnostic criterion for DM, and the committee also recommended HbA1c testing for diagnostic purposes in asymptomatic adolescents.[18] Nevertheless, the diagnostic role of HbA1c remains a controversial issue.[21,22] Glycated HbA1c has several disadvantages in the pediatric population, and there is limited evidence on the use of HbA1c testing for the diagnosis of DM and pre-diabetes in children and adolescents. A recent series of pediatric studies appears to show that HbA1c has lower sensitivity than FPG or 2-h OGTT.[23-25]

Persons with impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) are at greater risk of progression to overt type 2 DM than persons with normal glucose tolerance.[26] Both IFG and IGT are considered to be pre-diabetes by the ADA.[27] Because the diagnosis of IGT requires an OGTT, it has been suggested by the International Diabetes Federation (IDF) that IGT/pre-diabetes be measured by HbA1C, which does not require the patient to fast.[28] Glycated HbA1c of 5.7–6.4% has been chosen as being diagnostic of pre-diabetes. Studies have compared the ability of HbA1C versus OGTT to identify persons with pre-diabetes.[29-33] have reported discordance between the two methods.

The degree of agreement between the two methods varies among various ethnic groups.[34] Information on the degree of correlation between the HbA1c and the OGTT in the city of Port Harcourt, Niger Delta region of Nigeria, is scanty. This study, therefore, was aimed at filling this gap in knowledge by comparing HbA1c versus OGTT in the identification of Nigerian subjects with DM and the underlying cardiovascular risk factors.

Materials and Methods

Study Design and Site

The study was a cross-sectional descriptive study of 400 consecutive recently diagnosed hypertensive and non-hypertensive patients. It was done at the medical and general outpatient clinics of the University of Port Harcourt Teaching Hospital. The hospital is a 700-bed facility that serves as a referral center for Rivers State and the neighboring Bayelsa, Imo, and Abia States. It is located in Alakahia in the Obio-Akpor local government area of Rivers State and shares boundaries with the University of Port Harcourt. Port Harcourt is a cosmopolitan town and a hub of commercial activities. The study population consisted of four hundred subjects, aged 30 years and above, 200 of whom had been recently diagnosed as hypertensive at either the medical or general out-patient clinics of the University of Port Harcourt Teaching Hospital, Port Harcourt.

Recruitment and Data Collection

From April 01 to December 30, 2014, using convenience sampling, 269 consecutive hypertensive patients attending the medical and general outpatient clinics of the University of Port Harcourt Teaching Hospital were recruited to participate in the study after a general health talk was given by the investigator. Of these, 200 of them were eventually recruited, while the rest were excluded for various exclusion criteria reasons. In addition, 200 non-hypertensive similarly matched subjects were recruited from the relatives of the patients and staff of the hospital. The total sample size was thus 400, made up of both hypertensive and non-hypertensive subjects. Using a well-structured interviewer-administered questionnaire, such data as age, gender, weight, height (and then body mass index [BMI]), and waist circumference (WC) were obtained. Using aseptic procedures, a venous blood sample (5 mL) was collected from the brachial vein in the antecubital fossa of each subject after an overnight 8–10-h fast for FPG, fasting lipid profile, glycated HbA1c, and another 3 mL of blood 2 h later for post-prandial glucose measurement.

Fasting total cholesterol (TC) and triglyceride (TG) levels were measured using the enzymatic method; the fasting high-density lipoprotein cholesterol was measured in two stages (the deproteinization and the reaction stage), while the low-density lipoprotein cholesterol was calculated from the Freidwald formula.[35] The plasma glucose levels were measured using the glucose oxidase method of Trinder.[36] While the HbA1C was measured in the laboratory by the turbidimetric immunoassay method using a spectrophotometer set at a wavelength of 600 nm.

Inclusion Criteria

Patients who had been recently diagnosed as hypertensive and non-hypertensive, >30 years of age, and who gave written, informed consent.

Exclusive Criteria

Patients, who had previously been diagnosed with diabetic, were pregnant, had other major medical illnesses such as renal, hepatic, or cardiovascular diseases, and had inter-current malignancies. Patients who were taking medications that may interfere with glucose metabolisms, such as thiazide diuretics, corticosteroids, anti-psychotics, and β-blockers, and patients with sickle cell disease and other HbA1copathies, were excluded from the study. Patients with chronic anemia, a history of cigarette smoking, or with established forms of secondary hypertension, or who did not consent to be included in the study were excluded.

Ethical Considerations

Before the commencement of the study, ethical approval for the study was obtained from the ethical committee of the University of Port Harcourt Teaching Hospital (UPTH/ADMN/90/S.11/Vol. IX/425, dated March 20th, 2013). Written informed consent was obtained from each one of the subjects before their recruitment into the study. The cost of any investigation for the purpose of the study was borne by the investigator. In the course of the study, subjects found to have abnormalities were appropriately advised and referred for proper treatment and follow-up. Subjects who wanted to opt out of the study at any time did so without suffering any disadvantages.

Statistical Analysis

The data were entered into and analyzed using version 20.0 of the Statistical Package for the Social Sciences software. The results were presented as mean ± standard deviation, percentages, and tables as appropriate. Statistical comparisons between different groups of continuous variables were compared using the student's *t*-test, while proportions or categorical parameters were compared with the Chi-square test or two-tailed Fischer's exact test, as appropriate. Pearson's correlation coefficient was used to test for colinearity between the continuous variables. Furthermore, multiple regression analysis was carried out to assess some cardiovascular risk factors that correlate with glycated haemoglobin in the study population. A $P < 0.05$ was considered statistically significant.

Definition of Operational Terms

Dyslipidemia

This is a disorder of lipoprotein metabolism, including lipoprotein overproduction or deficiency. It may be manifested by elevated levels of TC, TG, and low-density lipoprotein or a decrease in high-density lipoprotein.

The following cut-off points are used to denote elevated (abnormal) levels of the respective biochemical variables in dyslipidemia:

TC >200 mg/dL

TG >150 mg/dL

LDL-c >100 mg/dL

HDL-c <30 mg/dL in males and <40 mg/dL in females.

Gold standard test

This is a diagnostic test that is regarded as definitive.

Prevalence

Prevalence of a disease is the total number of individuals in a population who have the disease at point in time or over a specific period of time, usually expressed as a percentage of the population.

Risk factor

A condition which when present, increases the likelihood of a clinical condition occurring.

Screening

This is the process of identifying those individuals who are at sufficiently high-risk of a specific disorder to warrant further investigation or direct action. It is usually carried out on asymptomatic, apparently healthy people.

Sensitivity

The sensitivity of a screening test is the proportion of people with a disease that test positive on the screening test. {(True positives/True positives + False Negatives)}.

Specificity

This is the proportion of people that have a disorder that test negative on a screening test {(True Negatives/True Negatives + False Positives)}.

Results

A total of 200 hypertensive patients, 96 (48%) males and 104 (52%) females, participated in the study, and most of them were middle aged. The rest, 200 were normotensive patients. The mean age of the 400 participants was 48 ± 10 years.

These demographic characteristics are shown in Table 1.

The mean FPG of the hypertensive subjects was 91.8 ± 19.8 mg/dL and ranged from 57.6 to 145.8 mg/dL.

The number of subjects who were diagnosed with DM using the 2 h post-glucose load (PGL) of the OGTT was 16 (4.0% of the study population), while 11 subjects (2.8%) were diagnosed using the glycated HbA1c test ($P < 0.001$).

Table 1: Demographic characteristics of the hypertensive study population

Variable	*Frequency (%)*
Sex	
Male	96 (48.0)
Female	104 (52.0)
Age group (years)	
30–39	48 (24.0)
40–49	77 (38.5)
50–59	45 (22.5)
60–69	28 (14.0)
70 and above	2 (1.0)

The number of subjects who had pre-diabetes using the 2 h PGL of the OGTT was 98 (24.5%) of the study population, while when the glycated HbA1c was done, those with pre-diabetes were 31 (7.8% of the study population) ($P < 0.001$), as shown in Table 2. The sensitivity of the glycated HbA1c test for the diagnosis of DM was 62.5%, while the specificity was 99.7%.

There was a significant positive correlation between the glycated HbA1c and the FPG (r = 0.557, $P < 0.001$) and the 2 h PGL of the OGTT (r = 0.652, $P < 0.001$), as shown in Table 3.

Correlations between HbA1c and some cardiovascular risk factors are shown in Table 4 below.

When multiple regression analysis was applied to assess how much of the variance in the glycated HbA1c could be explained by the risk factors, the variables combined accounted for 42% of the variance observed (F = 42.403, $P < 0.001$). Total cholesterol was the strongest predictor of glycated HbA1c, accounting for 58.2% ($P < 0.001$) of the variation in glycated HbA1c. Other risk factor contributions are shown in Table 5. The WC, waist-hip ratio, and diastolic blood pressure did not, however, have any significant impact, as shown in Table 5.

Discussion

The main findings from this study included a diagnosis of DM in 2.8% of the study population using the glycated HbA1c, while at the same time, DM was diagnosed in 4% of the study population using the OGTT. The sensitivity of the glycated HbA1c test for the diagnosis of DM was 62.5%, while the specificity was 99.7%; being less sensitive suggest that using HbA1C will miss some people who have DM. Again, there was a strong positive correlation between HbA1C and the FPG, OGTT, and some cardiovascular risk factors in this study.

FPG and 2-h plasma glucose level following an OGTT (2-h OGTT) have been the gold standard tests for the diagnosis of DM but are cumbersome and difficult for both the primary care physician and the patient.[18] In contrast, measuring HbA1c levels is more convenient for diagnosing DM than fasting blood glucose and OGTT. For example, it does not require patients to fast before the test, has lower intra-individual variability, is not affected by acute stress or short-term lifestyle changes, and can be related to the risk of long-term diabetic complications.[14,37-39] For these reasons, it is being advocated by the ADA and the IDF. The cons of the HbA1c testing include that it may fail to detect cases of Type 1 DM, as hyperglycemia develops over a short period. It may also vary with age and different ethnic groups.[40] and its results are reported to be affected by factors related to red blood cell lifespan, such as iron deficiency anemia, sickle cell disease, and thalassemia.[41]

Table 2: Frequency of diabetes mellitus and pre-diabetes using two different screening methods

Variable	*HbA1c (%)*	*2 h PGL (%)*	χ^2	*P-value*	*CI*
Diabetes	11 (2.8)	16 (4.0)	−19.790	0.001*	−1.05460, −0.86548
Pre-diabetes	31 (7.8)	98 (24.5)	−26.325	0.001*	−3.9870, −5.8793

HbA1c: Glycated hemoglobin; PGL: Post-glucose load, CI: Confidence interval; χ^2: Chi-squared test, *Significant value

Table 3: Correlation of glycated hemoglobin to other screening tools for diabetes mellitus

Variable	*Correlation coefficient (r)*	*P-value*
2 h PGL (mmoL/L)	0.652	0.001*
FPG (mmoL/L)	0.557	0.001*

2 h PGL: 2 h plasma glucose level, FPG: Fasting plasma glucose

Table 4: Correlation between glycated hemoglobin and some cardiovascular risk factors in the study population

Variable	*Correlation co efficient (r)*	*P-value*
Age	0.318	0.001*
BMI (kg/m^2)	0.379	0.001*
WC (cm)	0.303	0.001*
DBP (mmHg)	0.297	0.001*
SBP (mmHg)	0.340	0.001*
WHR	0.176	0.001*
TC (mmoL/L)	0.582	0.001*
TG (mmoL/L)	0.445	0.001*
LDLc (mmoL/L)	0.560	0.001*
HDLc (mmoL/L)	−0.166	0.001*

BMI: Body mass index, WC: Waist circumference, SBP: Systolic blood pressure; DBP: Diastolic blood pressure, TC: Total cholesterol, TG: Triglycerides, HDLc: High-density lipoprotein cholesterol, LDLc: Low-density lipoprotein cholesterol; WHR: Waist-hip ratio,*Significant *P* value

Table 5: Multiple regression of factors that correlate with glycated hemoglobin in the study population

Model	*Standardized*			
	Beta	*t-test*	*P-value*	*95-CI*
Constant		−2.769	0.006	−2.567, −0.435
WC	0.115	1.456	0.146	−0.003, 0.020
SBP	0.209	3.496	0.001*	0.004, 0.016
DBP	0.047	0.778	0.437	−0.006, 0.013
HDLc	0.088	2.201	0.028*	0.039, 0.693
TGD	0.132	3.135	0.002*	0.154, 0.674
BMI	0.145	3.347	0.001*	0.021, 0.079
WHR	−0.069	−0.937	0.349	−1.771, 0.627
AGE	0.160	4.215	0.001*	0.008, 0.622
TC	0.582	14.280	0.001*	0.611, 0.806
LDLc	0.423	9.389	0.001*	0.413, 0.632

WC: Waist circumference, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, HDL: High-density lipoprotein, TGD: Triglyceride, BMI: Body mass index, WHR: Waist-hip ratio, LDL: Low-density lipoprotein, *Statistically significant

DM was diagnosed in fewer number of the subjects (2.8%) by the HbA1c testing compared to the OGTT (4%) in the index study, and because the sensitivity of the HbA1c testing was low (62.5%), this means that some subjects with DM will be missed if the HbA1c testing is used alone. The specificity of the HbA1c testing being very high in the index study is a plus for it as a screening test, suggesting that a high percentage of the people who do not have DM were correctly excluded from having DM. The sensitivity and specificity of HbA1c tests in the index study are comparable to the reported sensitivity and specificity of HbA1C ≥65%, which were 32.2% and 93.5%, respectively, for predicting DM.[42]

The positive correlations between the HbA1c and the OGTT in the index study are comparable to what was reported by these studies[14,43,44]. The obvious implication of this correlation study is that HbA1c testing, with all its inherent advantages, can serve as a replacement for OGTT in the diagnosis of DM. The degree of agreement with the OGTT as far as the diagnosis of DM is concerned is very high.

In the index study, of all the indices of dyslipidemia, total cholesterol had the most positive correlation with the FPG, HbA1c, and 2 h PGL levels. There was a negative correlation between the HDL-c and the HbA1c and FPG values in both the hypertensive and normotensive subjects. The present study finding is comparable to what was found in these local reports[45,46] in which a high prevalence of dyslipidemia was reported.

In conclusion, generally, individuals who are classified as non-diabetic by either the glycated HbA1c or the OGTT criteria show a more favorable cardiovascular profile than those classified as diabetic by either HbA1c or OGTT. Groups that fulfill the glycated HbA1c criteria for a positive diagnosis of DM, however, tend to have greater measures of BMI and WC, lower values of HDL, and higher values of FPG.[47]

Conclusion

This study has shown that glycated HbA1c is positively correlated with the FPG and the 2 h post-prandial glucose load of the OGTT in the diagnosis of DM. The specificity of the HbA1c test was quite high, suggesting high positive predictive values.

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