

The Use of Glycated Albumin in the Diagnosis of Gestational Diabetes Mellitus

Atochi Prince Woruka¹, Celestine Osita John²

¹Obstetrics and Gynecology Department, University of Port Harcourt Teaching Hospital, Port Harcourt, Nigeria

²Obstetrics and Gynecology Department, University of Port Harcourt, Port Harcourt, Nigeria

Email: celestine.john@uniport.edu.ng

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Abstract

Gestational diabetes mellitus is the most common endocrine disorder in pregnancy and a cause of maternal and fetal morbidities and mortalities. The oral glucose tolerance test is the gold standard for diagnosing gestational diabetes mellitus. Nevertheless, the oral glucose tolerance test is time-consuming and requires patient preparation. On the contrary, Glycated albumin does not require patient preparation or administration of any substance. Most studies on glycated albumin in pregnancy were among the non-African population, and black Americans have higher glycated albumin levels than Caucasians. This study determined the use of glycated albumin in diagnosing gestational diabetes mellitus among pregnant women. The study was a prospective study of 160 pregnant women between 24 and 28 weeks of gestation at the University of Port Harcourt Teaching Hospital. The diagnosis of gestational diabetes mellitus was based on the World Health Organization 2013 criteria. The diagnostic value of glycated albumin was determined using the area under the receiver operator characteristic curve. The prevalence of gestational diabetes mellitus was 9.4% and the mean glycated albumin was 16.91% (± 2.77). The area under the receiver operator characteristic curve for glycated albumin was 0.845 (95% CI 0.733 - 0.956; $p = 0.0001$). The optimal cut-off value of glycated albumin in the diagnosis of gestational diabetes mellitus was 18.9%. Glycated albumin was useful in the diagnosis of gestational diabetes mellitus at 24 to 28 weeks of gestation.

Keywords

Glycated Albumin, Gestational Diabetes Mellitus, Oral Glucose Tolerance Test, University of Port Harcourt Teaching Hospital

1. Introduction

Gestational diabetes mellitus (GDM) is the most common endocrine disorder in

pregnancy complicating about 5% of all pregnancies [1]. In 2019, about 20 million women had hyperglycemia first detected in pregnancy and over 16.5 million of these women had GDM [2]. Gestational diabetes mellitus (GDM) occurs when the fasting plasma glucose (FPG) is between 5.1 to 6.9 mmol/L, or when the one-hour 75 g oral glucose tolerance test (OGTT) is more than 10.0 mmol/l, or when the two-hour 75 g OGTT is between 8.5 to 11.1 mmol/L [2] [3]. The prevalence of GDM in Sub-Saharan Africa is 14.3% [4]. This prevalence is three times more than the global prevalence of 4.4% [5] and two times more than the European prevalence of 5.4% [6]. The prevalence of GDM in Port Harcourt, south-south Nigeria, is 10.5% which is in keeping with the high prevalence of GDM in Sub-Saharan Africa [7].

Gestational diabetes mellitus develops when the body fails to regulate the effects of diabetogenic hormones produced in pregnancy [8]. Risk factors include advanced maternal age, ethnicity, previous GDM, Previous fetal macrosomia, family history of diabetes mellitus, and body mass index of ≥ 30 mg/m² [8] [9]. The fetal complications of GDM are prematurity, growth restriction, fetal macrosomia, and sudden infant death [10]. Fetal macrosomia may lead to shoulder dystocia, instrumental vaginal delivery, and birth injuries [10] [11]. After delivery, the child may have hyperglycemia, hypoglycemia, increased bilirubin, and respiratory distress syndrome [11] [12]. The complications in the neonate may lead to admission into the special care baby unit and death [10] [12]. Long-term complications of the child are obesity, type II diabetes mellitus, and cardiovascular disease later in life [13] [14]. Maternal complications are hypertension, pre-eclampsia, preterm rupture of membranes, antepartum hemorrhage, perineal injuries at delivery, and increased risk of induction of labor and cesarean section [12] [15]. Almost half of these women may develop obesity and type II diabetes mellitus later in life [8] [14].

The World Health Organization (WHO) has recommended the OGTT as a gold standard for GDM diagnosis [2] [3]. It is also recommended that all pregnant women should have screening for GDM irrespective of whether she has risk factors for hyperglycemia or not using a single-step 75 g OGTT [3] [16]. Not all countries have adopted universal screening for GDM probably due to cost. The National Institute for Health and Care Excellence in its 2015 guideline recommends a selective screening of women with one or more risk factors: first-degree relation with diabetes mellitus, BMI ≥ 30 kg/m², previous delivery of a large baby (≥ 4.5 kg), and ethnicity with a high rate of diabetes mellitus [9]. However, not all women with GDM have a risk factor. In a prospective study of 1000 women, 44.2% of women without risk factors had GDM and only 45.8% of women with risk factors had GDM [17].

The preanalytical requirements and the procedure for OGTT have some drawbacks. Preanalytical preparation of the patient requires a woman to have her usual diet for three days and an overnight fast for at least 8 hours [18] [19]. Studies have shown that most women are not well prepared for an OGTT. In a review of pre-analytical errors in OGTT, it was found that about 25% of caregiv-

ers do not have adequate knowledge of patient preparation [20]. Other factors that may affect the OGTT result are drugs, acute illness, exercise, and physical stress [18] [19]. A delay in sample analysis may lead to extravascular glycolysis resulting in an alteration of the result [18] [19]. Due to the failure to achieve appropriate analytical conditions, OGTT results may vary in the same individual at different times [19] [21]. The glucose solution can cause nausea and vomiting and has been reported as a reason some women withdraw from the test [22]. Oral glucose tolerance test requires multiple samples collection, and some women have a phobia of needle pricks: Therefore, the woman may not endure repeated needle pricks. All these challenges have led to poor acceptance of OGTT and the need for a simple method for screening GDM.

The drawbacks of OGTT have led to the search for a simple method of screening and diagnosis of GDM. Examples of alternative glycemic markers are glycosylated hemoglobin, glycosylated albumin, B-cell activating factor, tumor necrosis factor, platelet-activating factor, methylglyoxal, and 1,5 anhydroglucitol [23] [24]. Single fasting plasma glucose has gained popularity because it is simple, cheap, and can predict adverse pregnancy outcomes [25]. However, fasting plasma glucose is affected by fasting, carbohydrate diet, acute illness, stress, and medications [26].

Glycosylated albumin is a product of a non-enzymatic reaction between reducing sugars and albumin [27]. The plasma concentration of glycosylated albumin reflects the degree of hyperglycemia for up to 20 days [23] [28]. Therefore, unlike fasting plasma glucose and OGTT, it is not affected by fasting [29]. However, it can be affected by conditions that reduce plasma albumin [23] [29]. Glycosylated albumin can be measured accurately, and the analysis is not affected by extravascular glycolysis [27] [30]. However, GA assay is not routinely done in many laboratories in our environment. Most studies on glycosylated albumin in the diagnosis of diabetes mellitus and GDM were in non-African black populations [31] [32]. However, studies have shown that blacks have higher glycosylated albumin levels than Caucasians [33].

2. Aim

This study determined the usefulness of glycosylated albumin in the diagnosis of gestational diabetes mellitus among women receiving antenatal care at the University of Port Harcourt Teaching Hospital.

3. Methodology

The study was a prospective cross-sectional study of pregnant women between 24 to 28 weeks of gestation, who attended the antenatal clinic of the University of Port Harcourt Teaching Hospital between January and June 2022. This hospital is located in Choba, Port Harcourt, Rivers State, and serves as a referral center for the state and neighboring states.

The simple random sampling technique was used to select 160 participants. Women with diabetes mellitus, chronic liver disease, or chronic kidney disease

were excluded from the study. Those who were not sure of their last menstrual period and had no early ultrasound scan determination of their gestational age were also excluded.

The participants presented for blood sample collection between 7:00 to 7:30 am after fasting from 10:00 pm the previous day. They were allowed to rest for 30 minutes before samples were collected. The blood samples were collected into fluoride oxalate bottles for glucose analysis and into an Ethylene diamine tetra-acetic acid (EDTA) bottle for glycated albumin analysis. The plasma glucose was analyzed using the glucose oxidase method and the analysis of the glycated albumin was done using the Enzyme-Linked Immunosorbent Assay (ELISA) technique. The WHO 2013 diagnostic criterion was used for the diagnosis of GDM.

The analysis of the data was done using the Statistical Product and Services Solutions version 25.0. The comparison of means was done using the Student's T-test. The confidence interval was at 95% and the significance was at a p-value of <0.05. The diagnostic accuracy of glycated albumin was determined using the area under curve (AUC) of the receiver operator characteristic (ROC) curve.

4. Results

4.1. Demographic Characteristics

Table 1 shows the demographic characteristics of the women. The mean age of the women was 31.08 (± 5.12) years. Almost half (44.4%) of the women were nulliparous. More than a third of these women (38.8%) had body mass index ≥ 30 kg/m².

Table 1. Demographic characteristics of the study population.

SN		Frequency (n = 160)	Percentage
1	Age (years)		
	≤19	3	1.9
	20 - 34	117	73.1
	≥35	40	25.0
2	Parity		
	P0	71	44.4
	P1	41	25.6
	P2	29	18.1
	P3	7	4.4
	P4	10	6.3
	≥P5	2	1.2
3	Body mass Index (kg/m²)		
	18.5 - 24.9	14	8.7
	25 - 29.9	84	52.5
	≥30	62	38.8

4.2. Diagnostic Value of Glycated Albumin

Figure 1 is the ROC curve of GA at different cut-off values. The area under the ROC curve is above the diagonal line with a value of 0.85 (95% CI 0.73 - 0.96; $p = 0.0001$). **Figure 2** shows the plot of different cut-off values of GA and their respective Youden's J index. From the graph, the highest Youden's J index value of 0.66 corresponds to a GA value of 18.9%. **Table 2** shows a summary of the ROC findings.

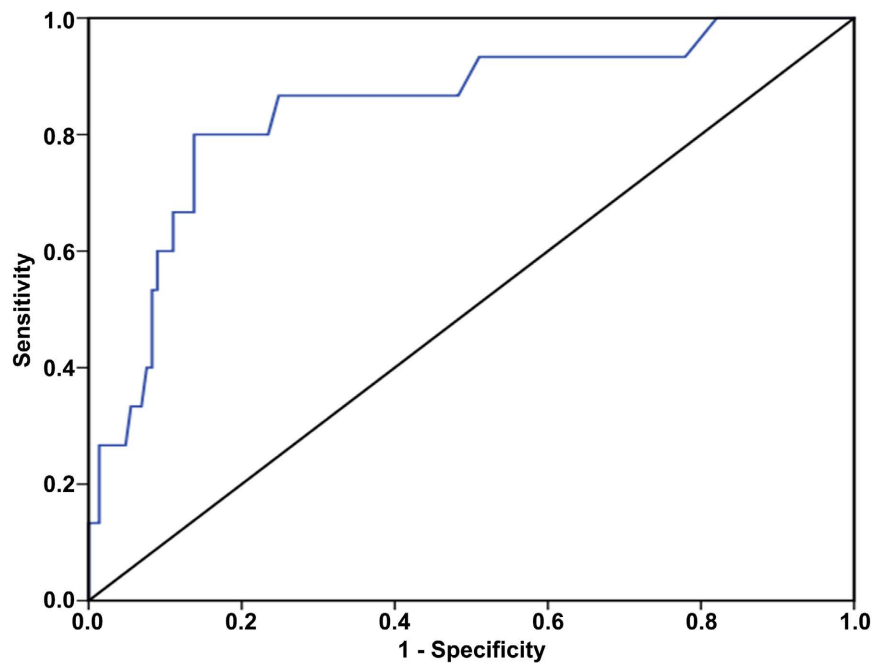


Figure 1. ROC curve showing various cut-offs of Glycated albumin in GDM diagnosis.

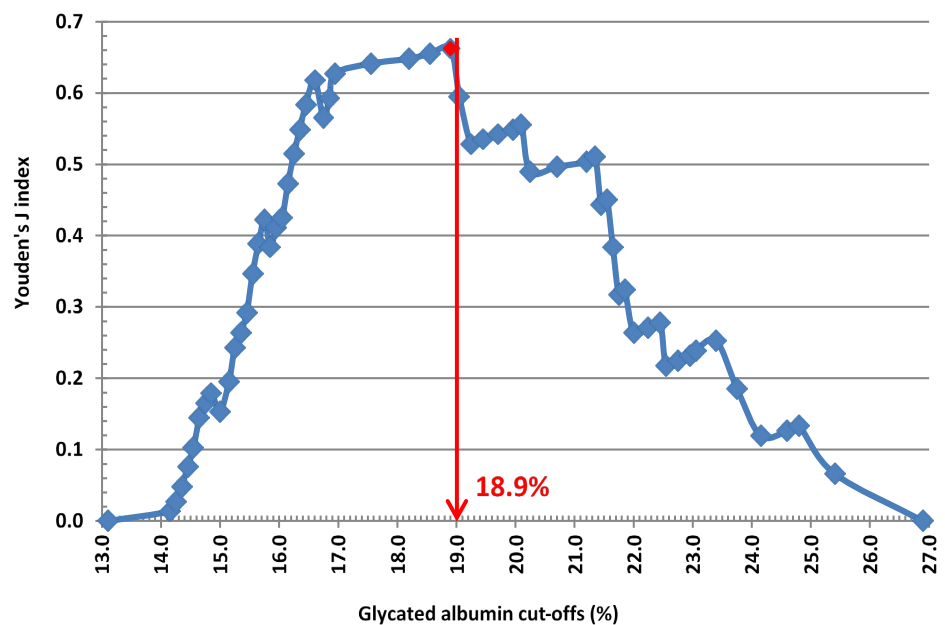


Figure 2. Graph showing the optimal cut-off of Glycated Albumin in the diagnosis of GDM.

Table 2. Summary of ROC curve findings on Glycated albumin.

ROC findings	Values
AUC (95% CI)	0.85 (0.73 - 0.96)
p-value	<0.0001*
Optimal cut-off value	18.9%

SD—Standard deviation; AUC—Area Under the Curve; CI—Confidence intervals; *Statistically significant.

5. Discussion

Gestational diabetes mellitus is the most common endocrine disorder in pregnancy. Most pregnant women are asymptomatic and may only present when they have complications. Therefore, every healthy pregnant woman should be screened for GDM. Screening for GDM may be selective or universal, and there are different screening methods. Universal screening is the practice at the University of Port Harcourt Teaching Hospital.

The diagnostic criterion used in this study was the WHO 2013 diagnostic criteria, and the prevalence of GDM in this study was 9.4%. The screening method and the diagnostic criteria for GDM may affect the prevalence of GDM. The prevalence of GDM in another study done in Port Harcourt using the WHO 1999 diagnostic criteria was 10.5% [7]. Although both studies had similar study populations, the difference in the diagnostic criteria may explain the higher prevalence. A systematic review and meta-analysis of the GDM prevalence in Sub-Saharan Africa gave a prevalence of 14.0% [4]. This higher prevalence may be because the systematic review included 23 studies in the region with different screening methods and diagnostic criteria.

The area under the ROC curve is an important tool in evaluating the ability of a test to correctly differentiate a person with a disease from a healthy person. An AUC value closer to 1 indicates that the test has a good diagnostic ability, while a value closer to 0 means that the test has a poor diagnostic ability [34]. The area under the ROC curve for GA in the diagnosis of GDM was 0.85 (95% CI 0.73 - 0.96). This means that GA can correctly differentiate women with GDM from women without GDM. The ROC curve finding in this study is similar to the finding in other studies. Li *et al.* evaluated the value of GA in defining glycemic control in women with GDM, they reported that the area under the ROC of GA was 0.87 (95% CI 0.81 - 0.93) [32]. In another study by Zhu *et al.*, the area under the ROC for GA for the diagnosis of GDM was 0.57 (95% CI 0.53 - 0.61) [35]. The study by Zhu *et al.* used the ADA diagnostic and GA analysis was done with a chromatography method. The difference in the diagnostic criteria and GA analysis may contribute to the lower ROC value in this study.

Another important use of the ROC curve is to identify the optimal cut-off value of a diagnostic test. The ROC curve plots the sensitivity and specificity in opposite directions, and the optimal cut-off value is a balance between the best sensitivity and specificity. The optimal cut-off point is adjusted to minimize false

negative results (prioritize sensitivity) or false positive results (prioritize specificity). The optimal cut-off value of GA in the diagnosis of GDM in this study was $\geq 18.9\%$. This cut-off value is a choice because, at 18.9%, GA had the highest sensitivity and specificity. The optimal cut-off value in this study was higher than that reported in most studies. A study in China reported that the optimal diagnostic cut-off point at which GA in the diagnosis of GDM was 11.6% [32]. The racial differences in the study populations may be a possible reason for the higher optimal cut-off value reported in our study.

6. Conclusion

Gestational diabetes mellitus is a cause of maternal and fetal morbidity and mortality. The prevalence of GDM in this study is 9.4%. The recommended gold standard for diagnosis of GDM is the OGTT. Because the OGTT requires patient preparation, drinking glucose solution, and multiple sample collection, there is a need for a simple test. Glycated albumin is a possible alternative marker for hyperglycemia in pregnancy. From this study, the area under the ROC curve for glycated albumin in the diagnosis of GDM was 0.85 (95% CI 0.73 - 0.96). This means that glycated albumin can differentiate women with GDM from women without GDM.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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