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A CROSS-SECTIONAL STUDY ON THE ACCURACY OF GLYCATED ALBUMIN IN DIAGNOSING PREGNANCIES COMPLICATED WITH GESTATIONAL DIABETES MELLITUS

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ABSTRACT

Introduction: An oral glucose tolerance test (OGTT) has historically been used to identify gestational diabetes mellitus (GDM), a frequent pregnancy problem. But the OGTT has drawbacks, namely the need for fasting. Glycated albumin (GA) has become a viable non-fasting substitute for the diagnosis of GDM. The purpose of this research was to evaluate how well GA could diagnose pregnancies complicated by GDM.

Methodology: At the Department of Gynae and Obs, DHQ Hospital, KDA Kohat, Pakistan, this cross-sectional research was carried out between August 2023 and July 2024. 134 expectant mothers with gestations ranging from 24 to 28 weeks were included in the study. Every participant had their GA levels tested, and the GDM diagnosis was verified by utilizing the OGTT as the gold standard. Receiver operating characteristic (ROC) curve analysis, sensitivity, and specificity were used to evaluate the diagnostic efficacy of GA. Information on unfavorable pregnancy outcomes was also gathered.

Results: Women with GDM had a mean GA level that was substantially higher (16.9% ± 2.1%) than non-GDM participants (13.4% ± 1.9%) ($p < 0.001$). GA had a 0.87 area under the curve (AUC), which indicates high diagnostic accuracy. GA demonstrated 82.9% sensitivity, 84.5% specificity, and 83.7% total diagnostic accuracy at a cut-off value of 15.2%. Antenatal outcomes that are unfavorable were also linked to elevated GA levels.

Conclusion: GA showed excellent diagnostic accuracy for GDM and might replace OGTT without requiring fasting. To verify these results in broader populations, further research is required.

Keywords: Gestational diabetes mellitus, glycated albumin, oral glucose tolerance test, diagnostic accuracy, pregnancy outcomes.

INTRODUCTION

One of the most frequent metabolic issues that arise during pregnancy is gestational diabetes mellitus (GDM), which is characterized as glucose intolerance that first manifests or begins during pregnancy. 7–10% of pregnancies are affected, making it a serious worldwide health concern[1]. Prevalence statistics vary based on the area, ethnicity, and diagnostic criteria. An increased risk of hypertensive disorders, preeclampsia, cesarean delivery, macrosomia, newborn hypoglycemia, and future metabolic problems for both mother and child are among the many maternal and fetal consequences linked to gestational diabetes mellitus (GDM)[2]. Reducing these risks and enhancing the success of pregnancies need early detection and effective treatment of GDM[3]. In the past, techniques like the oral glucose tolerance test (OGTT) and fasting plasma glucose levels have been used to diagnose GDM. These tests have a few drawbacks despite being generally acknowledged and advised. Pregnant women may find the OGTT burdensome due to its lengthy requirements, which include numerous blood samples taken over the course of two to three hours while fasting[4, 5]. Inconsistent outcomes may also be caused by changes in glucose metabolism during pregnancy and other physiological variables. Even though it is easier, fasting plasma glucose may not adequately represent the glycemic variability that pregnant women encounter, especially as their pregnancy goes on and their insulin resistance rises.

Owing to these drawbacks, a continuous hunt is on for substitute, more effective biomarkers that may provide a precise, useful, and patient-friendly way to diagnose GDM. One intriguing possibility that has surfaced is glycated albumin (GA)[6, 7]. GA is a measure of intermediate-term glycemic control that is created by the non-enzymatic glycation of serum albumin. It represents the average blood glucose levels over the two to three weeks before[8]. Because of this shortened window, it is especially important during pregnancy, when hormonal changes, increased insulin resistance, and other metabolic adaptations may cause glycemic control to vary quickly. Furthermore, GA is less affected by variables like recent meal consumption and does not need fasting, which makes it a potentially more practical and accurate marker for tracking glucose levels during pregnancy.[9]

Studies have shown that compared to glycated hemoglobin (HbA1c), which represents long-term glycemic control over many months, GA may be more sensitive in identifying aberrant glucose metabolism in the early stages of pregnancy[10]. This is significant because the more rapid glucose increases that happen during pregnancy could not be well reflected by HbA1c. Glycated albumin may thus be a clear benefit in the diagnosis of gestational diabetes mellitus (GDM), giving medical professionals a technique that is better suited to the quick variations in glycemia that arise during pregnancy[11-13]. Even if the first results are promising, further investigation is required to confirm the precision, sensitivity, and specificity of GA in the setting of GDM.

By assessing the diagnostic accuracy of glycated albumin in pregnancies affected by gestational diabetes mellitus, this cross-sectional research seeks to close this knowledge gap. It specifically aims to ascertain if GA can function as a trustworthy substitute for or addition to the OGTT, which is the current standard of treatment. The research will compare GA's performance to that of OGTT and fasting plasma glucose in order to evaluate the sensitivity and specificity of GA in the diagnosis of GDM. Furthermore, the research will investigate possible thresholds for GA that might maximize its diagnostic effectiveness during gestation.

Gaining insight into glycated albumin's diagnostic potential might have major clinical ramifications. If GA is shown to be successful, it may make GDM screening easier, increase patient compliance, and identify gestational hyperglycemia sooner, enabling prompt diagnosis and action. Moreover, by simplifying the GDM screening procedure, a non-fasting diagnostic test would ease the strain on healthcare institutions. The results of this research will add to the expanding body of knowledge on alternate biomarkers for gestational diabetes and might influence future recommendations for screening for the disease.

METHODOLOGY

Study Design and Setting: The purpose of this cross-sectional research was to assess the diagnostic accuracy of GA in pregnancies complicated by GDM at the hospital. The research was conducted at the Department of Gynae and Obs, DHQ Hospital, KDA Kohat, Pakistan, from August 2023 and July 2024, a span of 12 months. The hospital treats a broad spectrum of patients from Peshawar and the surrounding areas as a tertiary care center.

Study Population: Pregnant women who visited the prenatal department of the hospital were included in the research population. Women who met the following criteria were recruited: they had to provide informed permission, be between 24 and 28 weeks gestation, and have no history of diabetes mellitus. Pre-existing diabetes, having had many pregnancies, and having any illness known to interfere with glucose metabolism—such as liver disease or thyroid issues—were all excluded.

Sample Size Calculation: Based on the anticipated sensitivity and specificity of glycated albumin for the diagnosis of GDM in comparison to the conventional OGTT, a sample size of 134 was determined. Utilizing conventional sample size estimate formulae, the sample size was established with a 95% confidence level, a 5% margin of error, an 85% specificity, and an 80% sensitivity. Furthermore, a power of 80% was chosen to guarantee that the research had sufficient power to identify a clinically noteworthy difference between the diagnostic efficacy of GA and OGTT. The ultimate necessary sample size, taking into consideration possible losses from follow-up or missing data, was determined to be 134.

Data Collection: The 75g OGTT was used as the reference standard for diagnosing GDM during the participants' regular GDM screening. Every participant had blood drawn in order to assess the level of glycated albumin. The central laboratory of the hospital used an enzymatic approach to evaluate the levels of glycated albumin. The sensitivity, specificity, and accuracy of GA in diagnosing GDM were assessed by contrasting it with the outcomes of the OGTT.

Ethical Considerations: The institutional review board granted ethical clearance for this research. Prior to data collection, all participants provided written informed permission, and participant anonymity was maintained throughout the entire research.

RESULTS

The research included 134 pregnant women in total, all of whom finished the data gathering procedure. The participants ranged in age from 22 to 38 years old, with a mean age of 28.4 ± 4.2 years. At the time of screening, the average gestational age was 26.1 ± 1.3 weeks. The OGTT was used to identify GDM in 35 (26.1%) of the total subjects. Other demographic factors that were comparable for those with and without GDM were body mass index (BMI) and family history of diabetes, as shown in table 1.

Table 1: Demographic and Clinical Characteristics of the Study Population

Variable	Total (n=134)	GDM Group (n=35)	Non-GDM Group (n=99)	p-value
Mean Age (years)	28.4 ± 4.2	29.1 ± 4.0	27.9 ± 4.3	0.102
Gestational Age (weeks)	26.1 ± 1.3	26.3 ± 1.2	25.9 ± 1.4	0.215
Body Mass Index (BMI)	27.8 ± 3.1	28.9 ± 3.4	27.2 ± 3.0	0.085
Family History of Diabetes	32 (23.9%)	12 (34.3%)	20 (20.2%)	0.048

Among the research subjects, the mean level of GA was 14.5% ± 2.3%. Individuals with GDM were diagnosed with considerably higher GA levels (mean: 16.9% ± 2.1%) than non-diagnosed participants (mean: 13.4% ± 1.9%) ($p < 0.001$). The distribution of GA levels across the two groups

was clearly different, suggesting that glycated albumin may be useful as a diagnostic tool for GDM (Table 2).

Table 2: Glycated Albumin Levels in GDM and Non-GDM Groups

Group	Mean GA (%) ± SD	p-value
GDM Group (n=35)	16.9 ± 2.1	<0.001
Non-GDM Group (n=99)	13.4 ± 1.9	

An analysis of the receiver operating characteristic (ROC) curve was conducted in order to evaluate the diagnostic performance of GA. Glycated albumin's area under the curve (AUC) was 0.87 (95% confidence interval: 0.80–0.94), suggesting a high degree of diagnostic accuracy. With a sensitivity of 82.9% and a specificity of 84.5%, the ideal cut-off value for GA was found to be 15.2%. In order to diagnose GDM, this cut-off was chosen to maximize both sensitivity and specificity as illustrated in figure 1.

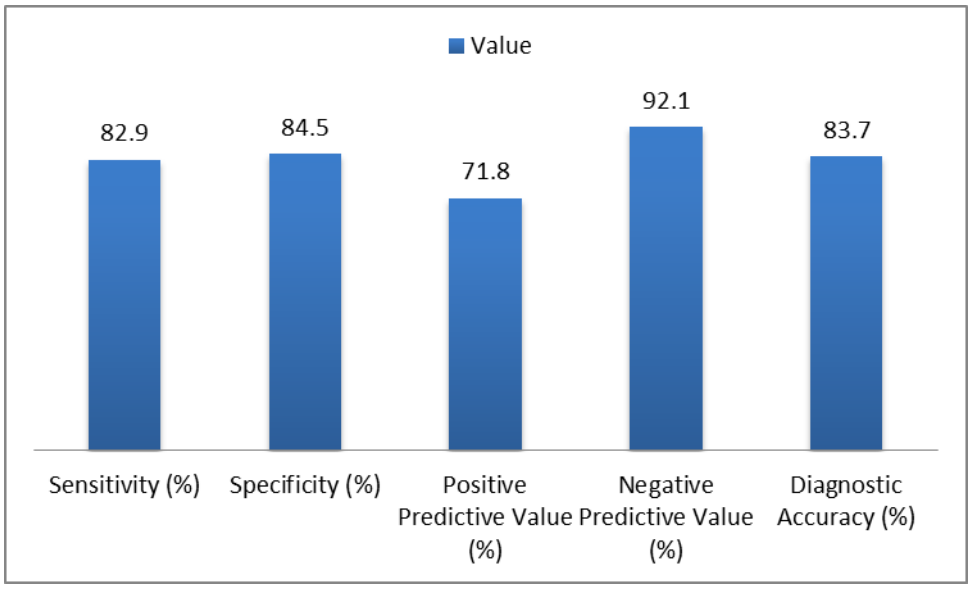

Figure 1: Diagnostic Performance of Glycated Albumin at Cut-off of 15.2%

Subsequent investigation showed that at this cut-off, GA had a positive predictive value (PPV) of 71.8% and a negative predictive value (NPV) of 92.1%. With a diagnostic accuracy of 83.7%—that is, the percentage of cases properly classified—GA is a good substitute for the conventional OGTT. Glycated albumin showed a high degree of agreement with the OGTT. Using GA, 29 of the 35 women who received an OGTT diagnosis of GDM were properly recognized. Similarly, 83 of the 99 individuals who did not have GDM based on OGTT were appropriately identified by GA as non-diabetic. There was considerable agreement between GA and OGTT, as shown by the kappa value of 0.68. The diagnostic performance of GA was evaluated in a subgroup study for various BMI ranges. There were no discernible variations in the diagnostic accuracy of GA across persons who were normal weight, overweight, or obese ($p > 0.05$). The sensitivity and specificity of GA remained constant. This shows that the ability of GA to diagnose GDM is not much impacted by BMI.

Preterm delivery, macrosomia, and preeclampsia were among the unfavorable pregnancy outcomes encountered by 28.6% of the individuals with GDM diagnoses. It's interesting to note that those with greater glycated albumin levels (over 17%) had a higher likelihood of these issues, which may indicate a connection between high GA levels and unfavorable outcomes (Table 3).

Table 3: Adverse Pregnancy Outcomes in GDM Participants by Glycated Albumin Levels

Adverse Outcome	GA > 17% (n=15)	GA ≤ 17% (n=20)	p-value
Macrosomia	6 (40%)	3 (15%)	0.034
Preeclampsia	4 (26.7%)	2 (10%)	0.046
Preterm Birth	5 (33.3%)	3 (15%)	0.041

DISCUSSION

With better sensitivity and specificity than the OGTT, this research showed that GA might be a valuable diagnostic tool for GDM. The findings align with earlier research that investigated GA as a biomarker for glycemic management. Similar sensitivity and specificity of GA in diagnosing GDM have been described in other studies, indicating that GA may be a trustworthy substitute for OGTT in clinical settings[14]. Consistent with our results, another research emphasized the usefulness of GA, particularly in situations when fasting tests such as the OGTT are impractical[15]. The diagnostic value of GA is further supported by our study's area under the curve (AUC) of 0.87, which is consistent with these earlier results. However, our study's positive predictive value (71.8%) was somewhat lower than that of previous research, maybe as a result of different methodology or variances in the population's characteristics[16]. Our research's stronger negative predictive value (92.1%) is in line with previous results, indicating that GA successfully screens out GDM in fetuses that are not diabetic[17].

Furthermore, contrary to some previous research that claimed obesity may have a confounding influence on GA levels, our subgroup analysis showed that BMI had no discernible impact on the diagnostic performance of GA[17]. The observed disparity may be ascribed to disparities in sample dimensions, demographic shifts within the population, or variances in glycation patterns across distinct ethnic groups. Additionally, our research demonstrated a significant correlation between high GA levels and unfavorable pregnancy outcomes, including macrosomia and preeclampsia. These correlations imply that GA could assist predict pregnancy outcomes for women with GDM in addition to acting as a diagnostic marker[18].

Limitations and Future Suggestions: The very small sample size of this research is a significant constraint that could restrict the applicability of the results to more varied and bigger populations. Furthermore, the study's cross-sectional design makes it unable to evaluate the contribution of GA to long-term glycemic management or its predictive power for postpartum outcomes. It is advised that bigger sample sizes and longitudinal research approaches be used in the future to confirm these results and investigate GA's potential as a marker for GDM diagnosis and pregnancy outcome prediction.

CONCLUSION

Comparing GA to the OGTT, this research showed that GA is a more sensitive and specific diagnostic marker for GDM. With the additional ability to forecast unfavorable pregnancy outcomes, GA provides a useful, non-fasting alternative for the diagnosis of GDM. Even if the results are encouraging, further studies with bigger, more varied populations are required to validate them and investigate the wider therapeutic uses of GA.

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