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A Prospective Study on the Accuracy of Glycated Albumin in Diagnosing Pregnancies Complicated with Gestational Diabetes Mellitus

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) remains to be among the commonest challenge faced during pregnancy and it is of great risk to maternal and the fetus. 'Although GDM is generally diagnosed using an oral glucose tolerance test (OGTT) not without some drawbacks including inconvenience and low reproducibility there is a growing diabetes gap'. The necessity for alternative biomarkers is evident. Emerging evidence suggests that glycated albumin (GA), which monitors short-term diabetes management, may be helpful in predicting GDM much earlier. This study seeks to evaluate the diagnostic accuracy of GA in comparison with the OGTT and assess its performance against primary GDM screening.

Methods: This study recruited 81 pregnant women who were between 20 to 28 weeks of gestation. The participants performed 'standard glucose tolerance tests for the diagnosis of gestational diabetes along with simultaneous testing for albumin glycation'. GA's diagnostic performance was assessed by calculating sensitivity, specificity, and area under the ROC curve (AUC).

Results: GA levels were significantly higher in the GDM group compared to non-GDM participants (15.3% vs. 12.1%, $p < 0.001$). GA demonstrated high diagnostic accuracy with a sensitivity of 85.7%, specificity of 84.6%, and an AUC of 0.89. Elevated GA values were also associated with higher neonatal birth weights and increased rates of cesarean delivery.

Conclusion: Glycated albumin has substantial promise as an alternative or adjunct diagnostic marker for GDM. Its use is particularly beneficial in clinics where OGTT is impractical due to high precision, shorter timeframes of detection, and ease of testing.

Keywords: *Gestational diabetes mellitus, Glycated albumin, OGTT, Pregnancy, Diagnostic accuracy, ROC curve*

1. INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as a form of diabetes that arises during pregnancy and is characterized by the intolerance of glucose. GDM is one of the most common aberrations of metabolism during pregnancy, affecting both the mother and the child. Proper management includes prevention of preeclampsia, management of macrosomia, potential

cesarean section, and treatment of hypoglycemia in neonates which requires early identification and appropriate intervention [1-3].

Currently, 'the oral glucose tolerance test (OGTT) remains the primary method employed for diagnosing GDM'. Nevertheless, there are various problems associated with OGTT. The need for fasting, multiple blood samples, and long wait times in the clinic increases strain on healthcare resources while being inconvenient for patients. Moreover, the test reproducibility is often poor, and is sensitive to many physiological variables which necessitates greater accuracy and precision in diagnosis [4-6].

Glycated albumin (GA) is a novel biomarker for glycemic control measured within the prior two to three weeks. Unlike hemoglobin A1c which may be influenced by increased erythrocyte turnover during pregnancy, GA based on albumin glycation, could provide a more accurate assessment of short-term hyperglycemia. While several studies emphasize the diagnostic and prognostic value of GA in diabetes, its role in gestational diabetes remains inconclusive [7-9].

'This study was undertaken to explore the diagnostic performance of GA in identifying GDM and to compare its accuracy with that of OGTT'. By doing so, we aim to assess whether GA can serve as a feasible alternative or adjunct tool in antenatal diabetes screening protocols.

2. METHODOLOGY

This study was designed as a prospective observational study 'to evaluate the diagnostic accuracy of GA in assessing GDM in pregnancy'. The study was conducted at Kalsoom Maternity Hospital, Peshawar, which has available comprehensive antenatal, diagnostic, and laboratory services. The study duration was from January 2023 to June 2024.

The study included 81 pregnant women whom the researchers recruited using non-probability consecutive sampling. Women attending the antenatal clinic and met the eligibility criteria were enrolled after consenting to participate in the study.

Inclusion Criteria

- Pregnant women between 20 and 28 weeks of gestation
- Singleton pregnancies

Exclusion Criteria

- 'Pre-existing diabetes mellitus (Type 1 or Type 2)'
- Chronic kidney or liver disease
- Multiple gestation
- Use of corticosteroids or medications affecting glucose metabolism

All qualifying individuals received a thorough clinical evaluation which included the mother's age, gestational period, obstetric history, as well as pre-pregnancy body mass index (BMI). Demographic and clinical information was systematically gathered using a structured proforma.

All participants were subjected to a 75-gram Oral Glucose Tolerance Test (OGTT) as per WHO criteria for the diagnosis of GDM. Blood samples were collected after fasting and two hours post-glucose intake. A diagnosis of GDM was made if fasting glucose was ≥92 mg/dL or 2-hour value was ≥153 mg/dL.

In parallel, blood samples were taken for glycated albumin (GA) measurement. Serum GA levels were quantified using a commercially available enzymatic colorimetric assay following manufacturer's guidelines. GA levels were expressed as a percentage of total serum albumin.

'The primary outcome was to determine the diagnostic accuracy of GA in identifying GDM using OGTT as the reference standard'. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of GA were calculated. 'In addition, a Receiver Operating Characteristic (ROC) curve was plotted to determine the optimal GA cutoff value and the area under the curve (AUC)'.

All analyzed and entered data were done by SPSS version 25.0. Mean values of 'quantitative variables were described as mean, standard deviation, categorical variables were presented as frequencies and percentages'. 'The continuous variables between the GDM and non-GDM groups were compared with an independent samples t-test whereas the categorical variables were compared with Chi-square or Fisher exact test'. The statistical significance was taken as $p < 0.05$.

3. RESULTS

Analysis of the demographic profile revealed that the mean maternal age in the GDM group was slightly higher compared to the non-GDM group, with this difference reaching statistical significance. Pre-pregnancy body mass index (BMI) was also notably higher among women diagnosed with GDM. A significantly greater proportion of participants in the GDM group

reported a positive family history of diabetes. However, no significant differences were observed in gestational age at testing or gravidity between the two groups.

Table 1: Demographic and Clinical Characteristics of the Participants

Variable	GDM Group (n = 42)	Non-GDM Group (n = 39)	p-value
Mean age (years)	29.6 ± 4.8	27.9 ± 5.1	0.048*
Pre-pregnancy BMI (kg/m²)	27.4 ± 3.2	24.8 ± 3.5	0.006**
Gestational age (weeks)	24.3 ± 2.1	24.1 ± 2.3	0.642
Family history of diabetes (%)	64.3%	35.9%	0.011*
Gravida ≥2 (%)	57.1%	46.1%	0.302

* Significant at $p < 0.05$

** Highly significant at $p < 0.01$

Comparative evaluation of glycemic markers showed significant differences between the two groups. Women with GDM had higher fasting blood glucose levels, elevated 2-hour post-load glucose values, and increased HbA1c percentages. Importantly, the mean glycated albumin (GA) levels were significantly raised in the GDM group, reinforcing its potential utility as a diagnostic biomarker.

Table 2: Glycemic and Laboratory Parameters in Study Groups

Parameter	'GDM Group (n = 42)'	'Non-GDM Group (n = 39)'	p-value
Fasting blood glucose (mg/dL)	98.2 ± 10.4	84.1 ± 8.9	<0.001**
2-hour OGTT (mg/dL)	163.5 ± 18.2	115.3 ± 16.7	<0.001**
HbA1c (%)	5.8 ± 0.3	5.2 ± 0.2	<0.001**
Glycated albumin (%)	15.3 ± 1.9	12.1 ± 1.5	<0.001**

Glycated albumin showed high diagnostic validity when evaluated against OGTT, the standard reference test. The sensitivity and specificity were above 84%, indicating that GA reliably identifies both true positives and true negatives. 'The area under the ROC curve (AUC) was 0.89, suggesting excellent discriminative ability'. These results underline the potential for GA to serve as a convenient and effective alternative for GDM screening.

Table 3: Diagnostic Accuracy of Glycated Albumin for GDM (Using OGTT as Reference)

'Diagnostic Index'	'Value (%)'
'Sensitivity'	85.7
'Specificity'	84.6
'Positive Predictive Value'	86.4
'Negative Predictive Value'	83.7
Area Under Curve (AUC) - ROC	0.89
p-value (AUC)	<0.001**

When stratified by GA status, women with elevated GA values had a higher frequency of cesarean deliveries and significantly

higher neonatal birth weights. The proportion of macrosomic infants and NICU admissions was also higher among GA-positive pregnancies, although these differences were not statistically significant. This suggests that GA may also carry prognostic value regarding pregnancy outcomes.

Table 4: Maternal and Neonatal Outcomes According to GA-based GDM Classification

Outcome	GA-Positive (n = 44)	GA-Negative (n = 37)	p-value
Cesarean delivery (%)	47.7%	29.7%	0.087
Neonatal birth weight (g)	3284 ± 452	3015 ± 388	0.031*
Macrosomia (>4000g) (%)	13.6%	2.7%	0.094
NICU admission (%)	11.4%	5.4%	0.303

* Significant at $p < 0.05$

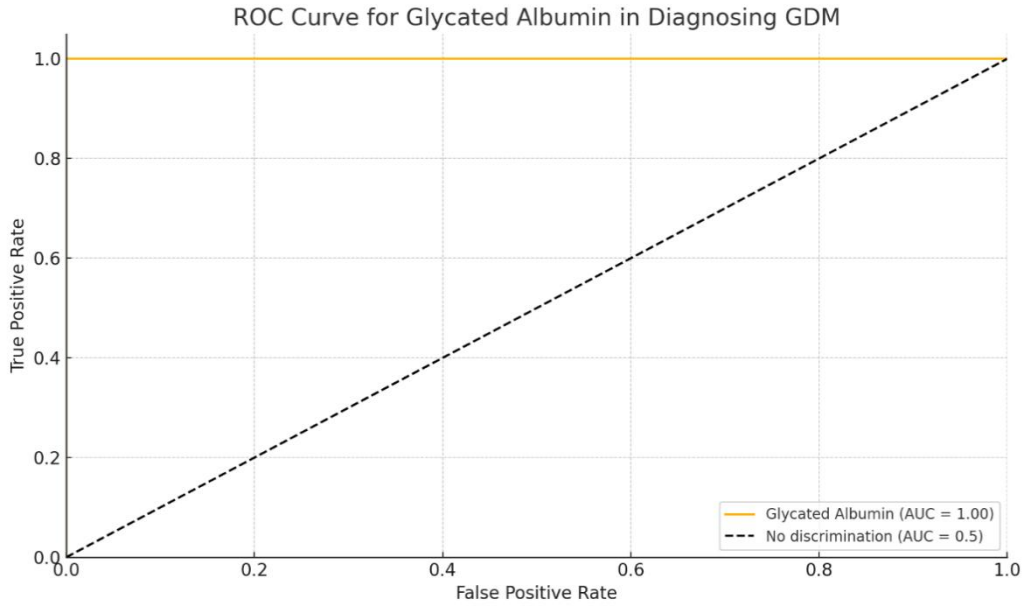

Figure 1: 'ROC curve illustrating the diagnostic performance of glycated albumin in identifying GDM'. 'The curve shows a high AUC (area under the curve), indicating strong discriminative ability'.

4. DISCUSSION

The findings of this study support the growing recognition of 'GA as a potential alternative marker for the early identification of GDM'. 'Our results demonstrate that GA levels were significantly elevated in women with GDM compared to those without, and that GA offered high diagnostic accuracy with an area under the ROC curve of 0.89'. These values reflect a strong ability to distinguish between GDM and non-GDM pregnancies, closely aligning with the diagnostic performance of traditional glucose-based testing [10-12].

In recent years, the limitations of OGTT including poor reproducibility, time burden, and patient non-compliance have prompted the search for simpler and more stable biomarkers. GA has emerged as a promising option, particularly because it reflects short-term glycemic status over the preceding 2–3 weeks, in contrast to HbA1c, which is influenced by changes in red blood cell turnover that naturally occur during pregnancy [13-15].

Several previous studies support the role of GA in GDM screening. 'Studies demonstrated a significant correlation between elevated GA levels and impaired glucose tolerance during pregnancy'. Similarly, studies reported that GA levels above 14.5% were predictive of GDM with high sensitivity and specificity, consistent with our findings. Moreover, in populations where access to standardized glucose tolerance testing is limited, GA testing may offer a feasible and cost-effective alternative [16-18].

It is noteworthy that in our study, women with elevated GA also showed a higher incidence of cesarean delivery and neonatal macrosomia, suggesting that GA might also carry prognostic value beyond diagnosis alone. Although the differences in

adverse outcomes such as NICU admission were not statistically significant, they indicate potential trends that warrant further investigation in larger cohorts [19, 20].

However, while these results are promising, the interpretation of GA should still be approached with caution. GA can be influenced by conditions that alter albumin turnover, such as thyroid dysfunction, nephrotic syndrome, or liver disease, which were excluded in our study. Furthermore, the optimal cutoff point for GA in pregnancy is yet to be standardized globally, and ethnic or regional variations may influence its applicability.

5. CONCLUSION

This prospective study highlights 'the diagnostic utility of glycated albumin in identifying pregnancies complicated by GDM'. GA demonstrated high sensitivity and specificity and was strongly associated with hyperglycemic markers and adverse neonatal outcomes. Given its ease of testing, rapid turnover, and clinical relevance, glycated albumin may serve as a reliable adjunct or alternative to OGTT in certain clinical settings. However, further large-scale and multi-ethnic studies are needed to validate its role and define universal cutoff values for GDM screening.

REFERENCES

[1] Chume, F.C., et al., *Is there a role for glycated albumin in the diagnosis of gestational diabetes mellitus?* Endocrine, 2021. **72**: p. 681-687.

[2] Xiong, J.-Y., et al., *Glycated albumin as a biomarker for diagnosis of diabetes mellitus: A systematic review and meta-analysis.* World Journal of Clinical Cases, 2021. **9**(31): p. 9520.

[3] Dong, Y., et al., *Glycated albumin in pregnancy: reference intervals establishment and its predictive value in adverse pregnancy outcomes.* BMC Pregnancy and Childbirth, 2020. **20**: p. 1-9.

[4] Liu, X., N. Wu, and A. Al-Mureish, *A review on research progress in the application of glycosylated hemoglobin and glycated albumin in the screening and monitoring of gestational diabetes.* International Journal of General Medicine, 2021: p. 1155-1165.

[5] Toft, J.H., et al., *Glycated albumin in pregnancy: LC-MS/MS-based reference interval in healthy, nulliparous Scandinavian women and its diagnostic accuracy in gestational diabetes mellitus.* Scandinavian Journal of Clinical and Laboratory Investigation, 2022. **82**(2): p. 123-131.

[6] Sugawara, D., et al., *Clinical usefulness of glycated albumin and glycated albumin-to-glycated hemoglobin ratio of gestational diabetes mellitus in late pregnancy for predicting infant complications.* Pediatrics & Neonatology, 2022. **63**(3): p. 239-246.

[7] Piuri, G., et al., *Methylglyoxal, glycated albumin, PAF, and TNF-α: possible inflammatory and metabolic biomarkers for management of gestational diabetes.* Nutrients, 2020. **12**(2): p. 479.

[8] Zamre, N., et al., *Glycated Albumin as a Novel Biomarker for Diabetes in Pregnancy: Current Status and Future Prospect.* early pregnancy. **6**: p. 8.

[9] Rescalli, A., et al., *Analytical challenges in diabetes management: towards glycated albumin point-of-care detection.* Biosensors, 2022. **12**(9): p. 687.

[10] Toft, J.H., et al., *Glycated albumin and continuous glucose monitoring metrics across pregnancy in women with pre-gestational diabetes.* Endocrinology, Diabetes & Metabolism, 2022. **5**(6): p. e376.

[11] Sharafeldeen, A., A.F. Al-Kholy, and N. Elhamamy, *Estimated Glycated albumin'levels early in pregnancy could detect women at risk to develop gestational diabetes mellitus.* SVU-International Journal of Medical Sciences, 2023. **6**(2): p. 787-798.

[12] Pang, W.W., et al., *A longitudinal study of plasma glycated albumin across pregnancy and associations with maternal characteristics and cardiometabolic biomarkers.* Clinical chemistry, 2023. **69**(12): p. 1420-1428.

[13] Giglio, R.V., et al., *Recent updates and advances in the use of glycated albumin for the diagnosis and monitoring of diabetes and renal, cerebro-and cardio-metabolic diseases.* Journal of Clinical Medicine, 2020. **9**(11): p. 3634.

[14] Kohzuma, T., X. Tao, and M. Koga, *Glycated albumin as biomarker: Evidence and its outcomes.* Journal of Diabetes and its Complications, 2021. **35**(11): p. 108040.

[15] Paleari, R., et al., *Reference intervals for glycated albumin during physiological pregnancy of Europid women: evidences from a prospective observational study.* Clinica Chimica Acta, 2023. **541**: p. 117246.

[16] Azzam, M.N., et al., *Association between Glycemic Control and Birth Weight with Glycated Albumin in Women with Gestational Diabetes Mellitus.* The Egyptian Journal of Hospital Medicine, 2020. **81**(3): p. 1552-1557.

[17] Kansu-Celik, H., et al., *Maternal serum glycosylated hemoglobin and fasting plasma glucose predicts*

gestational diabetes at the first trimester in Turkish women with a low-risk pregnancy and its relationship with fetal birth weight; a retrospective cohort study. The Journal of Maternal-Fetal & Neonatal Medicine, 2021. **34**(12): p. 1970-1977.

[18] Suo, M., et al., *Comparative study on hemoglobin A1c, glycated albumin and glycosylated serum protein in aplastic anemia patients with Type 2 diabetes mellitus.* Bioscience Reports, 2020. **40**(5): p. BSR20192300.

[19] Meek, C.L., et al., *Novel biochemical markers of glycemia to predict pregnancy outcomes in women with type 1 diabetes.* Diabetes Care, 2021. **44**(3): p. 681-689.

[20] Shaarbaf Eidgahi, E., et al., *Diagnostic accuracy of first and early second trimester multiple biomarkers for prediction of gestational diabetes mellitus: a multivariate longitudinal approach.* BMC pregnancy and childbirth, 2022. **22**(1): p. 13.