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The Level of Glycated Albumin Is Closely Correlated with The Level of Glycated Hemoglobin in Patients with Type 2 Diabetes Mellitus

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Abstract: Glycated albumin demonstrates a convincing correlation with glycated hemoglobin levels in patients with type 2 diabetes mellitus. This indicator allows one to evaluate the state of carbohydrate metabolism, reflecting the average glucose level over a shorter period of time compared to glycated hemoglobin. Such ratio makes glycated albumin an important marker for monitoring the course of the disease, especially in cases where it is necessary to quickly respond to changes in blood glucose levels.

Keywords: Glycated albumin, glycated hemoglobin, type 2 diabetes mellitus, medium-term glycemic control.

Introduction:

Glycated hemoglobin (HbA 1c) is a retrospective marker that allows determining the average glycemia level over the past two to three months and is currently considered the gold standard in assessing glycemic control. At the same time, glycated albumin (GA) is increasingly recognized as a marker of short- and medium-term blood sugar control, since its indicators reflect the glycemic status over a period of about three weeks. The study was aimed at analyzing the levels of GA , HbA 1c and fasting glycemia in patients diagnosed with type 2 diabetes mellitus.

Methods - Adult patients with type 2 diabetes mellitus (n = 135) were randomly selected from the Diabetes Clinical Center in Cluj-Napoca, Romania, meeting inclusion and exclusion criteria. Commercially available methods for measuring fasting glucose, GA, HbA1c , and creatinine were used to evaluate parameters .

Results - Among the entire group of participants, 62 patients (45.9%) were men. The average age of the participants was 62.1±8.6 years. The body mass index was within 31.8±6.1 kg/m², and the average duration of diabetes was 10.0 (4.0; 15.0) years. Fasting glycemia was at the level of 162±13.7 mg/ dL , the GA indicator was 28.0 (21.0; 40.0)%, and the HbA 1c level was 8.9±2.3%. Data analysis showed a significant correlation of GA with HbA 1c (correlation coefficient r = 0.19 ; p = 0.029) and with fasting glycemia (r = 0.32; p < 0.001). In turn, HbA 1c also demonstrated a significant relationship with fasting glycemia levels (r = 0.40; p < 0.001).

Conclusions - The results of the study confirmed that GA has a significant correlation with both HbA 1c and fasting glycemia in patients with type 2 diabetes. Although HbA 1c remains the standard tool for monitoring long-term glycemic control in clinical practice, the use of GA may be useful for assessing short-term or medium - term control of sugar levels. This is especially important in cases where HbA 1c testing is difficult or where rapid clinical decision-making is required.

Patients with diabetes are constantly monitored, and the key indicators of disease control are fasting and two-hour post-meal blood glucose levels, as well as glycated hemoglobin (HbA1c). HbA1c, which is a standard test for assessing the average glucose level over the past 2-3 months, is not without its drawbacks. Its results can be distorted by various factors related to both the patient's health and the testing technique. This can lead to a discrepancy between HbA1c values and the actual average

glycemia, making it difficult to objectively assess the effectiveness of diabetes treatment and control. For example, hemolytic anemia or bleeding can artificially lower the HbA1c level, while iron deficiency anemia, thalassemia, or other hemoglobinopathies can lead to its overestimation.

Thus, HbA1c results may be inaccurate and may not reflect the true picture of glycemic control. Due to these limitations, in recent years, more attention has been paid to glycated albumin (GA) as an additional, and in some cases more reliable, indicator of blood sugar monitoring. GA is formed as a result of non-enzymatic glycation of albumin, a serum protein. Unlike HbA1c, which reflects the average glucose level over a long period (2-3 months), GA provides information on short- and medium-term changes in blood sugar levels. This is due to the half-life of albumin, which is approximately three weeks. This time interval allows for a more up-to-date picture of glycemic control.

The key advantage of GA is its independence from factors that affect the accuracy of HbA1c measurement. Since GA is not bound to erythrocytes (red blood cells), its level is not affected by blood diseases such as hemolytic anemia, bleeding, iron deficiency anemia, thalassemia and other hemoglobinopathies. This makes GA a particularly valuable tool in the diagnosis and treatment of diabetes in patients with these diseases, when HbA1c results may be unreliable. In such cases, GA helps to get a more accurate picture of the average glycemia and the effectiveness of the therapy. Moreover, GA can be especially useful for patients with large fluctuations in blood glucose levels, which is typical for some forms of diabetes. Glycemic instability complicates the interpretation of HbA1c results, while GA, reflecting a shorter period of time, provides a more accurate assessment of the current situation.

GA may also be preferable in patients with a high risk of hypoglycemia (a sharp decrease in blood sugar levels), since it allows for prompt monitoring of the dynamics of glycemic changes and adjustment of treatment. Finally, GA may be an indispensable tool in patients with progressive chronic kidney disease. Renal insufficiency can significantly affect the accuracy of HbA1c measurements, while GA, although it may change slightly with renal dysfunction, remains a more informative indicator than HbA1c in these complex clinical situations. Thus, the use of GA in combination with HbA1c allows for a more complete and objective picture of glycemic control in patients with diabetes mellitus, especially in complex clinical situations when standard monitoring methods may be insufficiently informative. The choice between the use of GA and HbA1c, or their combined use, should be based on individual patient characteristics and the clinical situation. This allows the physician to make the most informed decision on treatment tactics and ensure the best blood glucose control for each specific patient.

The aim of the study was to comprehensively analyze glycated hemoglobin (HbA1c), glycated albumin (GA), and fasting glucose levels in patients with type 2 diabetes mellitus. This was an observational rather than interventional study, meaning that we did not interfere with the treatment of patients but only collected and analyzed existing data. Participants were randomly recruited from the adult population hospitalized at the Clinical Center for Diabetes, Nutrition, and Metabolic Diseases in Cluj-Napoca, Romania, between 2013 and 2018. A total of 135 patients (n=135) with a confirmed diagnosis of type 2 diabetes mellitus participated in the study. Diagnosis of type 2 diabetes mellitus and associated chronic complications was performed strictly according to the criteria established by the American Diabetes Association (ADA) [1]. It is important to note that this organization is an authoritative source in the field of diabetology , and the use of its criteria ensures uniformity and scientific validity of the diagnostic process. At the same time, standard criteria were used to determine hypertension: blood pressure (BP) of 140/90 mm Hg and above, or the use of antihypertensive drugs [1]. This implies that hypertension was diagnosed both by the results of BP measurements and by the presence of drug treatment.

To ensure the reliability of the study results, patients with a number of specific conditions that could distort the HbA1c and HA indicators were excluded from the sample. Such conditions include various unstable clinical conditions requiring emergency medical care, hematological diseases (e.g., anemia of various etiologies, thalassemia), malignant neoplasms at any stage, nephrotic syndrome, liver cirrhosis, hyperthyroidism and hypothyroidism. In addition, patients with an estimated glomerular filtration rate (SFR) of less than 30 ml/min/1.73 m^2, which indicates a significant decrease in kidney function, were excluded from the study. The presence of such diseases could affect the accuracy of the data obtained, so the exclusion of these patients was a necessary step to ensure the validity of the results. Also excluded from the study were patients taking steroid drugs, having blood transfusions within six months before the start of the study, as well as pregnant and lactating women [3,4]. These factors

could have significantly affected the HbA1c and GA levels, distorting the study results and complicating the interpretation of the data obtained. Inclusion of these patients in the study could have led to incorrect data and incorrect conclusions.

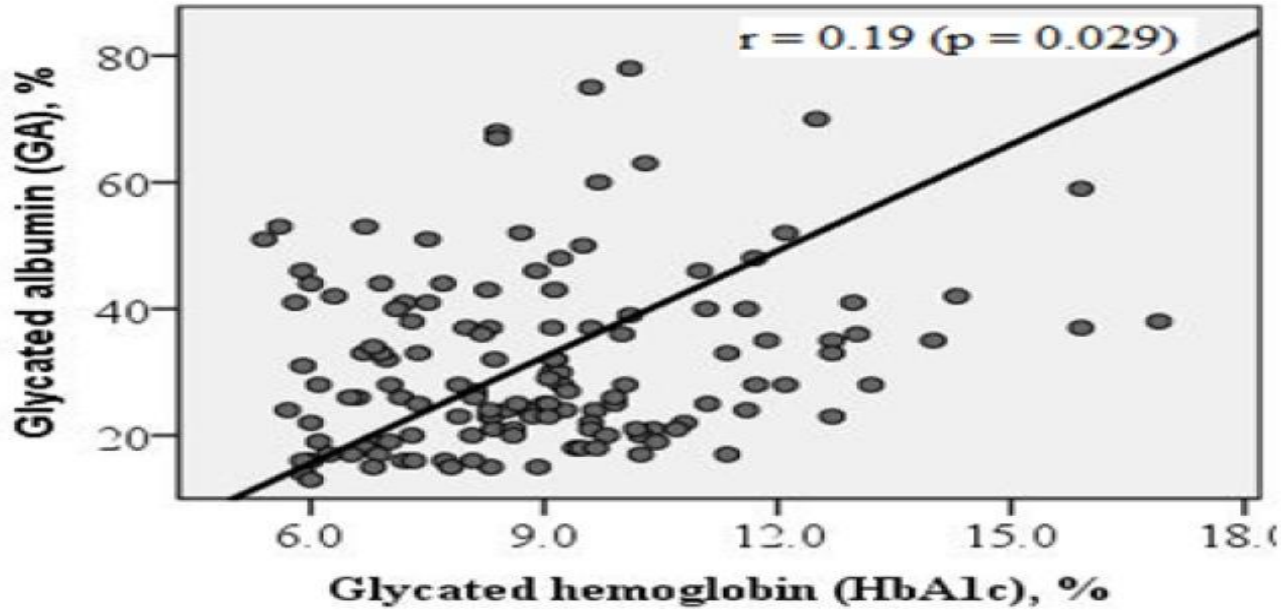
The study was conducted in full compliance with the provisions of the World Medical Association Declaration of Helsinki (2000 edition, Edinburgh) and current institutional guidelines. The study protocol was reviewed in advance and approved by the local Ethics Committee of the Iuliu University of Medicine and Pharmacy. Hatieganu , located in Cluj-Napoca, Romania. This ensures that the study was conducted in compliance with the highest standards of ethical correctness and all necessary measures to protect the rights of participants. Before any actions related to data collection, each patient was thoroughly informed about the objectives of the study, its methods, possible risks and potential benefits. Obtaining written informed consent was a mandatory condition for participation, which ensured voluntary and informed inclusion in the research process. This approach guaranteed the correctness of both the research process itself and its final results.

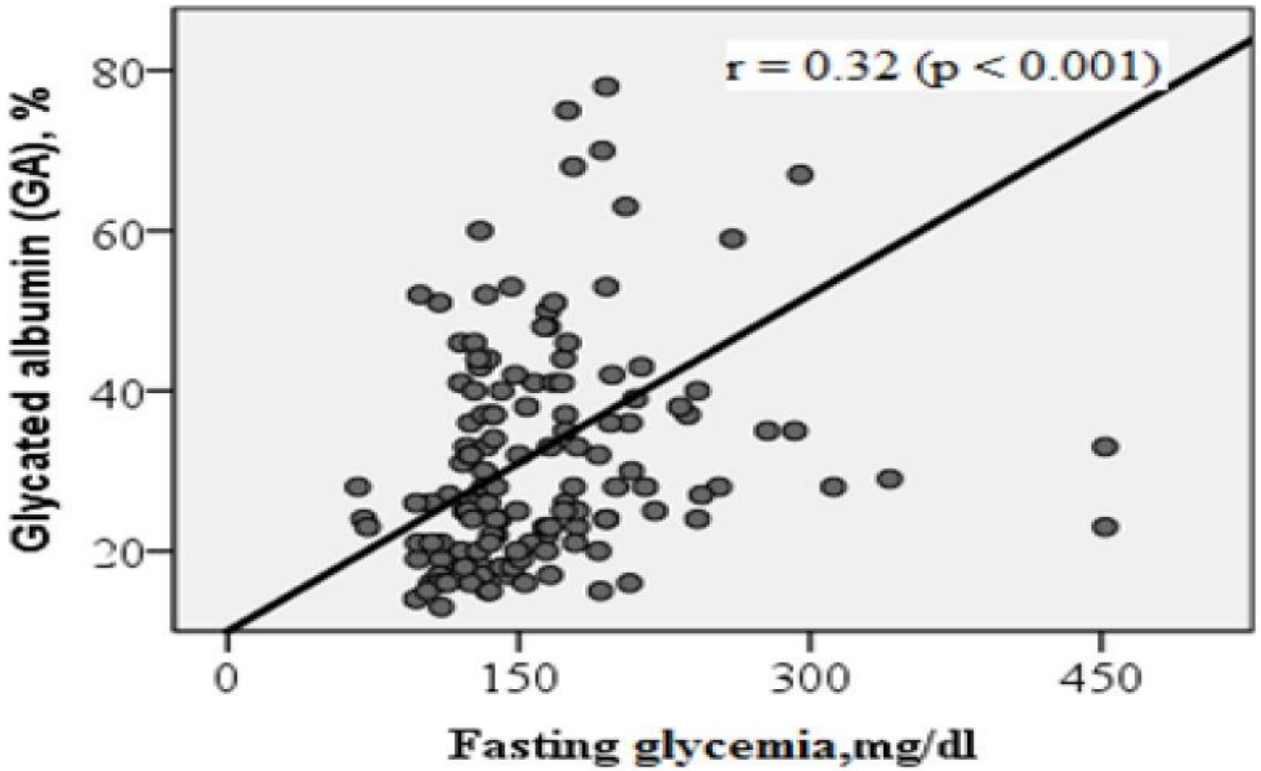
The study participants had their height, weight, waist circumference (fasting, in light clothing, without shoes) measured and their BMI calculated. Blood pressure and heart rate were measured with the BP-8800C automatic device on both arms after 10 minutes of rest in a sitting position. Fasting venous blood was collected from each patient to determine glucose, HbA1c, complete blood count and creatinine levels. The analysis was performed in the Central Laboratory of the Cluj County Emergency Hospital using reagents and a Beckman Coulter AU480 analyzer. Glucose was determined by the hexokinase method, HbA1c – by the turbidimetric immunoinhibition method. Serum samples were frozen for further analysis of glycated albumin (GA) levels, which were measured by the QuantILab ® enzymatic method and expressed as a percentage of the total albumin. Creatinine was determined colorimetrically, and SCF was calculated using the CKD-EPI equation. Calibration standards and controls with a coefficient of variation of less than 2% were used in laboratory studies.

Statistical analysis was performed using IBM SPSS Statistics version 22.0. The Kolmogorov-Smirnov test was used to check the normality of distribution of continuous variables. All data were checked for outliers using the interquartile range and 2.2 coefficient. Results were displayed as mean ± standard deviation or median with 25th and 75th percentiles. Descriptive method with numerical values and percentages was also used. Correlation between parameters was estimated using Spearman or Pearson coefficients with the accepted significance level of $p < 0.05$. The Spearman and Pearson correlation coefficients are statistical measures used to assess the strength and direction of the relationship between two variables. The Pearson correlation coefficient measures a linear relationship, while the Spearman (rank) correlation coefficient measures a monotonic relationship, which may be linear or nonlinear.)

Demographic and clinical characteristics of the participants. The mean age was 62.1 ± 8.6 years, with 45.9% being male. Active smokers were 11.9% of the participants; the mean duration of diabetes was 10 years and that of hypertension was 11 years.

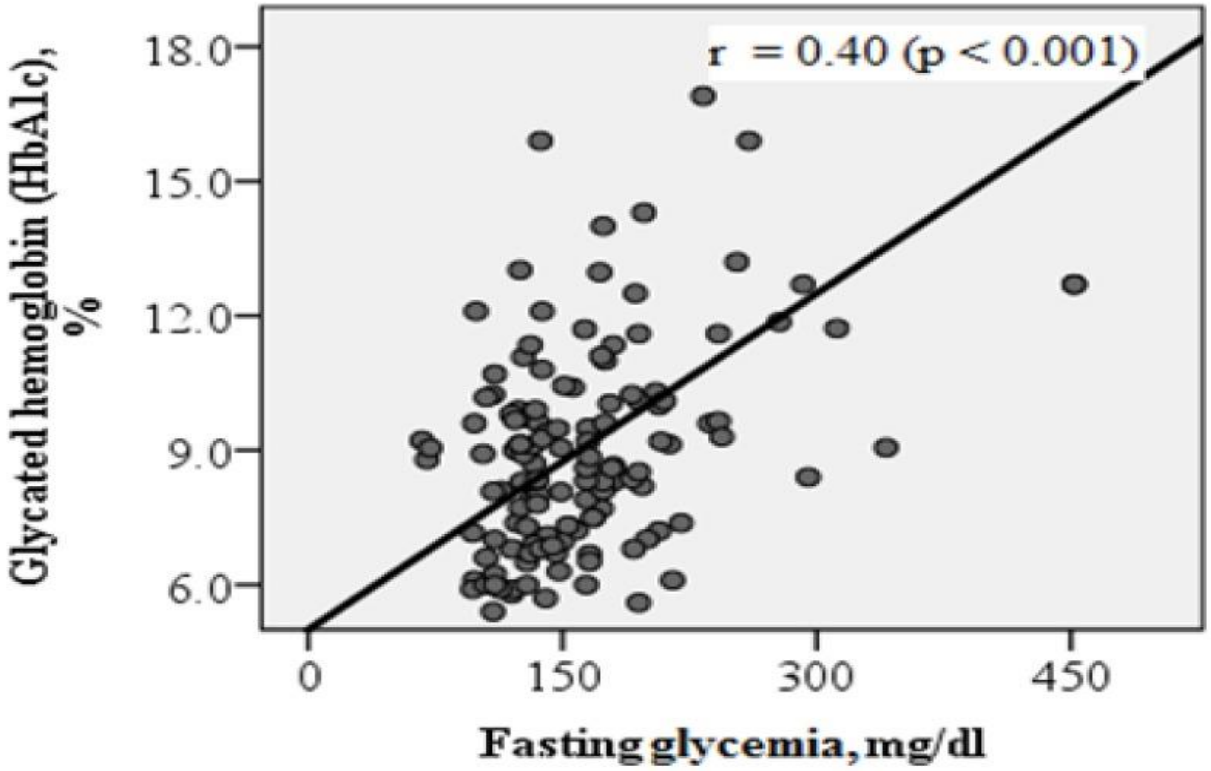
Correlation of glycated albumin (GA) with glycated hemoglobin (HbA1c).





Correlation **of glycated albumin (GA)** with fasting glycemia.

Correlation of **glycated hemoglobin (HbA1c) with** fasting glycemia**.**



GA was found to correlate significantly with both HbA1c and fasting glycemia in patients with type 2 diabetes included in our observational study. This significant correlation found between GA and HbA1c confirms that GA is an indicator of protein glycation as well as HbA1c and that GA is directly dependent on the effect of glucose on protein. GA and HbA1c are parameters that reflect blood glucose control, but at different time periods. HbA1c measurement is considered the gold standard for monitoring average glycemic levels over the past 2–3 months [1], while GA reflects glycemic control over the past 3 weeks [4]. Previous studies have shown that GA correlates with

both HbA1c and fasting glycemic values and that short-term glycemic assessment may be useful as an adjunct to HbA1c measurement [10–12].

The low strength of correlation between GA and HbA1c reported in our study may be explained by the time course of glycemic control reflected by each of these parameters. This is thought to be because GA reflects a shorter-term glycemic control status compared to HbA1c [10]. In a prospective study, changes in GA were more pronounced than changes in HbA1c, while the highest GA levels did not correspond to HbA1c levels [13]. However, a strong correlation between HbA1c and GA has been reported in cross-sectional studies involving participants without known diabetes [14] and in patients with type 2 diabetes [15].

The low correlation between GA and HbA1c could be further explored if postprandial glucose data were available. GA is thought to better reflect postprandial glycemia and glucose fluctuations than HbA1c. Studies show that fasting glycemia has a stronger relationship with GA and HbA1c than postprandial values. However, we were unable to evaluate this correlation in our study due to insufficient data. It is also important that the study population was selected using criteria to avoid bias. GA may be useful for assessing glucose levels in certain patient populations, as it more quickly reflects the average glycemic status.

Blood sugar control in patients with diabetes reduces the risk of chronic complications. Intensive treatment with insulin or antidiabetic drugs slows down the development of microangiopathies in type 1 and type 2 diabetes. Studies have shown that lower HbA1c levels are associated with a lower incidence of complications. The relationship between HbA1c and GA has also been noted in other studies such as DCCT and ARIC. In our observational study, no significant associations were found between chronic complications and these parameters. In addition, GA may be more valuable in predicting the success of therapy at an early stage of treatment compared to HbA1c. Our work has limitations: small sample size and lack of consistent glycemic data.

CONCLUSIONS

GA was significantly correlated with both HbA1c and fasting glucose in patients with type 2 diabetes. Although HbA1c is recognized as the reference test for monitoring diabetes control, GA may be a useful additional biomarker for short- and medium-term blood glucose fluctuations, which is especially important in situations where the HbA1c test may be biased or even unreliable, or when earlier clinical decision making is required.

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