

Postprint: Research Progress on Glycated Albumin in Gestational Diabetes Mellitus Monitoring

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Abstract

Gestational diabetes mellitus is one of the most common complications during pregnancy, posing a serious threat to maternal and infant health; therefore, monitoring and controlling blood glucose during pregnancy is crucial. Glycated albumin reflects the average blood glucose level over the 2-3 weeks prior to measurement and serves as a short-term blood glucose monitoring indicator. Compared with other blood glucose monitoring indicators, glycated albumin demonstrates greater advantages in applications involving gestational diabetes and can serve as a good indicator for monitoring blood glucose during pregnancy and predicting maternal and infant complications. However, glycated albumin has been less frequently applied in pregnant women, and its normal reference range has not yet been standardized. This review summarizes the research progress regarding glycated albumin in gestational diabetes mellitus.

Full Text

Research Progress of Glycated Albumin in Gestational Diabetes Monitoring

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Abstract

Gestational diabetes mellitus (GDM) is one of the most common complications during pregnancy, posing significant risks to maternal and neonatal health. Effective blood glucose monitoring and control during pregnancy are therefore essential. Glycated albumin (GA) reflects average blood glucose levels over the

preceding 2-3 weeks and serves as a short-term glycemic monitoring indicator. Compared with other blood glucose monitoring methods, GA offers distinct advantages in GDM and can serve as an effective indicator for monitoring blood glucose during pregnancy and predicting maternal and neonatal complications. However, GA has been understudied in pregnant women, and its normal reference range has not yet been standardized. This review summarizes research progress on glycated albumin in gestational diabetes mellitus.

Keywords: Gestational diabetes mellitus; Glycated albumin; Glycosylated hemoglobin; Childbirth outcome

Gestational diabetes mellitus (GDM) refers to varying degrees of glucose intolerance that occur during pregnancy or are first detected during gestation [1]. Risk factors for GDM include abnormal pre-pregnancy BMI and family history of type 2 diabetes [2]. According to 2017 data from the International Diabetes Federation, the global prevalence of GDM is 16.2% [3], while in the United States, the incidence ranges from 6.9% to 17.8% [4]. As diagnostic methods evolve and living standards improve, the incidence of GDM continues to rise annually. A 2010-2012 study of 17,186 pregnant women across 13 hospitals in China reported a domestic GDM incidence of 17.5% [5], representing a 3.4-fold increase from the 5.078% reported in 2006 [6]. Given its close association with both short-term and long-term maternal and neonatal complications [7-9], blood glucose monitoring and achieving good glycemic control are critical in GDM management. Glycosylated hemoglobin (HbA1c) reflects average blood glucose levels over the preceding 2-3 months, but its use in GDM monitoring suffers from a “delayed effect” and is susceptible to influences from hemoglobin concentration and ferritin levels. In contrast, glycated albumin (GA) reflects average blood glucose levels over the preceding 2-3 weeks, is unaffected by changes in globulin and chylomicrons, and has gained increasing attention in diabetes research. GA is well-suited for blood glucose monitoring in GDM, though it has not yet received formal recommendation in relevant clinical guidelines. This review examines various aspects including GDM monitoring methods, measurement techniques and influencing factors, and reference ranges for GA concentrations both domestically and internationally.

1 GDM Monitoring Methods

Clinical blood glucose monitoring methods primarily include urine glucose, blood glucose, and glycated proteins. Urine glucose monitoring is non-invasive and relatively inexpensive, but increased glomerular filtration rate during pregnancy often produces false-positive results, compromising accuracy. Blood glucose monitoring mainly consists of venous plasma glucose measurement and capillary blood glucose self-monitoring. Venous plasma glucose measurement is unsuitable for multiple daily measurements, while capillary blood glucose self-monitoring reflects immediate blood glucose levels. Although multiple daily measurements can provide a preliminary understanding of overall glycemic patterns, results are susceptible to instrument precision and operator factors

[10], as well as emotional fluctuations, exercise, diet, and medications, leading to significant variability. Consequently, capillary glucose monitoring serves primarily as a self-management tool during pregnancy and often cannot serve as a basis for clinical decision-making. Glycated proteins represent important clinical indicators in diabetes diagnosis and management, including both HbA1c and GA.

1.1 Limitations of HbA1c in GDM Monitoring

HbA1c is a product of slow, continuous, and non-enzymatic glycation between glucose and hemoglobin, with its concentration positively correlated with glucose levels, and has become the gold standard for evaluating long-term glycemic control. HbA1c concentration is influenced by red blood cell lifespan; with human red blood cells living approximately 120 days, HbA1c reflects average blood glucose levels over the preceding 2-3 months. The short course of GDM combined with the long half-life of hemoglobin means HbA1c cannot reflect short-term blood glucose levels, creating a “delayed effect.” Furthermore, HbA1c concentration is associated with ferritin metabolism and red blood cell turnover rate. In late pregnancy, increased iron demand and active red blood cell proliferation lead most women to develop iron deficiency or even anemia. Hashimoto et al. [11] demonstrated that elevated HbA1c levels in late pregnancy are associated with iron deficiency, with an inverse correlation between ferritin and HbA1c levels during pregnancy. Therefore, the characteristic iron metabolism during pregnancy may cause HbA1c to overestimate blood glucose levels. Additionally, vitamin C, a common component of prenatal multivitamins, has been shown to inhibit glycation and reduce HbA1c levels [12], potentially leading to underestimation of blood glucose levels during pregnancy. These factors collectively limit the utility of HbA1c for GDM monitoring.

1.2 Advantages of GA in GDM Monitoring

GA formation is dependent on blood glucose concentration and albumin half-life. Compared with red blood cell lifespan, albumin has a much shorter half-life of approximately 17-18 days, making GA a short-term glycemic monitoring indicator that reflects average blood glucose levels over the preceding 2-3 weeks [13]. The 2015 edition of the *Chinese Guidelines for Clinical Application of Blood Glucose Monitoring* notes that GA levels are gradually gaining acceptance and use in diabetes monitoring [14]. However, research on using GA to monitor blood glucose levels during pregnancy remains limited, and GA has not yet received formal recommendation in relevant clinical guidelines.

2 GA Measurement Methods and Influencing Factors

2.1 GA Measurement Methods

GA measurement methods include high-performance liquid chromatography (HPLC), ion exchange chromatography, colorimetric methods, and affinity chro-

matography [15]. The ion-exchange liquid chromatography method developed by Japanese researchers was the earliest approach for GA detection, but its high cost and limited sample processing capacity prevented widespread clinical application. Subsequently, the United States developed a solid-phase enzymatic method for GA detection with high specificity, though results could be affected by factors such as amino acid infusion. Building upon the solid-phase enzymatic method, Japan developed a liquid-phase enzymatic method for measuring GA concentration that incorporates glycated amino acid oxidase to react with endogenous glycated amino acids, preventing interference with test results. Additionally, bromocresol purple was substituted for the original bromocresol green method, reducing the influence of globulin on measurements and improving specificity and accuracy [16]. The liquid enzymatic GA assay kit (Lucica GA-L) developed in Japan is now widely used in clinical practice, with most hospitals and published studies employing this method. China began clinical application of the Japanese liquid enzymatic method for GA measurement in 2003 [17], though the imported reagents remain expensive. In 2016, Lian Guojun et al. [18] established a novel ketamine oxidase method for GA measurement that utilizes specific proteases to cleave GA and release glycated amino acids, which are then oxidized by ketamine oxidase to release hydrogen peroxide. After color development via Trinder's reaction, GA content is determined by comparison with standard solutions. This method shows no significant difference in measurement results compared with the GA assay kit provided by Japan's ASAHI Company, with good correlation, while reagent costs are only approximately one-eighth of the imported price. However, related research remains limited and requires further investigation.

2.2 Factors Influencing GA Monitoring

GA concentration is expressed as the percentage of glycated albumin to total protein and is therefore unaffected by albumin concentration, eliminating bias from individual differences in albumin levels. However, GA is influenced by albumin half-life, and any factor affecting albumin half-life can alter GA values.

2.2.1 Age Age is one factor influencing GA levels, showing a positive correlation. Okada et al. [19] demonstrated that as age increases, albumin metabolism slows, leading to elevated GA values.

2.2.2 Body fat content Body mass index (BMI) shows a negative correlation with GA levels [20-22], possibly related to increased metabolic rate, accelerated albumin turnover, and enhanced catabolism in obese individuals. Reynolds et al. [23] found that glycated albumin levels are lower in adults with higher BMI values.

2.2.3 Infectious or non-infectious inflammatory states Both infectious and non-infectious inflammatory states accelerate albumin synthesis and increase consumption, potentially leading to decreased GA values.

2.2.4 Thyroid hormones Thyroid hormones promote albumin catabolism, thereby affecting GA levels. Koga et al. [24] demonstrated that GA shows significant positive correlation with TSH and significant negative correlation with free T3, free T4, and thyroid hormone (TH). In hyperthyroidism, accelerated serum albumin turnover leads to lower GA values, while hypothyroidism results in higher GA values. Therefore, caution should be exercised when using GA for blood glucose monitoring in pregnant women with thyroid dysfunction.

2.2.5 Other factors Liver cirrhosis slows albumin turnover, resulting in elevated GA levels. In cirrhotic patients with hyperglycemia and hypoalbuminemia (albumin <30 g/L), GA should not be used to assess blood glucose levels [25]. Nephrotic syndrome causes massive albumin loss through urine, leading to hypoalbuminemia and low GA values independent of blood glucose levels. Diabetic patients with nephrotic syndrome also exhibit low glycosylated albumin levels [26]. Excessive glucocorticoids enhance albumin catabolism and shorten its half-life, decreasing GA values, while deficiency increases GA values.

3 GA Reference Ranges

3.1 Non-pregnant GA reference range

All GA values in current research are measured using the Japanese liquid enzymatic method. In 2006, the Japan Diabetes Association proposed a GA reference range of 12.3%–16.9%. A 2011 study of 1,575 Japanese individuals (aged 26–78) without diabetes history suggested that GA $\geq 15.5\%$ could serve as a diagnostic cutoff for diabetes [27]. Kohzuma et al. [28] proposed a reference range of 11.9%–15.8% for healthy American populations. In 2009, Zhou Jian et al. [29] measured GA levels in 380 individuals with normal weight and normal glucose regulation (aged 20–69) across 10 centers in China, recommending 10.8%–17.1% as the normal reference range for Chinese populations. Zhou Xianghai et al. [30] studied 576 individuals without diabetes history in Beijing in 2009, finding a normal GA reference range of 11.89%–16.87%. In 2011, Liu Yansu et al. [31] monitored and analyzed GA in 3,628 non-diabetic individuals, identifying a reference range of 9.17%–18.60%. In 2016, Huang Di et al. [32] studied 3,032 healthy individuals aged 18–70 in Guangzhou, establishing a normal GA reference range of 11%–15%, with the upper limit increasing by approximately 0.4% for each 15-year age increment after age 30.

3.2 Pregnancy GA reference range

As a novel monitoring method for GDM, GA has a relatively short history of application, and all current research employs the liquid enzymatic method. In 2010, the Japan Diabetes and Pregnancy Society recommended GA measurement for preventing perinatal complications in mothers and infants. In 2012, Hiramatsu et al. [33] measured GA levels in 574 pregnant Japanese women with normal glucose metabolism, proposing a reference range of 11.5%–15.7% and

noting that GA values significantly decrease in late pregnancy, with reference ranges of $(14.4 \pm 2.2) \pm 1.9 \pm 2.0\%$ for the first, second, and third trimesters, respectively. Wang Yan [34] compared 80 healthy pregnant women with 50 GDM patients diagnosed during the same period, finding statistically significant differences in GA levels during the second and third trimesters, suggesting GA as an effective indicator for GDM monitoring. Wang Jing et al. [35] studied 101 healthy non-GDM pregnant women in the second trimester in 2013, proposing a normal reference range of 10.9%-15.3% for the second trimester. In 2014, Wang Fenghuan et al. [36] studied 908 normal pregnant women, establishing a GA range of 9.40%-14.70%, with reference ranges of 10.53%-15.30%, 10.00%-13.98%, and 9.03%-13.50% for gestational weeks 12-16, 24-28, and 36-38, respectively. Hao Baojun et al. [37] proposed a normal reference range of 11.1%-15.3% for the second trimester in 2015. Most of these studies excluded cases with thyroid, liver, or kidney diseases that might affect serum albumin turnover, limiting the applicability of these reference ranges.

4 Correlation between GA and HbA1c concentrations during pregnancy

HbA1c is widely used in clinical practice, and studying its correlation with GA helps further understand the clinical significance of GA monitoring. Domestic and international studies show good correlation between GA and HbA1c in non-pregnant populations [38-40], with GA levels roughly ranging from 17.0%-20.0% when HbA1c is 6.5%. The correlation between HbA1c and GA during pregnancy may differ from that in non-pregnant populations. HbA1c concentration shows bidirectional changes during pregnancy, decreasing significantly in the second trimester and increasing in the third trimester, with no significant difference between early and late pregnancy, while GA values are significantly lower in the second and third trimesters compared to early pregnancy [33]. In 2013, Jiemin Pan et al. [41] studied 713 pregnant women (aged 20-35) and found that GA was more closely associated with fasting and postprandial blood glucose than HbA1c ($r=0.511$ for fasting, $r=0.420$ for 2-hour postprandial). They also reported that both HbA1c and GA were associated with insulin resistance, with HbA1c positively correlated with HOMA-IR and GA negatively correlated with HOMA-% β . In 2016, Zhang Shuo et al. [42] analyzed 323 GDM pregnant women (full-term delivery, singleton, without other complications) and found a linear positive correlation between GA and HbA1c ($r=0.4$), with the regression equation $GA = 5.9 + 0.9HbA1c$, indicating that when HbA1c is 5.7%, GA concentration is 11.3%. In the same year, Qiu Fenfang et al. [43] studied 200 pregnant women (98 normal, 57 with impaired glucose tolerance, 45 with GDM) and found correlations between GA and HbA1c levels in all three groups, with r values of 0.587, 0.764, and 0.834, respectively. Jin Yuewen et al. [44] conducted a study on 1,201 pregnant women aged 35 years and found that HbA1c and GA were positively correlated ($r=0.206$, $P<0.01$), with combined detection of HbA1c and GA providing important value in assisting GDM diagnosis in advanced maternal age pregnancies.

5 Correlation between GA concentration and delivery outcomes

Abnormal glucose metabolism in GDM patients often leads to adverse delivery outcomes for both mothers and infants. Maternal hyperglycemia is a primary cause of macrosomia. Wang Fenghuan [45] demonstrated a positive correlation between GA levels at 24-28 weeks and 36-38 weeks of gestation and neonatal birth weight. In 2016, Hua-Ping Li et al. [46] reported that GA concentration exceeding 13.0% at 24-28 weeks of gestation increased the risk of neonatal birth weight >3500g and macrosomia. At 36-38 weeks, GA concentration exceeding 12.0% similarly increased these risks. In the same year, Sugawara et al. [47] conducted a retrospective study of 42 pregnant women (diabetic group mean gestational age 38.2 ± 1.4 weeks, normal group 38.1 ± 1.0 weeks) and found that using 15.8% as the GA cutoff value yielded sensitivities and specificities of 70% and 81.2% for neonatal hypoglycemia, 87.5% and 79.4% for myocardial hypertrophy, and 75% and 85.3% for macrosomia. In 2017, Sugawara [48] further demonstrated that GA showed significant positive correlation with infant complications including neonatal hypoglycemia, hypocalcemia, and polycythemia.

In summary, GA shows promise as an effective monitoring tool for GDM and for predicting delivery outcomes. Efforts should be made to accumulate data necessary for establishing GA reference ranges and diagnostic cutoffs to promote its clinical application in gestational diabetes diagnosis and management.

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