Effectiveness of fructosamine and glycated albumin tests for monitoring glycemic control in diabetes mellitus: a systematic review

Eficácia dos exames frutosamina e albumina glicada para monitoramento do controle glicêmico no diabetes mellitus*: uma revisão sistemática*

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Abstract

Objective: To evaluate the effectiveness of fructosamine and glycated albumin (GA) tests for glycemic monitoring in *diabetes mellitus* (DM). *Methods*: The search for articles was carried out in the Medline/PubMed, Web of Science, Embase and Virtual Health Library databases. The eligibility criteria were cohorts that compared the effectiveness of fructosamine and/or AG tests with glycated hemoglobin (HbA1c) for glycemic monitoring in DM. The reference standard for glycemic monitoring consisted of self-monitoring of blood glucose or continuous sensor glucose monitoring or blood glucose assessed on at least three days for at least two months. *Results*: Among the 11 studies that evaluated patients with dialysis or non-dialysis chronic kidney disease, 7 found greater efficacy of AG and/or fructosamine in relation to HbA1c, 3 found similar efficacy and 1 found lower efficacy. Iron deficiency anemia or erythropoietin deficiency was evaluated in 3 studies and all found that AG and/or fructosamine were more effective than HbA1c. Among the 5 studies that evaluated patients with T1DM or T2DM who did not have clinical conditions that interfere with HbA1c, 4 found similar efficacy between AG and/or fructosamine and HbA1c and 1 observed greater effectiveness of AG. *Conclusion*: Fructosamine and AG have similar efficacy to HbA1c for monitoring glycemic control in patients with T1DM or T2DM who do not have clinical conditions that interfere with HbA1c, however, in situations where there is a change in the quantity or half-life of red blood cells, fructosamine and AG are more effective than HbA1c.

Keywords: *Diabetes Mellitus*. Fructosamine. Glycated Serum Albumin. Blood Glucose. Glycemic Control.

Resumo

Objetivo: Avaliar a eficácia dos exames frutosamina e albumina glicada (AG) para monitoramento glicêmico no *diabetes mellitus* (DM). *Métodos*: A busca dos artigos foi realizada nas bases de dados Medline/PubMed, Web of Science, Embase e Biblioteca Virtual em Saúde. Os critérios de elegibilidade foram coortes que compararam a eficácia dos exames frutosamina e/ou AG com a hemoglobina glicada (HbA1c) para monitoramento glicêmico no DM. O padrão de referência do monitoramento glicêmico consistiu em automonitoramento da glicemia ou sensor de monitoramento contínuo de glicose ou glicemia avaliada em pelo menos 3 dias durante pelo menos 2 meses. *Resultados*: Dentre os 11 estudos que avaliaram pacientes com doença renal crônica dialítica ou não dialítica, 7 encontraram maior eficácia da AG e/ou frutosamina em relação à HbA1c, 3 encontraram eficácia semelhante e 1 menor eficácia. A anemia ferropriva ou deficiência de eritropoietina foi avaliada por 3 estudos e todos verificaram que a AG e/ou frutosamina foram mais eficazes do que a HbA1c. Dentre os 5 estudos que avaliaram pacientes com DM1 ou DM2 que não apresentavam condições clínicas que interferem na HbA1c, 4 encontraram eficácia semelhante entre AG e/ou frutosamina e HbA1c e 1 observou maior eficácia da AG. *Conclusão*: A frutosamina e a AG apresentam eficácia semelhante à HbA1c para monitoramento do controle glicêmico em pacientes com DM1 ou DM2 que não possuem condições clínicas que interferem na HbA1c, entretanto, nas situações em que há alteração na quantidade ou meia-vida das hemácias, a frutosamina e a AG apresentam eficácia superior à HbA1c.

Palavras-chave: *Diabetes Mellitus*. Frutosamina. Albumina Sérica Glicada. Glicemia. Controle Glicêmico.

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Received on 06/21/2024 | Approved on 01/09/2025 | DOI: 10.21877/2448-3877.202500189

INTRODUCTION

The glycated hemoglobin (HbA1c) test is the most recommended method for monitoring glycemic control in patients with type 1 (T1DM) and type 2 *Diabetes mellitus* (T2DM). HbA1c results from a non-enzymatic and irreversible glycation process of hemoglobin, reflecting the average blood glucose levels over the past 3 to 4 months, as the lifespan of red blood cells is approximately 120 days. This allows for long-term glycemic control evaluation.[1]

However, the HbA1c test has certain limitations, as some clinical conditions characterized by alterations in red blood cell count or lifespan may interfere with test results, preventing it from accurately reflecting actual glycemic control in patients with *Diabetes mellitus* (DM). Several factors can lead to falsely reduced HbA1c levels, including hemolytic anemias; bone marrow impairment due to radiation, toxins, or tumors; blood loss; erythropoietin deficiency secondary to chronic kidney disease (CKD); administration of high doses of vitamin C or E, which inhibit hemoglobin glycation; use of antiretroviral drugs, ribavirin, or dapsone, which reduce red blood cell lifespan; and pregnancy. During pregnancy, increased blood volume leads to a decrease in red blood cell concentration and physiological anemia, resulting in a falsely reduced HbA1c level.[2,3]

Conversely, other factors can result in falsely elevated HbA1c levels, such as iron, vitamin B12, or folic acid deficiency, which increases red blood cell lifespan; the presence of carbamylated hemoglobin in patients with kidney disease; the presence of acetylated hemoglobin in patients using high doses of acetylsalicylic acid; chronic alcoholism; the use of phenobarbital, which enhances glucose reactivity with hemoglobin; and conditions that lead to an increase in red blood cell count and/or hematocrit levels.[2,3]

Some hemoglobinopathies may result in falsely elevated or falsely reduced values, or may not interfere with HbA1c measurement at all, depending on the method used for its laboratory measurement. Additionally, glycemic variability throughout the day cannot be assessed using HbA1c, as patients who experience episodes of both hyperglycemia and hypoglycemia may still present HbA1c levels within the therapeutic target range.[2]

Given the limitations of HbA1c measurement, fructosamine and glycated albumin (GA) have emerged as alternative tests for monitoring blood glucose levels in patients with DM. Fructosamine consists of plasma proteins irreversibly bound to glucose, with the majority corresponding to albumin, whereas GA specifically measures plasma albumin irreversibly bound to glucose. Since albumin has a half-life of approximately 21 days, GA and fructosamine reflect glycemic control over the past 2 to 3 weeks, allowing for short-term monitoring of glycemic control.[4]

These tests are not affected by clinical conditions that alter red blood cell lifespan or count. Additionally, the non-enzymatic glycation rate of albumin is approximately ten times higher than that of hemoglobin. As a result, GA exhibits greater fluctuation compared to HbA1c, allowing for the faster detection of glycemic changes. However, conditions that alter plasma protein levels, such as nephrotic syndrome, chronic hepatitis, and thyroid diseases, may interfere with fructosamine and GA levels. Nevertheless, the use of the GA/total albumin ratio helps minimize this interference.[4]

Given the limitations of using HbA1c for monitoring glycemic control in patients with DM and the need for alternative methods—especially for patients with clinical conditions affecting red blood cell lifespan or count—conducting a systematic review to assess the efficacy of fructosamine and GA tests for glycemic control monitoring in DM is essential.

MATERIALS AND METHODS

Study Design

A systematic review conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[5] and the Preferred Reporting Items for a Systematic Review and Meta-analysis of Diagnostic Test Accuracy Studies (PRISMA-DTA) recommendations.[6]

Search Strategy

Article selection was conducted in Medline (PubMed), Web of Science, Embase, and the Virtual Health Library (VHL) using the descriptors "fructosamine" and "glycated serum albumin" along with their respective entry terms, in combination with the descriptor "diabetes mellitus" and its entry terms, applying "AND" between terms. The descriptors were defined according to Medical Subject Headings (MeSH).

Eligibility Criteria

The eligibility criteria were established following the PRISMA-DTA[6] recommendations and consisted of prospective or retrospective cohort studies that assessed the effectiveness of fructosamine and GA tests compared to HbA1c for glycemic control monitoring in DM.

Only studies whose experimental design allowed for the distinction of the following points, as per the PIRTS acronym, were included in the systematic review:

- ***Participants***: Patients with DM.
- ***Index test***: Fructosamine and/or GA compared to HbA1c.
- ***Reference standard***: Average blood glucose assessed through self-monitoring of blood glucose, continuous glucose monitoring (CGM) sensor, or blood glucose measured on at least three different days over at least two months.
- ***Target conditions***: Effectiveness in assessing glycemic control.
- ***Study design***: Prospective or retrospective cohort study.
- The article search in the databases was conducted from May 11, 2023, to September 14, 2023, with no restrictions on publication year or language.

Article Selection

The study selection was carried out in two stages, both conducted independently by two reviewers. In the first stage, duplicate articles were removed, followed by a preliminary screening of titles and abstracts to include only prospective or retrospective cohort studies evaluating the effectiveness of fructosamine and GA tests for glycemic control monitoring in DM. In the second stage, the pre-selected articles were read in full to assess their eligibility based on the predefined criteria. A flowchart was then developed summarizing the number of articles included and excluded at each stage according to the established criteria, following PRISMA recommendations.[5]

Data Extraction from Selected Articles

The following data were extracted from the studies for table construction: author, year of publication, country, study design, patient characteristics, age, sample size, methods used for HbA1c, GA, and fructosamine measurement, method used for glycemic monitoring assessment, effectiveness of GA and/or fructosamine for glycemic control monitoring, and results.

Assessment of Study Quality

The methodological quality assessment of the studies included in the systematic review was conducted independently by two reviewers. The Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool,[7] which evaluates the risk of bias in diagnostic accuracy studies, was used for the assessment of study quality. This tool comprises four domains: patient selection, index test, reference standard, and flow and timing. All domains are assessed for risk of bias, and the first three domains are also evaluated for study applicability. The risk of bias and study applicability are classified as "low," "high," or "uncertain."

RESULTS

The stages of the article selection process are presented in a flowchart (Figure 1). After applying the eligibility criteria, 19 cohort studies were included in the systematic review, of which 17[8-15,17-22,24-26] were prospective cohorts (89.5%) and 2[16,23] were retrospective cohorts (10.5%).

Table 1 presents the location, study design, patient characteristics, sample size, age, methods used for HbA1c, GA, and fructosamine measurement, and the evaluation of glycemic monitoring in the studies included in the systematic review.

Regarding the location of the studies, 6 of them[8,17,20,22,24,25] (31.6%) were conducted in Japan, 4[12,14,15,26] (21.1%) in the United States, and one study (5.3%) was conducted in each of the following countries: Norway,[9] Greece,[10] Italy,[11] Egypt,[13] Brazil,[16] Taiwan,[19] New Zealand,[21] and South Korea.[23] The sample size of the studies ranged from 21 to 903 patients.

Regarding patient characteristics, 2 studies (10.6%) assessed patients with T2DM undergoing hemodialysis (HD) and without nephropathy.[17,24] Each of the following patient groups was assessed in one study (5.3%): patients with T2DM,[22] patients with and without T2DM,[26] patients with T2DM undergoing HD,[8] patients with T2DM with and without CKD,[14] patients with T2DM and CKD with iron deficiency anemia or erythropoietin deficiency,[18] obese adolescents with prediabetes or T2DM,[15] children with T1DM with and without iron deficiency anemia,[13] adults with T1DM,[20] patients with T1DM or T2DM,[12] patients with T1DM or T2DM undergoing HD,[11] pregnant women with pre-gestational diabetes (T1DM or T2DM or maturity-onset diabetes of the young [MODY]),[9] pregnant women with T1DM or T2DM or gestational *Diabetes mellitus* (GDM) or overt diabetes,[16] patients undergoing HD with and without diabetes,[10] patients with diabetes undergoing peritoneal dialysis (PD),[19] patients with diabetes with and without CKD,[23] patients with diabetes undergoing HD without nephropathy,[21] and patients with diabetes with end-stage CKD (ESCKD) (pre-dialytic or dialytic) without nephropathy.[25]

Regarding age range, 2 studies[13,15] (10.5%) included children and adolescents aged 5 to 18 years. The other 17 studies[8-12,14,16-26] (89.5%) conducted their research with adults and older adults.

The most commonly used method for evaluating HbA1c was high-performance liquid chromatography, employed by 15 studies[9,10,12,14-23,25,26] (78.9%). One study[11] (5.3%) used capillary electrophoresis, one study[13] (5.3%) used the colorimetric method, one study[24] (5.3%) used immunoturbidimetry, and one study[24] (5.3%) did not report the method used.

The enzymatic method was the most commonly used for evaluating GA, utilized by 12 studies[8,13-15,17,18,20-25] (63.2%). Two studies[11,12] (10.5%) used the colorimetric method, one study[10] (5.3%) used ELISA, one study[9] (5.3%) used liquid chromatography-mass spectrometry, one study (19) (5.3%) used immunoturbidimetry, and two studies[16,26] (10.5%) did not report the method used for this analysis.

The colorimetric method was the most commonly used for evaluating fructosamine, employed by 7 studies[14-16,18,19,21,26] (36.8%). Only one study[12] (5.26%) used the enzymatic method, and 11 studies[8-11,13,17,20,22-25] (57.9%) did not report the method used for this measurement.

Glycemic control assessment was conducted using CGM sensors in 11 studies[8-10,14,15,17-21,26] (57.9%), 5 studies[12,13,16,22,25] (26.3%) used self-monitoring with a glucometer, and 3 studies[11,23,24] (15.8%) measured blood glucose at different times during the research.

Table 2 describes the main results and indicates whether GA and/or fructosamine were effective or not for monitoring glycemic control in the studies included in the systematic review.

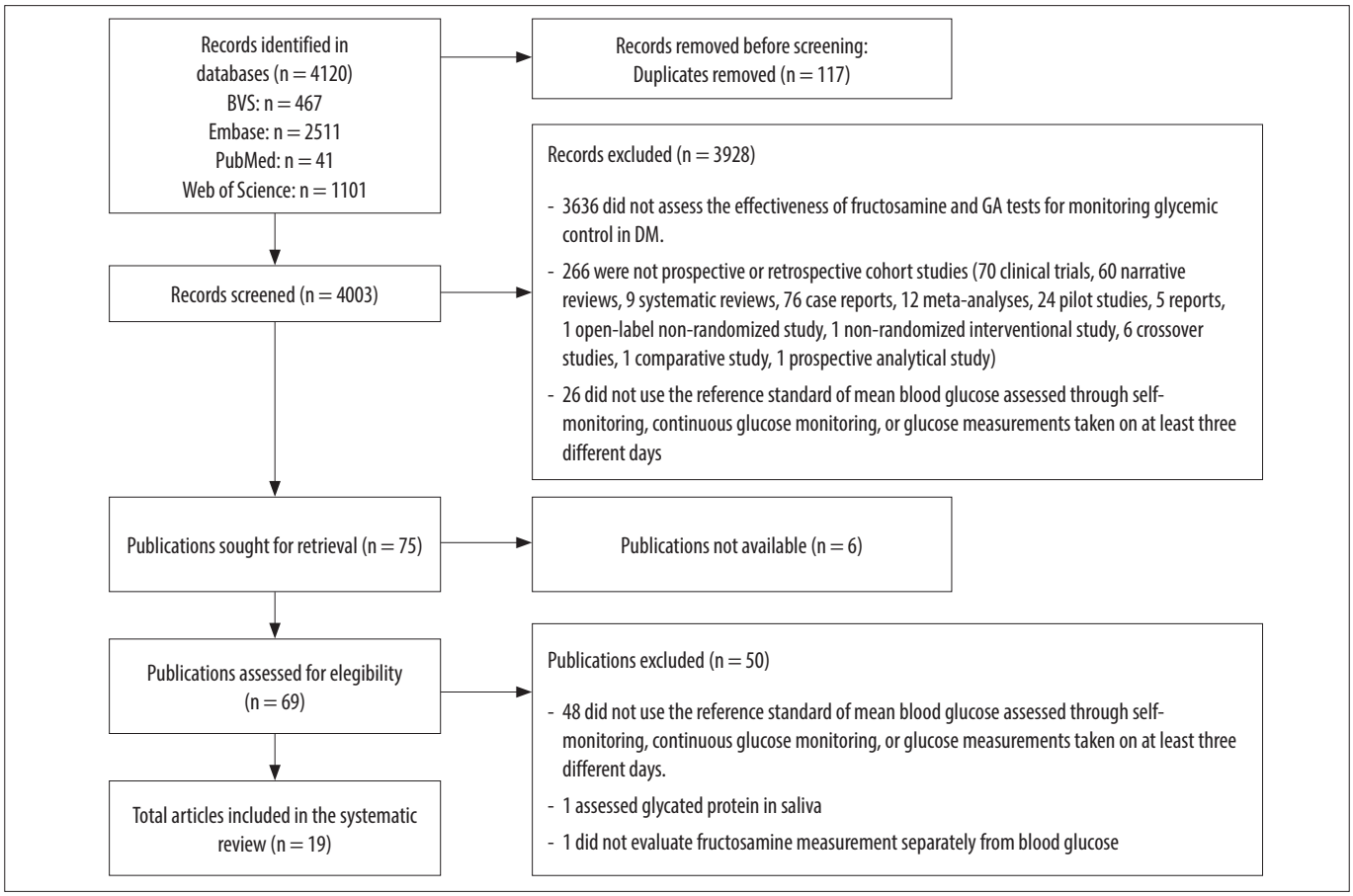

Figure 1

Flowchart of the article selection process for studies evaluating the effectiveness of fructosamine and glycated albumin tests in monitoring glycemic control in *Diabetes mellitus*, included in the systematic review. Source: Authors.

Table 1

Location, study design, patient characteristics, sample size, age, methods used for measuring HbA1c, glycated albumin, and fructosamine, and for assessing glycemic monitoring in the studies included in the systematic review.

Author, Year	Country	Study Design	Patient characteristics and sample size	Age (years)	Methods used for measuring HbA1c, glycated albumin, and fructosamine	Method used for assessing glycemic monitoring
Hayashi et al., 2023[8]	Japan	Prospective Cohort	107 patients with T2DM on HD	62 ± 12	NI; Enzymatic; NA	Use of CGM sensor for 48 hours. The estimated mean CGM glucose level was calculated. The percentage of time glucose levels were between 70 and 180 mg/dL was considered TIR, <70 mg/dL as TBR, and >180 mg/dL as TAR.
Toft et al., 2022 [9]	Norway	Prospective Cohort	40 pregnant women with pregestational diabetes (23 with T1DM, 13 with T2DM, 1 with MODY)	30.9 ± 5.5	HPLC LC-MS/MS; NA	Use of CGM sensor. Blood glucose concentrations were estimated every 10 or 15 minutes from interstitial glucose levels during the 14 days preceding each blood sample collection at weeks 12, 20, 24, 28, 32, and 36 of pregnancy. The estimated mean CGM glucose level was calculated. The percentage of time with glucose levels <63 mg/dL was defined as TBR, >140 mg/dL as TAR, and <54 mg/dL as TBR2.
Divani et al., 2021 [10]	Greek	Prospective Cohort	37 patients with T1DM or T2DM on HD	62.0 ± 17.3	HPLC; ELISA; NA	Use of CGM sensor. Blood glucose concentrations were estimated every 5 minutes from interstitial glucose levels over 7 days. The estimated mean CGM glucose level was calculated. Glycemia between 70 and 180 mg/dL in <50% of readings was considered TIR, <70 mg/dL in >10% of readings as TBR, and >250 mg/dL in >1% of readings as TAR.
Martino et al., 2021[11]	Italy	Prospective Cohort	160 patients on HD (60 with DM, 98 without DM, 2 with impaired glucose tolerance).	64.1 ± 12.6	Capillary electrophoresis; Colorimetric; NA	Glycemia was assessed at five time points: T0, T1 (after 30 days), T2 (after 60 days), T3 (after 90 days), and T4 (after 6 months).
Desouza et al., 2020[12]	United States	Prospective Cohort	150 patients with DM (73 with T1DM and 77 with T2DM).	50.5 ± 15.63	HPLC; Colorimetric; Enzymatic.	Fasting glucose was assessed at weeks 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24. Self-monitoring of capillary blood glucose was performed 7 times, at least 1 day per week, using a glucometer.
Mahgoob e Moussa, 2020[13]	Egypt	Prospective Cohort	147 children with T1DM (72 with iron deficiency anemia and 75 without iron deficiency anemia).	9.9 ± 3.40 years with anemia; 10.4 ± 2.91 years without anemia.	Colorimetric; Enzymatic; NA	Self-monitoring of blood glucose by measuring capillary glucose seven times a day for 30 days using a glucometer. The 30-day mean glucose level was calculated.
Zelnick et al., 2020 [14]	United States	Prospective Cohort	105 patients with T2DM (81 with moderate to severe CKD and 24 without CKD).	68.4 ± 9.6 years with CKD; 64.3 ± 10.3 years without CKD.	HPLC; Enzymatic; Colorimetric.	Use of CGM sensor during two non-consecutive 6-day periods separated by 2 weeks. Blood glucose concentrations were estimated every 5 minutes from interstitial glucose levels. The estimated mean CGM glucose level was calculated from all valid CGM measurements in both periods.
Chan et al., 2017 [15]	United States	Prospective Cohort	56 obese adolescents with prediabetes or T2DM.	14.3 (12.5 – 15.9)	HPLC; Enzymatic; Colorimetric.	Use of CGM sensor for 72 hours. The estimated mean CGM glucose level was calculated.
Fujimoto et al., 2016 [16]	Brazil	Prospective Cohort	158 pregnant women (11 with T1DM, 36 with T2DM, 109 with GDM, 2 with overt diabetes).	NI	HPLC; NA; Colorimetric	Self-monitoring of blood glucose, measuring capillary glucose four to seven times a day, depending on insulin use, for 20 days. The frequency of hyperglycemia (glucose levels above the therapeutic target for the time of measurement) and hypoglycemia (glucose levels <70 mg/dL) was calculated.
Hayashi et al., 2016 [17]	Japan	Prospective Cohort	97 patients with T2DM (41 on HD, 56 without nephropathy).	60.2 ± 11.7 years on HD; 55.9 ± 16.7 years without nephropathy.	HPLC; Enzymatic; NA	Use of CGM sensor for 72 hours. The estimated mean CGM glucose level and the glucose standard deviation were calculated. The following markers of glucose variability were calculated: difference between the highest and lowest glucose levels, J index (combination of the mean and standard deviation of all glucose values), mean amplitude of glucose excursions, degree of dissociation from the ideal glucose level, glycemic control index (sum of hyperglycemic and hypoglycemic indices), and the average daily difference between glucose values at the same time of day on two consecutive days.
Konya et al., 2013 [18]	United Kingdom	Prospective Cohort	30 patients with T2DM and CKD stages 3b or 4 (15 with iron deficiency anemia and 15 with erythropoietin deficiency).	72 (68-74) years with iron deficiency anemia; 70 (62-75) years with erythropoietin deficiency.	HPLC; Enzymatic; Colorimetric.	Use of CGM sensor 1 month before the start of therapy with iron or erythropoiesis-stimulating agent and 1 month after the end of therapy. The estimated mean CGM glucose level was calculated.

Table 1 (continuation)

Author, Year	Country	Study Design	Patient characteristics and sample size	Age (years)	Methods used for measuring HbA1c, glycated albumin, and fructosamine	Method used for assessing glycemic monitoring
Lee et al., 2013 [19]	Taiwan	Prospective Cohort	25 patients with DM on PD.	59 ± 13	HPLC; Immunoturbidimetry; Colorimetric.	Use of CGM sensor for 3 days. Blood glucose concentrations were estimated every 5 minutes. The AUC of the 3-day mean glucose level was calculated.
Tsutsumi et al., 2013 [20]	Japan	Prospective Cohort	21 patients with T1DM.	42 (25- 75)	HPLC; Enzymatic; NA	Use of CGM sensor for 72 hours. The estimated mean CGM glucose level, glucose standard deviation, and coefficient of variation were calculated. The following markers of glucose variability were calculated: AUC for glucose levels > 180 mg/dL and < 70 mg/dL, TAR (percentage of time glucose was > 180 mg/dL), TBR (percentage of time glucose was < 70 mg/dL), J index (combination of the mean and standard deviation of all glucose values), high glucose index, low glucose index, degree of dissociation from the ideal glucose level, glycemic control index (sum of hyperglycemic and hypoglycemic indices), and the average daily difference between glucose values at the same time of day on two consecutive days.
Vos et al., 2012 [21]	New Zealand	Prospective Cohort	50 patients with DM (25 with CKD stages 4 or 5 and 25 without CKD).	60.2 (32-79) years with CKD; 59.3 (40-76) years without CKD.	HPLC; Enzymatic; Colorimetric.	Use of CGM sensor for 48 hours. Blood glucose concentrations were estimated every 5 minutes. The estimated mean CGM glucose level was calculated.
Sakuma et al., 2011 [22]	Japan	Prospective Cohort	40 patients with T2DM	66.2 ± 8.8	HPLC; Enzymatic; NA	Self-monitoring of blood glucose 3 times a day for more than 2 days during 1 to 2 weeks and 3 to 4 weeks prior to the monthly measurement of HbA1c and glycated albumin, which were measured monthly for 4 months.
Park et al., 2009 [23]	Korea	Prospective Cohort	108 patients with DM (70 in HD and 38 without CKD).	58.4 ± 12.8 years in HD; 56.8 ± 11.6 years without CKD.	HPLC; Enzymatic; NA	Blood glucose measurements from 1 month ago, 2 months ago, and 3 months ago.
Inaba et al., 2007 [24]	Japan	Prospective Cohort	903 patients with T2DM (538 in HD and 365 without CKD).	NI	Immunoturbidimetry; Enzymatic; NA.	The average values of 3 casual blood glucose measurements obtained during the 2 months prior to the HbA1c and glycated albumin measurements.
Chujo et al., 2006 [25]	Japan	Prospective Cohort	86 patients with DM with ESCKD (49 pre-dialysis and 37 on dialysis) and 40 with DM without CKD	63.9 ± 13.1 pre-dialysis; 64.4 ± 11.1 on dialysis; 57.7 ± 14.4 without CKD.	HPLC; Enzymatic; NA	Self-monitoring of blood glucose 7 times a day and the mean blood glucose was calculated.
Cefalu et al., 1989 [26]	United States	Prospective Cohort	40 with T2DM 16 without DM	78 ± 2 with T2DM 83 ± 3 without DM	HPLC; NA; Colorimetric	Fasting blood glucose was evaluated monthly for 4 months. Use of CGM sensor by 13 patients with T2DM. The average capillary glucose from CGM was calculated.

T1DM = Type 1 *Diabetes mellitus*; T2DM = Type 2 *Diabetes mellitus*; GDM = Gestational *Diabetes mellitus*; DM = *Diabetes mellitus*; PD = Peritoneal dialysis; CKD = Chronic kidney disease; ESCKD = End-stage chronic kidney disease; ELISA = Enzyme-linked immunosorbent assay; HbA1c = Glycated hemoglobin; HD = Hemodialysis; LC-MS/MS = Liquid chromatography-tandem mass spectrometry; CGM = Continuous glucose monitoring; NA = Not assessed; NI = Not informed; TAR = Time above range; TBR = Time below range; TIR = Time in range; HPLC = High-performance liquid chromatography; AUC = Area under the curve; T0 = Time zero; T1 = Time one; T2 = Time two; T3 = Time three; T4 = Time four.

Table 2

Main results and efficacy of glycated albumin and/or fructosamine for monitoring glycemic control in the studies included in the systematic review.

Author, Year	Results	Efficacy of glycated albumin and/or fructosamine for monitoring glycemic control
Hayashi et al., 2023 [8]	The higher the TIR, the lower the HbA1c and glycated albumin levels. No significant correlations were found between TBR and HbA1c, or TBR and glycated albumin ($R^2 = 0.030$, $p = 0.0749$; $R^2 = 0.032$, $p = 0.0652$, respectively). Significant correlations were found between TAR and HbA1c, and TAR and glycated albumin ($R^2 = 0.45$, $p < 0.0001$; $R^2 = 0.26$, $p < 0.0001$, respectively).	Glycated albumin and HbA1c were equally effective in monitoring glycemic control in patients with T2DM on hemodialysis.
Toft et al., 2022 [9]	Correlations were observed between glycated albumin and mean glucose 0.49 (0.28, 0.62), TIR -0.58 (-0.77, -0.27), TAR 0.56 (0.35, 0.71), and TBR -0.09 (-0.47, -0.25), and between HbA1c and mean glucose 0.63 (0.32, 0.79), TAR 0.58 (0.22, 0.77), and TBR -0.44 (-0.64, -0.14). The adjusted AUCs for glycated albumin in detecting TIR < 70%, TAR > 25%, TBR > 4%, and TBR2 > 1% were 0.78 (0.60 - 0.95), 0.82 (0.70 - 0.94), 0.56 (0.31 - 0.82), and 0.66 (0.42 - 0.90), respectively. The adjusted AUCs for HbA1c in detecting TIR < 70%, TAR > 25%, TBR > 4%, and TBR2 > 1% were 0.60 (0.41 - 0.78), 0.72 (0.54 - 0.90), 0.30 (0.13 - 0.47), and 0.32 (0.13 - 0.52), respectively. The ideal cutoff value for glycated albumin to detect TIR < 70% was > 10.5%, with a sensitivity of 68% (52% - 83%) and specificity of 73% (51% - 95%). The ideal cutoff value for glycated albumin to detect TAR > 25% was > 11%, with a sensitivity of 70% (54% - 87%) and specificity of 79% (62% - 96%).	Glycated albumin was more effective than HbA1c in monitoring glycemic control in pregnant women with pre-gestational diabetes, as glycated albumin was more accurate than HbA1c in detecting TIR < 70% and TAR > 25%.
Divani et al., 2021 [10]	Glycated albumin levels were higher in patients with TIR < 50% (21.9 ± 4.6%) than in those with TIR ≥ 50% (15.0 ± 4.1%) ($p < 0.001$). HbA1c levels did not differ between patients with TIR < 50% (7.1 ± 1.3%) compared to those with TIR ≥ 50% (6.3 ± 1.4%) ($p = 0.10$). The AUC for glycated albumin and HbA1c for detecting TIR < 50% was 0.878 (0.728 - 0.962) and 0.682 (0.508 - 0.825), respectively. The AUC for glycated albumin was significantly higher than the AUC for HbA1c, with a difference of 0.196 (0.062 - 0.330) ($p < 0.01$). The ideal cutoff for glycated albumin was > 18.96%, with sensitivity of 90.9% and specificity of 88.4%, resulting in a Youden index of 0.793. The ideal cutoff for HbA1c was > 6.29%, which did not provide a satisfactory combination of sensitivity (81.8%) and specificity (61.5%) in detecting TIR > 50%. The Youden index was 0.433, indicating lower diagnostic efficiency of HbA1c. The AUC for glycated albumin and HbA1c in detecting a TAR > 10% was 0.939 (0.808 - 0.991) and 0.854 (0.699 - 0.945), respectively. The difference in AUCs was not statistically significant, with a difference between areas of 0.085 (-0.034 - 0.204) ($p = 0.16$). The ideal cutoff for glycated albumin was > 16.27%, with 100% sensitivity and 79.2% specificity, resulting in a Youden index of 0.791. The ideal cutoff for HbA1c was > 6.29%, with sensitivity of 92.3% and specificity of 70.8%, yielding a Youden index of 0.631. The AUC for detecting a TBR > 1% was 0.712 (0.539 - 0.848) for glycated albumin and 0.740 (0.570 - 0.870) for HbA1c. Neither glycated albumin nor HbA1c had a satisfactory combination of sensitivity and specificity for detecting TBR > 1%. The Youden index was 0.429 and 0.471 for glycated albumin and HbA1c, respectively, indicating lower efficiency of both biomarkers in detecting hypoglycemia.	Glycated albumin was more effective than HbA1c in monitoring glycemic control in patients with T1DM or T2DM on hemodialysis, as glycated albumin was more accurate than HbA1c in detecting TIR < 50% and TAR > 10%.
Martino et al., 2021 [11]	For the cutoff point of 14.5% glycated albumin, sensitivity was 84.77% and specificity was 77.95%. For the cutoff point of 48 mmol/mol HbA1c, sensitivity was 39.51% and specificity was 99.55%. The ROC curves for glycated albumin and HbA1c showed AUCs of 0.883 and 0.927, respectively ($p < 0.001$). In uremic patients, both diabetic and non-diabetic, the discrepancies between glycated albumin and HbA1c were 21.2% and 20.8%, respectively. These discrepancies were characterized by glycated albumin values above the cutoff point already at T0 and by HbA1c values within the normal range at T0, with a progressive increase in subsequent measurement times.	Glycated albumin was more effective than HbA1c in monitoring glycemic control in HD patients with and without DM, as glycated albumin showed greater predictive capacity in the early detection of glycometabolic issues than HbA1c.

Table 2 (continuation)

Author, Year	Results	Efficacy of glycated albumin and/or fructosamine for monitoring glycemic control
Desouza et al., 2020 [12]	In patients with HbA1c between 7.5% and 12.0% (n = 98), during the first 3 months of the study, the Spearman correlations were 0.481 between glycated albumin and average blood glucose, and 0.233 between HbA1c and average blood glucose, with a significant difference of 0.249 (0.130 - 0.367) ($p < 0.0001$). The Kendall correlations (which analyze the direction in which changes in glucose indices occurred) were higher between glycated albumin and average blood glucose (0.341) than between HbA1c and average blood glucose (0.160), with a significant difference of 0.181 (0.096 - 0.265) ($p < 0.0001$). Although there was a high level of agreement between glycated albumin and fructosamine, as measured by Pearson (0.9198), Spearman (0.9491), and Kendall (0.7639) correlations, glycated albumin consistently showed higher correlations with HbA1c and average blood glucose than fructosamine. The correlations between glycated albumin and HbA1c (0.585) and between glycated albumin and average blood glucose (0.548) were significantly higher than those observed between fructosamine and HbA1c (0.395) and between fructosamine and average blood glucose (0.413) ($p < 0.001$). Changes in glycated albumin were consistent (either increased or decreased in the same direction) with changes in average blood glucose 60.8% of the time, with fructosamine in 55.5%, and with HbA1c in 45.5%.	Glycated albumin was more effective than HbA1c and fructosamine in monitoring glycemic control in patients with T1DM or T2DM, as glycated albumin showed a stronger correlation with average blood glucose than both HbA1c and fructosamine.
Mahgoob e Moussa, 2020 [13]	In patients without iron-deficiency anemia, the average blood glucose showed significant correlations with HbA1c ($r = 0.73$, $p < 0.01$) and glycated albumin ($r = 0.47$, $p < 0.01$). In patients with iron-deficiency anemia, the average blood glucose showed a correlation only with glycated albumin ($r = 0.52$, $p < 0.01$). The ROC curve analysis for HbA1c and glycated albumin in predicting uncontrolled DM in patients with iron-deficiency anemia showed that glycated albumin, with a cutoff point > 16.9%, had a sensitivity of 87.2% and specificity of 75.8%. On the other hand, HbA1c, with a cutoff point > 7.09%, had a sensitivity of 80.0% and specificity of 57.6%.	Glycated albumin was more effective than HbA1c in monitoring glycemic control in patients with T1DM and iron deficiency anemia, as glycated albumin showed a stronger correlation with average blood glucose and higher sensitivity and specificity for predicting uncontrolled diabetes compared to HbA1c.
Zelnick et al., 2020 [14]	The Pearson correlations of HbA1c, glycated albumin, and fructosamine with estimated average blood glucose were similar both for patients without CKD ($r = 0.76$; $r = 0.72$; $r = 0.63$, respectively) and for those with CKD ($r = 0.78$; $r = 0.78$; $r = 0.71$, respectively). For patients without CKD, the values of HbA1c, glycated albumin, and fructosamine were within 10% of the value predicted by estimated average blood glucose in 78%, 52%, and 43% of the cases, respectively. For patients with CKD, the values of HbA1c, glycated albumin, and fructosamine were within 10% of the value predicted by estimated average blood glucose in 75%, 55%, and 64% of the cases, respectively. HbA1c, glycated albumin, and fructosamine were significantly more variable as markers for estimated average blood glucose in patients with lower GFR. For patients with the same estimated average blood glucose, glycated albumin and fructosamine levels were lower in those with lower age, higher BMI, lower serum iron, lower transferrin saturation, lower serum albumin, and higher albuminuria, while HbA1c levels were lower in those with higher albuminuria. The change in estimated average blood glucose during the two periods was more strongly correlated with the change in glycated albumin ($r = 0.67$) than with the change in fructosamine ($r = 0.48$) or HbA1c ($r = 0.26$).	Glycated albumin and fructosamine were less effective than HbA1c in monitoring glycemic control in patients with T2DM and CKD, as they showed greater variability than HbA1c and had more sources of bias.
Chan et al., 2017 [15]	Fructosamine correlated with mean blood glucose ($r = 0.42$, $p = 0.002$), glucose peak ($r = 0.34$, $p = 0.01$), mean amplitude of glycemic excursions ($r = 0.33$, $p = 0.01$), percentage of time with blood glucose > 120 mg/dL ($r = 0.40$, $p = 0.002$), > 140 mg/dL ($r = 0.33$, $p = 0.01$), and > 200 mg/dL ($r = 0.37$, $p = 0.006$). Glycated albumin correlated with mean blood glucose ($r = 0.34$, $p = 0.001$), glucose peak ($r = 0.38$, $p = 0.004$), AUC > 180 ($r = 0.33$, $p = 0.01$), glycemic standard deviation ($r = 0.41$, $p = 0.002$), mean amplitude of glycemic excursions ($r = 0.45$, $p = 0.0006$), percentage of time with blood glucose > 120 mg/dL ($r = 0.43$, $p = 0.02$), > 140 mg/dL ($r = 0.37$, $p = 0.005$), and > 200 mg/dL ($r = 0.43$, $p = 0.001$). HbA1c correlated with mean blood glucose ($r = 0.36$, $p = 0.006$), glycemic standard deviation ($r = 0.32$, $p = 0.02$), mean amplitude of glycemic excursions ($r = 0.38$, $p = 0.003$), percentage of time with blood glucose > 120 mg/dL ($r = 0.32$, $p = 0.02$), and > 140 mg/dL ($r = 0.34$, $p = 0.01$).	Glycated albumin, fructosamine, and HbA1c were equally effective in monitoring glycemic control in obese adolescents with prediabetes or T2DM.

Table 2 (continuation)

Author, Year	Results	Efficacy of glycated albumin and/or fructosamine for monitoring glycemic control
Fujimoto et al., 2016 [16]	The Kendall's τ coefficients obtained were $T = 0.19$ between fructosamine and HbA1c ($p < 0.001$); $T = 0.29$ between fructosamine and hyperglycemia frequency ($p < 0.001$); $T = 0.09$ between fructosamine and hypoglycemia frequency ($p = 0.046$); $T = 0.50$ between HbA1c and hyperglycemia frequency ($p < 0.001$); and $T = 0.25$ between HbA1c and hypoglycemia frequency ($p < 0.001$). For predicting hyperglycemia frequency, the fructosamine measurement showed a linear correlation coefficient of $R^2 = 0.26$ ($p < 0.001$), while the HbA1c measurement showed a linear correlation coefficient of $R^2 = 0.513$ ($p < 0.001$). A 1% increase in HbA1c levels predicts a 17.2% increase (15.15–19.24%) in hyperglycemia frequency in 51.3% of cases ($p < 0.001$). A 1 µmol/L increase in fructosamine levels predicts a 0.29% increase (0.24–0.35) in hyperglycemia frequency in 26.5% of cases ($p < 0.001$). The fructosamine measurement showed a linear correlation coefficient of $R^2 = 0.033$ for predicting hypoglycemia frequency ($p = 0.003$), whereas the HbA1c measurement showed a linear correlation coefficient of $R^2 = 0.059$ for predicting hypoglycemia frequency ($p < 0.001$). Only 3.3% of the variation in hypoglycemia frequency can be explained by variations in fructosamine levels, while 5.9% can be explained by variations in HbA1c levels.	Fructosamine was less effective than HbA1c in monitoring glycemic control in pregnant women with T1DM, T2DM, gestational diabetes, or overt diabetes, as fructosamine showed a lower correlation with the frequency of hyperglycemia and hypoglycemia compared to HbA1c.
Hayashi et al., 2016 [17]	Mean blood glucose correlated with HbA1c in patients on hemodialysis ($r = 0.59$, $p < 0.0001$) and in those without nephropathy ($r = 0.40$, $p < 0.005$). Mean blood glucose correlated with glycated albumin in patients on hemodialysis ($r = 0.42$, $p < 0.01$) and in those without nephropathy ($r = 0.60$, $p < 0.0001$). HbA1c correlated with glycemic standard deviation in patients on hemodialysis ($r = 0.47$, $p = 0.005$) but not in those without nephropathy. Glycated albumin correlated with glycemic standard deviation in patients on hemodialysis ($r = 0.68$, $p = 0.0001$) and in those without nephropathy ($r = 0.31$, $p = 0.05$). Both HbA1c and glycated albumin correlated with glycemic variability markers.	Glycated albumin and HbA1c were equally effective in monitoring glycemic control in patients with T2DM on HD.
Konya et al., 2013 [18]	In patients with iron deficiency anemia, HbA1c levels decreased from 7.4% (5.5–8.9%) to 7.0% (5.1–8.6%) after iron therapy ($p < 0.001$); however, glycated albumin, fructosamine, and estimated average glucose levels did not change after iron therapy. HbA1c levels decreased from 7.3% (5.5–9.7%) to 6.6% (5.1–8.7%) after erythropoiesis-stimulating agent therapy ($p = 0.01$); however, glycated albumin, fructosamine, and estimated average glucose levels did not change after erythropoiesis-stimulating agent therapy.	Glycated albumin and fructosamine were more effective than HbA1c in monitoring glycemic control in patients with T2DM and CKD stages 3b or 4, especially those with iron-deficiency anemia or erythropoietin deficiency. This is due to the higher sensitivity of these markers in reflecting short-term glycemic fluctuations and their lower interference from conditions such as anemia, which can affect HbA1c levels.
Lee et al., 2013 [19]	The AUC of the 3-day average blood glucose correlated with fructosamine ($r = 0.45$, $p = 0.05$), fructosamine corrected by albumin ($r = 0.54$, $p = 0.01$), and HbA1c ($r = 0.51$, $p < 0.01$). The AUC of the 3-day average blood glucose did not correlate with glycated albumin ($r = -0.26$, $p = 0.26$) or with fasting glucose ($r = 0.36$, $p = 0.08$).	Corrected fructosamine by albumin and HbA1c were equally effective in monitoring glycemic control in patients with diabetes mellitus on PD and were more effective than glycated albumin.
Tsutsumi et al., 2013 [20]	Mean blood glucose correlated with HbA1c ($r = 0.59$, $p = 0.0052$) and with glycated albumin ($r = 0.58$, $p = 0.0055$). Glycated albumin correlated with markers of glycemic variability: glycemic standard deviation, AUC for glucose levels > 180 mg/dL, TAR > 180 mg/dL, J-index, elevated glycemia index, degree of dissociation from the ideal glucose level, and glycemic control index. HbA1c correlated with glycemic variability markers: AUC for glucose levels > 180 mg/dL, TAR > 180 mg/dL, elevated glycemia index, and degree of dissociation from the ideal glucose level.	Glycated albumin and HbA1c were equally effective in monitoring glycemic control in patients with T1DM.

Table 2 (continuation)

Author, Year	Results	Efficacy of glycated albumin and/or fructosamine for monitoring glycemic control
Vos et al., 2012 [21]	Mean blood glucose correlated with glycated albumin in patients without CKD ($r = 0.49$, $p < 0.05$) and in those with CKD ($r = 0.54$, $p < 0.01$). Mean blood glucose correlated with fructosamine in patients without CKD ($r = 0.44$, $p < 0.05$) and in those with CKD ($r = 0.56$, $p < 0.01$). Mean blood glucose correlated with HbA1c in patients without CKD ($r = 0.66$, $p < 0.001$) but not in those with CKD nephropathy ($r = 0.38$, $p = 0.07$).	Glycated albumin and fructosamine were more effective than HbA1c in monitoring glycemic control in patients with diabetes and CKD, as they correlated with mean blood glucose.
Sakuma et al., 2011 [22]	HbA1c correlated with the 4-week fasting mean blood glucose ($R = 0.68$, adjusted $R^2 = 0.46$, $p < 0.0001$) and with the 4-week postprandial (1 and 2 hours after breakfast) mean blood glucose ($R = 0.58$, adjusted $R^2 = 0.31$, $p < 0.0001$). Glycated albumin correlated with the 4-week fasting mean blood glucose ($R = 0.51$, adjusted $R^2 = 0.26$, $p < 0.0001$) and with the 4-week postprandial (1 and 2 hours after breakfast) mean blood glucose ($R = 0.74$, adjusted $R^2 = 0.52$, $p < 0.0001$). Multivariate regression analysis demonstrated that fasting blood glucose is the strongest predictor of HbA1c, while postprandial blood glucose is the strongest predictor of glycated albumin.	Glycated albumin and HbA1c were equally effective in monitoring glycemic control in patients with T2DM.
Park et al., 2009 [23]	The correlation coefficients between HbA1c and the weighted mean blood glucose over 3 months, 2 months, and 1 month in patients without CKD were 0.735 (0.543–0.854), 0.766 (0.592–0.872), and 0.783 (0.618–0.882), respectively. The correlation coefficients between glycated albumin and the weighted mean blood glucose over 3 months, 2 months, and 1 month in patients without CKD were 0.640 (0.402–0.796), 0.641 (0.404–0.797), and 0.677 (0.457–0.820), respectively. The correlation coefficients between HbA1c and the weighted mean blood glucose over 3 months, 2 months, and 1 month in patients undergoing HD were 0.625 (0.457–0.750), 0.597 (0.422–0.730), and 0.568 (0.385–0.709), respectively. The correlation coefficients between glycated albumin and the weighted mean blood glucose over 3 months, 2 months, and 1 month in patients undergoing HD were 0.713 (0.574–0.812), 0.691 (0.544–0.796), and 0.682 (0.532–0.790), respectively. The slope of the simple linear regression equation between HbA1c and the weighted mean blood glucose over 3 months, 2 months, and 1 month in patients undergoing HD was 0.014 (0.010–0.018), 0.014 (0.009–0.018), and 0.012 (0.008–0.017), respectively. In patients without CKD, the corresponding slopes were 0.032 (0.024–0.040), 0.031 (0.024–0.038), and 0.029 (0.022–0.035), with a significant difference between the two groups ($p = 0.001$, 0.001, and <0.001, respectively). The slope of the simple linear regression equation between glycated albumin and the weighted mean blood glucose over 3 months, 2 months, and 1 month in patients undergoing HD was 0.090 (0.066–0.115), 0.089 (0.064–0.114), and 0.080 (0.055–0.104), respectively. In patients without CKD, the corresponding slopes were 0.147 (0.111–0.184), 0.141 (0.106–0.176), and 0.130 (0.097–0.162), with no significant difference between the two groups ($p = 0.224$, 0.335, and 0.139, respectively).	Glycated albumin was more effective than HbA1c in monitoring glycemic control in HD patients, as glycated albumin correlated better with the weighted average blood glucose of the past 3 months than HbA1c.
Inaba et al., 2007 [24]	Mean blood glucose correlated with glycated albumin ($r = 0.539$, $p < 0.001$) and HbA1c ($r = 0.520$, $p < 0.001$) in patients with DM undergoing hemodialysis (HD). Mean blood glucose also correlated with glycated albumin ($r = 0.498$, $p < 0.001$) and HbA1c ($r = 0.630$, $p < 0.001$) in patients with DM without CKD. The linear regression slope between HbA1c and mean blood glucose was significantly lower in patients with DM undergoing HD than in those with DM without CKD ($p < 0.001$). In contrast, the regression slope between glycated albumin and mean blood glucose did not differ significantly between these groups ($p = 0.10$). Patients with DM undergoing HD were categorized into four groups based on HbA1c values: Excellent (< 6.0%): 307 patients (57.1%); Good (6.0–7.0%): 128 patients (23.7%); Fair (7.0–8.0%): 65 patients (12.1%); Poor (> 8.0%): 38 patients (7.1%). Similarly, patients with DM undergoing HD were categorized based on glycated albumin values: Excellent (< 18.0%): 152 patients (28.3%); Good (18.0–21.0%): 106 patients (19.7%); Fair (21.0–24.0%): 84 patients (15.6%); Poor (> 24.0%): 196 patients (36.4%); The proportions of glycemic control categories based on HbA1c differed significantly from those based on glycated albumin ($p < 0.001$). HbA1c correlated with the weekly dose of erythropoietin ($r = 0.159$, $p < 0.001$) in patients with T2DM undergoing HD, whereas glycated albumin did not show a significant correlation ($r = 0.055$, $p = 0.201$). Mean blood glucose and glycated albumin did not differ significantly between patients with T2DM undergoing HD who received erythropoietin and those who did not. However, HbA1c was significantly lower in patients receiving erythropoietin than in those not receiving it ($p < 0.05$).	Glycated albumin was more effective than HbA1c in monitoring glycemic control in patients with T2DM on HD, as glycated albumin showed no significant changes in regression slopes for patients on hemodialysis and without nephropathy, and was not affected by anemia resulting from erythropoietin deficiency.

Table 2 (continuation)

Author, Year	Results	Efficacy of glycated albumin and/or fructosamine for monitoring glycemic control
Chujo et al., 2006 [25]	HbA1c correlated with mean blood glucose in pre-dialysis patients ($r = 0.47$, $p < 0.0005$), dialysis patients ($r = 0.42$, $p < 0.01$), and patients without CKD ($r = 0.67$, $p < 0.0001$). The regression line slope for patients with advanced CKD (both pre-dialysis and dialysis) was lower when compared to patients without CKD, and a significant difference was observed ($p = 0.045$) among the three regression slopes in the analysis of variance. This indicates that in patients with advanced CKD, HbA1c levels were lower than those predicted by mean blood glucose. Glycated albumin correlated with mean blood glucose in pre-dialysis patients ($r = 0.56$, $p < 0.0001$), dialysis patients ($r = 0.50$, $p < 0.0005$), and patients without CKD ($r = 0.68$, $p < 0.0001$). No significant difference was observed among the three regression slopes in the analysis of variance.	Glycated albumin was more effective than HbA1c in monitoring glycemic control in patients with diabetes and ESCKD, as glycated albumin showed no significant changes in regression slopes for patients with ESCKD and without CKD.
Cefalu et al., 1989 [26]	The 4-month fasting mean blood glucose correlated with fructosamine ($r = 0.79$, $p < 0.001$) and with HbA1c ($r = 0.78$, $p < 0.001$). The mean capillary blood glucose from continuous glucose monitoring (CGM) correlated with fructosamine ($r = 0.66$, $p < 0.001$) and with HbA1c ($r = 0.74$, $p < 0.001$).	Fructosamine and HbA1c were equally effective in monitoring glycemic control in patients with T2DM.

T1DM = Type 1 *Diabetes mellitus*; T1DM = Type 2 *Diabetes mellitus*; GDM = Gestational *Diabetes mellitus*; DM = *Diabetes mellitus*; PD = Peritoneal dialysis; CKD = Chronic kidney disease; ECSKD = End-stage chronic kidney disease; HbA1c = Glycated hemoglobin; HD = Hemodialysis; CGM = Continuous glucose monitoring; GFR = Glomerular filtration rate; BMI = Body mass index; TAR = Time above range; TBR = Time below range; TIR = Time in range; AUC = Area under the curve.

Among the 6 studies[8,10,11,17,23,24] (31.6%) that evaluated patients on hemodialysis (HD), 4 studies[10,11,23,24] (66.7%) found greater efficacy of GA compared with HbA1c, and in 2 studies[8,17] (33.3%), GA showed equal efficacy to HbA1c. Only 1 study[19] (5.3%) evaluated patients on peritoneal dialysis (PD) and found that fructosamine corrected by GA and HbA1c was equally effective in glycemic monitoring. Among the 4 studies[14,18,21,25] (21.0%) that evaluated CKD, 3 studies[18,21,25] (75.0%) observed greater efficacy of GA and fructosamine for glycemic monitoring when compared with HbA1c, while 1 study[14] (25.0%) found lower efficacy of GA and fructosamine relative to HbA1c.

Among the 2 studies[9,16] (10.5%) that evaluated pregnant women, 1 study[9] (50.0%) found that GA showed greater efficacy in glycemic monitoring when compared with HbA1c. Meanwhile, the other study[16] (50.0%) observed that fructosamine was less effective than HbA1c. The presence of iron deficiency anemia or erythropoietin deficiency was evaluated by 3 studies[13,18,24] (15.9%), and all of them (100.0%) found that GA and fructosamine were more effective in glycemic monitoring when compared with HbA1c.

Among the 5 studies[12,15,20,22,26] that evaluated patients with T1DM or T2DM without clinical conditions that interfere with the HbA1c test, 4 studies[20,22,26] (80.0%) found that GA and/or fructosamine were as effective as HbA1c for glycemic monitoring, and 1 study[12] (20.0%) observed greater efficacy of GA for glycemic monitoring when compared with HbA1c.

Regarding the risk of bias, the quality assessment of the articles included in the systematic review demonstrated that all studies[8-26] presented a high risk of bias for the index test topics. The results of the index tests (fructosamine, GA, and HbA1c) were interpreted with prior knowledge of the reference standard results (glycemic monitoring), and the cutoff points used were not pre-defined. Additionally, there was a risk of bias in flow and timing, because although the index test and reference standard were evaluated simultaneously, the reference standard differed between studies.

Conversely, all articles[8-26] showed a low risk of bias for patient selection topics, as patients were included consecutively or randomly, all studies were cohort studies, and no inappropriate exclusions were made. The reference standard also presented a low risk of bias, as it enabled correct evaluation of glycemic monitoring and was interpreted without prior knowledge of the index test results.

Regarding applicability, the quality assessment demonstrated that all studies[8-26] presented a high risk for the "reference standard" topic, as the reference standard was interpreted using different cutoff points. For the "patient

selection" topic, 11 studies[8, 10, 11, 14, 17-19, 21, 23-25] presented a high risk, as the patients had dialytic or non-dialytic CKD, which can interfere with fructosamine and GA tests, while 8 studies[9, 12, 13, 15, 16, 20, 22, 26] presented a low risk, as the patients did not have clinical conditions that could interfere with these tests.

Regarding the "index test" topic, 16 studies[9, 10, 12, 14-26] presented a low risk because they employed appropriate methodologies for HbA1c measurement (HPLC or immunoturbidimetry). In contrast, 2 studies[11, 13] presented a high risk due to the use of inadequate methodologies (colorimetric method or capillary electrophoresis), and 1 study[8] had an uncertain risk, as it did not report the methodology used for HbA1c measurement.

Table 3 presents the quality assessment of the studies conducted using the QUADAS-2 tool.[7]

Table 3

Evaluation of the quality of studies according to the QUADAS-2 tool.[7]

Author, Year	Risk of Bias				Applicability		
	Patient Selection	Index Test	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Hayashi et al., 2023 [8]	B	A	B	A	A	?	A
Toft et al., 2022 [9]	B	A	B	A	B	B	A
Divani et al., 2021 [10]	B	A	B	A	A	B	A
Martino et al., 2021 [11]	B	A	B	A	A	A	A
Desouza et al., 2020 [12]	B	A	B	A	B	B	A
Mahgoob e Moussa, 2020 [13]	B	A	B	A	B	A	A
Zelnick et al., 2020 [14]	B	A	B	A	A	B	A
Chan et al., 2017 [15]	B	A	B	A	B	B	A
Fujimoto et al., 2016 [16]	B	A	B	A	B	B	A
Hayashi et al., 2016 [17]	B	A	B	A	A	B	A
Konya et al., 2013 [18]	B	A	B	A	A	B	A
Lee et al., 2013 [19]	B	A	B	A	A	B	A
Tsutsumi et al., 2013 [20]	B	A	B	A	B	B	A
Vos et al., 2012 [21]	B	A	B	A	A	B	A
Sakuma et al., 2011 [22]	B	A	B	A	B	B	A
Park et al., 2009 [23]	B	A	B	A	A	B	A
Inaba et al., 2007 [24]	B	A	B	A	A	B	A
Chujo et al., 2006 [25]	B	A	B	A	A	B	A
Cefalu et al., 1989 [26]	B	A	B	A	B	B	A

B – Low risk; A – High risk; ? – Uncertain risk [7].

DISCUSSION

The studies included in this systematic review observed that fructosamine and GA, in general, show efficacy similar to HbA1c for monitoring glycemic control in patients with T1DM or T2DM who do not present clinical conditions that interfere with HbA1c measurement. Tsutsumi et al. (2013) [20] demonstrated that the correlations of mean glucose with HbA1c ($r = 0.59$, $p = 0.0052$) and with GA ($r = 0.58$, $p = 0.0055$) were similar in patients with T1DM. Cefalu et al. (1989)[26] found strong correlations between the 4-month mean fasting glucose and fructosamine ($r = 0.79$, $p < 0.001$) or HbA1c ($r = 0.78$, $p < 0.001$), and between mean capillary glucose from CGM and fructosamine ($r = 0.66$, $p < 0.001$) or HbA1c ($r = 0.74$, $p < 0.001$) in patients with T2DM. Chan et al. (2017)[15] also observed a good correlation between mean glucose and fructosamine ($r = 0.42$, $p = 0.002$), GA ($r = 0.34$, $p = 0.001$), and HbA1c ($r = 0.36$, $p = 0.006$) in obese adolescents with prediabetes or T2DM.

Sakuma et al. (2021)[22] also observed that HbA1c and GA correlated with the 4-week mean fasting glucose (HbA1c: $R = 0.68$, adjusted $R^2 = 0.46$, $p < 0.0001$; GA: $R = 0.51$, adjusted $R^2 = 0.26$, $p < 0.0001$) and with the 4-week mean glucose 1 and 2 hours after breakfast (HbA1c: $R = 0.58$, adjusted $R^2 = 0.31$, $p < 0.0001$; GA: $R = 0.74$, adjusted $R^2 = 0.52$, $p < 0.0001$) in patients with T2DM. They also demonstrated that fasting glucose is the strongest predictor of HbA1c, while postprandial glucose is the strongest predictor of GA in these patients. Desouza et al. (2020),[12] in turn, found a better correlation between GA and mean glucose ($r = 0.481$) than between HbA1c and mean glucose ($r = 0.233$) during the first 3 months of the study in patients with T1DM or T2DM with poor glycemic control (HbA1c between 7.5% and 12.0%) whose treatment had been modified aiming for better glycemic control, with the difference between correlations being 0.249 (0.130 - 0.367) ($p < 0.0001$). The authors also observed that Kendall correlations, which analyze the direction of change in glycemic indices, were higher between GA and mean glucose (0.341) than between HbA1c and mean glucose (0.160), with a difference between correlations of 0.181 (0.096 - 0.265) ($p < 0.0001$). These findings demonstrate that GA is an interesting marker to quickly evaluate the effect of treatment changes on glycemic control in patients with T1DM or T2DM.

Given the similar efficacy between HbA1c and GA and fructosamine tests for monitoring glycemic control in patients with T1DM or T2DM who do not have conditions that interfere with the HbA1c test, HbA1c should be routinely used for long-term monitoring of glycemic control in these patients, according to the recommendations of the Brazilian Diabetes Society (2022).[27] Fructosamine and GA tests can be used in situations where short-term glycemic control assessment is necessary, such as preoperative care, initiation of treatment, or therapy changes, since fructosamine reflects the average glucose of the last 2 to 3 weeks.[4]

In patients with CKD, the increase in uremic products leads to a reduction in the lifespan of red blood cells. Additionally, kidney damage affects the production of erythropoietin, consequently leading to a low production of red blood cells. As a result, there is a lower amount of hemoglobin in systemic circulation, which falsely reduces HbA1c levels, as fewer red blood cells will be available to bind to glucose.[28] Moreover, patients with CKD present an inflammatory state, which results in bone marrow resistance to the action of erythropoietin. This inflammatory state also promotes an increase in the production of hepcidin, a peptide that inhibits intestinal iron absorption and the mobilization of iron from the reticuloendothelial system, resulting in absolute or functional iron deficiency, respectively, and anemia.[28,29]

Most studies included in this systematic review, which evaluated patients with *Diabetes mellitus* (DM) with non-dialysis or dialysis CKD, found that fructosamine and GA are more effective than HbA1c for monitoring glycemic control. Vos et al. (2012)[21] observed that GA ($r = 0.54$, $p < 0.01$) and fructosamine ($r = 0.56$, $p < 0.01$) correlated with mean blood glucose levels in CKD patients; however, HbA1c did not show a significant correlation with mean blood glucose levels in these patients ($r = 0.38$, $p = 0.07$). Park et al. (2009)[23] also found that GA correlated better with the weighted average of 3-month blood glucose levels than HbA1c in patients on HD.

Chujo et al. (2006)[25] observed that both HbA1c and GA correlated with mean blood glucose levels in pre-dialysis, dialysis, and non-CKD patients. However, the slope of the regression line in the variance analysis for HbA1c was lower for pre-dialysis and dialysis patients than for non-CKD patients, indicating that HbA1c levels were lower than those indicated by mean blood glucose in CKD patients. Conversely, there was no significant difference among the three regression slopes in the variance analysis for GA. Inaba et al. (2007)[24] also found that the slope of the linear regression between HbA1c and mean blood glucose was lower in patients on HD compared to those without CKD ($p < 0.001$), whereas the slope between GA and mean blood glucose did not differ significantly between the two groups ($p = 0.10$).

Divani et al. (2021)[10] also demonstrated that GA was more accurate than HbA1c in detecting time in range < 50% and time above target > 15% in patients with T1DM or T2DM on HD. Martino et al. (2021)[11] observed that GA showed a greater predictive ability for early detection of glycometabolic alterations compared to HbA1c. In patients with erythropoietin deficiency, Konya et al. (2013)[18] found that HbA1c levels significantly decreased after therapy with an erythropoiesis-stimulating agent, while no changes were observed in fructosamine and GA levels. Inaba et al. (2007) [24] also demonstrated that HbA1c was significantly lower in HD patients receiving erythropoietin compared to those not receiving erythropoietin, whereas GA did not differ significantly between the two groups.

Hayashi et al. (2016)[17] and (2023)[18] observed that GA and HbA1c were equally effective for monitoring glycemic control in HD patients. Lee et al. (2013)[19] demonstrated that fructosamine corrected for albumin and HbA1c were equally effective in monitoring glycemic control in PD patients, but both were more effective than GA. The greater efficacy of fructosamine corrected for albumin compared to GA can be explained by the fact that GA levels are affected by albumin loss in urine, and this interference can be minimized by dividing fructosamine levels by albumin levels.[19]

Conversely, Zelnick et al. (2020)[14] found that GA and fructosamine were less effective than HbA1c for monitoring glycemic control in T2DM patients with CKD, as they exhibited greater variability than HbA1c and more sources of bias. This may be due to the fact that fructosamine and GA reflect short-term glycemic control and are more influenced by the use of medications and recent medical interventions than HbA1c. [14] Nonetheless, these authors observed that the correlations between HbA1c, GA, and fructosamine with estimated mean blood glucose were similar for both non-CKD patients (r = 0.76; r = 0.72; r = 0.63, respectively) and CKD patients (r = 0.78; r = 0.78; r = 0.71, respectively).

Iron deficiency anemia is one of the most common deficiencies in developing countries, predominantly affecting women and children.[30] Iron deficiency in the body arises from nutritional deficiency and insufficient storage, excessive loss, or inadequate utilization of this trace element.[31] Iron deficiency anemia can result in a false increase in HbA1c levels, as the lack of iron in the body can lead to terminal glycation of proline, altering the structure of red blood cells, reducing their renewal rate, and causing them to remain in the plasma longer, exposed to glucose binding. Additionally, iron deficiency may induce peroxidation and accelerate glycation, leading to increased HbA1c levels in patients with or without diabetes who have iron deficiency anemia.[32]

Both studies included in this systematic review, which evaluated patients with diabetes and iron deficiency anemia, found that fructosamine and GA are more effective than HbA1c for monitoring glycemic control. Mahgoob and Moussa (2020)[13] observed that average blood glucose correlated with GA but not with HbA1c in patients with iron deficiency anemia, and GA showed greater sensitivity and specificity for predicting uncontrolled diabetes in these patients compared to HbA1c. Konya et al. (2013)[18] also found that in patients with iron deficiency anemia, HbA1c levels significantly decreased after iron therapy, while fructosamine and GA levels remained unchanged.

Therefore, in clinical situations where there is an alteration in the quantity or lifespan of red blood cells, such as dialytic or non-dialytic CKD and iron deficiency anemia, leading to misinterpretations of HbA1c, alternatives like fructosamine and GA are necessary for monitoring glycemic control in individuals with T1DM or T2DM.

In pregnant women, various metabolic changes occur during the first weeks of gestation, the most significant of which is insulin resistance. These modifications are attributed to various humoral factors of maternal and placental origin that aim to increase the demand for nutrients for the fetus.[33] Additionally, there is an increase in blood volume, resulting in hemodilution and physiological anemia, leading to a false reduction in HbA1c levels.[2,3] Due to increased hematopoiesis and blood volume, glucose is diluted in the blood, reducing fasting glucose levels. Given these alterations in glycemic and HbA1c levels throughout pregnancy and the lack of established reference values for HbA1c levels for each gestational trimester, HbA1c is limited in monitoring glycemic control during pregnancy.[34]

In pregnant women with pregestational diabetes, Toft et al. (2020)[9] observed that GA was more accurate than HbA1c in detecting time in range < 70% and time above target > 25%. However, Fujimoto et al. (2016)[16] found that fructosamine had a lower correlation with the frequency of hyper- and hypoglycemia than HbA1c in pregnant women with T1DM, T2DM, gestational *Diabetes mellitus* (GDM), or overt diabetes.

Given the limitations of using HbA1c for glycemic monitoring during pregnancy, the Brazilian Diabetes Society (2023)[34] recommends that pregnant women perform self-monitoring of blood glucose until delivery. Pregnant women with pregestational diabetes should measure capillary blood glucose before and one hour after the three main meals and at

bedtime. Those with GDM undergoing non-pharmacological treatment should measure glucose levels while fasting and one hour after the main meals, while those receiving pharmacological treatment should measure glucose levels before and one hour after the main meals. These measures aim to monitor blood glucose, preventing severe hypoglycemic events, as well as to assess treatment efficacy and adherence, which cannot be adequately evaluated by HbA1c, since it provides retrospective data on average glucose levels but does not assess glycemic variability throughout the day.[34]

Regarding the methods used for glycemic monitoring assessment, most studies[8-10,12-22,25,26] included in this systematic review used CGM or capillary blood glucose self-monitoring, as these are the best methods for evaluating glycemic control and variations in patients with *Diabetes mellitus*.[34] Only three studies[11,23,24] did not use these methods to assess glycemic monitoring. However, all three studies evaluated patients' blood glucose at least three different times over a minimum period of two months.

Regarding the method used for HbA1c measurement, most studies employed high-performance liquid chromatography (HPLC) or immunoturbidimetry, which are standardized and recommended methods for HbA1c measurement.[35] For GA measurement, enzymatic, immunoturbidimetric, colorimetric, ELISA, and liquid chromatography methods were used, while enzymatic and colorimetric methods were employed for fructosamine measurement. These methods are precise and appropriate for performing these assays.[4]

The articles included in this systematic review showed significant diversity in the clinical characteristics of the patients. While some studies included patients with T1DM or T2DM who did not have clinical conditions that interfere with HbA1c measurement, others included patients with diabetes who had conditions that could affect HbA1c results, such as dialysis-dependent or non-dialysis chronic kidney disease, iron-deficiency anemia, and pregnancy. Additionally, there was considerable variation among studies in terms of patient age range, the method used for blood glucose monitoring, and the statistical analysis methodology applied to the results. The quality assessment of the articles included in this systematic review demonstrated that all studies presented a high risk of bias in the index test and flow and timing domains, as well as a high applicability risk in the reference standard domain. This was due to the absence of predefined cutoff points for fructosamine and GA, differences in the reference standards used among studies, and the interpretation of results using varying cutoff values. These challenges represent limitations of the present study, preventing the performance of meta-analyses.

It is important to highlight that the QUADAS-2 tool[7] was developed to assess the risk of bias in diagnostic accuracy studies. However, the studies included in this systematic review aimed to evaluate the efficacy of GA and fructosamine tests for monitoring glycemic control in patients previously diagnosed with *Diabetes mellitus*. In the absence of a specific tool to assess the quality of studies focused on glycemic control monitoring, we chose to use the QUADAS-2 tool despite its limitations for this purpose, which may have contributed to a high risk of bias in certain domains.

FINAL CONSIDERATIONS

Fructosamine and GA show similar efficacy to HbA1c in monitoring glycemic control in patients with T1DM or T2DM who do not have clinical conditions that interfere with HbA1c measurement. It is recommended that HbA1c be used for long-term glycemic control monitoring in these patients, following national and international guidelines, and that fructosamine and GA tests be employed in situations where short-term glycemic control assessment is necessary.

Conversely, fructosamine and GA are more effective than HbA1c for monitoring glycemic control in patients with T1DM or T2DM who have clinical conditions that alter the quantity or lifespan of red blood cells, such as dialysis and non-dialysis chronic kidney disease and iron deficiency anemia. In these cases, it is recommended to use fructosamine or AG tests for glycemic monitoring.

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