



Research Article

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Measuring the Level of HbA1c (Glycated Hemoglobin) Among Patients with Diabetes: A Systematic Literature Review

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This systematic literature review aims to explore the measurement of HbA1c (Glycated Hemoglobin) levels among patients with diabetes. HbA1c is a crucial marker used to assess long-term glucose control in individuals with diabetes. The review will identify and analyze existing research on the measurement methods, interpretation of HbA1c levels, and their clinical implications for patients with diabetes. Additionally, the review will examine the relationship between HbA1c levels and diabetes management outcomes, such as glycemic control, complications, and overall health outcomes. The findings of this review will provide healthcare professionals with valuable insights into the interpretation and clinical implications of HbA1c levels, enabling them to optimize treatment plans and enhance the overall health and well-being of patients with diabetes.

Keywords: HbA1c; glycated hemoglobin; diabetes; measurement techniques; standardization; clinical implications**Introduction**

Diabetes is a prevalent chronic condition that affects millions of individuals worldwide [1]. It is characterized by elevated blood glucose levels due to either insulin deficiency or insulin resistance [2]. Effective management of diabetes requires monitoring and maintaining optimal glucose control over the long term. HbA1c, also known as glycated hemoglobin, is a widely used marker for assessing average blood glucose levels over a period of 2-3 months [3]. HbA1c measurement plays a critical role in diabetes management as it provides valuable information about a patient's glycemic control and helps healthcare professionals tailor treatment plans accordingly [4]. By assessing HbA1c levels, healthcare providers can evaluate the effectiveness of current treatment regimens, make

necessary adjustments, and guide patients towards achieving optimal glucose control [5].

The measurement of HbA1c levels has evolved over the years, with various methods and techniques available for accurate assessment [6]. Laboratory-based assays and point-of-care testing are commonly used methods to measure HbA1c levels [7]. These measurements aid in understanding a patient's average blood glucose levels, enabling healthcare professionals to make informed decisions regarding treatment strategies. Interpretation of HbA1c levels is crucial in clinical practice, as it helps establish target ranges for glycemic control in individuals with diabetes [8]. Different guidelines and recommendations exist regarding optimal

HbA1c targets based on individual factors such as age, duration of diabetes, and presence of co-morbidities [9]. Understanding the interpretation of HbA1c levels can assist healthcare providers in setting realistic and achievable glycemic targets for their patients [10]. Furthermore, HbA1c levels have significant clinical implications for individuals with diabetes. Studies have shown that maintaining lower HbA1c levels is associated with reduced risks of diabetes-related complications, such as retinopathy, nephropathy, and cardiovascular diseases [11]. Monitoring HbA1c levels allows healthcare professionals to identify individuals at higher risk of complications and intervene accordingly to prevent or manage these adverse outcomes [3]. In light of the importance of HbA1c measurement in diabetes management, this systematic literature review aims to explore the various aspects related to the measurement of HbA1c levels among patients with diabetes. By analyzing existing research, this review will provide insights into the different measurement methods, interpretation of HbA1c levels, and the clinical implications of these levels for diabetes management outcomes. The findings of this review will contribute to enhancing the understanding and utilization of HbA1c measurement in clinical practice, ultimately improving the overall health and well-being of patients with diabetes.

Methods

To conduct this systematic literature review, a comprehensive search will be performed in electronic databases, including PubMed, Scopus, and Web of Science. The search strategy will be developed using a combination of relevant keywords and Medical Subject Headings (MeSH) terms. The search will be limited to articles published between 2010 and 2023 to ensure the inclusion of recent research. The following keywords and MeSH terms will be used in the search strategy: "HbA1c," "glycated hemoglobin," "diabetes," "measurement," "assay," "laboratory," "point-of-care," "interpretation," "clinical implications," "glycemic control," "complications," and "health outcomes." These terms will be combined using Boolean operators (AND, OR) to refine the search and retrieve relevant articles.

- a) Inclusion criteria for article selection will include
 - a. Studies published in English.

- b. Studies focused on human subjects diagnosed with diabetes.
 - c. Studies that discuss the measurement of HbA1c levels.
 - d. Studies that provide information on the interpretation of HbA1c levels.
 - e. Studies that investigate the clinical implications of HbA1c levels, including glycemic control, complications, and overall health outcomes.
- b) Exclusion criteria will include
 - a. Studies not published in English.
 - b. Studies that do not focus on HbA1c measurement in patients with diabetes.
 - c. Studies that primarily focus on animals or in vitro experiments.
 - d. Studies that are duplicates or have insufficient data.

The screening process will involve two stages: title and abstract screening, followed by full-text review. Two independent reviewers will conduct the screening process, and any disagreements will be resolved through discussion or consultation with a third reviewer if necessary. Data extraction will be performed using a standardized form, including study characteristics (e.g., author, year, and study design), measurement methods, interpretation of HbA1c levels, and clinical implications. The extracted data will be synthesized and analyzed to identify common themes, trends, and gaps in the literature as shown in Table 1. The quality of the included studies will be assessed using appropriate tools, such as the Newcastle-Ottawa Scale for observational studies or the Cochrane Risk of Bias tool for randomized controlled trials. This quality assessment will provide insights into the strength of evidence presented in the selected studies. The findings of this systematic literature review will be synthesized and presented in a narrative format, highlighting key findings and implications for clinical practice. Limitations of the included studies and potential areas for future research will also be discussed.

Table 1: Included Study Characteristics.

Author/year	Insight	Methods used	Main results	outcomes	Practical implication
Emily et al/2023 [12]	The paper focuses on trends in HbA1c among people with diabetes who use insulin from 2009 to 2020	Retrospective analysis using data from the National Health and Nutrition Examination Survey (NHANES) Regression analysis to assess trends in HbA1c over time	Mean HbA1c values were 8.0% (T1DM), 8.6% (T2DM-MTI), and 8.6% (T2DM basal-only). Approximately 25% of PwDs achieved glycemic targets.	Approximately 25% of people with diabetes achieve glycemic targets. Improved therapies are needed to better manage glycemic targets in people with diabetes.	Approximately 25% of people with diabetes achieve glycemic targets. Improved therapies are needed to better manage glycemic targets in people with diabetes.
Reeta et al /2023 [13]	The paper discusses the measurement of HbA1c levels in patients with diabetes and its correlation with blood glucose levels.	Fasting and postprandial blood glucose levels were measured using venous blood samples. HbA1c levels were measured in venous blood using the immunoturbidimetric method.	The study found a significant positive correlation between HbA1c levels and both fasting and postprandial blood glucose levels. The p-value for the correlation between postprandial blood glucose and HbA1c was statistically significant.	The study found a significant positive correlation between HbA1c levels and fasting and postprandial blood glucose levels. The correlation suggests that HbA1c levels can be used as a preferred method to assess glycemic control in diabetics	The study highlights the correlation between HbA1c levels and blood glucose levels in type 2 diabetes patients. This information can be used for monitoring and managing diabetes in clinical practice.

Pavan et al /2023 [14]	The paper discusses various techniques for measuring the level of HbA1c, including chromatography, spectroscopy, immunoassays, capillary electrophoresis, and fluorometry.	Chromatography, spectroscopy, immunoassays, capillary electrophoresis, fluorometry Sensors incorporating nanostructured materials for specific and accurate quantification of HbA1c.	Recent advances in electrochemical detection for HbA1c Emerging trends and challenges in PoC devices for HbA1c	Development of sensors incorporating nanostructured materials for specific and accurate quantification of HbA1c. Attempts to improve detection speed, accuracy, and reduce sample volumes and costs.	Development of sensors for specific and accurate quantification of HbA1c. Improvement in detection speed, accuracy, and reduction in sample volumes and costs.
Arabinda et al /2022 [15]	The paper discusses the measurement of HbA1c using two methods: High Performance Liquid Chromatography (HPLC) and immunochromatography analyzer.	High Performance Liquid Chromatography (HPLC) method Immunochromatography method (Nycocard)	The study found a positive correlation between hemoglobin levels and HbA1c values obtained by HPLC method. No such correlation was found with the Nycocard method.	HbA1c levels measured by HPLC method may be influenced by hemoglobin variants. Nycocard method accurately measures HbA1c levels but does not identify hemoglobin variants.	HbA1c estimation by HPLC may be influenced by hemoglobin variants. Nycocard method accurately measures HbA1c levels but cannot identify hemoglobin variants.
Zi-min et al/2022 [16]	the various methods used to determine HbA1c levels and the factors that can influence its interpretation	Cation-exchange chromatography Electrophoresis Immunoassays Affinity chromatography	The paper discusses the various methods used to determine HbA1c levels. The paper highlights the need for caution when interpreting HbA1c values.	The findings highlight the need for caution when interpreting HbA1c values in clinical practice. The paper summarizes and classifies the effects of HbA1c interactions with inherited and acquired diseases.	HbA1c assessment is crucial for diabetes care Clinical HbA1c values need to be analyzed with caution.
Joshua et al/2022 [17]	The provided paper investigates the association between mean HbA1c levels, HbA1c variability, and all-cause mortality and diabetes-related macrovascular complications in patients with diabetes.	Retrospective cohort study using patients present in the Singapore Health Services diabetes registry (SDR) during 2013 to 2014. Mean HbA1c assessed using three models: baseline mean, mean across follow-up, and time-varying yearly mean	Both low (<6.0%) and high (≥8.0%) levels of glycaemic control are associated with increased all-cause mortality and diabetes-related macrovascular complications. Glycaemic variability is independently associated with increased risk for these outcomes.	Patients with stable glycemic levels of 6-8% are at the lowest risk of complications. Both low and high levels of glycemic control are associated with increased mortality and complications.	Both low and high levels of glycaemic control are associated with increased mortality and macrovascular complications in patients with diabetes. Glycaemic variability is independently associated with increased risk for these outcomes.
Louis et al/2022 [18]	The paper discusses the assessment of HbA1c variability and its implications for adverse outcomes in diabetes, but it does not specifically investigate the clinical implications of HbA1c levels, glycemic control, complications, or overall health outcomes.	Assessment of HbA1c variability using quarterly fluctuations Conversion of %CV for HbA1c into visit-to-visit differences in absolute HbA1c levels	The risk for adverse outcomes in diabetes increases when the coefficient of variation for HbA1c (%CV for HbA1c) is above 5.0%. HbA1c dependent limits (± 0.X%) can be used to assess HbA1c stability and adjust treatment.	Quarterly HbA1c fluctuations can be used as a metric for assessing diabetes complications. The risk for adverse outcomes increases when the coefficient of variation for HbA1c is above 5.0%.	Long-term variability of glucose homeostasis is a risk factor for adverse outcomes in diabetes. Risk for adverse outcomes increases when the coefficient of variation for HbA1c is above 5.0%.
Enrique et al/2021 [19]	The specific glycemic control targets recommended for individuals with type 2 diabetes based on HbA1c levels are not mentioned in the provided paper.	Real-world data analysis from the Multinational Observational Study Assessing Insulin Use (MOSA1c) study. Analysis of baseline characteristics, psychosocial data, and diabetes medication use.	Only 18.8% of people with T2DM reached their HbA1c targets after initial insulin therapy. Factors such as baseline HbA1c levels and the difference between baseline and target HbA1c levels influenced the likelihood of reaching HbA1c targets.	Personalized management strategies are needed to achieve glycemic targets in T2DM. Factors such as baseline HbA1c and difference between baseline and target HbA1c levels influence target achievement.	Factors associated with establishing and reaching HbA1c targets Personalized management of glycemic targets is necessary
Matteo et al/2021 [20]	The specific glycemic control targets recommended for individuals with type 2 diabetes based on HbA1c levels are not mentioned in the provided paper.	Meta-analysis of randomized controlled trials Assessment of effects of glycemic control on various outcomes	Improvement of glycemic control is associated with lower risk of major cardiovascular events and renal adverse events. Drugs not inducing hypoglycemia reduce risk of chronic vascular and renal complications and all-cause mortality.	Improving glycemic control with drugs not inducing hypoglycemia reduces long-term complications and mortality. Different pharmacological strategies have varying effects on glycemic control outcomes.	Improvement of glycemic control with drugs not inducing hypoglycemia reduces long-term complications and mortality. Hypoglycemic drugs have a protective effect on microvascular complications but increase severe hypoglycemia risk.

<p>Jayachandra, & Patil/ 2017 [21]</p>	<p>To assess the serum magnesium and HbA1c levels in type 2 diabetes patients</p>	<p>a case control study</p>	<p>The serum magnesium levels are significantly lower in diabetic patients when compared to controls (P<0.001). There was a significant correlation between the diabetic status and low serum magnesium levels. The values of HbA1C (%) were positively correlated with blood glucose level and negatively correlated with serum magnesium levels</p>	<p>The supplementation of magnesium and proper exercise to maintain the weight are advisable to prevent the diabetes associated complications in the future.</p>	<p>Hypomagnesaemia is associated with micro vascular complications and poor glycemic control. It is important to regularly monitor magnesium levels in all type 2 diabetic patients.</p>
<p>Silva et al/2018 [22]</p>	<p>The present study aims to understand how subjects with diabetes deal with the fact that they are chronically ill and how being aware of their situation influences the way they take care of their health.</p>	<p>a participatory research with a qualitative and reflexivity-centered approach</p>	<p>All 16 (sixteen) participants live with Type 2 Diabetes Mellitus, of whom 12 (twelve) are females and 4 (four) are males aged from 57 to 90 years. Based on the perspective I "Recognizing diabetes" and on the objectives of this study, the results were organized into three categories discussed below, namely: the impact of the diagnosis; the denial of the illness and the acceptance of the illness.</p>	<p>it is indispensable to respect and encourage the personal autonomy of the subjects, making them co-responsible for their treatment</p>	<p>The emotional aspects of subjects diagnosed with diabetes mellitus strongly influence the acceptance or denial of the illness, interfering in their personal adherence to treatment. As a chronic condition, involving life-longing care practices, which intervenes in therapeutic participation, it is indispensable to respect and to encourage the personal autonomy of the subjects.</p>
<p>Nakagami et al/2017 [23]</p>	<p>This study examined the association between Hb and HbA1c, together with the factors possibly affecting HbA1c in Japanese without anemia or diabetes.</p>	<p>Comparison</p>	<p>Men had more unfavorable cardiovascular risk profiles and higher hematological parameters compared with women. In both men and women, age, BMI and FPG had positive associations, while Hb had a negative association with HbA1c in the univariate linear regression model (all P < 0.001). The multivariable linear regression analysis showed that HbA1c was negatively affected by Hb, independent of age, sex, BMI, FPG, and smoking and alcohol habits in both men and women (both P < 0.001). An interaction between sex and Hb was shown in the effects on HbA1c (P < 0.05)</p>	<p>The interpretation of HbA1c values should be cautious in the screening of glucose intolerance.</p>	<p>HbA1c levels decreased with increasing Hb levels, independent of FPG and covariates in Japanese men and women without diabetes or anemia. There was an interaction between sex and Hb in the effects on HbA1c. This should be appreciated when interpreting HbA1c</p>
<p>Rahman /2023 [24]</p>	<p>to analyze the correlation between HbA1c levels and blood sugar levels in patients with diabetes mellitus</p>	<p>Descriptive methods with an analytical descriptive study with a cross-sectional</p>	<p>The average HbA1c level was 3.9% while the average fasting blood sugar level was 82 mg/dl. There is a significant correlation between HbA1c concentration and fasting blood sugar with p (0.000) < (0.05). According to the test results, the value r = 0.666 means the correlation is very strong (0.51-0.75)</p>		<p>There is a strong correlation between HbA1c levels and fasting blood sugar level, the correlation happens to be positive, meaning there is a one-way relationship if HbA1c levels increases (High), fasting blood sugar levels will also increase (High). If the HbA1c levels is reduced (low), then the fasting blood sugar level is also reduced (low), and if the HbA1c level is normal, the blood sugar level is also normal.</p>

Omer & Ali/2019 [25]	To assess glycated hemoglobin levels and inflammatory biomarkers among T2DM and find such correlation and compare data with healthy control.	Cross-sectional case control study	HbA1c, C-reactive protein, IL6 and TNF-alpha were increased among T2DM patients than healthy subjects, giving increased significant difference for each, as p value	Improvement of glycemic control reduce risk markers for development of diabetic complications.	higher levels of inflammatory biomarkers associate with increase with glycated hemoglobin
Davis et al/2014 [26]	To assess associations between increases in glycated hemoglobin (HbA1c) levels and medication adjustments among patients with diabetes. A secondary objective was to measure the effect of adjustments on subsequent HbA1c levels	A retrospective analysis of administrative data	Medication adjustments were the exception, occurring among less than a fourth of patients. Compared with patients without HbA1c increases, patients with <1% HbA1c increases made adjustments 20% more frequently, and patients with increased HbA1c levels of 1% or more made adjustments 60% more frequently. Patients with similar HbA1c increases were more likely to adjust their medications if they had higher baseline HbA1c levels. Medication adjustments were mostly for oral diabetes medications; insulin use was seldom initiated, and then primarily by patients with HbA1c levels of 9% or higher. Patients with medication adjustments averaged about 0.40% lower HbA1c levels when reassessed after 120 days or more	Clinical inertia and patient concerns are discussed as factors possibly limiting the frequency of medication adjustments.	Limited responsiveness to increases in HbA1c levels and a low initiation rate of insulin use. Patients adjusting their medications, however, had clinically significant improvements in their HbA1c level
Kassaian et al/ 2012 [27]	to investigate whether a pre- and post-procedural glycaemic control in diabetic patients was related to major advance cardiovascular events (MACE) during follow up	evaluated	The adjusted risk of MACE in diabetic patients with poor glycaemic control (HbA1c > 7%) was 2.1 times of the risk in non-diabetics (adjusted HR = 2.1, 95% CI: 1.10 to 3.95, p = 0.02). However, the risk of MACE in diabetics with good glycaemic control (HbA1c ≤ 7%) was not significantly different from that of non-diabetics (adjusted HR = 1.33, 95% CI: 0.38 to 4.68, p = 0.66).	Protocol for calibrating HbA1c levels, and guidelines of reporting ensures high accuracy, HbA1c measurement error might be still a concern especially because this index was not derived from repeated measurements over time.	There is an association between good glycaemic control to obtain HbA1c levels ≤7% (both pre-procedural glycaemic control and post-procedural) with a better clinical outcome after PCI.
Kahlon& Pathak /2011 [28]	To find out correlation between levels of plasma glucose and glycosylated hemoglobin in diabetics and to calculate IDRS of the study population.	A cross sectional study	Fifty-two percent of the population had fasting plasma glucose level between 125-150 mg/dl, 21% had this level between 151-175 mg/dl. Thirteen percent of the study subjects had HbA1C between 6.5-7.5, more than half (57.3%) had this value between 7.5-8.5, 12% and 18% had values between 8.5-9.5 and 9.5-10.5, respectively. Twelve percent of the participants had HbA1C level higher than 10.5. Correlation of fasting plasma glucose level and HbA1C was also studied and found that correlation coefficient came out to be .311. This correlation was found to be statistically significant (P = .007). Sixty-five percent of the case had IDRS higher than 60.	Development of diabetes can be prevented or well delayed by identifying risk factors by the individual himself. This can be brought about by educating the mass about importance of IDRS and how to calculate their own IDRS and bring the appropriate changes in their lifestyle.	Glycaemic control in diabetics can be better assessed with glycosylated hemoglobin and FPG together. A positive correlation between FPG and HbA1c allows for the use of HbA1c along with FPG in diagnosing type 2 DM but the two should not be used interchangeably. IDRS can be used as a screening tool for diabetes.

Results and Discussion

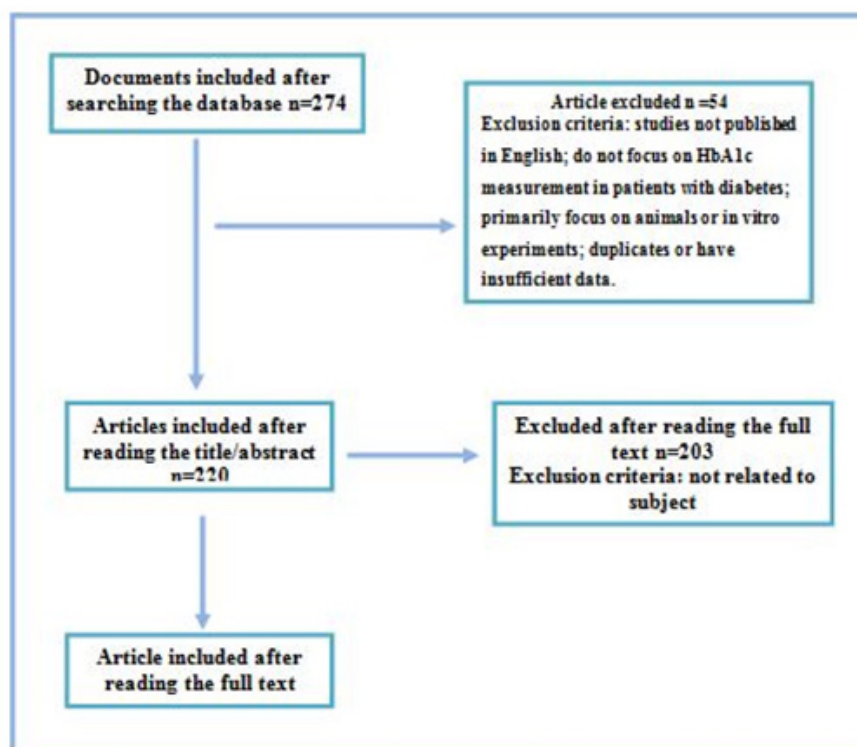


Figure 1: Flowchart of the study selection process.

The systematic literature review revealed several key findings regarding the measurement of HbA1c levels among patients with diabetes as shown in Figure 1.

Measurement Methods

The review identified various measurement methods for HbA1c levels, including laboratory-based assays and point-of-care testing. Laboratory-based assays, such as high-performance liquid chromatography (HPLC), and immunoassays are commonly used in clinical settings for accurate and precise measurement of HbA1c levels. Point-of-care testing, on the other hand, offers the advantage of providing rapid results at the patient's bedside or in community settings. Both methods have their advantages and limitations, and the choice of method depends on factors such as availability, cost, and convenience.

Interpretation of HbA1c Levels

The review found that interpretation of HbA1c levels is crucial for guiding diabetes management. Different guidelines and recommendations exist regarding target HbA1c ranges, depending on factors such as age, duration of diabetes, and presence of co-morbidities. For most individuals with diabetes, the recommended target HbA1c level is below 7%. However, in certain populations, such as older adults or those with significant co-morbidities, a higher target range may be considered to avoid hypoglycemia and

improve quality of life.

Clinical Implications

The review highlighted the clinical implications of HbA1c levels in diabetes management. Lower HbA1c levels have been associated with improved glycemic control and a reduced risk of diabetes-related complications. Studies have shown that reducing HbA1c levels by 1% can lead to a significant decrease in the risk of microvascular complications, such as retinopathy and nephropathy. Additionally, maintaining optimal HbA1c levels has been linked to a lower risk of cardiovascular diseases and mortality in individuals with diabetes. However, it is important to note that HbA1c levels alone do not provide a complete picture of diabetes management. Other factors, such as self-monitoring of blood glucose, patient adherence to treatment, and individualized care, also play crucial roles in achieving optimal glycemic control and preventing complications.

Limitations and Future Research

While the systematic literature review provided valuable insights, there were some limitations to consider. The included studies varied in design, sample size, and methodology, which may have influenced the overall findings. Additionally, most of the studies focused on Type 2 diabetes, and there were a limited number of studies specifically addressing HbA1c measurement in

special populations, such as pregnant women or individuals with Type 1 diabetes. Future research should aim to address these gaps by conducting well-designed studies that explore the impact of HbA1c measurement on diabetes management outcomes in diverse populations. Additionally, the development of standardized protocols for HbA1c measurement and interpretation could further enhance the consistency and reliability of results.

Conclusion

In conclusion, this systematic literature review has provided valuable insights into the measurement of HbA1c levels among patients with diabetes. The review identified various measurement methods, including laboratory-based assays and point-of-care testing, and highlighted the importance of accurate and precise measurement for effective diabetes management. Interpretation of HbA1c levels is crucial in setting glycemic targets and guiding treatment plans, considering factors such as age, duration of diabetes, and co-morbidities. The clinical implications of HbA1c levels were also explored, revealing the association between lower HbA1c levels and improved glycemic control, reduced risk of complications, and better overall health outcomes. However, it is important to consider HbA1c levels in conjunction with other factors, such as self-monitoring of blood glucose and patient adherence to treatment, for comprehensive diabetes management. While the review provided valuable insights, it is important to acknowledge the limitations, such as variations in study design and the focus on specific populations. Future research should aim to address these limitations and further explore the impact of HbA1c measurement on diabetes management outcomes in diverse populations. Overall, this systematic literature review contributes to enhancing the understanding of HbA1c measurement in diabetes management. The findings can guide healthcare professionals in optimizing treatment plans, improving glycemic control, and ultimately enhancing the overall health and well-being of patients with diabetes.

Competing Interests

None to declare.

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