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HbA1c overestimates the glucose management indicator: a pilot study in patients with diabetes, chronic kidney disease not on dialysis, and anemia using isCGM

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Abstract

Introduction: There are multiple mechanisms by which HbA1c values can be altered in chronic kidney disease (CKD), which limits its usefulness as a strategy to assess glycemic control in this population.

Methods: Concordance and agreement study between two diagnostic tests: HbA1c and glucose management indicator (GMI) measured by intermittently scanned continuous glucose monitoring (isCGM), based in a prospective cohort of patients with diabetes, CKD (glomerular filtration rate between 15 and 60 ml/min/1.73 m^2), and anemia. The isCGM was performed for 3 months, and the GMI was compared with the HbA1c levels taken at the end of isCGM. Agreement was evaluated using Bland–Altman graph analysis and Lin's concordance correlation coefficient (CCC). The concordance of the measures with good glycemic control (<7%) was also evaluated.

Results: A total of 74 patients were enrolled (median age 68.5 years, 51.3% female, 64.9% with CKD stage 3, hemoglobin 11.1 ± 1.2 g/l). The Bland–Altman analysis shows a mean difference between GMI and HbA1c of 0.757 ± 0.687% (95% limits of agreement: −0.590 and 2.105). Difference was greater as the values of GMI and HbA1c increased. The agreement was poor [CCC 0.477; 95% confidence interval (CI): 0.360–0.594], as well as the concordance of values with good glycemic control according to GMI *versus* HbA1c (67.5% *versus* 29.7%, $p < 0.001$) (Kappa 0.2430; 95% CI: 0.16–0.32).

Conclusion: The HbA1c overestimates the GMI values with highly variable ranges of difference, which prevents a precise correction factor. isCGM probably is a safer option for monitoring and decision-making in this population, especially in patients treated with insulin where the risk of hypoglycemia is greater.

Keywords: anemia, chronic kidney disease, continuous glucose monitoring, diabetes, glucose management indicator, glycated hemoglobin

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Introduction

The International Diabetes Federation estimates that 537 million people will be living with type 2 diabetes in the world by 2021 and 784 million by 2045.[1] Up to a quarter of them live with chronic kidney disease (CKD), with a prevalence that is increasing due to the improvement in life expectancy.[2] It is, therefore, essential to achieve timely glycemic control that has an impact on mortality and cardiorenal outcomes. American Diabetes

Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO) recommend evaluating glycated hemoglobin at least twice a year in controlled patients, and at least four times a year in noncontrolled patients.[3] However, there are multiple metabolic interactions between CKD and diabetes; thus, the interpretation of good control is not equivalent to that in patients without CKD. These include impaired glucose clearance by muscle due to uremia, decreased insulin clearance by a damaged kidney, persistence of a constant proinflammatory state, and overproduction of counterregulatory hormones.

In terms of glycated hemoglobin (HbA1c), there are multiple variables that make its interpretation difficult: race, the presence of anemia, the frequent use of erythropoietin-stimulating agents, and the reduction in the half-life of erythrocytes due to uremia make the value of HbA1c at follow-up biased or imprecise.[4,5] Therefore, other biomarkers such as glycated albumin and fructosamine have been proposed; however, they lack precision and validation studies at the population level.[6]

Diabetes technology and specifically continuous glucose monitoring (CGM) systems may be useful to overcome these difficulties. Multiple studies have supported the use of CGM in the population with diabetes.[6] Both intermittently scanned continuous glucose monitoring (isCGM) and real-time continuous glucose monitoring allow the calculation of internationally accepted metrics to assess glycemic control, such as the glucose management indicator (GMI) from interstitial glucose measurements,[7] with the advantage that they are not affected by the metabolic alterations or deterioration of glomerular rate filtration.[8] The GMI is based on the glucose average to give a value analogous to HbA1c and provides information for a more personalized diabetes management plan, which may be useful in patients with renal failure or anemia in whom there may be discrepancies between the HbA1c result and the patient's actual mean blood glucose.[9]

One explanation for the dissociation between GMI and HbA1c is that erythrocyte turnover affects HbA1c levels. This has been found in the nondiabetic population and in patients with type 1 diabetes (T1D) and type 2 diabetes (T2D).[5] Therefore, GMI could be useful in the follow-up of patients with pathologies that affect red blood cell turnover, such as CKD and anemia. There are few studies to evaluate whether its use would more accurately assess glycemic control in patients with diabetic kidney disease and anemia. The aim of this study is to describe the concordance and reproducibility between HbA1c and GMI, in patients with diabetes, CKD, and anemia, using isCGM.

Methods

Study design

This is a concordance and agreement study between diagnostic tests (HbA1c *versus* GMI as measured by isCGM) based in a prospective cohort, evaluating patients with diabetes, CKD, and anemia, managed at two centers: the Hospital Universitario San Ignacio and renal unit of the Clínica Colsanitas in Bogotá, Colombia, between June 2020 and October 2022. The Ethics and Research Committee of the Hospital Universitario San Ignacio and Unisanitas – Clínica Colsanitas, approved the protocol FM-CIE-0554-19. All patients signed an informed consent for sensor insertion, HbA1c measurement, and use of clinical and isCGM data.

Participants

We included patients with T1D or T2D over 18 years, with any type of antidiabetic treatment, with a glomerular filtration rate between 15 and 60 ml/min/1.73 m² and who met the World Health Organization definition of anemia.[10] Patients unable to use the isCGM device and those with diseases or treatments that affect red blood cell turnover such as: blood product transfusions, hemoglobinopathies, cancer, renal transplant, pregnancy, use of dexamethasone, or mannitol were excluded.

Follow-up

At an initial first visit, the isCGM (Abbott Diabetes Care, Alameda, CA, USA) was implanted, and patients were instructed on the use of the device and the LibreView platform (Abbott Diabetes Care) for data download. Patients were instructed to perform at least four daily scans and corroborate extreme values (<70 or >400 mg/dl) recorded by the isCGM with self-monitored blood glucose. In addition, patients were instructed to download the data at least once

a week to ensure that it was stored in the network. Follow-up phone calls were then made every 14 days to ensure proper use of the device, to answer questions, to reinforce education, and to indicate the change of sensor. After 3 months of follow-up, a new in-person visit was made to complete the download of the data and to obtain blood samples for measurement of HbA1c using high-performance liquid chromatography, the standardized method recommended by the ADA. To reduce bias, patients who did not complete 90-day isCGM data were excluded from the analysis.

Variable definitions

The diagnosis of T2D and T1D was confirmed according to the 2020 ADA criteria.[11] The glomerular filtration rate was calculated according to the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.[12,13] Stage of CKD was classified according with KDIGO criteria. Stage 3 included estimated glomerular filtration rate (eGFR) between 30 and 59 ml/min, and Stage 4 eGFR between 15 and 29 ml/min. Anemia was considered a serum hemoglobin (Hb) value <13 g/dl in men and <12 g/dl in women.[10] From a 90-day isCGM, the ambulatory glucose profile was evaluated including: time in range (TIR), which represents the percentage of time of the day that the patient spends between 70 and 180 mg/dl, time below range (TBR <70 and 54 mg/dl), and time above range (TAR >180 and 250 mg/dl). The coefficient of variation (%CV) corresponds to the division between the standard deviation (SD) and the glucose average multiplied by 100. A CV $>36\%$ was defined as high variability. The GMI is based on the glucose average to give a value analogous to glycated hemoglobin, and its formula is GMI (%) = 3.31 + average glucose (mg/dl) $\times$ 0.02392.[14]

Sample size

The sample size was calculated according to the method proposed by Hong *et al.*[15] to evaluate the agreement between two measurement techniques (GMI and HbA1c) that dichotomize the values. Assuming a prevalence of bad metabolic control of 20%, with the minimum acceptable percent agreement between two raters assumed to be 75%, whereas the expected percent agreement in the study is 90%. The calculated sample size was 75 patients with a power of 80% and $\alpha = 5\%$.

Statistical analysis

Quantitative variables are described as means and SD or median and interquartile range (IQR) depending on whether the assumption of normal distribution was met. The Shapiro–Wilk test was used to test this assumption. To determine the agreement between the HbA1c values and the GMI, we used the Bland–Altman graphic analysis and the Lin correlation coefficient (CCC) classifying the agreement as almost perfect with values greater than 0.99, substantial from 0.95 to 0.99, moderate from 0.90 to 0.95, and poor below 0.90. In an exploratory manner, this analysis was repeated in subgroups according to the level of anemia (greater and less than 10 g/dl) and glomerular filtration rate (greater and less than 30 ml/min). Finally, the concordance between the GMI and HbA1c levels was evaluated, dichotomizing the values according to metabolic control (HbA1c or GMI <7 or $\geqslant 7$) using a Kappa coefficient. Stata software was used to perform the analyses (StataCorp. 2020. Stata Statistical Software: Release 16; StataCorp LP, College Station, TX, USA).

Results

A total of 86 patients were invited to participate. Seven of them died and five were lost to follow-up before completing the data collection, 74 patients were finally included in the analysis. The clinical and sociodemographic characteristics are presented in Table 1. The median age was 68.5 years (IQR 59–77). Less than 40% had HbA1c $<7\%$ (<53 mmol/mol). The average serum hemoglobin was 11.1 ± 1.2 g/l. Most patients (64.9%) were classified as stage 3 CKD according to the KDIGO categories. The mean TIR was $73 \pm 14.4\%$, with TBR <70 mg/dl of $3.4 \pm 4.4\%$ and TBR <54 mg/dl of 1.1 ± 1.9 (Table 2).

A total of 12 patients diagnosed with T1D were included. The median age for patients with T1D was 46 (RIQ 41–63) years and for patients with T2D was 71 (RIQ 63–79) years, ($p < 0.001$). Median HbA1c in patients with T1D and T2D was 7.4% with RIQ 6.3–8.2% (57 mmol/mol, RIQ 45–66) and 7.55% with RIQ 6.8–8.9% (59 mmol/mol, RIQ 51–71), $p = 0.886$, respectively. Serum Hb was 11.7 g/dl (RIQ 10.4–11.9 g/dl) in patients with T1D and 11.4 g/dl (10.3–11.9 g/dl) in patients with T2D, $p = 0.757$. The

Table 1. Demographic and clinical characteristics.

Variables	*n* = 74
Age, years, median (IQR)	68.5 (59–77)
Sex, female, *n* (%)	38 (51.3)
BMI, *n* (%)	
Normal (18–24.9)	29 (41.4)
Overweight (25–29.9)	31 (44.2)
Obesity (⩾30)	9 (12.8)
Type of diabetes, *n* (%)	
Type 1	12 (16.2)
Type 2	62 (83.8)
Type of treatment, *n* (%)	
Oral antidiabetics	57 (78)
Basal-bolus regimen	33 (45.2)
Comorbidities, *n* (%)	
High blood pressure	64 (86.5)
Cardiovascular disease	28 (39.4)
Stage of chronic kidney disease (GFR), *n* (%)	
G4 (15–29)	26 (35.1)
G3 (30–59)	48 (64.9)
Serum Hb, mean (SD)	11.1 (1.2)
Baseline HbA1c, mean (SD)	7.8 (1.3)

BMI, body mass index; G3, Stage 3 chronic kidney disease; G4, Stage 4 chronic kidney disease; GFR, glomerular filtration rate; Hb, hemoglobin; HbA1c, glycated hemoglobin; IQR, interquartile range; SD, standard deviation.

Table 2. Glycemic control metrics for 90-day period by isCGM in adults with diabetes, chronic kidney disease, and anemia.

Variables	isCGM metrics
% TIR 70–180 mg/dl, mean (SD)	73 (14.4)
% TAR >180 mg/dl, mean (SD)	17.1 (9.4)
% TAR >250 mg/dl, mean (SD)	5.4 (7.1)
% TBR <70 mg/dl, mean (SD)	3.4 (4.4)
% TBR <54 mg/dl, mean (SD)	1.1 (1.9)
% CV, mean (SD)	33.6 (6.5)
Average glucose, median (IQR)	145 (124–159)
% Sensor wear, median (IQR)	71 (55–81)

%CV, coefficient of variation; IQR, interquartile range; isCGM, intermittently scanned continuous glucose monitoring; TAR, time above range; TBR, time below range; TIR, time in range; SD, standard deviation.

percentage of patients with stage 3 renal disease in patients diagnosed with T1D and T2D was 66.6% and 64.5%, $p = 0.886$, respectively.

The correlation between GMI and HbA1c was moderate ($r = 0.728$, $p < 0.05$) with a 1.5 percentage point increase in HbA1c values (16 mmol/mol) for every 1% increase in GMI [Figure 1(a)]. The Bland–Altman graphic analysis showed an average difference between GMI and HbA1c values of 0.757 ± 0.687%, with 95% limits of agreement between −0.590 and 2.105. The difference was greater as the GMI and HbA1c increased [Figure 1(b)]. Agreement was poor according to Lin's CCC (0.477; 95% CI: 0.360–0.594). These findings were consistent in the subgroup analysis according to glomerular filtration rate and serum Hb level (Figure 2).

In a subgroup analysis, concordance was similar in patients with stage 4 CKD (Lin's CCC 0.452; 95% CI: 0.245–0.660) or stage 3 CKD (Lin's CCC 0.476; 95% CI: 0.332–0.619). The mean difference between GMI and HbA1c values and the limits of agreement were also similar in both groups [Figure 2(a) and (b)]. Similarly, the agreement and the average difference between GMI and HbA1c values were similar between patients with hemoglobin values higher or lower than 10 g/dl [Figure 2(c) and (d)].

When comparing the patients with HbA1c <7% (<53 mmol/mol) according to each of the tests used, we found that the proportion is much higher for GMI than for HbA1c (67.5% *versus* 29.7%, $p < 0.001$). In 40.5% of the patients, HbA1c was ⩾7% (⩾53 mmol/mol) even when GMI was in target. Otherwise, for 2.7% of the patients, the GMI was compatible with poor glycemic control, while the HbA1c was in target (Table 3). The agreement between tests was low (Kappa 0.2430; 95% CI: 0.16–0.32).

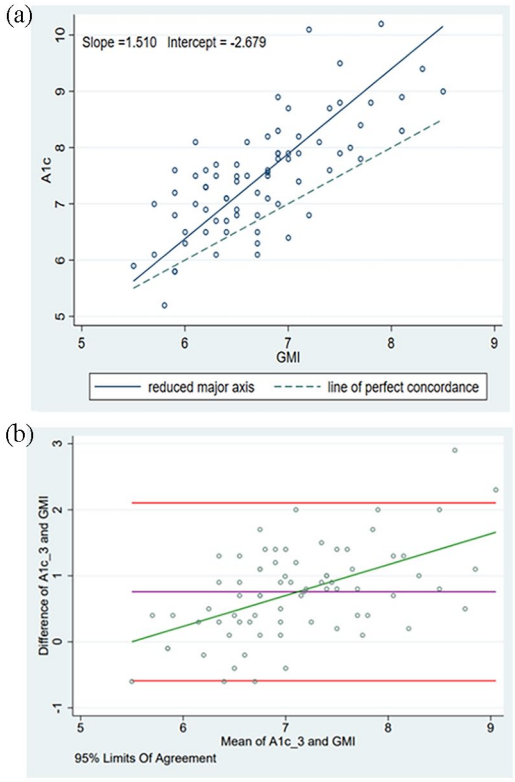

Figure 1. (a) Correlation between HbA1c and GMI in adults with chronic kidney disease and anemia. (b) Bland–Altman analysis (agreement) between HbA1c and GMI. Mean of HbA1c_3 and GMI: 3-month glycated hemoglobin and GMI average. Difference of HbA1c_3 and GMI: difference of 3-month HbA1c and GMI.
GMI, glucose management indicator; HbA1c, glycated hemoglobin.

Discussion

CKD stages 4 and 5 is known to underestimate HbA1c relative to mean glucose, and this same effect had been described at GFR <60 ml/min (CKD stage 3 or worse).[16] In the present study, we prospectively evaluated the agreement and concordance between GMI and HbA1c in patients with CKD stages 3 and 4. We found a moderate correlation between both diagnostic methods. However, we found a low concordance to define adequate metabolic control and overestimation of HbA1c with respect to GMI using different comparison methods. Additionally, we found that given the width of the confidence limits, it is not accurate to calculate the GMI value based on the HbA1c or vice versa.

This low concordance has been previously reported in other studies, and one of them included people without diabetes.[5] Oriot *et al.* documented, in an observational study, a positive difference >0.5% when comparing HbA1c values respect to GMI in 68.2% of individuals with CKD *versus* 42.2% in the group without CKD. Similarly, in the Bland–Altman analysis, the HbA1c values were 0.63% higher compared to GMI calculated from the isCGM.[17] Similar findings were reported in the Perlman real-world study where 50% of patients had HbA1c-GMI differences ⩾0.5% and 22% of patient differences ⩾1%. CKD was the only clinical factor that increased this discrepancy.[16]

Possible explanations include elevated HbA1c levels in patients with metabolic acidosis in association with cross-detection of carbamylated hemoglobin, which is indistinguishable from HbA1c in some types of assays.[18] Additionally, CKD pathophysiological conditions, such as decreased production of erythropoietin hormone, increased red blood cell lifespan, iron deficiency, the proinflammatory effect, hyperparathyroidism, inhibitory uremia, and metabolic acidosis, can alter this enzymatic interaction and the serum levels of HbA1c[19] and may result in discrepancies between the HbA1c result and the patient's true mean glycemia.[20] To clarify this, we performed a subgroup analysis based on serum Hb level and CKD stage according to glomerular filtration rate, where no significant differences were found in the conclusions. These findings indicate that neither anemia nor CKD is the root cause of the difference. However, we recognize that the sample size is insufficient, so this hypothesis should be further explored in studies with a larger number of patients.

On the other hand, the fact that in 40.5% of our patients, HbA1c reported poor metabolic control (defined as HbA1c ⩾7% or ⩾53 mmol/mol) when the GMI showed the opposite. GMI may provide better representation of diabetes control than HbA1c and may be more helpful to healthcare providers[5] in this population. Therefore, the trend in current clinical practice should be toward greater use of isCGM in patients with GFR <60 ml/min/1.73 m^2. The pathophysiological alterations that make this population more susceptible to complications such as hypoglycemia and high glycemic variability have already been mentioned. However, the risk of making wrong clinical decisions is more critical, such as increasing the dose of a hypoglycemic medication based

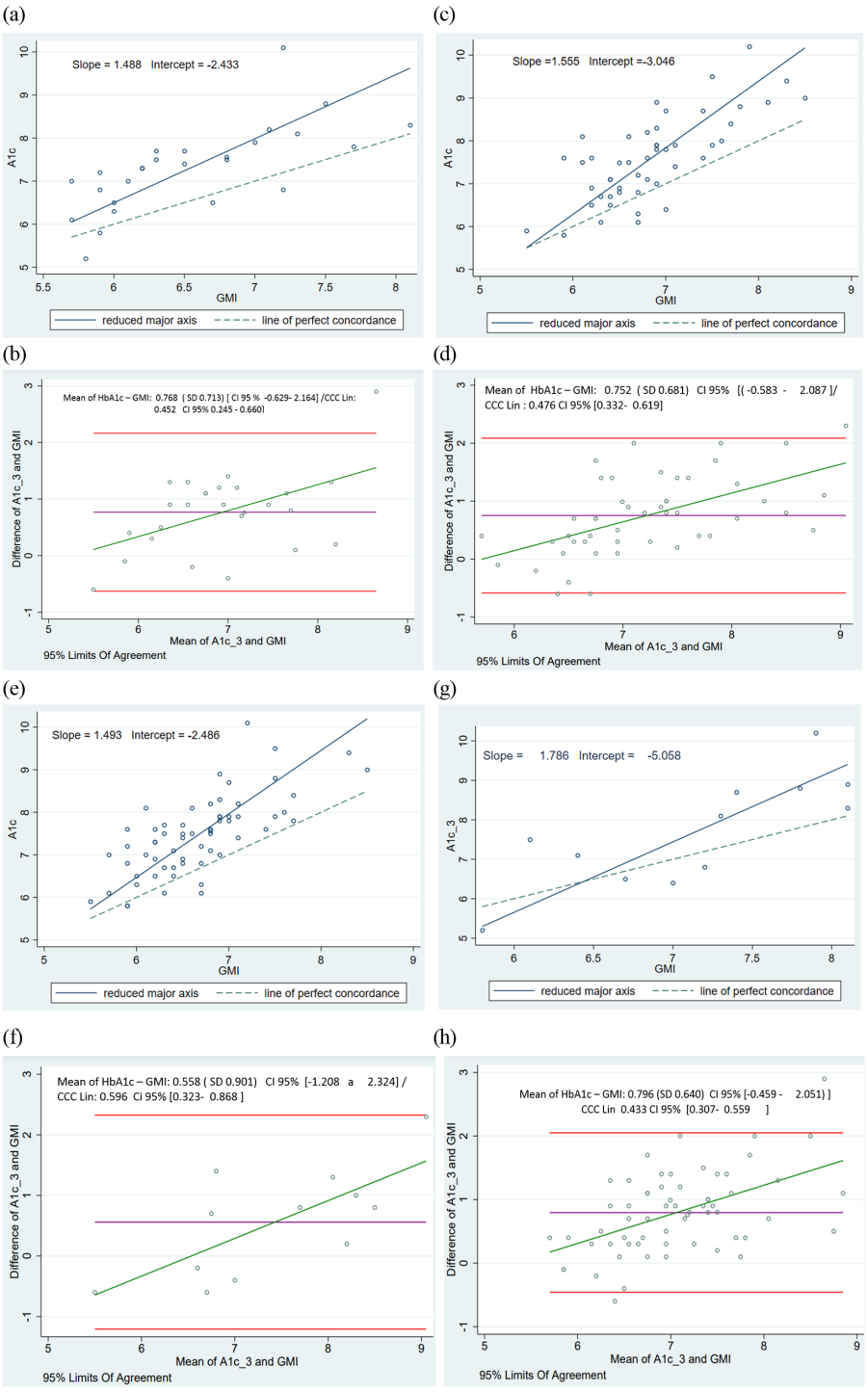

Figure 2. Subgroup analysis. (a) Correlation between HbA1c and GMI in adults with chronic kidney disease (G4) and anemia. (b) Bland–Altman analysis (agreement) between HbA1c and GMI in chronic kidney disease (G4). (c) Correlation between HbA1c and GMI in adults with chronic kidney disease (G3) and anemia. (d) Bland–Altman analysis (agreement) between HbA1c and GMI in chronic kidney disease (G3). (e) Correlation between HbA1c and GMI in adults with chronic kidney disease and anemia (Hb <10 g/dl). (f) Bland–Altman analysis (agreement) between HbA1c and GMI in chronic kidney disease and anemia (Hb <10 g/dl). (g) Correlation between HbA1c and GMI in adults with chronic kidney disease and anemia (Hb >10 g/dl). (h) Bland–Altman analysis (agreement) between HbA1c and GMI in chronic kidney disease and anemia (Hb >10 g/dl). Mean of HbA1c_3 and GMI: 3-month glycated hemoglobin and GMI average. Difference of HbA1c_3 and GMI: difference of 3-month HbA1c and GMI.
GMI, glucose management indicator; HbA1c, glycated hemoglobin.

Table 3. Concordance in the assessment of glycemic control with HbA1c and GMI in adults with type 2 diabetes, chronic kidney disease, and anemia.

GMI, *n* (%)	HbA1c, *n* (%)		Total
	<7%	⩾7%	
<7%	20 (27)	30 (40.5)	50 (67.5%)
⩾7%	2 (2.7)	22 (29.7)	24 (32.4%)
Total	22 (29.7%)	52 (70.2%)	74 (100%)

Kappa: 0.2430 (95% CI: 0.16–0.32).
GMI, glucose management indicator; HbA1c, glycated hemoglobin.

on glycated hemoglobin values far from true mean glycemia (as shown by the data from our study). Studies such as the one published by Grube *et al.*[21] have shown that in type 2 diabetes, the more the degree of kidney disease progresses, the greater the use of insulin, which in turn exponentially increases the risk of hypoglycemia, which would be even more accentuated if bad clinical decisions are taken.

This is the first study that used isCGM in patients with diabetic kidney disease and anemia not on dialysis and analyzed glycemic metrics over a 3-month period. The inclusion criteria guaranteed to obtain results in a specific population group, which is the most frequent in the endocrinology and nephrology consultation. Another strength of the study was the close follow-up that was carried out on the patients, which guaranteed proper use of the device, even giving the participants the possibility of downloading the data in our center in case they could not do it themselves. This study also included a very diverse Hispanic population, half of them female, both types of diabetes, being treated with both oral antidiabetics and insulin, and with different nonrenal complications, which makes its results valid for a broader population. However, there are limitations that must be considered. Although the patients met the definition of anemia, they had relatively high hemoglobin values; additionally, we did not have ferrokinetic measurements, which prevents us from a better evaluation of the impact of anemia and its type to explain the differences found. The sample size was small, limiting the number of patients in each stage of renal disease, but the proposed sample size was achieved. Only the Hispanic population was included and patients without anemia were excluded, limiting its application in other populations.

In conclusion, our study supports the evidence regarding the lack of concordance and reliability of HbA1c in the context of CKD, since it overestimates the values with respect to GMI, with highly variable ranges of difference, which does not allow an adjustment or a correction factor to be made. Given the absence of other standardized biomarkers to replace glycated hemoglobin, the use of CGM is proposed as a safer option for monitoring and decision-making in this population, especially in patients with insulin use where the risk of hypoglycemia is higher. The evidence warrants larger and more robust studies to assess the full effect of blood glucose and HbA1c levels in all stages of CKD, but certainly in stage 3 and 4 CKD in patients with diabetes.

Declarations

Ethics approval and consent to participate

The Ethics and Research Committee of the Hospital Universitario San Ignacio and Unisanitas – Clínica Colsanitas approved the protocol FM-CIE-0554-19.

Consent for publication

Informed consent for sensor insertion, analysis, and data publication was signed by all patients enrolled in the study.

Author contributions

Ana Gómez Medina: Conceptualization; Formal analysis; Investigation; Methodology; Project administration; Supervision; Validation; Writing – original draft; Writing – review & editing.

Camilo A. González: Data curation; Formal analysis; Investigation; Methodology; Writing – original draft.

Oscar M. Muñoz: Data curation; Formal analysis; Investigation; Methodology; Software; Supervision; Validation; Writing – original draft; Writing – review & editing.

Yaline Gómez: Data curation; Investigation; Methodology; Writing – original draft.

Pablo E. Jaramillo: Data curation; Formal analysis; Investigation; Methodology; Writing – original draft; Writing – review & editing.

Diana Henao: Data curation; Investigation; Methodology; Writing – original draft; Writing – review & editing.

Luis M. Rodríguez: Data curation; Investigation; Methodology; Writing – original draft.

Yurany Molina: Data curation; Investigation; Methodology; Writing – original draft; Writing – review & editing.

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Competing interests
AGM reports speaker fees from Novo Nordisk, Sanofi, Elli Lilly, Boehringer Ingelheim, Abbott, and Medtronic. DH reports speaker fees from Novo Nordisk, Sanofi, and Abbott. The other researchers report no conflicts of interest.

Availability of data and materials
Not applicable.

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Appendix

Abbreviations

%CV	coefficient of variation
GMI	glucose management indicator
HbA1c	glycated hemoglobin
isCGM	intermittently scanned continuous glucose monitoring
TAR	time above the range
TBR	time below the range
TIR	time in range