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EVALUATION OF THE ACCURACY OF A PORTABLE GLUCOSE METER COMPARED WITH LABORATORY-BASED SPECTROPHOTOMETRIC METHODS

PROCENA TAČNOSTI PRENOSIVOG MERAČA GLUKOZE U POREĐENU SA LABORATORIJSKIM SPEKTROFOTOMETRIJSKIM METODAMA

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Summary

Background: The accuracy of portable blood glucose monitoring systems is critical for the safe management and follow-up of Diabetes Mellitus. This study evaluated the accuracy of a capillary glucose monitoring device compared with laboratory-based spectrophotometric analysis of venous blood according to ADA recommendations and selected ISO 15197:2015 accuracy limits.
Methods: A cross-sectional study was conducted using 133 paired venous and capillary blood samples. Glucose concentrations were measured using the Humalyzer 2000 and Mindray BA-88A spectrophotometers and the Prodigy AutoCode® glucometer. Data were analysed using Kruskal-Wallis and Spearman correlation tests, with $p<0.05$ considered statistically significant.
Results: The glucometer reported slightly lower glucose values than the laboratory-based spectrophotometric methods. Correlation showed a weak association with the Humalyzer 2000 ($r=0.17$) and a moderate association with the Mindray BA-88A ($r=0.415$). Seventy-four per cent of measurements were within the ISO 15197:2015 acceptance limits compared with the Humalyzer 2000, whereas 92% were within the acceptance limits compared with the Mindray BA-88A for glucose concentrations <100 mg/dL. Bland–Altman analysis showed low systematic bias versus both analysers (-0.44 to -3.89 mg/dL), although agreement was more consistent with the Mindray BA-88A because of narrower limits of agree-

Kratak sadržaj

Uvod: Tačnost prenosivih sistema za praćenje glukoze u krvi od ključnog je značaja za bezbedno lečenje i praćenje dijabetes melitusa. U ovoj studiji je procenjena tačnost uređaja za merenje glukoze u kapilarnoj krvi u poređenju sa laboratorijskom spektrofotometrijskom analizom venske krvi, u skladu sa preporukama Američkog udruženja za dijabetes (ADA) i odabranim kriterijumima tačnosti standarda ISO 15197:2015.
Metode: Sprovedena je studija preseka u kojoj su analizirana 133 uparena uzorka venske i kapilarne krvi. Koncentracije glukoze merene su spektrofotometrima Humalyzer 2000 i Mindray BA-88A, kao i glukometrom Prodigy AutoCode®. Podaci su analizirani primenom Kruskal-Wallisovog testa i Spirmanovog testa korelacije, pri čemu je vrednost $p<0,05$ smatrana statistički značajnom.
Rezultati: Glukometrom su dobijene neznatno niže vrednosti glukoze nego laboratorijskim spektrofotometrijskim metodama. Analiza korelacije pokazala je slabu povezanost sa rezultatima dobijenim pomoću uređaja Humalyzer 2000 ($r=0,17$) i umerenu povezanost sa rezultatima uređaja Mindray BA-88A ($r=0,415$). U poređenju sa uređajem Humalyzer 2000, 74% merenja bilo je u okviru granica prihvatljivosti standarda ISO 15197:2015, dok je u poređenju sa uređajem Mindray BA-88A taj procenat iznosio 92% za koncentracije glukoze <100 mg/dL. Bland–Altmanova analiza pokazala je malu sistematsku pristrasnost u odnosu na oba analizatora (od -0,44 do

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List of abbreviations: ADA, American Diabetes Association; CDC, Centres for Disease Control and Prevention; DM, Diabetes Mellitus; FDA, Food and Drug Administration; GDM, gestational diabetes mellitus; GOD, glucose oxidase; Gmt, Prodigy AutoCode® glucometer; H-2000, Humalyzer 2000; KW, Kruskal-Wallis test; POD, peroxidase; SD, standard deviation; UNL, upper normal limit.

ment. Greater variability was observed at higher glucose concentrations, particularly with the Humalyzer 2000.
Conclusion: The glucometer demonstrated moderate performance and partial agreement with selected ISO 15197:2015 accuracy limits compared with laboratory-based spectrophotometric methods. Increased variability at higher glucose concentrations limits its applicability in settings requiring high analytical precision; therefore, results should be interpreted with caution.

Keywords: glycaemic control, blood glucose, glucometer, laboratory medicine, clinical chemistry

-3,89 mg/dL), mada je slaganje sa uređajem Mindray BA-88A bilo doslednije zbog užih granica slaganja. Veća varijabilnost zabeležena je pri višim koncentracijama glukoze, naročito u poređenju sa uređajem Humalyzer 2000.
Zaključak: Glukometar je pokazao umerenu pouzdanost i delimično slaganje sa odabranim kriterijumima tačnosti standarda ISO 15197:2015 u poređenju sa laboratorijskim spektrofotometrijskim metodama. Povećana varijabilnost pri višim koncentracijama glukoze ograničava njegovu primenu u uslovima koji zahtevaju visoku analitičku preciznost, pa rezultate treba tumačiti sa oprezom.

Ključne reči: kontrola glikemije, glukoza u krvi, glukometar, laboratorijska medicina, klinička hemija

Introduction

Point-of-care glucose monitoring is essential for detecting glycemic fluctuations in patients with diabetes, enabling timely adjustment of pharmacological treatment and evaluation of responses to diet and physical activity, thereby ensuring the maintenance of blood glucose levels within safe ranges (1, 2). Since the late 1970s, along with the development of new analytical approaches, a wide range of methodologies and devices for glucose measurement have been introduced, driven by their high clinical relevance (3). Spectrophotometric techniques have stood out for their accuracy and reliability, as well as for their capacity for automation, which has significantly improved data processing speed (4). On the other hand, portable blood glucose meters (glucometers) are ideal tools for glycemic measurement in patients with Diabetes Mellitus (DM), as they offer ease of use, relatively low cost, and the ability to perform self-monitoring of blood glucose in a home-based setting. This not only improves treatment adherence but also enables informed clinical decision-making, thereby reducing the risk of complications and adverse reactions (5). Although laboratory-based chemical analysers constitute the reference method recommended by the American Diabetes Association (ADA) for glucose measurement (6), whole blood is commonly used for rapid monitoring with these portable devices (7). The accuracy and precision of portable blood glucose meters may not always meet the levels specified by international regulatory bodies or those stated in each device's internal manual, which may directly impact patient well-being (8). Current recommendations from the ADA and the European standard ISO 15197:2015 define the minimum requirements and acceptable accuracy margins (9, 10). Nevertheless, despite the efforts of these organisations, as well as other regulatory bodies such as the Food and Drug Administration (FDA) and the Centres for Disease Control and Prevention (CDC), globally accepted standards for glucose testing have not yet been established, nor are there requirements for manufacturers to demonstrate the continued accuracy of their devices after initial approval (11). This lack of uniform quality specifications limits consistent comparison across studies. In addition, evidence regarding the performance of glucometers remains limited for several models widely available to the general population. Therefore, the aim of this study was to compare capillary blood glucose measurements obtained using the Prodigy AutoCode® glucometer with venous blood glucose measurements analysed by semi-automated laboratory instruments, in accordance with current international recommendations.

Materials and Methods

Study design

A cross-sectional study was conducted comparing 133 paired venous and capillary blood samples. Inclusion criteria comprised adults aged ≥18 years of both sexes who were considered clinically healthy at the time of sample collection. Participants with diagnosed chronic diseases that could affect blood glucose measurements were excluded. Additionally, individuals who had used paracetamol, vitamin C, or ibuprofen within 24 hours before blood sampling were excluded, as these factors may interfere with the assay according to the manufacturer's instructions.

Data availability statement

The dataset is not publicly available due to privacy considerations. Anonymised data may be available upon reasonable request from the corresponding author.

Blood sample collection

Samples were collected at the Clinical Biochemistry Laboratory of the Universidad Católica de Temuco. Capillary blood was obtained using an antiseptic technique with 70% alcohol on the fingertip of the index finger. The first drop was discarded, and approximately 0.7 μL of blood was applied to the

glucometer test strip. Venous blood was collected using a standard vacuum (Vacutainer®) system via antecubital venipuncture after antisepsis with 70% alcohol. A total of 4 mL of blood was drawn into a red-top tube without additives, then centrifuged at 3,500 rpm for 5 minutes. The serum was immediately aliquoted into 1 mL Eppendorf tubes. Capillary and venous samples were collected consecutively, with an approximately 30-minute interval between measurements. Both samples from each participant were obtained and analysed without refrigeration or freezing. Measurements were performed under controlled laboratory conditions, as single determinations, and operators were blinded to comparator results.

Instrumentation and analytical methods

Capillary blood samples were analysed using the Prodigy AutoCode® glucometer (Prodigy Diabetes Care, Charlotte, NC, USA), which is based on an electrochemical method. Serum samples were analysed using the Humalyzer 2000 (HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Wiesbaden, Germany) and the Mindray BA-88A (Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shenzhen, China) analysers, employing the glucose oxidase–peroxidase method (Glucose Liquicolor®, HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Wiesbaden, Germany) according to the manufacturer's instructions. This method catalyses glucose oxidation, producing gluconic acid and H_2O_2, which reacts with peroxidase, phenol, and 4-aminoantipyrine to form a red–violet complex quantified by measuring absorbance at 546 nm (12). Commercial quality control materials were used for analytical verification. Spectrophotometric analysers were monitored using HUMATROL (Normal and Pathology) controls (HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Wiesbaden, Germany), while the Prodigy AutoCode® glucometer was verified using the manufacturer-provided control solution. Calibration procedures were performed according to the manufacturers' instructions. Analytical runs were accepted when results were within the established acceptable ranges.

The glucose meter, test strips, and reagents used in this study were purchased through standard institutional procedures, and no manufacturer provided financial support, equipment, or materials for this research.

Statistical analysis

Data are presented as mean ± standard deviation. Statistical analyses were performed using GraphPad Prism version 10.4.1. The Shapiro-Wilk test was used to assess data normality. Differences between groups were evaluated using the Kruskal–Wallis test followed by Dunn's multiple comparisons post hoc test.

Associations were assessed using Spearman's correlation coefficient, and simple linear regression analysis was performed to evaluate the relationship between the studied methods. Bland–Altman analysis was used to assess agreement between measurements. Finally, accuracy analysis was conducted according to ADA recommendations and the European ISO 15197:2015 standard. A p-value <0.05 was considered statistically significant.

Ethical considerations

This study was approved by the Research Ethics Committee of the Universidad Católica de Temuco (No. 011601/23). It was conducted in accordance with the Declaration of Helsinki of the World Medical Association (ethical principles for medical research involving human subjects). All participants provided written informed consent before their inclusion in the study.

Results

Blood glucose levels in the volunteers were measured simultaneously using the Prodigy AutoCode® glucometer and the semi-automated H-2000 and Mindray analysers. Of the 163 volunteers initially enrolled, 30 (17%) were excluded from the analysis: 27 due to prior use of paracetamol, vitamin C, and/or ibuprofen, and 3 due to the presence of chronic diseases. Consequently, 133 samples were analysed, considering the variables sex, age, ethnicity, fasting status, chronic medication use and family history of diabetes.

The study population consisted predominantly of women (54.8%), while men accounted for 45.2%, with a mean age of 24 years. Thirty per cent (n=40) of participants self-identified as Mapuche. Additionally, 35.3% reported chronic use of other medications, 38% were in a fasting state at the time of sampling, and 63.9% reported a family history of diabetes. Glycemic measurements obtained with the three devices showed a non-parametric distribution ($p<0.05$). Analysis of mean values indicated that the glucometer yielded slightly lower glucose concentrations (87.0±9.6 mg/dL) compared with the Humalyzer 2000 (88.0±16.8 mg/dL) and the Mindray analyser (91.0±12.9 mg/dL; *Table I*).

The Kruskal–Wallis analysis revealed a significant difference between the glucometer and the semi-automated analysers ($p=0.022$). However, post hoc analysis using Dunn's test did not show

Table I Comparative analysis of blood glucose values obtained using the Prodigy AutoCode® glucometer and two semi-automated analyzers across subgroups.

Mean value (mg/dL) ± SD [range]					Dunn's Test, p-value	
Variable (n)	Gmt	H-2000	Mindray	KW test, p-value	Gmt vs H-2000	Gmt vs Mindray
All data (133)	87±9.6 [77.4–96.6]	88±16.8 [71.2–104.8]	91±12.9 [78.1–103.9]	**0.022***	>0.999	0.078
Sex						
Male (60)	86.8±9.6 [77.2–96.4]	87.3±16.9 [70.4–104.2]	90.8±12.9 [77.9–103.8]	0.076	>0.999	0.202
Female (73)	86.7±9.6 [77.1–96.3]	87.2±16.8 [70.4–104.1]	90.6±12.9 [77.6–103.6]	0.234	>0.999	0.536
Ethnicity						
Mapuche (40)	86.7±9.6 [77.1–96.3]	87.2±16.8 [70.4–104.1]	90.6±12.9 [77.6–103.6]	0.286	0.876	>0.999
Non -mapuche (93)	86.8±9.6 [77.2–96.4]	87.3±16.8 [70.4–104.1]	90.7±12.9 [77.8–103.7]	**0.035***	>0.099	**0.049***
Fasting						
Yes (51)	86.8±9.6 [77.2 – 96.4]	87.2±16.7 [70.4 - 104]	90.6±12.9 [77.7 – 103.6]	**<0.00***	**0.003***	0.926
No (82)	86.1±9.8 [76.2–95.9]	90.2±15.9 [74.3–106.2]	91.1±13.8 [77.3–105]	0.068	0.137	0.132
Medication Use						
yes (47)	86.8±9.6 [77.2–96.4]	87.2±16.7 [70.4–104]	90.6±12.9 [77.7–103.6]	0.085	0.833	0.080
No (86)	86.8±9.6 [77.2–96.4]	87.3±16.8 [70.4–104.2]	90.7±12.9 [77.7–103.7]	0.077	0.745	0.805
Family History of Diabetes						
Yes (85)	86.7±9.6 [77.1–96.3]	87.2±16.8 [70.4–104.1]	90.6±12.9 [77.6–103.6]	0.325	>0.999	0.506
No (48)	86.8±9.6 [77.2–96.4]	87.3±16.8 [70.4–104.1]	90.7±12.9 [77.8–103.7]	**0.022***	>0.999	0.152

* Statistically significant differences ($p<0.05$). Comparative analyses were performed using the Kruskal-Wallis test. Abbreviations: SD, standard deviation; KW, Kruskal-Wallis test; H-2000, Humalyzer 2000; Gmt, Prodigy AutoCode® glucometer; Mindray, Mindray BA-88A; N, sample size.

significant differences between the glucometer and the H-2000 ($p>0.999$) or between the glucometer and the Mindray analyser ($p=0.078$; *Table I*).

When glucose concentrations were evaluated according to other variables, significant differences were observed only for fasting status, ethnicity, and family history of diabetes ($p<0.05$). In the post hoc analysis, significant differences were found in fasting individuals when compared using the H-2000 ($p=0.003$) and in non-Mapuche participants using the Mindray analyser ($p=0.049$), with a trend toward

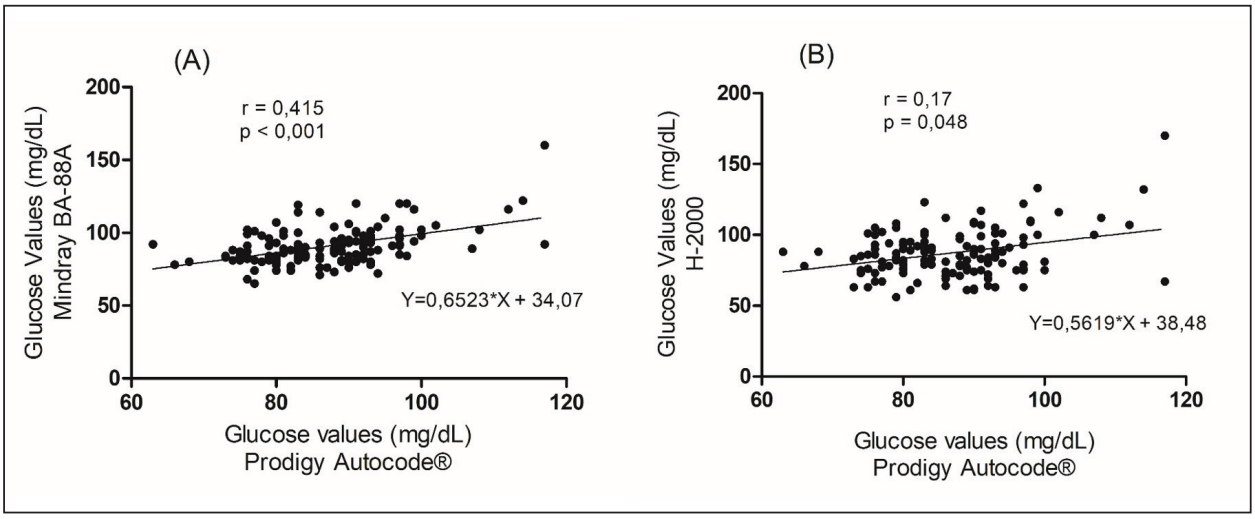

Figure 1 Scatter plots showing the relationship between glucose concentrations measured by the Prodigy AutoCode® glucometer (x-axis) and the H-2000 analyser (y-axis) (A), and between the Prodigy AutoCode® glucometer (x-axis) and the Mindray BA-88A analyser (y-axis) (B). Spearman correlation coefficients and simple linear regression lines are shown.

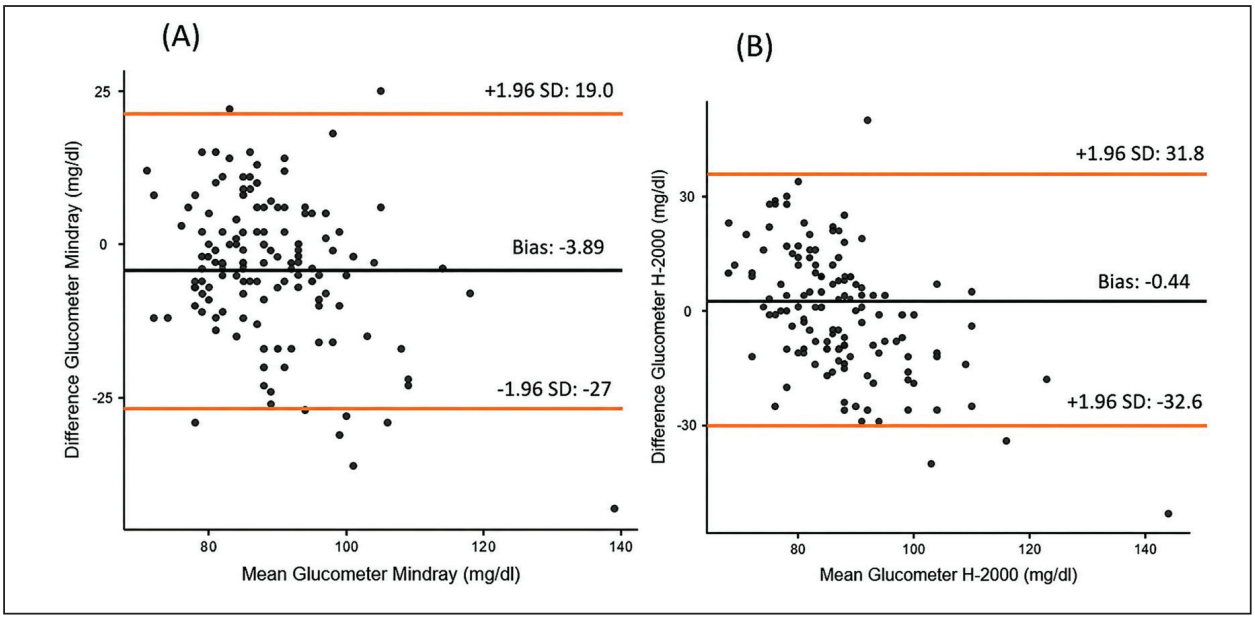

Figure 2 Bland-Altman plots comparing the Prodigy AutoCode® glucometer with the (A) Mindray BA-88A analyser and (B) Humalyzer 2000 analyser. The solid black line represents the mean bias, and the orange lines indicate the 95% limits of agreement (mean bias ± 1.96 SD). Differences are plotted against the mean glucose concentration of each paired measurement.

slightly lower glucose concentrations measured by the glucometer (*Table I*).

Spearman's correlation analysis showed a weak association (r=0.17) between glucose values obtained with the Prodigy AutoCode® glucometer and the H-2000 analyser, which was statistically significant (p=0.048; *Figure 1*). The linear regression equation (Y=0.5619X+38.48) indicates a positive relationship between measurements, with lower slope values suggesting differences in the proportional relationship between methods. A moderate association (r = 0.415) was observed between glucose values obtained with the glucometer and the Mindray analyser, with statistical significance (p<0.001; *Figure 1*). The corresponding linear regression equation (Y=0.6523X + 34.07) indicates a positive relationship between methods, with a slope below 1. To further evaluate the relationship between laboratory-based spectrophotometric methods, Spearman's correlation was

performed between H-2000 and Mindray BA-88A values. The result (r=0.592) indicates a moderate positive association between both laboratory methods, with a trend toward linearity (data not shown). Bland-Altman analysis (*Figure 2*) demonstrated low systematic bias for the Prodigy AutoCode® glucometer against both reference analysers: -3.89 mg/dL versus Mindray BA-88A (95% Limits of Agreement: [-27.0, 19.0] mg/dL) and -0.44 mg/dL versus Humalyzer 2000 (95% Limits of Agreement: [-32.6, 31.8] mg/dL). While these findings support acceptable agreement at the population level, the relatively wide limits of agreement, particularly with the Humalyzer 2000, highlight individual measurement variability that could be clinically relevant.

When results were analysed according to the criteria established by the American Diabetes Association and the ISO 15197:2015 standard, absolute error was calculated as the difference between the measured value and the reference value obtained with the semi-automated analysers. For glucose concentrations below 100 mg/dL, the allowable error margin is ±15 mg/dL. The proportion of measurements meeting this criterion was determined using laboratory-based spectrophotometric methods. The Prodigy AutoCode® glucometer results were within the ISO 15197:2015 acceptance limits in 74% (78/105) of measurements compared with the H-2000 analyser and in 92% (98/107) compared with the Mindray analyser.

For glucose concentrations ≥100 mg/dL, the permitted error margin corresponds to 15% of the reference value. This criterion was assessed by calculating upper and lower limits by adding and subtracting 15% of the reference value and determining whether the measured value fell within this range. It was observed that 43% (12/28) of glucometer measurements met the standard when compared with H-2000 results, while 54% (14/26) complied when contrasted with values obtained using the Mindray analyser.

Discussion

Diabetes mellitus is a chronic disease with a high global incidence. In 2021, it affected approximately 537 million adults worldwide, and this figure is projected to increase to about 783 million by 2045. Nearly 90% of cases correspond to type 2 Diabetes Mellitus, in which long-term complications are associated with impaired wound healing, retinopathy, nephropathy, and diabetic neuropathy, as well as severe cardiovascular events such as myocardial infarction and stroke (13). Considering that Diabetes Mellitus is not an adult-exclusive condition, it is crucial to promote glycemic control across all stages of life and in at-risk populations (14). In this study, 63.9% of participants reported a family history of Diabetes Mellitus, suggesting a high prevalence of potential hereditary risk factors (15).

Glucometers represent a fundamental tool for glucose monitoring in both clinical point-of-care settings and home-based contexts (16). Their ease of use, portability, and rapid turnaround time have established them as first-line devices for self-monitoring (17). In our study, the Prodigy AutoCode® glucometer yielded slightly lower glucose values than the H-2000 and Mindray analysers, showing partial compliance with the ISO 15197:2015 standard and greater variability at concentrations above 100 mg/dL. These findings indicate that elevated results should be interpreted with caution, particularly given the statistically significant difference observed between the glucometer and the H-2000 in fasting participants. Consistent with this, previous studies have reported that blood glucose values obtained with portable glucometers tend to be lower than those measured by reference laboratory methods, with this discrepancy increasing under hyperglycaemic conditions (18).

Castaño et al. (19) evaluated the Nova Biomedical StatStrip glucometer in 81 patients in intensive care units, reporting good correlation with laboratory methods, although with slightly lower values (19). Similarly, studies using the Roche Accu-Chek Active glucometer in patients with Gestational Diabetes Mellitus (GDM) demonstrated poor performance, suggesting that it should not be used for diagnostic purposes (20). In contrast, some studies have demonstrated adequate accuracy, such as the CONTOUR PLUS system, which showed performance exceeding 95% (21). In the study by Kuo et al. (22), more than 40% of the self-monitoring blood glucose systems evaluated met the minimum accuracy criteria established by ISO 15197; however, when stricter accuracy criteria of ±15% were applied, only the Bionime Rightest GM550 met this requirement (22). Pham et al. (23) reported that, among six evaluated glucometers, three met the required standards (Accu-Chek Inform II, Accu-Chek Performa, and OneTouch VerioVue), with a slight influence of hematocrit observed in the first two devices (23).

On the other hand, Arias et al. (24) conducted a systematic review and meta-analysis on the reliability of blood glucose measurements according to sample type (arterial, venous, capillary), concluding that capillary samples are only recommended in hemodynamically stable patients due to the risk of significant errors compared to reference methods (24). The Prodigy AutoCode® meter has been assessed in several clinical trials. In one, which included three triple-blind experiments with a total of 1,032 volunteers and 18 glucose meters (Roche, Bayer, Abbott, LifeScan, and BioSense), the Prodigy AutoCode®

device demonstrated moderate performance, meeting the established criteria in two of the three trials and achieving an overall average of 90% (25). In another trial analysing 53 participants exclusively with this device, low accuracy was observed compared with glucose concentrations obtained via venipuncture ($p<0.001$); approximately one-quarter of measurements exceeded the acceptable error margin of ±20%, failing to meet the accuracy standards required by ISO and the FDA (26). Finally, a study at Addis Ababa University and the Ethiopian Public Health Institute, including 52 patients with suspected diabetes mellitus, compared the performance of the Prodigy AutoCode® device with the Hexokinase (HK) reference method, reporting 94.4% accuracy for values <100 mg/dL and only 11.8% for values ≥100 mg/dL, indicating that the device does not comply with the minimum requirements of ISO 15197 standards (27).

Various technical, environmental, and physiological factors influence the accuracy of glucose meters. Technical aspects include the chemical basis of the test strips and the algorithms used to calculate plasma glucose (28, 29). Early chemical approaches relied on reducing properties, such as the Benedict and ferricyanide methods. Condensation methods are no longer employed due to low specificity, interference from other analytes, and the use of harmful reagents (30). Today, enzymatic approaches are widely used as a reference due to their speed and precision, notably the GOD-PAP method, based on glucose oxidase (GOD) and peroxidase (POD), and the hexokinase method, considered the "gold standard" for its high specificity and accuracy in glucose measurement (31). Most portable glucose meters employ electrochemical detection, measuring electrons released during the reaction between glucose and the reagent on the test strip (32). Others use a photometric principle, in which blood applied to a chemical strip reacts with glucose, producing a colour change that can be quantified by illuminating the test area and capturing the reflected light (33) .

Furthermore, environmental factors such as temperature and humidity can affect device performance by altering the chemical reaction and the physical properties of the sensors. As mentioned, physiological variations, such as hematocrit levels, can also influence measurements by modifying the proportion of plasma available in a drop of blood (28, 29). Among the main preanalytical factors affecting glucose concentration in venous blood samples is ex vivo glycolysis, especially when there are delays in processing and the sample is not kept refrigerated or centrifuged immediately after venipuncture (34). This can lead to a mean decrease in glucose concentration of 5–7% per hour, particularly in the presence of high leukocyte counts and elevated temperatures (35).

Among the limitations of this study is the sample collection method, as vacuum tubes without additives were used. Current recommendations suggest employing tubes containing early glycolysis inhibitors, such as sodium fluoride, sodium iodoacetate, lithium, D-mannose, or acidification of the blood (34). Nevertheless, the samples were immediately centrifuged and separated from the cellular phase to ensure stability (36). In addition, the glycemia range evaluated in this study was 56 to 170 mg/dL, which may be considered a limitation, as it did not allow assessment of accuracy and precision across the full reading range of the device (20–600 mg/dL; 1.1–33.3 mmol/L). Moreover, the study volunteers comprised a relatively homogeneous sample, consisting mainly of young individuals without chronic disease or diabetes mellitus, resulting in a limited range of glucose concentrations, with relatively few samples ≥100 mg/dL. Therefore, future studies should evaluate device performance in populations with diabetes and across a broader glycemic range.

Additionally, hematocrit, strip lot variability, and replicate measurements were not evaluated. The spectrophotometric comparison method used in this study was based on the GOD-PAP enzymatic method rather than the reference hexokinase method, which should be considered when interpreting the results. Finally, while the methodology allows comparison of measurement methods at a specific time point, it does not provide information on the temporal variability of measurements or the long-term stability of the device. Future studies incorporating these variables could provide a more comprehensive assessment of glucose meter performance.

In this study, volunteers reporting the use of medications that could interfere with the test were excluded. Nevertheless, 35.3% reported taking other drugs, mainly oral contraceptives, antidepressants, multivitamins, and antihistamines. These treatments were not considered exclusion criteria according to the study protocol. This is relevant, as drug-altered measurements are a common issue. Tang et al. (16) demonstrated that compounds such as ascorbic acid, acetaminophen, dopamine, and mannitol can affect glucose measurements in portable devices, highlighting the importance of considering exogenous factors when interpreting results (16). However, no significant differences associated with this variable were detected in our study.

While glucose meters offer important advantages, such as minimal sample volume, rapid result delivery, and the possibility of minimally invasive procedures, they also have limitations. These include reliance on test strips, whose commercial value is variable, shelf life is limited, and which are susceptible to degradation due to environmental changes. Therefore, proper device maintenance, correct cali-

bration, and adequate patient training are essential (37).

Glucose monitoring is moving toward more integrated and dynamic technologies, such as continuous monitoring systems and mobile applications, which provide real-time data and enable more precise decision-making. These advances not only optimise metabolic control but also support personalised approaches, enhancing the clinical management of diabetes with more sensitive tools tailored to individual patient needs (38, 39).

Evidence indicates that, despite FDA or other regulatory approval, not all glucose meters achieve the expected accuracy. This suggests that some devices may have been authorised under less stringent standards (25). Their use should focus on general glucose monitoring rather than contexts requiring high precision, such as diagnosis. This remains a challenge, especially in clinical settings where accuracy affects treatment choice, adjustment, and adverse outcomes (40). In particular, overestimations pose a significant risk of hypoglycaemia in patients using these devices (41).

Conclusions

Overall, the glucose meter demonstrated moderate performance, showing greater agreement with measurements obtained using the Mindray analyser at glucose concentrations below 100 mg/dL, with partial compliance with ISO 15197:2015. However, the present study was not designed to provide a complete validation according to the full ISO 15197:2015 protocol. Bland-Altman analysis showed low systematic bias between methods, but the relatively wide limits of agreement indicate substantial individual measurement variability. Increased variability and reduced accuracy were observed at glucose concentrations ≥100 mg/dL, indicating that results should be interpreted with caution in clinical settings requiring high analytical precision, particularly when considering factors such as fasting status, diabetes history, or ethnic background, and especially in home-based settings.

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Conflict of interest statement

All the authors declare that they have no conflict of interest in this work.

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