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Comparative Evaluation of the Hemocue® Glucose 201 RT Point-of-Care Device and the Mindray BS-240 Analyzer for Blood Glucose Measurement in a Clinical Laboratory Setting.

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Abstract

Background:
The Hemocue® Glucose 201 RT is widely used in the Democratic Republic of Congo; however, local validation data are lacking. This study aimed to compare glucose measurements obtained with the Hemocue® Glucose 201 RT device against those from the Mindray BS-240 analyzer to assess its suitability for implementation within the University Clinics of Kinshasa.

Methodology:
A cross-sectional, descriptive, and analytical study was conducted from May to June 2025. Venous blood samples (5 mL) were collected in sodium fluoride tubes, with immediate whole-blood glucose measurement performed using the Hemocue® Glucose 201 RT and plasma glucose measured within one hour using the Mindray BS-240 analyzer. Agreement between methods was assessed using Pearson correlation, Lin's Concordance Correlation Coefficient (CCC), Bland–Altman analysis, accuracy index (P10), RMSE, and Deming regression.

Results:
A total of 150 samples were analyzed. The Hemocue produced a mean glucose value of 104.7 ± 30.5 mg/dL, while the BS-240 yielded 99.5 ± 30.6 mg/dL. A very strong correlation was observed ($r = 0.99$; $p < 0.0001$), though overall concordance was moderate (CCC = 0.43 [0.38–0.48]). The Hemocue demonstrated a mean positive bias of –5.16 mg/dL and a significant constant bias based on Deming regression (intercept = 4.27 [1.67–6.94]). Accuracy remained high, with 93.3% of samples within ±10% of the BS-240 values.

Conclusion:
The Hemocue® Glucose 201 RT device showed strong correlation and acceptable clinical accuracy compared with the Mindray BS-240 analyzer, despite evidence of systematic overestimation. The device is appropriate for emergency and resource-limited settings, though result interpretation should consider observed bias.

Keywords:
Hemocue, Mindray BS-240, Blood Glucose, Point-Of-Care Testing, Laboratory Comparison, Kinshasa

Introduction

Blood glucose monitoring plays a fundamental role in detecting glycemic fluctuations arising from physiological responses, nutritional intake, physical activity, medication effects, and metabolic disorders such as diabetes mellitus [1]. As one of the most frequently requested laboratory tests, glucose measurement is essential for guiding timely therapeutic decisions in both outpatient and inpatient settings, particularly in emergencies where delays may affect patient triage and management [2].

Multiple analytical methods are currently available for blood glucose determination, with the enzymatic hexokinase method recognized as the reference technique in clinical laboratories [3]. Despite its accuracy and precision, automated analyzers commonly used for this method do not always provide rapid results, which may compromise urgent clinical interventions in critical care situations [4]. In such scenarios, point-of-care testing (POCT) offers a practical alternative by enabling decentralized, rapid glucose measurement that supports immediate clinical decision-making [5].

Several POCT devices are commercially available and widely used globally; however, ensuring their analytical reliability is crucial, especially in emergency departments, remote settings, and resource-limited environments where clinical staff depend on accurate results for prompt treatment. Both the WHO and ISO 15189:2022 emphasize the importance of local validation of diagnostic devices prior to their clinical implementation to ensure traceability, accuracy, and context-specific performance [6]. Additionally, regulatory guidance recommends that comparison methods be traceable to higher-order reference procedures to minimize analytical bias and support robustness of device evaluation [7].

At the University Clinics of Kinshasa (CUK), the absence of an analyzer employing the glucose hexokinase reference method necessitated a comparison of the Hemocue® Glucose 201 RT glucometer with the Mindray BS-240 analyzer, the primary validated instrument in routine use. The Hemocue® Glucose 201 RT is a photometric POCT device commonly utilized in several healthcare facilities across the Democratic Republic of Congo, yet no local performance evaluation has been documented to date. This gap underscores the need for a contextual assessment of its analytical agreement with the laboratory's current standard method.

Therefore, the objective of this study was to evaluate the agreement between blood glucose measurements obtained using the Hemocue® Glucose 201 RT device and those produced by the Mindray BS-240 analyzer to determine the POCT device's suitability for integration into clinical laboratory workflows at CUK.

Methodology

Study Design

This investigation employed a cross-sectional, descriptive, and analytical study design aimed at comparing blood glucose measurements obtained from the Hemocue® Glucose 201 RT point-of-care device with those produced by the Mindray BS-240 automated analyzer. The design allowed for simultaneous assessment of paired samples collected from the same participants, enabling an evaluation of concordance, bias, and statistical agreement between the two measurement methods.

Ethics

All study procedures adhered to the ethical standards of the Declaration of Helsinki. Informed consent was obtained from each participant or a parent/guardian for minors prior to sample collection. Ethical approval was granted by the Ethics Committee of the School of Public Health of the University of Kinshasa under reference ESP/CE/126/2025, ensuring that participant confidentiality, voluntary participation, and safe handling of biological material were maintained throughout the study.

Setting

The study was conducted between May 1 and June 30, 2025, within the Clinical Biology Laboratory of the University Clinics of Kinshasa (CUK). All blood sampling, handling, device testing, and analyzer-based measurements were performed at the Reception, Sampling, and Results Unit and the central biochemistry laboratory of the institution, ensuring standardized processing conditions.

Participants

Participants included all patients presenting to the Clinical Biology Department during the study period with a physician-requested laboratory order for blood glucose testing. Enrollment was based on convenience sampling. Individuals were eligible regardless of age or sex, provided they could give informed consent or have consent provided by a guardian. Patients from whom venipuncture could not be successfully performed were excluded from analysis. A total of 150 whole-blood specimens meeting inclusion criteria were ultimately analyzed.

Variables

The primary variable measured was blood glucose concentration, expressed in mg/dL. For each participant, paired glucose values were generated:

1. Glucose measured by Hemocue® Glucose 201 RT (whole blood, POCT)
2. Glucose measured by Mindray BS-240 (plasma, laboratory analyzer)

Other variables included bias (difference between methods), proportional bias, concordance, and error indices derived from statistical comparisons such as CCC, RMSE, and Bland–Altman parameters.

Data Sources and Measurement

For each participant, 5 mL of venous blood was drawn into sodium fluoride (NaF) tubes. Immediately after homogenization, an aliquot of whole blood was applied to a microcuvette for measurement using the Hemocue® Glucose 201 RT, which employs an enzymatic glucose dehydrogenase reaction and photometric detection at dual wavelengths (660 nm and 840 nm). The remaining sample was centrifuged at 3,500 rpm for 5 minutes, and plasma glucose was analyzed within one hour using the Mindray BS-240 analyzer via the enzymatic glucose oxidase spectrophotometric method. This dual approach ensured that paired measurements reflected minimal pre-analytical variation.

Bias

Potential sources of bias included differences in specimen types (whole blood vs plasma), the effect of hematocrit variation—particularly since hematocrit values were not measured—and possible delays in plasma processing. Hemocue devices are known to be sensitive to extreme hematocrit values outside the 20–70% range, which may influence accuracy. Additionally, differences in analytical principles between glucose dehydrogenase (Hemocue) and glucose

oxidase (BS-240) could introduce systematic or proportional bias. Procedural steps were standardized to minimize operator-dependent variability.

Study Size

Although method comparison guidelines from CLSI suggest a minimum of 40 samples, a larger convenience sample of 150 specimens was included to enhance statistical power, improve the stability of agreement estimates, and account for biological variability within the routine patient population at CUK.

Quantitative Variables

Quantitative outcomes including glucose concentrations from each method were treated as continuous variables. Normality was assessed using the Shapiro–Wilk test to determine appropriate statistical procedures. Depending on distribution, data were expressed as mean ± standard deviation or median with interquartile range. Differences between paired measurements were quantified as absolute and relative values, allowing further derivation of concordance indicators such as P10, CCC, and Bland-Altman limits of agreement.

Statistical Methods

Statistical analyses were performed using SPSS version 28 and XLStat. Paired comparisons of normally distributed glucose measurements were performed using the Student's t-test. Pearson's correlation coefficient (r) was used to assess linear association between the two methods, while Lin's Concordance Correlation Coefficient (CCC) quantified overall agreement. Accuracy was evaluated through the proportion of samples falling within 10% of the reference value (P10). Bias and limits of agreement were examined using Bland–Altman analysis, while proportional bias was tested through linear regression of differences against mean values. Root-mean-square error (RMSE) quantified total measurement error. To address measurement error in both methods, Deming regression was applied, providing estimates of constant and proportional bias with 95% confidence intervals. A p-value < 0.05 was considered statistically significant.

Results

Participants

A total of 150 venous blood samples were collected from patients who presented to the Clinical Biology Laboratory of the University Clinics of Kinshasa for routine blood glucose analysis. All participants had a valid laboratory request form indicating the need for glucose testing, and all met the study's inclusion criteria. No cases were excluded due to venipuncture failure or sample-related issues. The sample represented a heterogeneous patient population referred from various hospital departments, reflecting real-world clinical conditions under which glucose measurements are routinely performed.

Descriptive Data

Across all samples, glucose measurements were successfully obtained using both the Hemocue® Glucose 201 RT point-of-care device and the Mindray BS-240 automated analyzer. The Hemocue produced a mean glucose concentration of 104.7 ± 30.5 mg/dL, while the BS-240 analyzer produced a mean value of 99.5 ± 30.6 mg/dL. The mean difference (Δ glucose) between the two methods was –5.26 ± 2.85 mg/dL, indicating a systematic tendency for the Hemocue to provide slightly higher glucose values. Distribution analysis revealed that glucose values measured by both devices followed a normal distribution pattern, supporting the use of parametric statistical tests.

Outcome Data

Correlation analysis demonstrated a very strong linear relationship between glucose values obtained using the two methods, with a Pearson correlation coefficient of r = 0.99 (p < 0.0001). Agreement analysis provided complementary insight into the comparative performance of the devices. Lin's Concordance Correlation Coefficient (CCC) showed moderate agreement between the two methods at 0.43 (95% CI: 0.38–0.48), while 93.3% of samples fell within a 10% relative difference (P10 = 93.3% [85.5–98.1%]). Bland–Altman analysis revealed a mean bias of –5.16 mg/dL (95% CI: –5.62 to –4.70), demonstrating systematic overestimation by the Hemocue. Proportional bias was present, with discrepancies increasing at higher glucose levels. The RMSE value of 17.24 indicated a notable cumulative measurement error across samples.

Main Results

The Hemocue® Glucose 201 RT demonstrated strong correlation but only moderate concordance with the Mindray BS-240 analyzer. The Hemocue consistently generated slightly higher glucose values, as reflected in the negative mean bias and the significant constant bias identified through Deming regression, which yielded an intercept of 4.27 (95% CI: 1.67–6.94). The slope coefficient (0.991; 95% CI: 0.964–1.018) showed near-proportional scaling between the two methods, indicating that while the Hemocue results tracked closely with those of the BS-240 across the glucose range, a small systematic difference persisted. Despite this bias, the high proportion of values within 10% of the laboratory analyzer suggests that the Hemocue performs reliably enough for use in emergency settings or low-resource contexts where rapid glucose assessment is essential.

Table 1: Comparison of Blood Glucose Values Measured Using the Hemocue® Glucose 201 RT and the Mindray BS-240 Analyzer.

Variables	Hemocue® Glucose 201 RT	Mindray BS-240	Δ Glucose	p-value
Blood glucose (mg/dL)	104.7 ± 30.5	99.5 ± 30.6	–5.26 ± 2.85	< 0.001

Table 2: Agreement Metrics Between Hemocue® Glucose 201 RT and Mindray BS-240 Glucose Measurements.

Indicator	Value	95% CI
Lin's Concordance Correlation Coefficient (CCC)	0.43	0.38 – 0.48
P10 (Proportion within 10% difference)	93.3%	85.5 – 98.1
Mean Bias (mg/dL)	–5.16	–5.62 – –4.70
Standard Deviation of Bias (mg/dL)	2.85	1.44 – 4.26
Proportional Bias	2.49	1.14 – 3.84
Root Mean Square Error (RMSE)	17.24	12.42 – 29.05

Table 3: Deming Regression Parameters Comparing Hemocue® Glucose 201 RT and BS-240 Analyzer.

Indicator	Value	95% CI (Lower)	95% CI (Upper)
Intercept	4.270	1.672	6.944
Slope Coefficient	0.991	0.964	1.018

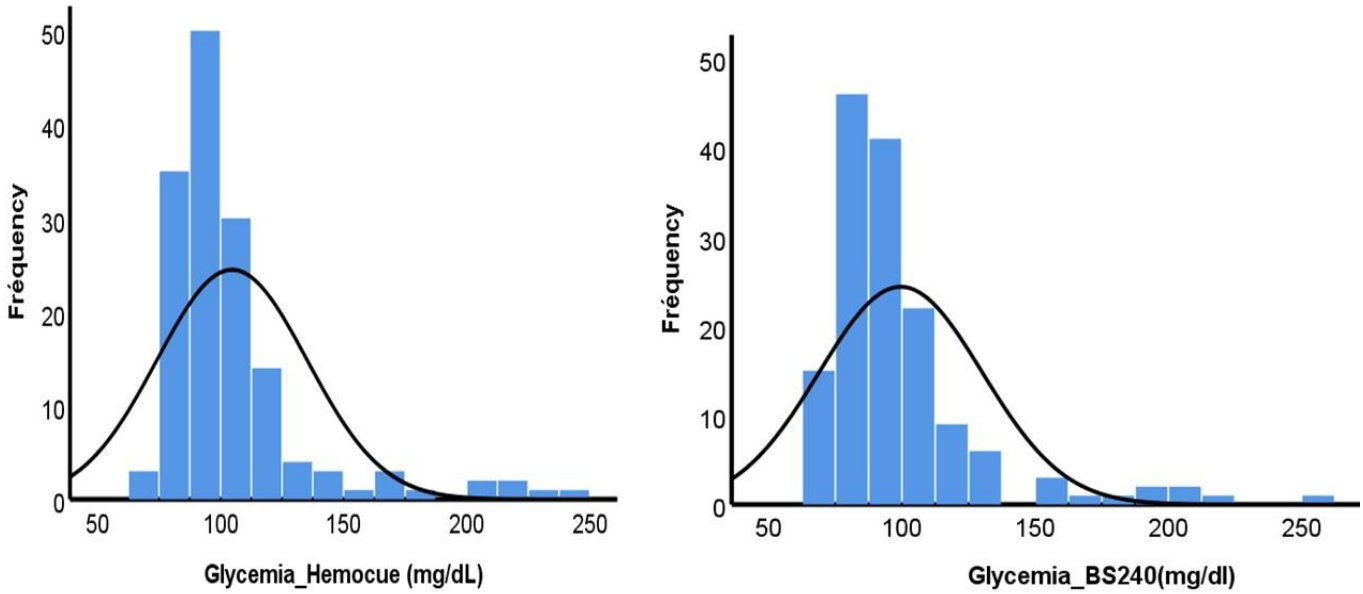

Figure 1: Distribution of Blood Glucose Values Measured by the Hemocue® Glucose 201 RT and Mindray BS-240 Analyzer

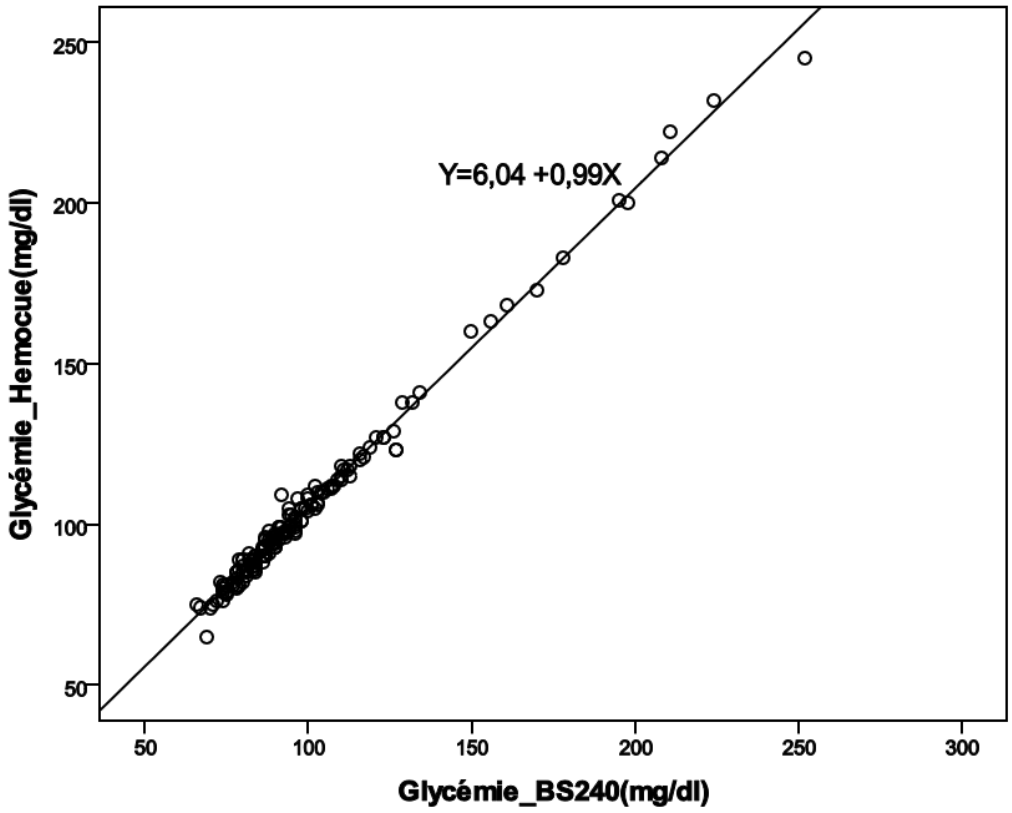

Figure 2: Correlation Between Blood Glucose Measurements Obtained Using the Hemocue® Glucose 201 RT Device and the Mindray BS-240 Analyzer

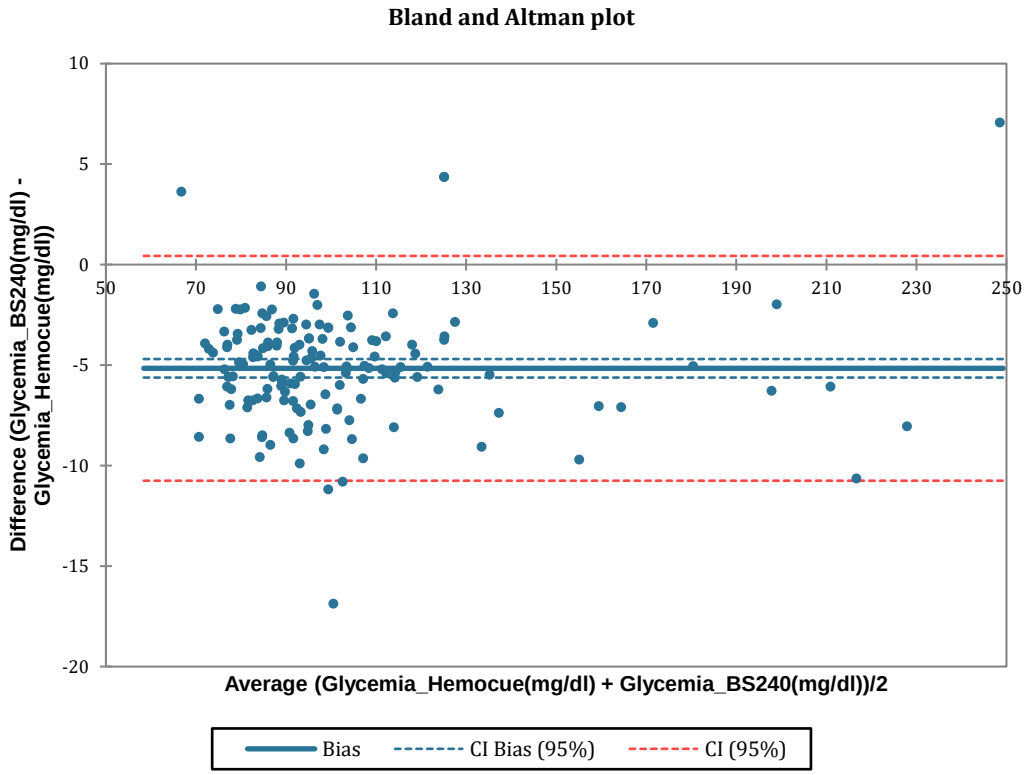

Figure 3: Bland–Altman Plot Showing Agreement Between Hemocue® Glucose 201 RT and Mindray BS-240 Glucose Measurements

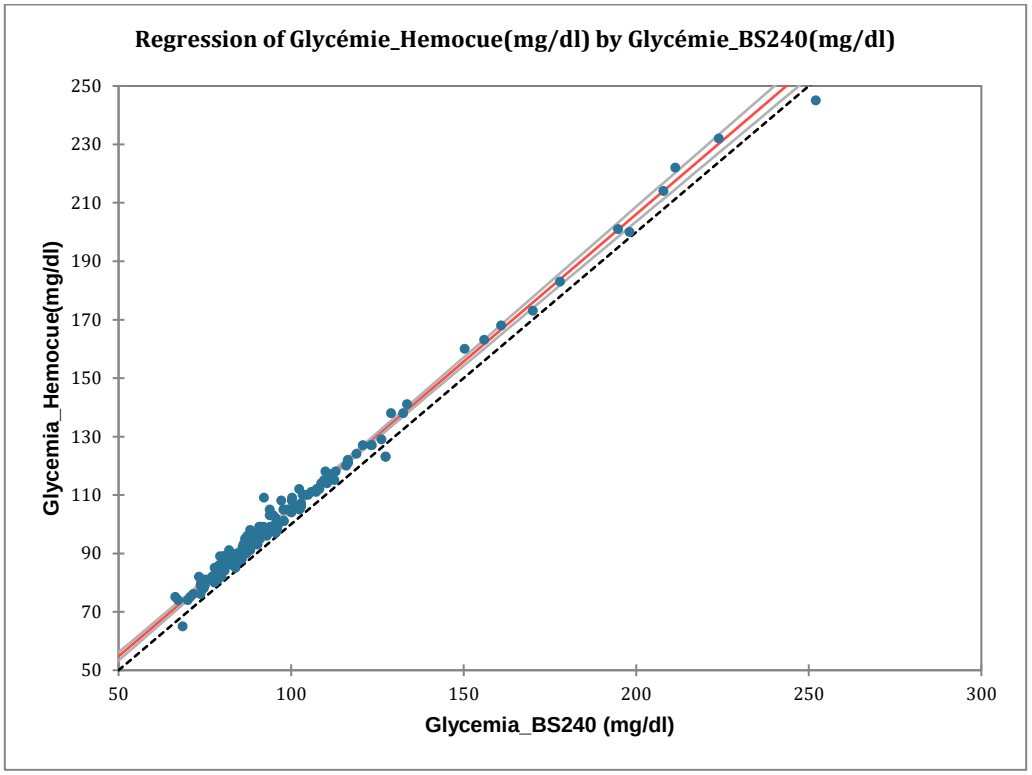

Figure 4: Deming Regression Analysis Comparing Hemocue® Glucose 201 RT and Mindray BS-240 Blood Glucose Measurements

Discussion

The present study evaluated the analytical agreement between the Hemocue® Glucose 201 RT point-of-care device and the Mindray BS-240 analyzer in the context of the University Clinics of Kinshasa. Method comparison remains an essential component of verification and validation processes outlined in ISO 15189, ensuring that new technologies or alternative methods provide clinically acceptable performance before adoption in routine laboratory practice. In this study, paired whole-blood and plasma glucose measurements were examined to determine whether the POCT device could serve as a reliable adjunct or substitute in settings where rapid decision-making is required.

The Hemocue® Glucose 201 RT yielded mean glucose concentrations slightly higher than those obtained with the BS-240 analyzer, a finding consistent with prior comparative studies conducted in other regions [9–10]. These similarities likely reflect shared analytical principles across enzymatic methods, particularly when devices use glucose dehydrogenase or glucose oxidase-based measurement systems. However, differences observed in other investigations, such as those involving hexokinase-based analyzers [11], emphasize that analytical method selection may significantly influence comparability. The BS-240 uses the glucose oxidase method, whereas the Hemocue measures total glucose following hemolysis of red blood cells, which can lead to intrinsic differences in measured values.

A key observation from this study was the very strong linear correlation between the two methods ($r = 0.99$; $p < 0.0001$), suggesting that the Hemocue reliably tracks changes in glucose values across the measurement range. This finding aligns with previous reports comparing Hemocue devices with high-tier analyzers such as the YSI reference system [13–14], supporting the device's overall stability and reproducibility. Nonetheless, correlation alone does not guarantee agreement. Lin's Concordance Correlation Coefficient demonstrated only moderate concordance, and Bland–Altman analysis confirmed a consistent positive bias, with the Hemocue tending to overestimate values relative to the BS-240. The presence of proportional bias indicates that discrepancies increase at higher glucose concentrations, which is clinically relevant when assessing hyperglycemia.

Deming regression further revealed a significant constant bias, indicating that the Hemocue overestimates values by approximately four units regardless of glucose level. The slope coefficient close to unity suggests proportional consistency between methods, yet even small systematic differences may influence clinical interpretation in borderline cases such as diagnosing hypoglycemia or monitoring gestational diabetes, where stringent accuracy criteria are required [15–16].

Differences in specimen type (whole blood versus plasma) provide a plausible explanation for some of the observed bias. Whole blood glucose is known to be lower than plasma glucose due to differences in water content, but when devices apply plasma-equivalent correction factors, small overestimations may occur, especially when hematocrit varies. Literature also documents known discrepancies between serum and plasma glucose measurements [17–18], further supporting the possibility that pre-analytical factors contributed to observed differences.

Overall, the Hemocue® Glucose 201 RT demonstrated acceptable clinical performance and strong correlation with the reference analyzer. While bias was evident, the high percentage of values falling within 10% of BS-240 measurements suggests that the Hemocue may be suitable for emergency use, rapid triage, or deployment in resource-limited settings where laboratory analyzers are unavailable or impractical. However, clinicians should remain aware of its tendency toward overestimation when making therapeutic decisions.

Limitations

Several limitations should be considered when interpreting the findings of this study. First, the work was conducted at a single center, which may limit generalizability to other institutions with different patient demographics or laboratory workflows. Second, hematocrit levels were not measured, even though Hemocue performance is known to be affected when hematocrit falls outside the 20–70% range. This may have introduced unmeasured analytical bias. Third, although efforts were made to standardize specimen handling, the study did not evaluate sample stability over time, and minor pre-analytical variations may have contributed to observed differences. Finally, the use of convenience sampling, while pragmatic, may not reflect the full spectrum of clinical conditions encountered in broader populations.

Conclusion

This study demonstrated that the Hemocue® Glucose 201 RT point-of-care device shows strong correlation and acceptable accuracy compared with the Mindray BS-240 analyzer, despite moderate concordance and a consistent positive bias. The Hemocue's rapid turnaround time and practical usability make it a valuable tool in emergency settings and in healthcare environments lacking automated analyzers. Nevertheless, because the device systematically overestimates glucose levels, results should be interpreted with caution, particularly in clinical scenarios requiring high precision. Continued local validation and periodic quality assessments are recommended to ensure optimal performance within diverse patient populations.

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