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Evaluation of Glucose Results Measured by 2 Different Glucometer Brands

Tevfik Noyan[1], Murat Cihan[2], Esra Yiğit[1], Fatih Ahmet Uzdu[1]

[1]Department of Biochemistry, Ordu University Faculty of Medicine, Ordu, Türkiye
[2]Department of Biochemistry, Memorial Şişli Hospital, Istanbul, Türkiye

ABSTRACT

Objective: The aim of this study was to retrospectively evaluate the performance of 2 glucometer devices using the accuracy criteria specified in ISO 15197:2015.

Methods: Glucose results obtained from Accu-Chek Inform II and Sejoy BG-707 glucometers, which measure according to the glucose dehydrogenase principle, were compared with glucose results obtained from the Cobas 8000 c702 autoanalyzer, which measures using the hexokinase method. Since the minimum number of patients required according to the ISO 15197:2015 protocol is 100, a total of two hundred patients were included using 2 independent samples, with 100 patient results included for each device.

Results: When compared with the autoanalyzer, the Passing-Bablok regression equation for the Accu-Chek brand glucometer was $y = 4.606 + .965x$, and for the Sejoy brand glucometer $y = 6.411 + .964x$. In the Bland–Altman plot, the mean difference between glucose values compared to the hexokinase method was for the Accu-Check brand glucometer, 1.41 mg/dL (.08 mmol/L), and for the Sejoy brand glucometer, .09 mg/dL (.005 mmol/L). Furthermore, 98% of the Accu-Chek Inform II results and also 98% of the Sejoy BG-707 results met the ISO 15197:2015 accuracy criteria. In addition, all results for both glucometers were located within Zone A of the Consensus Error Grid.

Conclusion: The results of the study showed that both glucometer measurement results were appropriate and reliable according to the ISO 15197:2015 guideline criteria, demonstrated strong agreement with autoanalyzer results using the hexokinase method, and revealed no statistically significant difference between glucometer and autoanalyzer measurements.

Keywords: Accuracy, blood glucose self-monitoring, diabetes mellitus, ISO 15197:2015, point of care testing

INTRODUCTION

The measurement of blood glucose levels is of vital importance in the diagnosis and treatment of medical conditions affecting glycemic status and is one of the most frequently performed measurements in clinical biochemistry laboratories.[1] Both hypoglycemia and hyperglycemia are associated with an increased risk of mortality. Various methods are used to measure glucose levels in routine practice. Measurements from plasma in hospitals may not always be practical, especially in critically ill patients requiring strict glycemic control, due to reasons such as the length of the preanalytical phase and the need for frequent blood sampling from the patient. Although glucometers are particularly used for out-of-hospital blood glucose monitoring of diabetic patients using insulin, today they are also used in routine practice in hospitals, especially in the monitoring of critically ill patients requiring strict glycemic control.[2] However, since there is a risk of clinical misinterpretation with the current use of multiple methods yielding different results, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) recommends the use of a constant multiplier of 1.11 for converting whole blood glucose measurements into plasma values as a result of their studies.[3]

Corresponding author:
Tevfik Noyan
✉ tevfiknoyan@hotmail.com
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In the literature, in addition to studies reporting significant differences between glucometers and selected reference methods,[4,5] there are also studies showing no significant difference between the 2 measurement methods.[6-9] Although many guidelines have been published regarding point-of-care glucose measurements, a universally accepted standard approach for technical and clinical evaluation in glucometer selection has not yet been established. One of the frequently preferred guidelines on this subject is the International Organization for Standardization (ISO) 15197:2015 criteria, which was last revised in 2015. According to the minimum accuracy performance criteria of this guideline, 95% of the glucose values measured by the glucometer should fall within ±15 mg/dL (±0.83 mmol/L) of the mean measured values of the reference measurement procedure at glucose concentrations <100 mg/dL (<5.55 mmol/L), or within ±15% limits at glucose concentrations ≥100 mg/dL (≥5.55 mmol/L).[10]

Consensus Error Grid (CEG) analysis is an evaluation chart that allows the comparison of blood glucose values measured by the glucometer and the reference method in terms of clinical accuracy. It displays the blood glucose values determined by the reference measurement method on the horizontal axis (x) and the blood glucose values measured by the glucometer on the vertical axis (y). The CEG analysis is divided into 5 zones indicating the degree of risk posed by inaccurate measurement: Zone A indicates that the difference has no effect on clinical decisions; Zone B indicates little or no effect on clinical decisions; Zone C indicates a high likelihood of affecting clinical decisions; Zone D indicates that it could pose a significant medical risk, and Zone E indicates that it could lead to dangerous consequences.[11] The ISO 15197:2015 guideline stipulates the acceptability of the difference between the 2 methods by requiring that 99% of the values fall within zones A and B in the CEG analysis.[10]

The aim of this study is to compare the measurement results of 2 different glucometer devices (Accu-Chek Inform II [Roche, Mannheim, Germany] and Sejoy BG-707 [Sejoy Biomedical Co., Shenzhen, China]) used in the hospital with plasma glucose values measured by the hexokinase method on the Cobas 8000 c702 biochemistry analyzer (Roche) and to evaluate their performance using the ISO 15197:2015 accuracy criteria.

METHODS

In this study, paired capillary whole blood glucose measurements obtained using 2 brands of glucometers and plasma glucose measurements obtained by the hexokinase method from venous blood samples collected simultaneously were retrospectively retrieved from the laboratory records of the inpatient wards of the hospital between 2023 and 2024. The data obtained in this study were derived from routine laboratory records that must be performed according to the Republic of Türkiye Ministry of Health's quality performance measurement standards procedures.[12] Within this routine workflow, glucose measurements in plasma samples obtained from venous blood samples taken simultaneously with capillary glucose measurements performed on a glucometer were analyzed in the central laboratory. As part of this standardized quality control procedure, hematocrit measurements were routinely performed on venous whole blood samples to ensure that capillary glucose measurements are not affected by variations in hematocrit levels. In routine practice, after Ethylenediaminetetraacetic acid (EDTA) anticoagulant whole blood samples arrived at the laboratory, hematocrit values were measured using a hematology analyzer. Then, the same samples were immediately centrifuged to obtain plasma samples, and glucose measurements were performed using the hexokinase method in an autoanalyzer. To fulfill the ISO 15197:2015 requirement for low glucose samples (≤ 50 mg/dL, 2.77 mmol/L), additional laboratory-prepared samples were generated and analyzed. Therefore, the study was designed as a hybrid study combining retrospective clinical data and laboratory-prepared samples.

This study was designed as a performance evaluation using the system accuracy criteria described in ISO 15197:2015 and in compliance with Good Clinical Practice guidelines, the Declaration of Helsinki, and all applicable legal and ethical requirements. This study was approved by the Ordu University, Non-Interventional Scientific Research Ethics Committee (Approval No: 04; Date: 03.01.2025). Since this study was retrospective, informed consent was not obtained from the patients.

Since the minimum number of patients required to be included in the study to ensure the appropriate sample distribution specified in the ISO 15197:2015 protocol is 100, the study was conducted with data from a total of two hundred patients, using 2 independent samples where 100 patient results were included for each device. The sample distribution established according to the ISO 15197:2015 protocol is presented in Table 1. As no hypoglycemic patient samples (≤50 mg/dL [≤2.77 mmol/L]) were available in the recorded dataset, the samples required for this concentration range were prepared in the laboratory in accordance with the procedure recommended by ISO 15197:2015. The guideline states that, when necessary, whole blood samples collected in tubes containing an appropriate anticoagulant may be incubated under controlled conditions to obtain samples with glucose concentrations of ≤50 mg/dL (2.77 mmol/L). Accordingly, all samples with glucose concentrations below 50 mg/dL used in this study were prepared by allowing venous whole blood collected in EDTA tubes to stand at room temperature until the target glucose concentration was reached. Once the target glucose concentration had been achieved, the whole blood sample was gently mixed and measured using the glucometer. To minimize further changes in glucose concentration, the samples were then centrifuged without delay, and the resulting plasma was analyzed using the autoanalyzer as the reference method.

Patients hospitalized in the inpatient wards of the hospital, aged between 18 and 80 years, with a hematocrit value between 30% and 45%, were included in the study. Venous whole blood samples taken from the patients were collected into vacuum tubes containing K2-EDTA (BD Vacutainer, Becton Dickinson and Company, USA),

Main Points

- *To the best of current knowledge, this is the first study to compare glucose measurement using Accu-Chek Inform II and Sejoy BG-707 brand glucometers with hexokinase measurement using the Cobas 8000 c702 brand autoanalyzer, according to ISO 15197:2015 criteria.*
- *Ninety-eight percent of the Accu-Chek Inform II measurements and 98% of the Sejoy BG-707 measurements fulfilled the ISO 15197:2015 accuracy criteria.*
- *Both glucometer devices demonstrated strong agreement with the hexokinase method, with no statistically significant difference observed between glucometer and autoanalyzer measurements.*
- *For both glucometers, all measurement results were located within Zone A of the Consensus Error Grid analysis.*
- *Both glucometers showed acceptable analytical and clinical performance for routine hospital use.*

Table 1. Glucose Concentration Ranges Recommended by ISO 15197:2015 and the Number of Samples Included in the Study for the Accu-Chek Inform II and Sejoy BG-707

A. The Glucose Concentration Ranges Recommended by ISO 15197:2015 and the Number of Accu-Chek Inform II Samples Included in the Study

Glucose Concentration mmol/L (mg/dL)	Sample size (N = 100)	Percentage of Samples (%)
≤2.77 (≤50)	5	5
>2.77-4.44 (>50-80)	15	15
>4.44-6.66 (>80-120)	20	20
>6.66-11.1 (>120-200)	30	30
>11.1-16.65 (>200-300)	15	15
>16.65-22.2 (>300-400)	10	10
>22.2 (>400)	5	5

B. The Glucose Concentration Ranges Recommended by ISO 15197:2015 and the Number of Sejoy BG-707 Samples Included in the Study

Glucose Concentration mmol/L (mg/dL)	Sample size (N = 100)	Percentage of Samples (%)
≤2.77 (≤50)	5	5
>2.77-4.44 (>50-80)	15	15
>4.44-6.66 (>80-120)	20	20
>6.66-11.1 (>120-200)	30	30
>11.1-16.65 (>200-300)	15	15
>16.65-22.2 (>300-400)	10	10
>22.2 (>400)	5	5

and after their hematocrit values were measured with a complete blood count analyzer (Sysmex, XN1000, Sysmex Corporation, Kobe, Japan), plasma samples were obtained by centrifuging at 1800*g for 10 minutes. Patients identified as using medications or supplements with a potential for interference listed in ISO 15197:2015 Annex A, and those with clinical signs of peripheral circulatory disorders, bleeding diathesis, and coagulation disorders were excluded from the study.

The test strips for Accu-Chek Inform II and Sejoy BG-707 glucometers measure glucose in capillary whole blood based on the glucose dehydrogenase reaction principle. During the study, Accu-Chek (LOT: 670665) and Sejoy (LOT: GS70066) brand glucose test strips were used. According to their user manuals, repeatability performances were evaluated with samples at 5 different concentrations; for the Sejoy brand glucometer, with the lowest being 46 mg/dL (2.55 mmol/L) and the highest being 370 mg/dL (20.5 mmol/L), and the %CV values were stated to be between 1.6% and 4.3%; for the Accu-Check brand glucometer, it was evaluated with samples at 5 different concentrations, with the lowest being 41.6 mg/dL (2.3 mmol/L) and the highest being 316.8 mg/dL (17.6 mmol/L), and the %CV values were stated to be between 3.6% and 4%. The measurement range for the Accu-Chek brand glucometer is 10-600 mg/dL (0.55-33.3 mmol/L), and the measurement range for the Sejoy brand glucometer is 9-600 mg/dL (0.5-33.3 mmol/L).

Glucometer measurement results were compared with reference to the measurement results of the Cobas 8000 c702 analyzer installed in the laboratory, which performs spectrophotometric measurements using the hexokinase method. The repeatability performance of the method was evaluated with samples at 5 different concentrations, the lowest being 59 mg/dL (3.27 mmol/L) and the highest being 651 mg/dL (36.1 mmol/L), and the %CV values ranged from 0.5% to 0.8%. The glucose measurement range of the method used as a reference is 2-750 mg/dL (0.11-41.62 mmol/L). The %CV value obtained from the internal quality control data of the laboratory for the glucose test was 0.97% for the level 1 control serum (Roche-PreciControl ClinChem Multi 1; LOT: 595441); and 1.04% for the level 2 control serum (Roche-PreciControl ClinChem Multi 2; LOT: 608368).

The annual average %Bias value for glucose obtained from the data of the external quality control program RIQAS (Randox International Quality Assessment Scheme) used in the laboratory was calculated as 1.49%. The total error (TE) at the 95% confidence interval (CI) (calculated using the formula %TE = %Bias + 1.65 * %CV) was calculated as 3.1% for the first-level control serum and 3.2% for the second-level control serum. Therefore, it was observed that the total error value for glucose was below the 8% TEa (Total Allowable Error) value most recently updated by CLIA (Clinical Laboratory Improvement Amendments) in 2025.[13] In addition, to reflect the autoanalyzer performance, a six sigma value was calculated for the glucose test using the formula [(%TEa - %Bias) / %CV]. The sigma values were calculated as 6.7 for the first-level control serum and 6.3 for the second-level control serum.

The statistical analysis of the study was performed using the MedCalc program. To evaluate the differences between the hexokinase method and the glucose values measured by the glucometers, Passing & Bablok regression analysis, paired *t*-test, and Bland–Altman analyses were performed. Pearson correlation analysis was used for correlation. Descriptive statistics were conducted via the Microsoft Excel program. Consensus Error Grid (CEG) analysis[14] was performed to evaluate the accuracy of the results. A *P*-value of < .05 was accepted for statistical significance.

RESULTS

In this study, when compared with the autoanalyzer results, for the Accu-Chek brand glucometer, 38 of 39 samples at glucose concentrations <100 mg/dL (<5.55 mmol/L) were within ±15 mg/dL (0.83 mmol/L), and 60 of 61 samples at glucose concentrations ≥100 mg/dL (≥5.55 mmol/L) were within the ±15% range of the reference values. For the Sejoy brand glucometer, 26 of 28 samples at glucose concentrations <100 mg/dL (<5.55 mmol/L) were within ±15 mg/dL (±0.83 mmol/L), and all 72 samples at glucose concentrations ≥100 mg/dL (≥5.55 mmol/L) were within the ±15% range of the reference values. Overall, 98% of the Accu-Chek Inform II measurements and also 98% of the Sejoy BG-707 measurements fulfilled the ISO 15197:2015 system accuracy criteria.

Data regarding the glucose measurements obtained using both brands of glucometers and the hexokinase method (mean, lowest

Table 2. Data Regarding Glucose Measurements Obtained Using both Glucometer Brands and the Autoanalyzer Results [mg/dL-(mmol/L)]

	Accu-Check	Cobas c702	Sejoy	Cobas c702
Minimum value	35 (1.94)	31 (1.72)	43 (2.39)	31 (1.72)
Maximum value	450 (25)	470 (26)	420 (23.3)	425 (23.6)
Mean ± SD	153.58 ± 97.82 (8.5 ± 5.43)	154.99 ± 102.6 (8.6±5.7)	170.41 ± 99.59 (9.46 ± 5.53)	170.5 ± 103.84 (9.46 ± 5.76)

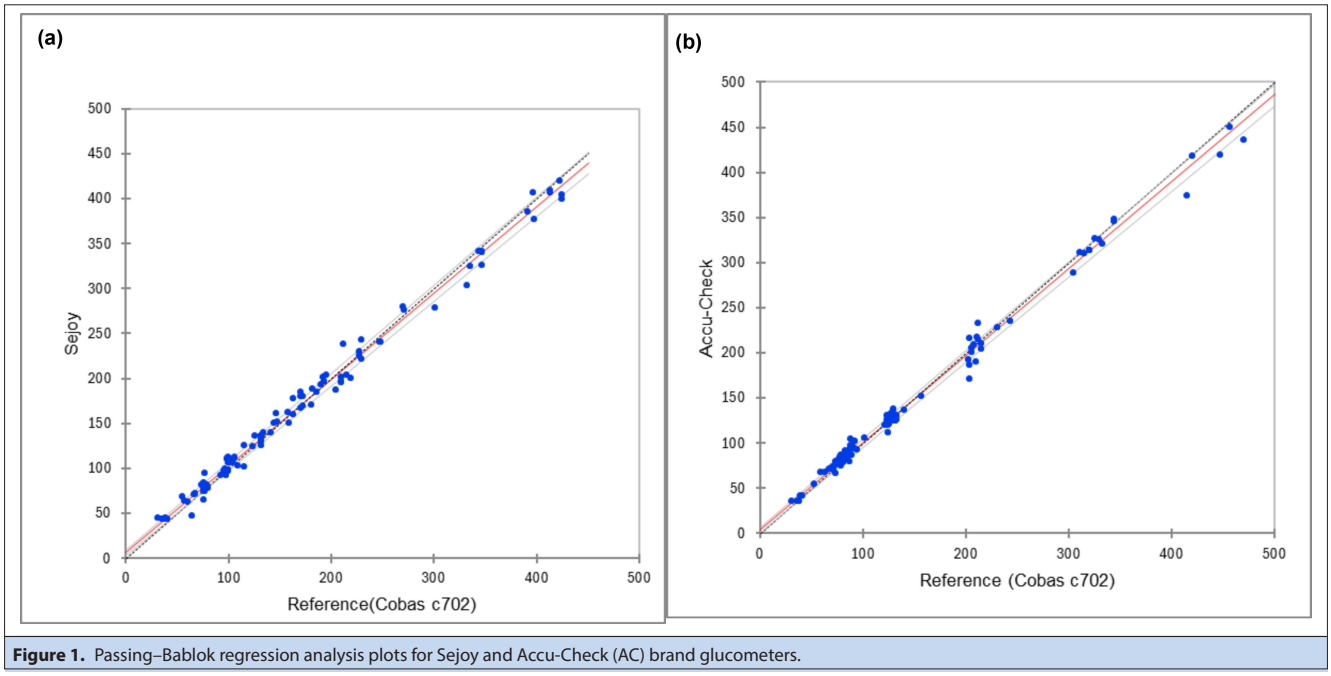

Figure 1. Passing–Bablok regression analysis plots for Sejoy and Accu-Check (AC) brand glucometers.

and highest measurement, and standard deviation values) are shown in Table 2. Passing & Bablok regression and Bland–Altman plots pertaining to the comparison of glucometers with the hexokinase method are shown in Figures 1 and 2.

According to Passing–Bablok regression analysis, the regression equation for the Accu-Chek Inform II was $y = 4.606 + 0.965x$, with an intercept of 4.606 (95% CI, 1.471-7.101) and a slope of .965 (95% CI, 0.944-0.981). For the Sejoy BG-707, the regression equation was $y = 6.411 + .964x$, with an intercept of 6.411 (95% CI, 3.578=9.014) and a slope of .964 (95% CI, .943-.984). The correlation coefficient was found to be .997 for the Accu-Chek brand glucometer and .996 for the Sejoy brand glucometer.

The Bland-Altman analysis demonstrated a mean bias of 1.41 mg/dL (.08 mmol/L) between the Accu-Chek glucometer and the hexokinase method (95% confidence interval: −.443 to 3.263 mg/dL, $P = .134$), with 95% limits of agreement ranging from −16.9 to 19.7 mg/dL, and a mean bias of .09 mg/dL (.005 mmol/L) between the Sejoy glucometer and the hexokinase method (95% confidence interval: −1.916 to 2.096 mg/dL, $P = .929$), with 95% limits of agreement ranging from −19.7 to 19.9 mg/dL. It was observed that there was no statistically significant difference between the measurements of the 2 methods ($P > .05$).

In the CEG analysis performed in accordance with the ISO 15197:2015 recommendation, all 100 measurements (100%) obtained with the Accu-Chek glucometer fell within Zone A, with no results in Zones

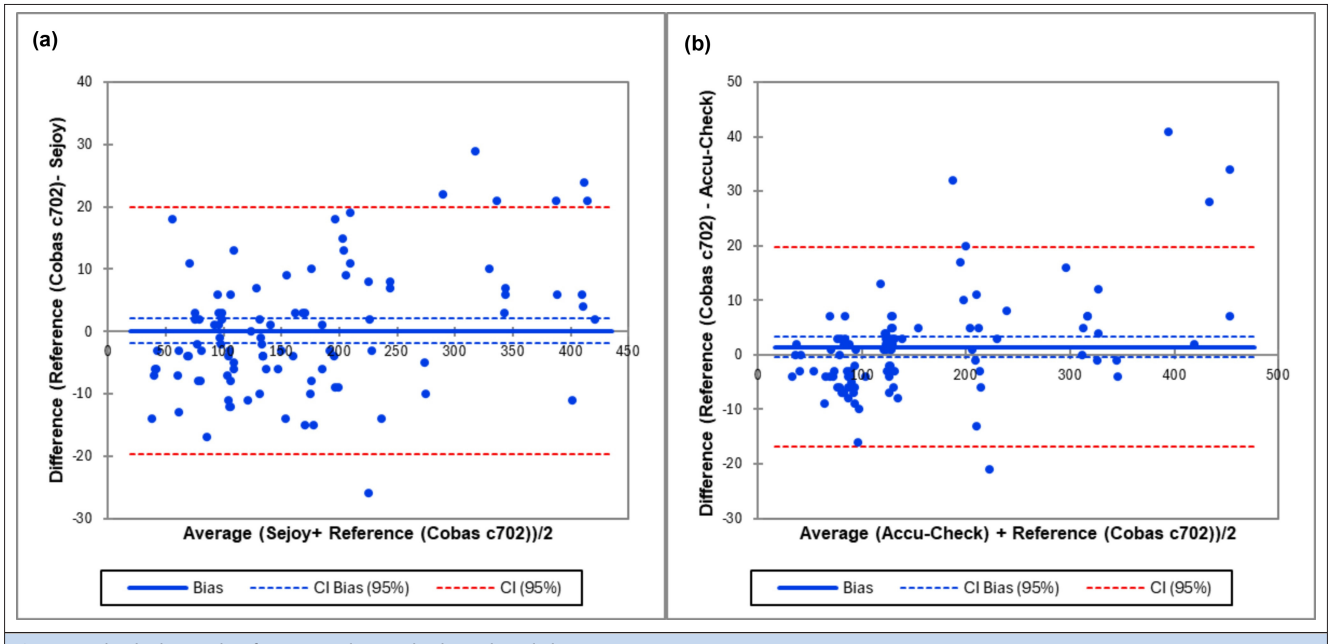

Figure 2. Bland–Altman plots for Sejoy and Accu-Check (AC) brand glucometers.

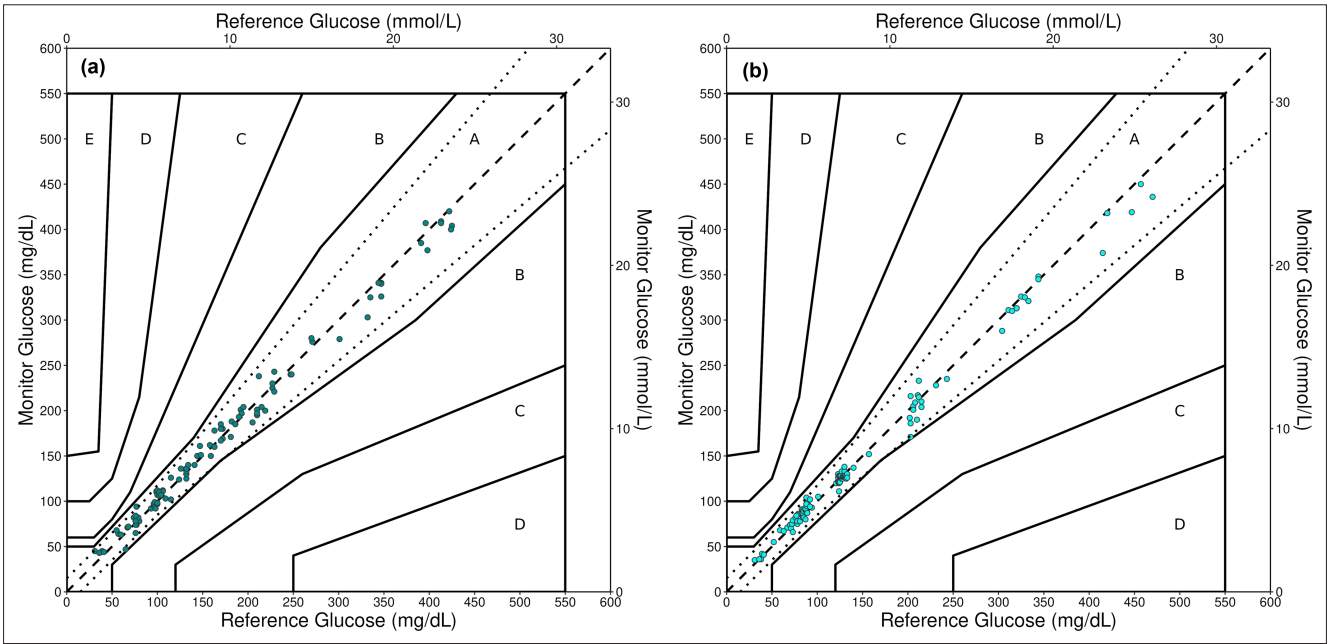

Figure 3. Consensus Error Grid plots for Sejoy and Accu-Check (AC) brand glucometers.

B-E. Similarly, all 100 measurements (100%) obtained with the Sejoy glucometer were located in Zone A, with no results in Zones B-E (Figure 3).

DISCUSSION

The American Diabetes Association (ADA) recommends self-monitoring of blood glucose (SMBG) to enable diabetic patients to achieve and maintain specific glycemic targets. Since glucometers are frequently used, particularly in the monitoring of patients requiring strict glycemic control, the reliability of glucometer measurement results is of critical importance for clinical decisions. Although the variety, precision, and accuracy of glucometers have increased over the years, uncertainties still exist regarding their standardization.[2,8] Although there are various guidelines published by different organizations on this subject, the internationally accepted ISO 15197:2015 guideline was preferred in this study.

When compared to the hexokinase method results according to the minimum accuracy performance criteria specified in ISO 15197:2015, it was observed that 98% of all results for both glucometer brands met the requirement of being within ±15 mg/dL (0.83 mmol/L) limits at glucose concentrations <100 mg/dL (<5.55 mmol/L) and within ±15% limits at glucose concentrations ≥100 mg/dL (≥5.55 mmol/L).

According to the Passing–Bablok regression analysis results, the slope being very close to 1 in the equations obtained for both glucometer brands reveals that the proportional error is minimal and the measurements show good linear agreement with the hexokinase method. Although intercepts differing from zero suggest a limited mild deviation at low glucose concentrations, the correlation coefficients ($r=0.997$ and $r=0.996$) support that the measurements are consistent with the hexokinase method.

The findings of the present study are consistent with previous reports evaluating the analytical and clinical performance of glucose meters.[9,15] Aral et al.[9] evaluated an electrochemical glucose meter based on the glucose oxidase principle by comparing capillary whole blood measurements with plasma glucose concentrations determined using an Olympus AU5223 autoanalyzer employing a glucose oxidase–peroxidase reference method. They reported a strong correlation between the 2 methods ($r=0.969$), with a regression equation of $y=.910x+7.008$. In addition, 97.2% of the measurements were located in Clarke Error Grid Zone A and 2.8% in Zone B, while approximately 97% of the results met the ISO 15197:2003 accuracy criteria. Nevertheless, the regression slope below unity and the calculated sigma value of 4.63 indicated greater proportional analytical error than that observed in the present study. In contrast, the regression slopes were closer to 1.0, all measurements were classified in Zone A, and the sigma values exceeded 6, indicating superior analytical performance.

Similarly, Chen et al.[15] assessed the analytical performance of the Sensorex electrochemical glucose meter, which utilizes glucose oxidase enzyme technology and amperometric detection, using the YSI 2300 Stat glucose analyzer as the reference method. Although a linear relationship was observed between capillary blood glucose and venous plasma glucose measurements, the reported correlation coefficient ($r=0.77$) and regression equation ($y=0.79x+50$) demonstrated considerably lower agreement with the reference method than that observed in the study. Furthermore, Clarke Error Grid analysis revealed that 84.3% of measurements were located in Zone A, 15.0% in Zone B, and 0.7% in Zone D, indicating that a small proportion of results could potentially lead to inappropriate clinical decisions. By comparison, all measurements in the study fell within Zone A, supporting the excellent clinical accuracy of the evaluated glucose meters. These findings suggest that advances in biosensor technology and analytical performance have substantially improved the accuracy and reliability of modern point-of-care glucose monitoring systems.

The Bland & Altman analysis results reveal that most of the measurement differences for both glucometer brands are within the 95% limits of agreement. However, even though no statistically significant difference was detected between the measurement results of the hexokinase method and the glucometers, when compared with the

hexokinase method, it is noteworthy that glucometers yield higher results at low glucose concentrations and lower results at high glucose concentrations. These results suggest that analytical variability may be higher for both glucometers at glucose values close to their lower and upper measurement limits. Indeed, Inoue et al.[4] stated that the error frequency is particularly higher for the hypoglycemia range and that glucometer results in critically ill patients should be evaluated with this awareness. Furthermore, Ekiz et al.[16] reported that glucose values measured by the hexokinase method were lower compared to glucose dehydrogenase (GDH) method and that the difference between the 2 methods increased in direct proportion to the glucose values.

The results of the regression and correlation analyses show that there is good agreement between the glucometers and the hexokinase method. Besides this, these analyses alone are not sufficient in the evaluation of clinical accuracy and significance, and it is recommended in previously conducted studies that an Error Grid Analysis based on medical decision thresholds be performed.[9,17] Considering that all results obtained with both the Accu-Chek and Sejoy glucometers were located in Zone A of the Error Grid analysis, the glucose values measured by both devices were not expected to lead to erroneous clinical decisions. Previous studies have similarly reported that the vast majority of results fall within Zones A and B, thereby meeting the acceptance criterion.[9,15,18]

Study Limitations

For system accuracy evaluation, ISO 15197:2015 recommends taking the average of duplicate measurements performed with strips of 3 different LOT numbers for each sample. However, since the study was derived from retrospective data, measurements were performed using strips with a single reagent LOT. This is the main limitation of the study. In this respect, the results evaluate the clinical routine accuracy performance of the device rather than the method accuracy.

CONCLUSION

The findings indicate that both glucometers demonstrated acceptable analytical performance when evaluated using the accuracy criteria specified in ISO 15197:2015. The findings indicate that the glucometers used in routine practice at the hospital can be safely used in areas such as emergency departments and intensive care units, where accurate and rapid measurement of glucose is critical. However, evaluating these findings along with other comparative studies in the literature and supporting them with studies encompassing larger samples and different patient groups would be beneficial.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of University of Ordu (Approval No: 04; Date: 03.01.2025).

Informed Consent: Since this study was retrospective, informed consent was not obtained from the patients.

Peer-review: Externally peer-reviewed.

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Declaration of Interests: The authors have no conflicts of interest to declare.

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