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Original Article

Can we trust the blood gas point of care analyzer? The compatibility of the point-of-care blood analyzer and biochemistry auto-analyzer

Kan gazı hasta başı analizörüne güvenebilir miyiz? POC analizörü ve biyokimya otoanalizörünün uyumluluğu

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ABSTRACT

Objective: The aim is to evaluate the compatibility of sodium, potassium, and glucose measurement procedures of point-of-care (POC) blood analyzer and biochemistry auto-analyzer.
Methods: Sodium, potassium, and glucose test results performed in our laboratory between 01-30 March 2021 were obtained retrospectively. Sodium, potassium and glucose tests were analyzed simultaneously (within half an hour) in the auto-analyzer, and the POC blood analyzer was included in this study. The compatibility between the POC blood analyzer and auto-analyzer results was evaluated by Passing-Bablok regression analysis and Bland-Altman plots.
Results: Passing-Bablok regression were y=-33.25+1.25x, y=0.35+1x, and y=-4,182+1.045x for sodium, potassium and glucose, respectively. There was no significant deviation from linearity for sodium, potassium, and glucose (p=0.50, p=0.68, and p=0.48 respectively). The mean absolute difference were -1 mmol/L (95% CI=-7 to 5), -0.42 mmol/L (95% CI=-1.38 to 0.54), and -3.5 mg/dL (95% CI=-35.4 to 28.3) for sodium, potassium and glucose, respectively.
Conclusion: Sodium, potassium, and glucose measurement method procedures measured in the POC blood analyzer and auto-analyzers are compatible. Random distribution of differences between values measured by both methods around zero (not showing a systematic distribution) showed a good fit between the methods. The calculated bias values do not exceed limits determined by Clinical Laboratory Improvement Amendment (CLIA). According to the data we have obtained, reporting that the results obtained with the POC blood analyzer are compatible with the test results of the automated analyzer and sharing these results with clinicians will contribute to the effective use of the test results obtained with the POC blood analyzer for patients.

Keywords: Abbott i-Stat1, measurement procedure comparison, point of care analyzer, Siemens Advia 1800

ÖZ

Amaç: Çalışmanın amacı, bakım noktası (POC) kan analizörü ile biyokimya otoanalizörünün sodyum, potasyum ve glikoz ölçüm prosedürlerinin uyumluluğunu değerlendirmektir.
Gereç ve Yöntem: Laboratuvarımızda 01-30 Mart 2021 tarihleri arasında çalışılan sodyum, potasyum ve glukoz test sonuçları geriye dönük olarak elde edildi. Otoanalizör ve POC analizöründe eş zamanlı olarak (yarım saat içinde) analiz edilmiş sodyum, potasyum ve glukoz test sonuçları çalışmaya dahil edildi. POC analizörü ile otoanalizör sonuçları arasındaki uyum Passing-Bablok regresyon analizi ve Bland-Altman grafikleri ile değerlendirildi.
Bulgular: Passing-Bablok regresyon denklemi sodyum, potasyum ve glukoz için sırasıyla y=-33,25+1,25x, y=0,35+1x ve y=-4,182+1,045x idi. Sodyum, potasyum ve glukoz için doğrusallıktan anlamlı bir sapma yoktu (sırasıyla p=0.50, p=0.68 ve p=0.48).

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Ortalama mutlak fark sodyum, potasyum ve glukoz için sırası ile, -1 mmol/L (%95 CI=-7 ila 5), -0,42 mmol/L (%95 CI=-1,38 ila 0,54) ve -3,5 mg/dL (%95 CI=-35,4 ila 28,3) idi.
Sonuç: POC analizörü ve otoanalizör sodyum, potasyum ve glikoz ölçüm prosedürleri birbiriyle uyumludur. Her iki yöntemle ölçülen değerler arasındaki farkların sıfır civarında rastgele dağılımı (sistematik bir dağılım göstermemektedir), yöntemler arasında iyi bir uyum olduğunu göstermiştir. Hesaplanan sapma değerleri, CLIA tarafından belirlenen sınırları aşmamaktadır. Elde ettiğimiz verilere göre, POC analizörleri ile elde edilen sonuçların otoanalizör test sonuçları ile uyumlu olduğunun raporlanması ve elde edilen verilerin klinisyenler ile paylaşılması, POC analizörü ile elde edilen test sonuçlarının hastalar için etkin bir şekilde kullanılmasına katkı sağlayacaktır.

Anahtar kelimeler: Abbott i-Stat1, Hasta başı cihazı, ölçüm prosedürü karşılaştırması, Siemens Advia 1800

INTRODUCTION

The point-of-care (POC) blood analyzer is used to describe diagnostic devices that can be used near the patient in healthcare settings. Medically trained users can easily use these analyzers. They provide fast turnaround times (TAT). Therefore, the importance of the development and widespread use of POC blood analyzers is gradually increasing (1). Arterial blood gas devices analyse arterial blood's oxygen and carbon dioxide partial pressures and acid-base balance. It is one of the vital devices used for evaluating and monitoring critical patients in areas such as the emergency room, operating room, and intensive care unit (2).

Arterial blood gas analyzers can perform sodium, potassium, and glucose levels and blood gases. Sodium, potassium imbalance, and hypoglycemia are important medical emergencies that must be treated quickly. The short TAT of the POC blood analyzer that performs arterial blood gas analysis helps speed up the management of patients' emergencies (3).

In the diagnosis of sodium, potassium imbalance, and hypoglycemia, there is uncertainty as to whether clinical decisions should be based on blood gas POC analyzer results or await laboratory auto-analyzer results. According to the study by Jose et al.[4], most clinicians agree that performing potassium level analysis on the POC blood analyzer is a useful method for obtaining rapid results. Despite this, it is reported that only 48.4% of clinicians rely on the POC blood analyzer test results when making important clinical decisions. A similar study evaluating clinicians' attitudes towards POC blood analyzer tests reported that the rate of clinicians who relied on POC blood analyzers when making their clinical decisions was 34% (5).

These studies support that for clinicians to exploit the potential advantages of POC blood analyzer effectively, results obtained with POC instruments should be demonstrated to be consistent with auto-analyzer test results.

In this context, our study aim is to evaluate the compatibility of the sodium, potassium, and glucose measurement procedures of the POC analyzer and the biochemistry auto-analyzer.

METHOD

Sodium, potassium, and glucose results were evaluated retrospectively using our laboratory information system between 01 - 30 March 2021. Sodium, potassium and glucose results (72 samples) performed simultaneously (within half an hour) in the auto-analyzer and the POC analyzer were included in the study. Blood gas analysis is performed with a whole blood sample with lithium heparin on a POC blood analyzer (Abbott i-Stat, Abbott Point of Care, Abbott Park, IL). The ion-selective electrode potentiometry method measures sodium and potassium in the blood gas analyzer. The glucose test is measured amperometrically. Glucose oxidation, catalyzed by the glucose oxidase enzyme, produces hydrogen peroxide (H_2O_2). The released hydrogen peroxide is oxidized at the electrode to produce a current proportional to the glucose concentration. Using a serum sample, the serum sample, the sodium, potassium, and glucose tests were analyzed in auto-analyzer (Siemens Advia 1800, Siemens Corp., Tarrytown, NY, USA). Sodium and potassium were analyzed by the ion-selective

electrode method. Glucose was measured by the hexokinase method. In the study, an auto-analyzer was accepted as the reference method for sodium, potassium, and glucose measurement procedures.

Statistical analysis

The normal distribution of data was tested with Shapiro-Wilk and Kolmogorov-Smirnov tests. Normally distributed data were expressed as mean (standard deviation) and non-normally distributed data as median (interquartile range). The Wilcoxon test analyzed the significance of the differences of the two dependent samples. The correlation was described with the Passing-Bablok regression fit. The distribution of differences between the methods was evaluated with the Bland-Altman plot. SPSS 22.0 (IBM, Chicago, USA) package program was used for the statistical evaluation of the data.

RESULTS

The results of the POC blood analyzer and autoanalyzer tests for sodium ($p<0.001$ and $p=0.004$, respectively), potassium ($p=0.004$ and $p=0.001$, respectively), and glucose ($p<0.001$ for both groups) were not normally distributed. The median, 25th, and 75th percentile values of sodium, potassium, and glucose tests measured on the POC blood analyzer, and auto-analyzer are shown in Table 1.

Sodium: The concentration range of serum samples measured on the POC blood analyzer was between 115 and 151 mmol/L. The median differences between sodium results were not significant ($p=0.058$). The correlation was described with the Passing-Bablok regression fit. Passing-Bablok regression was $y=-33.25 + 1.25 x$. There was no significant deviation from linearity ($p=0.50$) (Figure 1). Intercept value and slope value were calculated as -33.2 (95% confidence interval -67 to 1), and 1.25 (95% confidence interval 1 - 1.5), respectively. The 95% confidence interval of intercept contained the value "0" and the 95% confidence interval of the slope contained the value "1". The mean absolute difference was -1 mmol/L (95% CI=-7 to 5) (Figure 2).

Potassium: The concentration range of serum samples measured on the POC blood analyzer was between 2.6 and 6.3 mmol/L. The median differences between potassium results were not significant ($p=0.062$). Passing-Bablok regression was described with $y=0.35+1x$ equation. There was no significant deviation from linearity ($p=0.062$) (Figure 3). Intercept value and slope value were calculated as 0.35 (95% confidence interval -0,05893 to 0.8222), and 1 (95% confidence interval 0.8889 to 1.1071), respectively. The 95% confidence interval of intercept contained the value "0" and the 95% confidence interval of the slope contained the value "1". The mean absolute difference was -0.42 mmol/L (95% CI=-1.38 to 0.54) (Figure 4).

Glucose: The concentration range of serum samples measured on the blood analyzer was between 115 and 151 mg/dL. The median differences between glucose results were not significant ($p=0.83$). Passing-Bablok regression was described with $y=-4.182+1.045 x$ equation. There was no significant deviation from linearity ($p=0.48$) (Figure 5). Intercept value and slope value were calculated as -4,1818 (95% confidence interval -9.6029 to 1.0000), and 1.0455 (95% confidence interval 1.0000 to 1.0882), respectively.

Table 1. The median and 25th, and 75th percentile values of sodium, potassium and glucose tests performed on the POC blood analyzer and auto-analyzer.

Analyzers	Sodium (mmol/L)			Potassium (mmol/L)			Glucose (mg/dL)		
	Median	Percentile		Median	Percentile		Median	Percentile	
		25th	75th		25th	75th		25th	75th
Point-of-Care Blood Analyzer	138	135	140	4.00	3.6	4.4	129	101	180
Siemens Advia 1800 Auto-analyzer	139	135	141	4.40	4.1	4.8	133	97	176

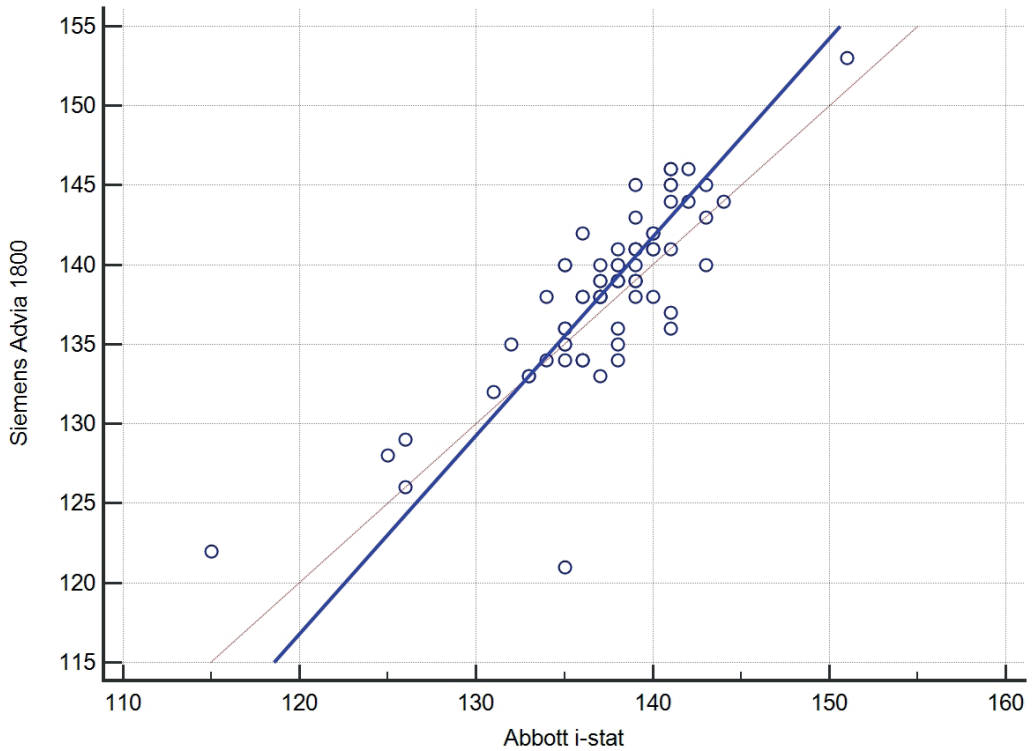

Figure 1. Passing-Bablok regression plot of sodium measurement procedure.

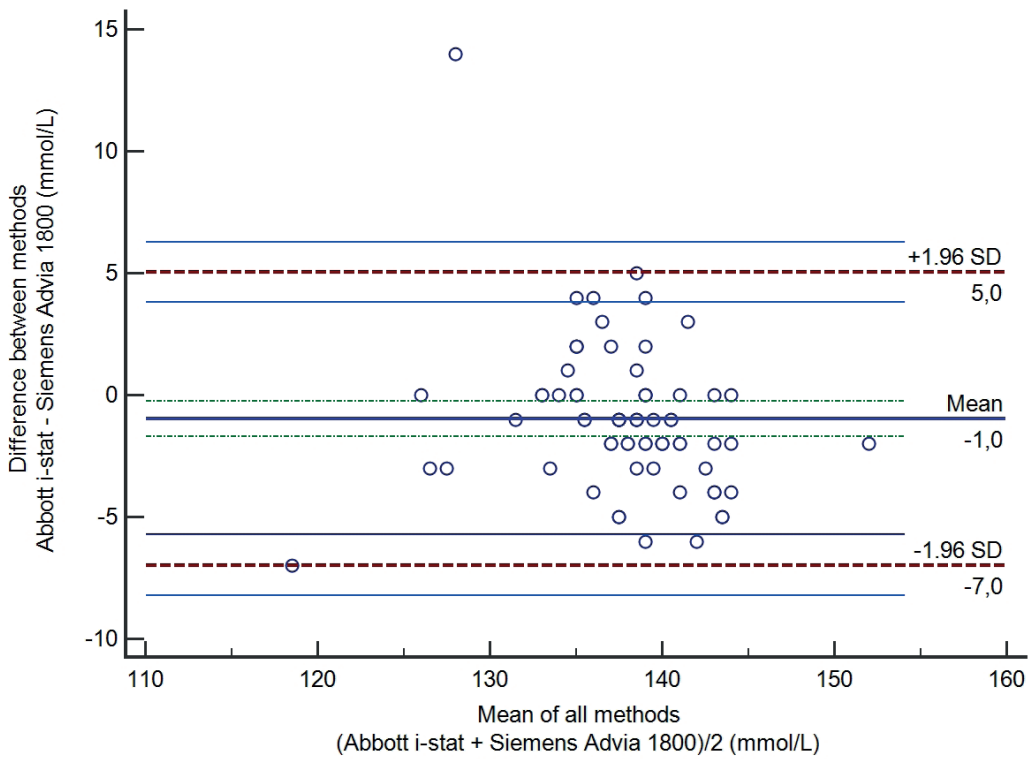

Figure 2. Bland-Altman plot of the difference in sodium measurement procedures as a function of mean sodium concentration for POC Blood analyzer and auto-analyzer.

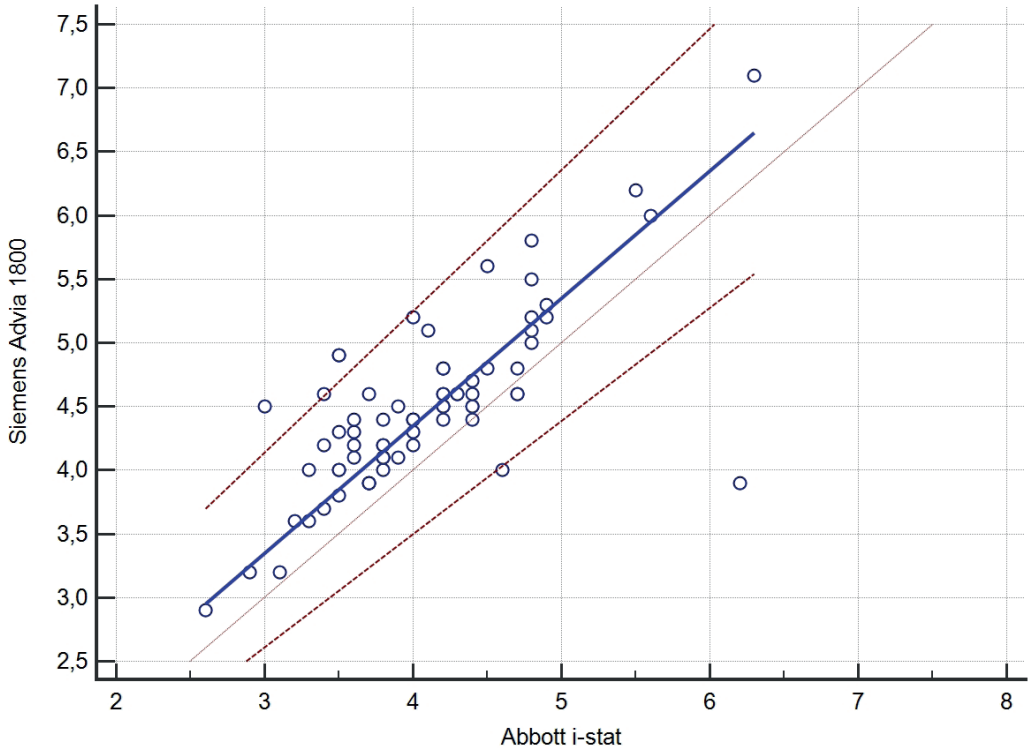

Figure 3. Passing-Bablok regression plot of potassium measurement procedure.

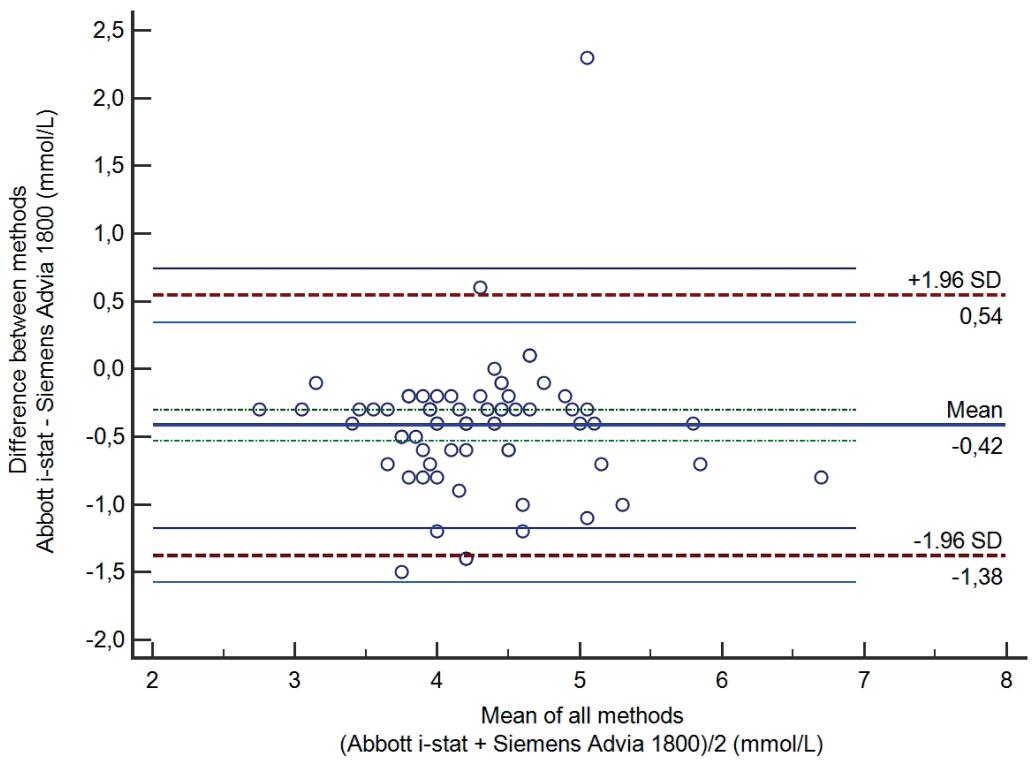

Figure 4. Bland-Altman plot of the difference in potassium measurement procedures as a function of mean potassium concentration for POC Blood analyzer and auto-analyzer.

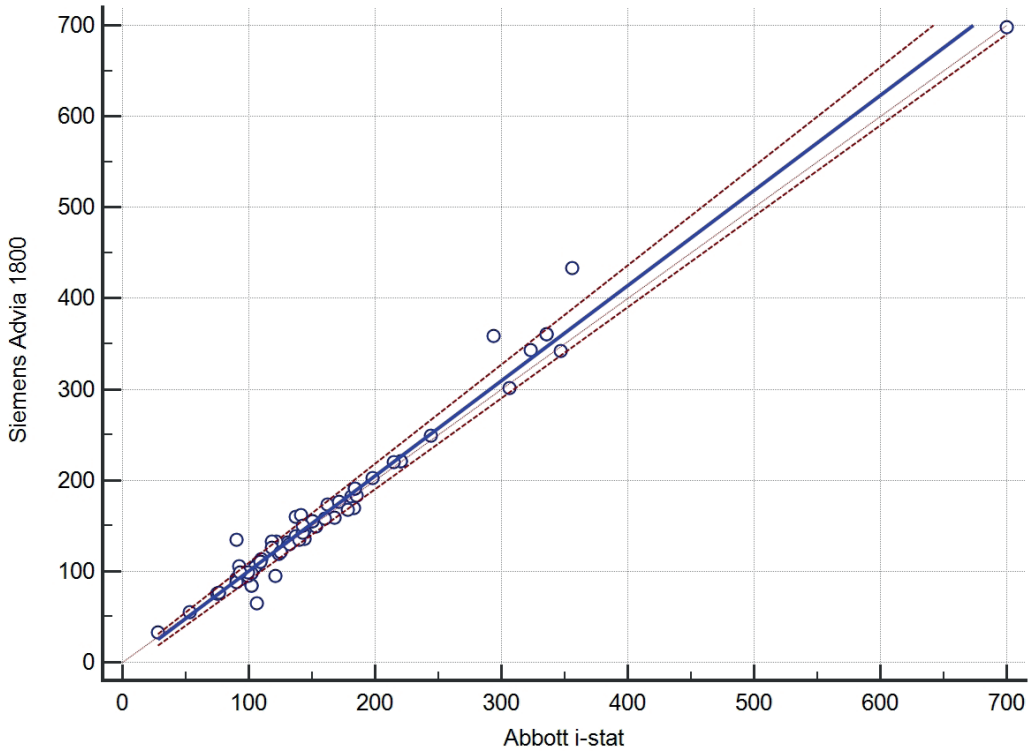

Figure 5. Passing-Bablok regression plot of glucose measurement procedure.

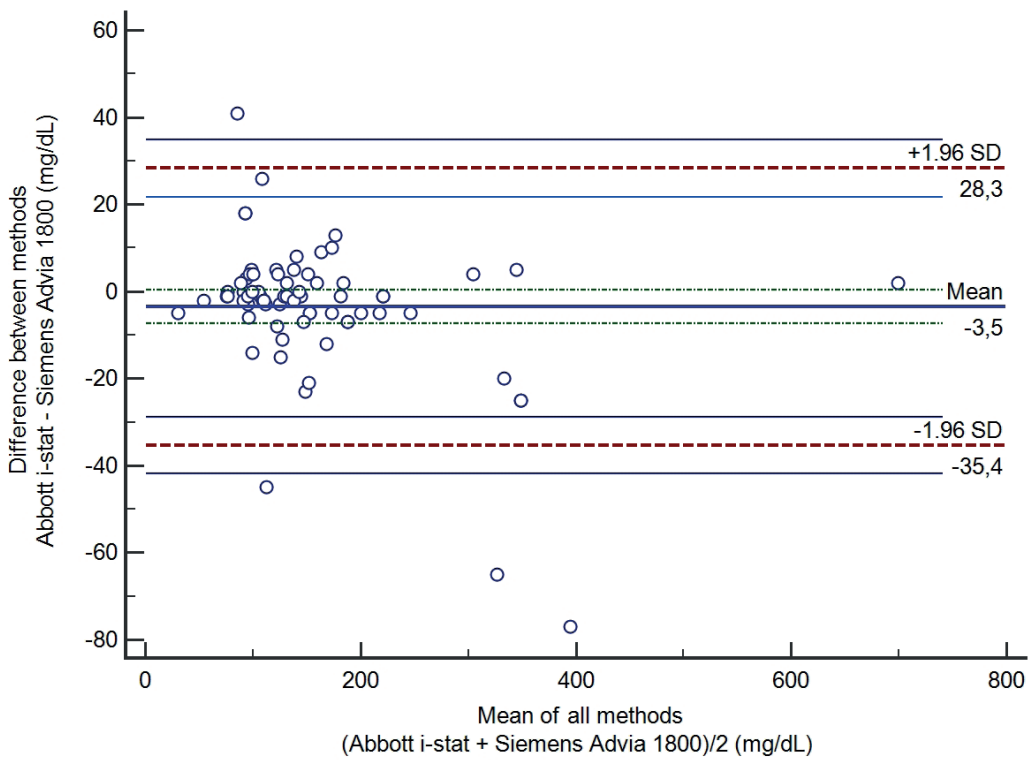

Figure 6. Bland-Altman plot of the difference in glucose measurement procedures as a function of mean glucose concentration for POC Blood analyzer and auto-analyzer.

The 95% confidence interval of intercept contained the value "0" and the 95% confidence interval of the slope contained the value "1". The mean absolute difference was -3.5 mg/dL (95% CI=-35.4 to 28.3) (Figure 6).

DISCUSSION

To support clinicians in making reliable and rapid decisions, laboratory professionals should demonstrate adequate agreement between the results obtained from portable blood gas devices and laboratory auto-analyzers in their conditions.

According to the results we obtained in our study, the sodium, potassium, and glucose measurement method procedures in the POC blood analyzer and auto-analyzers were compatible with each other. The random distribution of the differences between the values measured by both methods around zero (not showing a systematic distribution) showed a good fit between the methods. It was shown that there was an average of -1 mg/dL absolute difference between the glucose results measured on the POC blood analyzer and the glucose results measured on auto-analyzers. Only four samples showed a difference with observations beyond the 95% agreement limit. According to the Clinical Laboratory Improvement Amendment (CLIA) (6), the acceptable glucose bias is the target value ± 8% mg/dl. Based on our obtained study data, the mean deviations of glucose did not exceed the acceptable deviations determined by the CLIA. In the study of Liang et al.[7] in which they compared the glucose levels measured by the blood gas analyzer and the central laboratory analyzer, they reported that there was a bias of -3.1 mg/dL in the blood gas analyzer, and 98.1% of paired values meeting the 95% limits of agreement. In the study of Quinn et al.[2], the glucose levels analyzed in the blood gas analyzer were evaluated in accordance with the results of the venous analyzer, which is accepted as the gold standard, and a significant difference of 1.16 mmol/L was reported between the devices.

According to the data we obtained, the mean absolute difference between the sodium and potassium results measured on the POC blood analyzer and the results measured on the auto-analyzer were -1 and -0.42 mmol/L, respectively. One of the sodium samples and four of the potassium samples were out of the 95% agreement limit. The mean bias values of sodium and potassium are within acceptable limits according to the CLIA target values (CLIA acceptable values are "target value ±4 mmol/L" and "target value ±0.3 mmol/L" for sodium and potassium, respectively) (6). Mirzazadeh et al.[8] evaluated the results of blood gas and laboratory mainstream analyzers in a large retrospective study. They reported slope and intercept values as 1.04 and –5.7 for sodium, and 0.93 and 0.22 for potassium, respectively. They reported that there is sufficient agreement between the results obtained from blood gas and laboratory analyzers, and it is useful to use blood gas analyzer results to enable rapid clinical decisions.

Contrary to this study, Açıkgöz et al.[9] reported that they found a significant difference that could be clinically significant between serum potassium results measured in their blood gas analyzer and biochemistry analyzer. In the study of Solak[10], the absolute difference between the results measured in blood gas and auto-analyzer for different sodium levels was found to be more than 4 mmol/L. Similar to the results of Solak's study, in the study of Triplett et al.[11], the mean differences between the two methods are statistically significant for sodium (mean difference 1.49 mmol/L, 95% CI 1.23–1.76, $p<0.0001$) and potassium (mean difference 0.19 mmol/L, 95% CI 0.15–0.24, $p<0.0001$). The mean biases on the Bland–Altman plots are small and independent of the magnitude of the measurements.

It was not possible to determine if the patients received medical treatment throughout the sample process in our study. This constraint was reduced by incorporating samples taken in the POC blood analyzer and auto-analyzer within half an hour. When comparing the two approaches, no precision or accuracy experiments were conducted, and the number of samples outside the acceptable error rates was not identified. These are the study's limitations. Test results have an important role in patient decisions due to their impact on clinical interpretation. The POC blood analyzer performs with minimal processing steps. Being able to be used near the patient minimizes the problems that may be encountered during sample transport (1). Despite these advantages, published data on compatibility between blood gas POC blood analyzer and auto-analyzer are limited and reported biased data to differ (2). One of the important areas of responsibility of clinical biochemists is to determine device performances and compatibility between devices in their laboratory conditions. The next step is to share this information with clinicians and contribute to the effective use of test results for patients.

In conclusion, our study shows that we can rely on the blood gas analyzer's sodium, potassium, and glucose results. The sodium, potassium, and glucose results measured on the blood gas analyzer are lower than the results of the biochemistry device, but despite some limitations, the mean deviation between the results is not significant. The compatibility of both analyzers' sodium, potassium, and glucose results indicated that blood gas analyzer results can be accepted yerine 'can be reliable without achieving biochemistry results. The data of our study may contribute to reducing the negative consequences of diagnosis delays by providing greater confidence in the results of blood gas analyzers.

Ethics Committee Approval: The study protocol was approved by the Harran University Clinical Research Ethics Committee (2022/02).

Conflict of Interest: The authors have declared that they have no conflict of interest.

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