Point-of-care versus central laboratory measurements of electrolytes and hemoglobin: A prospective observational study in critically ill patients in a tertiary care hospital

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ABSTRACT

Background: A blood gas analyzer is a point-of-care (POC) testing device used in the Emergency Department (ED) to manage critically ill patients. However, there were differences in results found from blood gas analyzers for hemoglobin (Hgb) and electrolytes parameters. We conducted a comparative validity study in ED in patients who had requirements of venous gas analysis, complete blood count, and electrolytes. The objective was to find the correlation of Hgb, sodium (Na⁺), and potassium (K⁺) values between the blood gas analyzer and laboratory autoanalyzer.

Methods: A total of 206 paired samples were tested for Hgb, Na⁺, and K⁺. Total 4.6 ml of venous blood was collected from each participant, 0.6 ml was used for blood gas analysis as POC testing and 4 ml was sent to the central laboratory for electrolyte and Hgb estimation.

Results: The mean difference between POC and laboratory method was 0.608 ± 1.41 (95% confidence interval [CI], 0.41–0.80; P < 0.001) for Hgb, 0.92 ± 3.5 (95% CI, 0.44–1.40) for Na⁺, and 0.238 ± 0.62 (95% CI, −0.32–0.15; P < 0.001) for K⁺. POC testing and laboratory method showed a strong positive correlation with Pearson correlation coefficient (r) of 0.873, 0.928, and 0.793 for Hgb, Na⁺, and K⁺, respectively (P < 0.001).

Conclusion: Although there was a statistical difference found between the two methods, it was under the United States Clinical Laboratory Improvement Amendment range. Hence, starting the therapy according to the blood gas analyzer results may be beneficial to the patient and improve the outcome.

Key Words: Emergency department, hemoglobin, point-of-care testing, potassium, sodium

INTRODUCTION

Point-of-care (POC) testing is defined as a laboratory test performed outside a central laboratory, usually at or near a clinical treatment site or by a patient.[1] It is required when quick decision is needed for the management of a patient. Its advantages are shorter wait times for results and earlier discharge from the hospital.[2] As a POC testing device, a blood gas analyzer is mostly used by many critical care settings such as the Emergency Departments (EDs) and intensive care units (ICUs). It provides quick test results
for electrolytes and hemoglobin (Hgb) in addition to acid-base, blood gas, and various metabolic parameters.[9] On the other hand, laboratory test results are of great role in making diagnoses and management of critically ill patients of ED. However, it is time-consuming and increases the length of stay of patients in the ED, which may decrease the quality of care to patients of ED.[4]

Blood gas analyzers use direct ion-selective electrodes, whereas laboratory biochemistry autoanalyzers use indirect ion-selective electrodes.[5] Hematology autoanalyzers and blood gas analyzers measure Hgb concentration by various methods. Blood gas analyzer uses carbon monoxide-oximetry and hematology autoanalyzer uses cyanide-free reagent with a photometric method.[6] According to the United States Clinical Laboratory Improvement Amendment (USCLIA) 2003, it accepts a difference of 0.5 mmol/L in measured potassium (K⁺), 4 mmol/L in measured sodium (Na⁺), and 1.1 g/dl in measured Hgb, from the gold standard measure of standard calibration solutions.[7]

Electrolytes, complete blood count (CBC), liver function tests, and blood gases are often measured in critically ill patients who present to an ED. However, there are differences of opinion regarding the reliability of POC testing in various studies.[7-11] This prospective study was done to assess the correlation between the POC testing value of Na⁺, K⁺, and Hgb with that of the laboratory values. Furthermore, we wanted to know the magnitude of difference between the two methods of estimation so that early intervention can be done in the ED. The primary objective of the study was to determine if POC results for Na⁺, K⁺, and Hgb as measured by a blood gas analyzer are comparable to those obtained by traditional measurement by the institution’s central laboratory. In addition, the study aimed to clarify the significance of any observed result variability as well as the optimal correction value if indicated.

**METHODS**

This was a prospective comparative validity study conducted in the ED of a tertiary care hospital. Institutional ethics committee approval was obtained, and the study was registered prospectively with the Clinical Trials Registry-India. The manuscript adheres to the STROBE guideline. Patients who required CBC and electrolyte measurements were included in the study. Patients of age <18 years and more than 80 years were excluded from the study. The venous blood samples (4.6 ml) were collected. The first sample (0.6 ml) was collected in a lithium-heparin-coated syringe for blood gas analysis as POC testing. The second sample (2 ml) was collected in a nonadhesive silicone-coated tube and the third sample (2 ml) was collected in a vacutainer for electrolyte and Hgb estimation, respectively, in the central laboratory. The venous blood gas values for Hgb, Na⁺, and K⁺ were estimated immediately after collection using a NOVA arterial blood gas (ABG) analyzer (pHOx Ultra, Nova Biomedical, Waltham, USA) that has direct ion-selective electrodes. Serum electrolytes were processed in the central laboratory using the autoanalyzer (AU5800, Beckman Coulter, Inc, Brea, USA). The Hgb was analyzed by Sysmex XN-1000™ Hematology Analyzer (Sysmex America Inc., Lincolnshire, USA).

The previous study reported a mean difference of 0.192 g/dl with a standard deviation (SD) of the difference of 1.078 between the standard gold method and ABG analysis for Hgb measurements.[8] Considering these values, the effect size was calculated to be 0.1781. Taking the “α” value of 0.05 and power of 80%, the sample size was calculated to be 197. The sample size was calculated using G * power software (version 3.1.9.5, Heinrich Heine University Düsseldorf, Düsseldorf, Germany).[12] Data analysis was performed according to the Clinical and Laboratory Standard Institutes guidelines.[13] All the quantitative measurements were expressed in terms of mean and SD unless otherwise specified. All the categorical variables showed in terms of numbers and percentages. The Bland–Altman (BA) plot was used to determine the agreement between the blood gas analyzer and laboratory measurements with limits of agreement expressed as mean ± 1.9 SD. The Deming regression analysis was performed to adjust for random errors in the measurement by both methods. The correlation coefficient (r) and determination factor (r²) were used to measure the precision. The Concordance correlation coefficient and bias correction factors were used to measure accuracy. MedCalc® version 16.9 (MedCalc Software Ltd., Belgium) for Windows was used for statistical analysis. A P < 0.05 was considered statistically significant.

**RESULTS**

A total of 206 participants were included in the study. The mean age of the participants was 48.79 (±17.5; range 18–80) years, with a minimum of 18 years to a maximum of 80 years. Most of the study participants were male, 120 (58.3%). Among the enrolled patients, 9.8% had a cardiac illness, 14.7% had road traffic accidents, 13.7% had toxin consumption, 19.6% had a respiratory illness, 16.6% suffered from the gastrointestinal condition, 5.5% suffered from malignancy and complication of diabetes each, and the rest (13.7%) had either sepsis or fever.

The mean difference in the Hgb values between POC and laboratory method was 0.608 ± 1.41 (95% confidence interval [CI], 0.41–0.80; P < 0.001). Similarly, the mean difference in the Na⁺ and K⁺ level between POC and
laboratory methods was $0.92 \pm 3.5$ (95% CI, 0.44–1.40) and $-0.238 \pm 0.62$ (95% CI, $-0.32$–$-0.15$; $P < 0.001$). The details of Hgb, Na$^+$, and K$^+$ values are given in Table 1. The POC and laboratory methods showed a strong positive correlation with Pearson correlation coefficient ($r$) of 0.873, 0.928, and 0.793 for Hgb, Na$^+$, and K$^+$, respectively ($P < 0.001$) [Table 2]. The concordance correlation coefficient, which is the product of precision and bias correction factor, revealed moderate agreement for Na$^+$ (0.924), whereas the poor agreement for Hgb and K$^+$ measurements.

The BA plot for Hgb measurement showed a limit of agreement between $-3.4$ and $2.2$ [Figure 1]. Deming regression analysis [Figure 2] of the Hgb measurement yielded the formula:

$$\text{Hgb (laboratory)} = -0.776 + 1.014 \times (\text{Hgb POC}).$$

The BA plot for K$^+$ measurement showed a limit of agreement between $-0.95$ and $1.44$ [Figure 3]. The regression plot for lower values of K$^+$ in ABG and laboratory method show wide variation compared to the higher values. Deming regression analysis [Figure 4] of the K$^+$ measurement yielded the following formula:

$$\text{K}^+ \text{ (laboratory)} = 0.463 + 0.945 \times (\text{K}^+ \text{ POC}).$$

The BA plot for Na$^+$ measurement showed a limit of agreement between $-7.8$ and $5.9$ [Figure 5]. The regression line for Na$^+$ showed a high concordance compared to Hgb and K$^+$ measurements. Deming regression analysis [Figure 6] of the Na$^+$ measurement yielded the formula:

$$\text{Na}^+ \text{ (laboratory)} = 0.0822 + 0.992 \times (\text{Na}^+ \text{ POC}).$$

**DISCUSSION**

Although the observed differences in POC testing results for Na$^+$, K$^+$, and Hgb were statistically significant, the differences were not clinically significant as they fell lower values of K$^+$ in ABG and laboratory method show wide variation compared to the higher values.
within an acceptable USCLIA range for variability and a strong positive correlation as determined by the Pearson correlation coefficient was observed.

A single-center study by Zhang et al. involving 200 pairs of blood samples in an ED found statistically significant differences for Na⁺ and K⁺ between the ABG analyzer and the laboratory analyzer but no statistical difference for Hgb. They found all the variables were reliable to start therapy according to the POC testing value. Uysal et al. had compared the result of POC with laboratory values of Na⁺, K⁺, Hgb, hematocrit, glucose, and chloride. They found a strong correlation with all except chloride. We also found a strong correlation between POC and the laboratory value of Na⁺, K⁺, and Hgb. Mirzazadeh et al. found good agreement between the findings of Na⁺ and K⁺ obtained from blood gas and laboratory analyzer. Allardet-Servent et al. found POC value and laboratory value of Na⁺ and K⁺ are interchangeable, but Hgb was not. They have used the arterial samples while we have gone for the venous samples. We found all parameters are acceptable. This might be due to different tools being used. Triplett et al. conducted a prospective multicentric analytical observational study in five ICUs. They included the patients who required investigations for full blood count, electrolytes, and a blood gas within 1 h of ICU admission. They found a statistically significant difference between Na⁺ and K⁺ but no difference in Hgb values comparing the POC and laboratory findings. They found Hgb, Na⁺, and K⁺ agreed to each other under most clinical situations when the acquired values were within or close to the normal range. In our study, we have used a single prick venous sample for all tests in both POC testing and laboratory value with a wide variety of patients. We found Na⁺ has more agreement than K⁺ and Hgb and all the differences are under the USCLIA range.

The strength of our study was that all the samples were collected from a wide range of critically ill patients. We have included a wide range of values for Hgb, Na⁺, and
K+ for analysis. We calculated the correction factor so that the early intervention can be done on the patients in ED. We had not collected the data of patient outcomes according to POC testing value. This is a single-center study, and results are not generalized to another area.

CONCLUSION

We found a strong positive correlation between POC and laboratory methods for Hgb, Na+, and K+. A statistically significant difference was found for Hgb, Na+, and K+ which was under the USCLIA range. We suggest starting the treatment as per the results of POC value, however, if an extreme value of K+ is found, crosscheck with laboratory value is required.

Research quality and ethics statement

This study was approved by the Institutional Review Board/Ethics Committee at All India Institute of Medical Sciences Bhubaneswar (Approval No: T/IM-NF/TandEM/19/33; Approval date September 16, 2019). The study was prospectively registered with the Clinical Trials Registry-India (CTR/2019/10/021594). The authors followed the applicable EQUATOR Network (http://www.equator-network.org/) guidelines, specifically the STROBE guidelines, during the conduct of this research project.

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Conflicts of interest

There are no conflicts of interest.

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