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Comparison of Point-of-Care versus Central Laboratory Measurement of Electrolyte Concentration in Intensive Care Patient

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Abstract

Background: Electrolyte values are measured both by arterial blood gas (ABG) analyzers and central laboratory auto-analyzers (AA), but a significant time gap exists between the availability of both these results, with the ABG giving faster results than the AA. The authors hypothesized that there is no difference between the results obtained after measurement of electrolytes by the ABG analyzers and AA. *Methods:* We retrospectively analyzed the 122 sets of arterial blood samples from critically ill patients. Whole blood electrolytes were analyzed using a point-of-care blood gas (ABG) analyzer and serum electrolytes were analyzed in the central laboratory auto-analyzers. *Results:* There was a significant difference in the mean (±standard deviation) sodium value between whole blood and serum samples (134.59±13.11 Vs 144.20±14.11). There was a significant difference in the potassium values measured by ABG analyzers and AA (3.37±0.68 Vs 3.52 ±0.70). The correlation coefficient obtained for sodium was 0.931 and correlation coefficient obtained for potassium was 0.894. *Conclusion:* Results with two different measurement technologies differed significantly for plasma sodium and potassium concentrations.Therefore, clinicians should be careful when diagnosing sodium and potassium ion imbalance in critically ill patients and providing treatment.

Keywords: Blood Gas Analysis; Auto Analyzers; Sodium and Potassium.

Background

Electrolytes are charged elements that are essential for proper cellular functioning in most tissues of the body. Almost all metabolic processes are dependent upon or are mediated by electrolytes. Variation in electrolyte concentrations may be either the cause or the consequence of a variety of disorders; such problems must be identified to ensure adequate treatment. Electrolyte abnormalities can represent significant risks to life.

Signs and symptoms of electrolyte disorders may be nonspecific in an intensive care unit (ICU) patient. The therapies directed for maintaining vital organ functions affect the electrolyte balance. Consequently, electrolyte disorders are more common in critically ill patients than non-critically ill patients. The incidence of electrolyte disorders is nearly 25% in ICU patients. In recent studies, it is shown that in ICU patients, serum sodium and potassium levels are significant predictors of mortality [1-3]. Therefore, prompt and complete correction of electrolyte disorders in ICU patients is vitally important. Under these circumstances, the importance of obtaining the results of serum electrolyte levels at the earliest is obvious.

Two methods of electrolyte assay, one direct and one indirect, both employing ion-sensing electrodes (ISE), are currently in use in most hospitals. The indirect assay features pre-analytic dilution and is often employed in high-throughput central hospital laboratories running automated analyzers (AA). In the direct ISE method, the electrode surface contacts a

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complete undiluted blood sample; this approach is employed by arterial blood gas analyzers (ABG) or point-of-care testing (POCT) equipment. Indirect ISE devices use diluted plasma (or serum) samples; the results are generally comparable to those afforded by flame photometry (the recognized reference method). Sodium and potassium levels measured in whole blood and plasma have been shown to be essentially identical [4].

Blood gas analyzers; use the direct ISE method with short processing time that provides time and rapidity to the physician in the patient's treatment decisions.

There has also been a revolutionary achievement in the ways of managing dyselectrolytemia in medical practice which has also contributed to the importance of urgent electrolyte reporting. Despite the advantage of a rapid turnaround time with POCT, that may translate to prompt decision making, concerns have been raised regarding the accuracy and reliability of POCT devices[5]. In some recent studies, the data revealed the difference in the electrolyte levels between the ABG and AA results [6-8]. Physicians want to trust the veracity of the ABG results of electrolytes such as sodium and potassium because, by this method, the delay in reaching the results is surpassed, and risks arising from this delay may be reduced.

The present study was done with the objective to investigate whether the results from ABG analyzers and AA are equal when used to assess electrolyte levels (sodium, and potassium) in adult patients admitted in critical care unit.

Study Design and Methods

A retrospective analysis of data was conducted for a period of 3 months, i.e. April 2016 – July 2016. Patients with ASA- II,III &IV were studied. A total of 122 sets of arterial blood samples were taken daily in the morning at 7 AM. All samples were simultaneously sent for ABG analysis and to central laboratory. Electrolyte values (sodium, and potassium) are noted from both the methods and compared. For POCT, sample of 1.6 ml was collected from the arterial line in commercially available plastic ABG syringes. The second sample was collected in a BD vacutainer for serum (4.0 ml or 6.0ml) in a non-additive silicone coated tube, and sent to the central laboratory through the pneumatic system for serum electrolytes estimation.

The ABG (whole blood) electrolytes were estimatedon-site immediately after collection, using ABL-800 BASIC-I ABG analyzer that has direct ion-selective electrodes. Serum electrolytes were analyzed in the central laboratory using CLA-Dade RxL Dimension. Thischemistry analyzer uses indirect ion-selective electrodes and pre-dilutes the specimen before analysis. The study was funded by the Clinical Biochemistry Department of the Nizam's institute of medical sciences hospital.

Statistical analysis was done using SPPS software version 17. Data were tested for normality using the Kolmogorov-Smirnov test. Means, standard deviations, and coefficients of variation were calculated.

Agreement between the two analyzers was assessed using the Bland-Altman approach.1,2 Limit of agreement was defined as mean bias ± 2 standard deviation (SD). Paired student t-test was used to compare means. $p< 0.001$ was considered statistically significant.

Results

The statistical analysis showed that, there was a significant difference between sodium and potassium values measured by ABG and CLA methods ($P <0.05$) (Table 1). A Bland-Altman comparison of AA and ABG analyzer for the sodium measurement results revealed that the limits of agreement were between -19.89 to 0.684 and the mean difference was-5.25mmol/L (Figure 1). Similarly, for potassium the limit of agreement ranged from -0.765 to 0.497 and the mean difference was -0.32mmol/L (Figure 2).

Table 1: Comparison of statistics obtained from AA and ABG analyzer for sodium, and potassium.

Electrolyte/machine	samples	Mean	Standard deviation	Correlation coefficient	p-Value
Sodium					
AA	122	134.59	13.11	0.931	< 0.01
ABG analyzer	122	144.20	14.41		
Potassium					
AA	122	3.37	0.689	0.894	< 0.01
ABG analyzer	122	3.511	0.706		

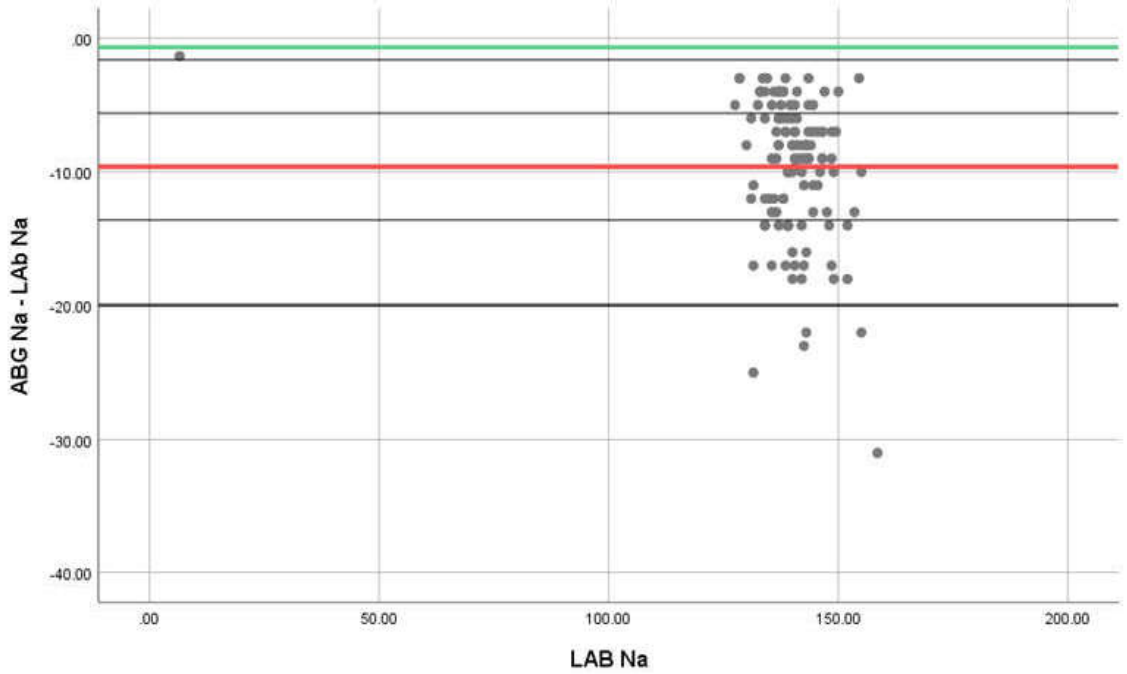

Fig. 1: Bland-Altman plot of sodium. Agreement was summarized by the mean difference with 95% limits of agreement (LOA)

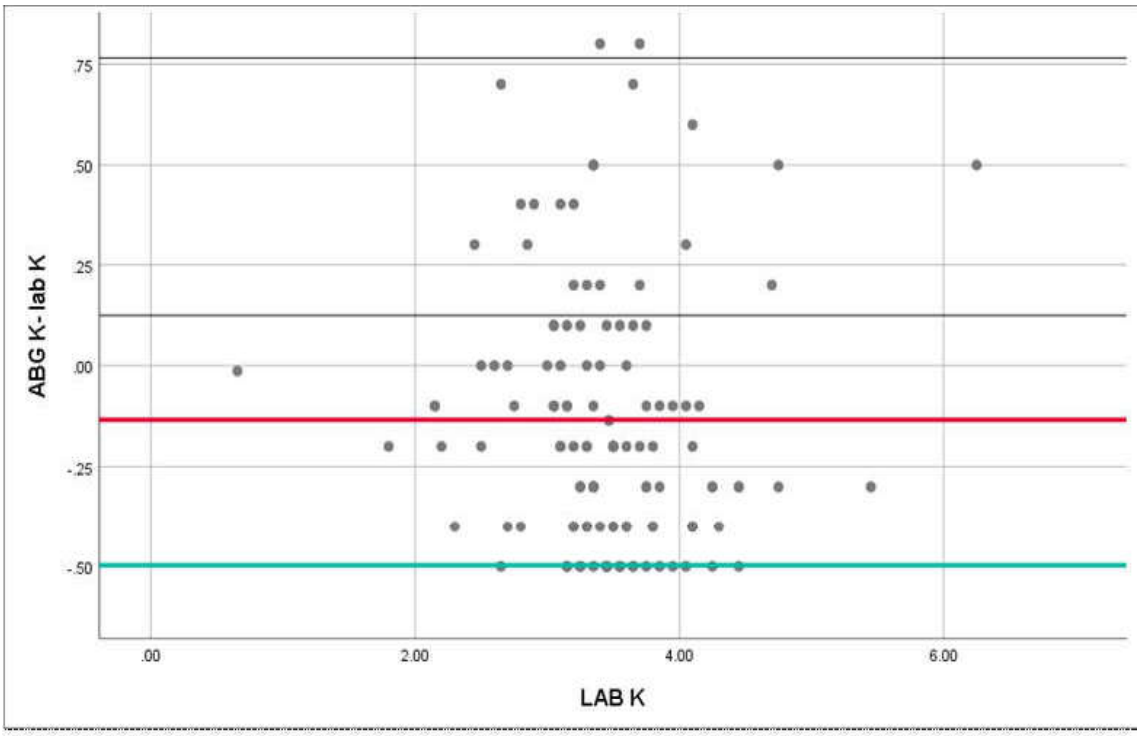

Fig. 2: Bland-Altman plot of potassium. Agreement was summarized by the mean difference with 95% limits of agreement (LOA)

A Bland-Altman comparison of AA and ABG analyzer for the sodium measurement results revealed that the limits of agreement were between -19.89 to 0.684 and the mean difference was -5.25 mmol/L.

A Bland-Altman comparison of AA and ABG analyzer for potassium measurement results revealed that the limit of agreement ranged from -0.765 to 0.497 and the mean difference was -0.32 mmol/L

Discussion

Point-of-care analyzers are force multipliers for clinicians working in the areas of critical care and emergency medicine. They have been proven to benefit clinical decision-making by reducing the turnaround time for routine biochemical investigations. Time critical decisions are enabled by point-of-care analyzers when biochemical parameters are beyond their normal limits. Several kinds of point-of-care testing equipment are in vogue in clinical practice today, and they have been widely evaluated in varied environments. Point-of-care testing has gained special favor in emergency transport systems, critical care departments, and cardiothoracic surgical departments, as is shown by the large volume of systems developed for all of these areas [9-11].

In the present study we investigated whether sodium, and potassium levels measured using different methods and equipment, namely an ABG and an AA, were equivalent. If so, the data could be employed interchangeably in routine practice. The US CLIA 1988 rules accept a difference of 0.5 mmol/L in potassium level, and 4 mmol/L in sodium level, compared to target values [5].

In our present study; the mean difference between the two sodium assays was 5.25mmol/L; this exceeded the acceptable value of 4 mmol/L. Our data are in line with those of previous studies [8, 12,13] showing that sodium values obtained using two different types of measurement differ significantly, and to an extent that may affect therapeutic choice. Our patients were critically ill in the intensive care unit (ICU). Chow et al [13] reported that direct ISE sodium and potassium figures were lower than those obtained using indirect ISE. This is associated with the low blood protein levels characteristic of critically ill patients. In such patients, direct ISE offers more accurate and consistent electrolyte results than does indirect ISE.

The mean between-assay difference in potassium levels was 0.322mmol/L. Although the mean difference between the results of the two potassium assays was within the range given by the US CLIA 1988 guidelines [5], a difference of 0.322mmol/l is clinically relevant when intra-individual variation is considered. When it is recalled that the intra-individual biological variation in potassium level has been reported to be 4.8% [14], any bias exhibited by either method did not exceed the acceptable level of inaccuracy [14]. It is important to emphasize that the cited criteria are very strict; the acceptable inaccuracy in terms of potassium measurement is only 1.8% [14]. It is likely that the observed variations in potassium values of paired samples are attributable to differences in sample type, thus serum or whole blood. It is well known that potassium is released from platelets during clotting and it is thus not surprising that serum potassium values are higher than are whole-blood levels. The magnitude of the difference observed by us was similar to that earlier reported (0.1-0.7 mmol/L) [12,15].

Although the differences in electrolyte levels obtained using the two methods are sufficiently small to not raise a risk of inappropriate therapy in most instances, Morimatsu et al [8] calculated the anion gap and the strong ion difference in critically ill patients using results obtained from a central laboratory analyzer and a POCT device; the Stewart-Figge formula was employed. The cited authors showed that the values calculated using data obtained by different methods differed significantly; clinical interpretation and consequent therapeutic decision-making could be adversely affected.

The observed differences between electrolyte levels measured using an ABG and an AA may be explained by a combination of factors, including sample transport, dilution of serum samples prior to testing (thus, the use of indirect vs. direct electrodes), and variations in instrument calibration [16].

It is known that ISE-based instruments from different manufacturers yield sodium /potassium values that differ by 2–5%; calibration of an AA using a NIST standard lowers the figures [17].

Our present study illustrates the importance of determining the concordance, for each individual hospital, of electrolyte values obtained by ABG and those obtained in the central laboratory. As instrument type and calibration methods may differ among hospitals, it is important that each center conducts an in-house study. Ideally, before installation of an ABG, it would be useful to carefully evaluate the clinical significance of any difference between data yielded by central laboratory devices and POCT instruments.

A limitation of our work is that, in the absence of clinical review, we were unable to identify any dataset as containing erroneous values. It was not possible to establish whether the central laboratory or ABG values were closer to the true values for either analyte.Another limitation was that the ABG samples were collected using conventional syringes containing liquid heparin. The use of dried heparin syringes could improve the accuracy of the results by decreasing the dilution of the sample.

Conclusion

Even though there is a significant statistical difference between potassium values measured by both methods, the difference is within acceptable range of CLIA guidelines which signifies the interchangeability of both the methods in measuring this cation. In case of sodium despite significant difference in the values good correlation between the methods helps us to follow the trends in ABG in clinical assessment. Central laboratory values remain the gold standard. However, it is a time taking process which limits its use in emergency situations. Physicians can rely upon ABG in emergency situations, values with evident clinical manifestations, and perioperative period in selected group of patients.

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