Original Article

Comparison of Sodium and Potassium by Point-of-Care Arterial Blood Gas Analyzer and Venous Serum by Central Laboratory Analyser in Emergency Clinical Decision Making

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ABSTRACT

Introduction: The Emergency Departments (ED) are equipped with Point-of-Care (POC) Blood Gas Analysers (BGA) which deliver fast results on multiple parameters of arterial/venous blood. There is no consensus among ED physicians on the reliability of electrolyte results by POC Arterial Blood Gas (ABG) analysis compared to venous serum electrolyte from Central Laboratory Analyser/Auto-Analyser (CLA/AA).

Aim: To compare the electrolyte (sodium and potassium) by POC arterial BGA (ABL800 Flex Radiometer) with venous electrolyte by CLA (Beckman Coulter AU 5800).

Materials and Methods: This cross-sectional study was performed in the ED and Central Laboratory of the tertiary teaching hospital from 1st July 2018 to 31st July 2019. A total of 254 critically ill adult patients with various aetiologies, were enrolled in the study. The arterial and venous blood samples were collected for electrolyte measurement within a span of 15 minutes. The ABG samples, anticoagulated with liquid heparin, were processed in POC BGA. The venous samples collected in plain tubes were analysed in CLA. The results of sodium and potassium were compared by the mean, correlation coefficient, p-value, and Bland Altman Plots {95% Limit of Agreement (LOA)}. **Results:** Out of 254 paired samples (mean age: 63 ± 15 years), 157 (61.8%) were males and 97 (38.2%) females. The mean sodium values were 131.9 \pm 7.7 mmol/L in ABG and 132.3 \pm 7.1 mmol/L in CLA (p-value <0.0001). The mean difference was 0.4 mmol/L. The mean potassium values were 3.9 ± 1.0 mmol/L (ABG) and 4.2 ± 0.9 mmol/L (CLA), {p-value <0.0001}. The mean difference was 0.3 mmol/L. These differences were within the accepted range specified by the United States Clinical Laboratory Improvement Amendments. There were statistically significant strong positive correlations between the measurements of the two instruments r=0.78 for sodium and r=0.76 for potassium. The 95% LOA for sodium and potassium on both the instruments were -10.03 to 9.09 mmol/L and -1.49 to 0.97 mmol/L respectively, both wide and unacceptable.

Conclusion: The arterial sodium and potassium measurements by BGA were not reliable in decision making in ED when compared to the venous serum by CLA as the 95% LOA was wide and unacceptable. Hence, sodium and potassium values by BGA alone might not be used as criteria for management without confirmation from venous serum values by CLA.

Keywords: Central laboratory testing, Electrolyte disorders, Point-of-care test, Turn-around time

INTRODUCTION

Emergency Medicine Departments (ED) utilises Point-of-Care Tests (POCT) for immediate clinical decision making and institution of resuscitative measures [1]. The critically ill patients presenting to ED can have physiological derangements due to various aetiologies. Electrolyte disorders are frequent in these patients requiring immediate resuscitation to manage cardiac arrest and cardiac arrhythmias, and to reduce the period of hospitalisation. Appropriate POCT reduce the Therapeutic Turn-Around Time (TTAT) enabling shorter door to clinical decision time [2,3]. Some of the advantages of POCT are rapidity, user-friendly instruments, ability to test multiple parameters with small sample volumes, accessibility, repeatability and portability.

The disadvantages are the concerns regarding analyser inaccuracy, interference by substances in the blood or anticoagulants, poorly trained non laboratory staff, and cost factors [2]. Fermann GJ and Suyama J after a review of 100 articles, asserted that POC technology is effective and reliable in the ED settings with improved patient care [4]. Many studies showed that POC ABG analysis lead to faster decision making, reduced TTAT, and better morbidity outcome compared to the Central Laboratory Technician (CLT) [5-9].

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The common electrolyte abnormalities encountered in ED are hyponatremia and hyperkalemia which need immediate resuscitation to reduce mortality and morbidity. Conventionally, serum electrolytes are measured by auto-analyzers in Central laboratory (CLA/AA) of hospitals which work on the principle of the Indirect ion Selective Electrode (ISE) method. They have prolonged Turn-Around Time (TAT) because of time delay in transportation of the samples to the Central Laboratory (CL), serum separation, dilution with diluents, and prolonged processing and, collection of results [10,11]. Their electrolyte estimation is affected by the unexpected solid particles in blood including albumin, other proteins, triglycerides, etc. [11-14]. The significant differences in sodium and potassium in POC ABG and CLT were probably attributed to the characteristics of different devices, variations in the calibrators, dilution agents, type of samples (whole blood/serum), and the effect of transportation of samples [13,15-17]. Haemolysis as well as thrombosis can lead to increased Potassium (K+) values [18]. Deficiency in the availability of human couriers or rapid transit systems for transporting samples to CLT can lead to long TTAT [13,14].

Still, CLA are considered close to flame photometry, the gold standard test [19]. The time to obtain laboratory electrolyte results could be more if the sample is inadequate, haemolysed, or mislabeled leading

to repetition. Hence, POCT such as BGA which can provide multiple variables, including blood gases {Oxygen O2 and carbon dioxide (CO₂) pressures, O₂ saturation, pH}, base excess, lactate, glucose, creatinine, haemoglobin, carboxyhaemoglobin, bilirubin, and electrolytes sodium, potassium, chloride, bicarbonate, calcium, and magnesium, etc., based on different technology using arterial (ABG) or venous samples (Venous Blood Gas {VBG}) are increasingly used in the daily assessment and monitoring of critically ill patients in ED. BGA utilise the direct ISE method for electrolyte measurement with a short processing time, helping the ED physician in critical treatment decisions [11]. Electrolyte levels in whole blood and plasma are considered equivalent [18,19]. Various studies showed that POCT of electrolytes reduced TTAT, in the ED [3,13,15-17,20,21]. But the comparison studies showed disparate results [13,16,22]. BGA measure electrolytes in anticoagulated whole blood and there is an advantage that the results are not affected by the level of albumin, Proteins, or triglycerides in the blood. The quick results on multiple parameters and easy accessibility enable the ED physicians to depend on BGA in critically ill patients [23].

Though ED physicians trust the ventilation and acid-base status data, provided by BGA, studies have shown that POCT measurements of sodium and potassium are not consistent with CLT of the same samples [9,13,16,24-37]. But the inference of studies cannot be extrapolated to generalization because the studies utilised equipment from different manufacturers and different technological methods. Moreover, the studies involved sample pairs comparing arterial vs. arterial, {prospective [13,24-28] and retrospective, [29,30]} arterial vs. venous, {prospective [9,31,32] and retrospective [16,33-35]} and venous vs. venous, {prospective[36]} with variable results [37]. Some researchers suggested studies at the individual center at or before installation of BGA instruments in the ED [24,38]. Some of these studies were not using comparable statistical methods. Limits of Agreement (LOA) were not included in the evaluation of the above-mentioned studies which could alter the inferences. In the present study, all three statistical methods were employed for the comparison. Another cause of the variable results could be that the studies compared instruments from different manufacturers and with different calibrators.

In this circumstance, this study aimed at a comparison between the arterial sodium and potassium values by point-of-care arterial BGA (ABL800 Flex Radiometer) with the venous serum sodium and potassium values by CLA (Beckman Coulter AU 5800) and their reliability in clinical decision making in ED by the venous electrolyte by CLA.

MATERIALS AND METHODS

This cross-sectional study was conducted in the ED and Central Laboratory of a tertiary teaching hospital in Government Medical College Kannur, Pariyaram, Kerala, India, with an average ED turnover of 300,000 per year, after obtaining Institutional Ethics Committee approval (No: G1 2747/12/ACME). The study was conducted from 1st July 2018 to 31st July 2019.

Inclusion criteria: Critically ill patients above the age of 18 years who presented to the ED and whose arterial blood samples were collected for ABG and venous samples were collected for CLT electrolyte measurement as part of their clinical management and the samples were taken within a maximum interval of 15 minutes were included in the study.

Exclusion criteria: Patients whose blood samples were withdrawn for ABG and venous electrolyte estimation by CLA at an interval of more than 15 minutes, were excluded. Those patients in whom medications were instituted in between the collection of samples were also excluded.

Sample size calculation: Based on the previous study, fixing the level of significance at 5% (corresponding standard variate value 1.96) and the power of the study fixed at 95% (corresponding standard variate value of 1.65) with mean and SD in first group as

140.4 \pm 5.6 and in the second group 138.3 \pm 5.9 respectively, as per the formula [16]:

$$\eta = 2 S_p^2 [Z_{1-\alpha/2} + Z_{1-\beta}]/\mu_d^2$$

Where $S_p^2 = (S_1^2 + S_2^2) / 2$

- S₁ : Standard deviation in the first group
- S₂ : Standard deviation in the second group
- μ_d : Mean difference between the samples
- α : Significance level
- 1-β : Power

A sample size of minimum of 60 subjects were required for the present study.

Procedure

A total of 254 adult patients were enrolled in the study strictly observing the inclusion and exclusion criteria. After obtaining the informed written consent, arterial samples were collected from radial or femoral arteries in 2 mL plastic syringes prerinsed with liquid heparin and were processed in the POC BGA {ABL 800 Flex Radiometer, Copenhagen, Denmark, with a processing time <3 minutes on minimum quantity of blood (<200 microliters)} immediately (within 30 seconds). The venous blood samples were drawn from peripheral veins or central veins as per accessibility, collected in plain bottles and transported for CLT by human couriers and serum processed in CLA (Beckman Coulter AU 5800 Inc., Miami, FL, USA). Both samples were taken before starting any treatment that could alter the electrolyte levels and time-gap did not exceed 15 minutes. Both the equipment were maintained and calibrated as per manufacturers' instructions. The mean difference for sodium was set less than 4 mmol/L and for potassium less than 0.5 mmol/L as per the United States Clinical Laboratory Improvement Amendments (US CLIA) [38].

Scattergrams: Scattergrams were plotted to display the relationship between the variables measured by the two methods. The scattergrams display the relationship between the sodium and potassium values obtained from the BGA and CLA. The relationships may be positive or negative, non linear or linear, and/or strong or weak. It is important that the two instruments that are designed to measure the same variable should have good correlation. The correlation is often represented by the correlation coefficient 'r'. The closer the r to +1, the greater the strength of the linear relation [39].

Bland-Altman plots: Bland-Altman plots are used for the evaluation of inter instrumental differences in the same variable. It is plotted with data points with the mean of the measurements of the same variable from two instruments on the X-axis and the difference between the two measurements on the Y-axis.

It is recommended that 95% of the data points should fall within ± 1.96 Standard Deviation (SD) of the mean difference termed Limits of Agreement (LOA). Three lines were drawn, a mean difference (Bias) level and upper level (+1.96 SD), and lower level (-1.96 SD) were plotted and the data points were marked. The LOA must be decided prior to the study. As per the US CLIA, the accepted values for sodium and potassium are 4 mmol/L and 0.5 mmol/L, respectively and in the present study, the 95% LOA is set prior as 2 SD ($\pm 8 \text{ mmol/L}$ for sodium and $\pm 1 \text{ mmol/L}$ for potassium) on either side of the mean difference line (bias). If the measurements are beyond these limits, the agreement between the two instruments is considered wide/poor. If the 95% LOA is within the set goals, the instruments are considered in agreement on the variable measured [40].

STATISTICAL ANALYSIS

The results from BGA and CLA were analyzed with the statistical tests {using IBM Corp. Released in 2016. IBM Statistical Package for the Social Science (SPSS) Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.}. Mean, standard deviation, Pearson's correlation and two-tailed p-value were used for statistical analysis

and p \leq 0.05 was considered statistically significant. Bland-Altman plots were drawn to show the 95% LOA between the instruments.

RESULTS

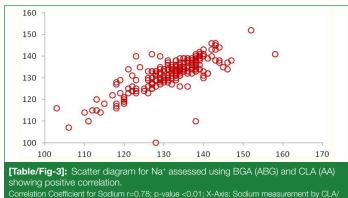
A total of 254 paired samples {males 157 (61.8%) and females 97 (38.2%); mean age: 63 ± 15 years} were analyzed in the present study. The mean ABG sodium value was 131.9 ± 7.7 mmol/L and the mean CLA sodium value was 132.3 ± 7.1 mmol/L (p<0.0001) [Table/Fig-1]. The mean difference was 0.4 mmol/L. The mean ABG potassium value was 3.9 ± 1.0 mmol/L and the mean CLA potassium value was 4.2 ± 0.9 mmol/L (p<0.0001) [Table/Fig-1]. The mean difference was 0.3 mmol/L.

Sodium	Mean±SD mmol/L	p-value	Potassium	Mean±SD mmol/L	p-value	
Arterial BGA	131.9±7.7	p<0.0001	ABG	3.9±1.0	p<0.0001	
Venous CLA	132.3±7.1		AA	4.2±0.9		
Mean difference	-0.4		-	-0.3		
[Table/Fig-1]: Sodium and Potassium assessed using arterial BGA and venous CLA. BGA: Blood gas analyser, CLA/AA: Central laboratory analyser/Auto-analyser; p≤0.05 is statisti- cally significant						

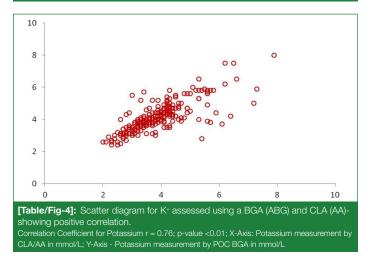
The correlation coefficients between the two types of sodium and potassium measurements were 0.78 (p-value <0.01) and 0.76 (p-value <0.01) respectively, [Table/Fig-2]. Scatter diagrams plotted for sodium and potassium showed strong positive correlation (statistically significant, p-value<0.01) [Table/Fig-3,4]. Bland-Altman plots drawn to show 95% LOA between the two instruments showed the 95% LOA as -10.03 to 9.09 mmol/L for sodium and -1.49 to 0.97 mmol/L for potassium (both wide and unacceptable) [Table/Fig-5,6].

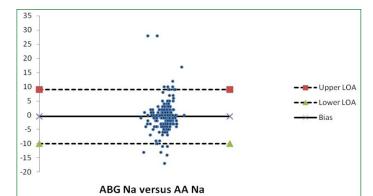
Variables	r-value	p-value			
Correlation of Sodium	0.78	<0.01			
Correlation of Potassium	0.76	<0.01			
[Table/Fig-2]: Karl Pearson Correlation coefficient of Sodium and Potassium as-					



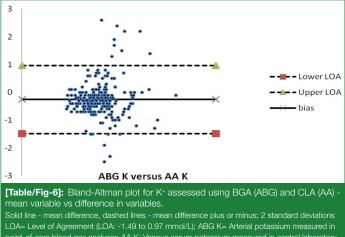


nmol/L; Y-Axis: Sodium measurement by POC BGA in mmol/L





[Table/Fig-5]: Bland-Altman plot for Na* assessed using BGA (ABG) and CLA (AA)- mean variable vs difference in variable. Solid line - mean difference, dashed lines - mean difference plus or minus 2; Standard deviations LOA= Level of Agreement (LOA: -10.03 to 9.09 mmol/L); ABG Na: Arterial sodium measured in point-of-care blood gas analyser; AA Na: Venous serum sodium measured in central laboratory auto-analyser; X-Axis: the average of the two paired measurements of sodium in POCBGA (a) and CLA (b) (a+b)/2); Y-Axis



point-of-care blood gas analyser; AA K: Venous serum potassium measured in central laboratory auto-analyser; X-Axis: the average of the two paired measurements of potassium in POC BGA (a') and CLA (b')= ((a'+b')/2); Y-Axis - the difference between the two paired measurements of potassium in POCBGA (a') and CLA (b')= (a'-b')

DISCUSSION

The mean differences for sodium and potassium were 0.4 mmol/L and 0.3 mmol/L respectively (p-value <0.0001). These differences were within the limit specified by United States Clinical Laboratory Improvement Amendments (US CLIA) which accepts a difference of 4 mmol/L in measured sodium (Na⁺) and 0.5 mmol/L, in measured potassium (K+), in comparison with Flame photometry, the gold standard [38]. Regarding correlation, sodium and potassium values showed strong positive correlation (r=0.78 and 0.76 respectively). But as per the Bland-Altman plot, 95% LOA for both sodium and potassium were wide and unacceptable (Sodium-10.03 and 9.09 mmol/L; Potassium-1.49 and 0.97 mmol/L) suggesting that arterial BGA measurements of sodium and potassium could not be considered in agreement with CLA values. For sodium, the acceptable range of 95% LOA is 8 mmol/L on either side of the mean bias of 0.4 mmol/L (±2 SD, -7.6 to +8.4 mmol/L). For potassium, the acceptable range of 95% LOA is 1 mmol/L on either side of the mean bias of 0.3 mmol/L (± 2 SD, -0.7 to +1.3 mmol/L). Thus, the present study suggests that ED physicians cannot make critical decisions in initiating resuscitation and management in critically ill patients presenting to the ED by arterial sodium and potassium from POC BGA alone before the CLA results are available.

Flegar-Mestric Z and Perkov S, found that the results from POC analyzers were comparable with CLA in 70 patients [9]. Leino A and Kurvinen K, recommended that though the BGA and core laboratory analysers could be used for critical care management, while monitoring patients, the use of a single analyser was recommended to avoid bias [41]. In contrast to the present study findings, in another prospective arterio-venous study, Wongyingsinn M and

Suksuriyayothin S observed that the mean difference of venous and arterial sodium was 3 mmol/L and potassium was 0.49 mmol/L. The intraclass correlation coefficient was 0.904 and 95% LOA was 0.839 to 0.943 (p-value<0.001). They concluded that there was agreement between ABG and venous potassium measurement and clinicians could use ABG's potassium level as a guideline for treatment instead of using the laboratory venous potassium level [32]. They proposed a correction formula for venous sodium. They concluded that sodium and potassium by ABG analyser and CLA were comparable [32]. In contrast with the present study findings, Auvet A et al., comparing 491 arterial samples, found that the bias of sodium was 1 with 95% LOA -3 to 4 and bias for potassium was 0.1 with 95% LOA 0.1 to 0.5, and suggested the results were inter changeable [27].

Chhapola V et al., revealed that the sodium and potassium measurement from POC were showing wide LOA and were not clinically acceptable in paediatric ICU population and showed that POC BGA underestimated sodium and potassium possibly due to liquid heparin which caused an increase in sample volume [15]. Banerjee A and Mehrotra G found significant difference between BGA and AA measurement of Na⁺ and K⁺ and coined correction factors and recommended comparison studies between the two methods at each center to find out the correction factor [28]. Other studies using arterial vs venous samples, the researchers found that though the mean bias for Na⁺ (1.3 to 1.7 mmol/L) and K⁺ (0.2 to 0.3 mmol/L) were in acceptable ranges as per CLIA, 95% LOA were unacceptable (Na $^{\scriptscriptstyle +}$ -9.4 to 12.6 mmol/L; K $^{\scriptscriptstyle +}$ -0.58 to 1.24 mmol/L) [26,27,39]. In our study, the samples were arterial vs venous. Similarly, Acikgoz SB et al., compared 118 patients with acute K⁺ elevations and found that the mean difference between the methods was 0.62± 0.43 mmol/L. They concluded that though correlation was strong, agreement was poor and hence, the results were significantly different [35].

In some other studies, potassium results were in agreement while sodium was not. In Turkey, Yilmaz S et al., investigated whether electrolyte levels measured by using ABG and AA were equivalent. In terms of sodium, the results were not equivalent and could not be used interchangeably as the Pearson's correlation coefficient was 0.561 only and the Bland-Altman 95% LOA were very wide (-9.4 to 12.6 mmol/L). However, they suggested urgent and vital decisions could be made by the potassium levels obtained from the ABG, as the Pearson's correlation coefficient was 0.812 and the Bland-Altman 95% LOA were acceptable (-0.58 to 1.24 mmol/L) [24]. Chacko B et al., showed that the mean bias in sodium was -4.07 mmol/L and 95% LOA -8.8 to +0.7 mmol/L, while the mean bias in potassium was -0.3 mmol/L and 95% LOA -0.72 to +0.13 mmol/L. They also found that at low potassium level of <3 mmol/L, the differences were significant. They concluded that differences in the measured sodium levels between the two methods were significantly different similar to the present study findings, while the agreement between whole blood and serum potassium was good, in contrast to the present study [13]. Pant V et al., found that the mean difference of sodium between AA and ABG analyser was 4.3 mmol/L and the LOA were between -4.45 to 13.1. For potassium, the LOA ranged from -1.15 to 1.24 and the mean difference was 0.04 mmol/L. They concluded that benchtop AA and ABG analysers may be used interchangeably for measurement of potassium but not for sodium [42]. Similar to the present study, Altunok I et al., in a study with 31,060 patients, found that though correlation coefficients between BGA and AA were good, LOA were not acceptable in parameters of sodium, potassium, hemoglobin, hematocrit, and glucose. They cautioned the clinicians on the shortcomings of POC BGA [43]

Johnston HL and Murphy R studied the agreement of potassium between arterial and venous blood in 50 cardiac arrest victims. They found that the mean difference between each pair of arterial and venous potassium measurement was low at 0.106 mmol/L and proposed that the differences may be due to unidentified

haemolysis [34]. Morimatsu H et al., in a comparison study, found significant difference in plasma sodium and chloride levels but not in potassium [16]. Jain A et al., found no significant difference in sodium measurements by ABG and AA for patients with hypernatremia (mean difference 3.8 mmol/L; p=0.3847). The mean differences in patients with borderline hyponatremia (serum sodium 120-135 mmol/l) and hyponatremia (serum sodium <120 mmol/l), were 7.4 mmol/l and 12.8 mmol/l respectively, which were beyond the accepted limits of US CLIA guidelines of 4.0 mmol/L, thus making the ABG sodium measurements unreliable. In patients with hyperkalemia, normokalemia, and hypokalemia the mean differences were 0.44 mmol/L (SD 0.05), 0.46 mmol/L (SD 0.03), and 0.42 mmol/L (SD 0.02), respectively, all of which were less than the limits laid by US CLIA of 0.5 mmol/L. So, they concluded that there were no significant differences between the K⁺ measured by the AA and the BGA [8].

There were also studies suggesting that there was no significant difference between ABG and AA measured electrolytes. Zhang JB et al., observed that the ABG potassium, sodium, and Haemoglobin (Hb) values were reliable as the statistical difference and biases between ABG and AA potassium, sodium, and haemoglobin did not exceed US CLIA limits. They also recommended monitoring and adjustment in management once the laboratory results became available [31]. Uysal E et al., studied 1094 adult patients in ED and demonstrated strong correlation for K⁺ and Na⁺ (0.823 and 0.854, respectively) along with Hb, haematocrit and glucose. They concluded that sodium and potassium results from BGA were reliable and recommended for critical decision making but with validation by AA results [44]. Mirzazadeh M et al., also found strong positive linear correlation coefficient between laboratory and blood gas results for sodium (0.92) and potassium (0.84) in 11000 paired samples [45]. Jose RJ and Preller J in a retrospective arterio-arterial study, found the difference between the two methods was 0.03 mmol/L with 95% LOA 0.011 to 0.056 for potassium suggesting acceptance [29]. Story DA et al., on evaluation of electrolytes with albumin levels, showed the bias increases with hypoalbuminemia levels [30]. Zhang JB et al., in a prospective study, comparing arteriovenous paired samples, found the mean difference for sodium and 95% LOA were within the acceptable range for the US CLIA. The average bias for potassium was 0.43 mmol/L with 95% LOA within the acceptable range for US CLIA [31]. In studies, the mean bias for sodium was 4.9 to 2.1 mmol/L with 95% LOA -0.97 to +10.05 mmol/L [16,37]. In a previous study, the authors compared paired venous samples by BGA and CLA and found that sodium and potassium measurements were reliable and could be utilized [36].

The BGA (arterial) and CLA (venous) sodium and potassium values cannot be used interchangeably because BGA and CLA use different techniques, BGA work on the principle of direct ISE technology while CLA in the central laboratory works on the principle of indirect ISE technology and need predilution of the sample. Different samples are used for both as whole blood is used in BGA while CLA analyzes serum. In this study arterial blood and venous samples collected at different timings (within 15 minutes) were studied. Liquid heparin is used as anticoagulant in BGA sampling syringes, which dilutes the whole blood and hence, non standardization of sampling might lower the levels of measured electrolyte estimation in BGA testing [46].

Limitation(s)

Protein levels were not measured in AA so possible preanalytical bias could not be avoided. Liquid heparin was used as anticoagulant with inherent dilution and change in electrolyte estimation. The aetiologies of electrolyte abnormalities were not considered in the study and

sampling errors were not evaluated. Underlying diseases or comorbidities were not considered in the sample selection. Different studies compared different instruments so that extrapolation is to be done with caution.

CONCLUSION(S)

The present study shows that the results of arterial sodium and potassium measurement by ABG analyzer were not reliable compared to venous CLA because of wide LOA. So, emergent clinical decisions in the ED might not be made by sodium and potassium levels obtained from the BGA alone and physician can wait for the venous serum results by CLA. Further studies are recommended in this field.

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