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Comparison of Point of Care Versus Laboratory Autoanalyzer Measurements of Sodium and Potassium Levels in Patients Admitted from the Emergency Department

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Abstract

Electrolyte problems are one of the most common cause of morbidity and mortality in the sick patients coming to the Emergency. Electrolytes measured in central lab usually takes 30-60 minutes or more whereas point of care device can give results within 5 to 10 minutes, however different instruments available and their values varies accordingly. Therefore, this study was done to investigate whether electrolyte i.e. sodium and potassium levels assessed using point of care device and auto analysers were equivalent.

Methods: We prospectively studied patients admitted from Emergency Department between January 2021 to October 2021. We had taken 60 paired convenience samples and analysed sodium and potassium levels in point of care device (epoc POC device, Siemens) and in Central Lab Auto Analyser (Siemens Dimension RxL Max Integrated chemistry analyzer or in Johnson & Johnson chemistry analyser model number 51 FS). Statistical method to compare the data included Boxplot view, Regression line, Spearman's correlation coefficient's, paired t-test for potassium and Wilcox test for sodium correlation, Regression equation, Deming regression and Bland Altman plots.

Results: The mean Sodium concentration in point of care device was 130.2 mmol/l and in Auto analyser was 130.5 mmol/l. The mean potassium level in point of care device was 4.013 mmol/l and in Auto analyser was 4.255 mmol/l. The Correlation coefficient obtained for sodium was 0.92 and for potassium was 0.818. Box plot view and regression line showed a good correlation. A difference above the CLIA criteria was noted for 10 pairs in sodium values and 07 pairs for potassium values.

Conclusion: Point of care sodium and potassium values can be used in the Emergency Department for critical decision making.

Keywords: Point of care devices; POC device; point of care Sodium; Potassium.

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Introduction

The most imperative aspect of patients in emergency and critical care settings is their dynamic physiological status with the rapid deterioration that may require early diagnosis and clinical decisions to be made for better patient outcomes. These settings include intensive care units (ICU) including burn, trauma, chest pain, and stroke units, operating rooms (OR), emergency department (ED), pre-hospital transport systems (ambulance).

Electrolyte abnormalities can trigger life-threatening events. In such situations, rapid and accurate assessment of electrolyte abnormalities may enable the institution offocused therapies.

To avoid delay in patient care, rapid assessment of electrolytes has thus been increasingly used in the emergency department (ED) like Arterial blood gas analyzer (point of care testing). Despite the advantage of rapid turnaround time with the point of care testing (POCT), that may translate to prompt decision making, concerns have been raised regarding the accuracy and reliability of POCT devices.

Inaccurate sodium results can lead to an inappropriate fluid administration which can result in hypernatremia. One of the reversible causes of cardiac arrest is abnormalities in potassium concentrations. Bradycardia and asystole can be caused by hyperkalemia and cardiac arrhythmias can be caused by hypokalaemia.

Two methods of electrolyte assay, one direct and one indirect, both employing ion sensing electrodes (ISEs), are currently in use in most hospitals.[2] The indirect assay features pre analytic dilution and is often employed in high throughput central hospital laboratories running automated analyzers (AAs). In the direct ISE method, the electrodesurface contacts a complete undiluted blood sample; this approach is employed by arterial blood gas analyzers (ABGs) or point of care testing (POCT) equipment.[2]

Indirect ISE devices use diluted plasma (or serum) samples; the results are generally comparable to those afforded by flame photometry (the recognized reference method).[3]

Sodium and potassium levels measured in whole blood and plasma have been shown to be essentially identical.

If an analysis is performed in the Emergency several processing steps can be eliminated, results are obtained rapidly, patient management is timely, and outcomes improve. This study will thus, have undertaken to assess the correlation between whole blood electrolytes measured by a point of care device and serum electrolytes measured at a central laboratory (whole blood is used at POCT and serum sample at the central laboratory).[4]

The present study was planned with the objective of whether we can rely on the sodium and potassium levels assessed by the point of care device. It is important to determine the concordance of sodium and potassium values obtained by the point of care device andautoanalyzer for each hospital as analyzer type and calibration methods may vary among different laboratories.[5]

Materials and Methods

We had conducted a prospective convenience observational study at the Emergency Department of AMRI hospital, Bhubaneswar. Which is a 400 beddedtertiary care hospital located inBhubaneswar, Odisha.

We had taken a convenience sample of sixty patients and studied patients who had been hospitalized through the Emergency and required blood gas and Electrolytes measurements. Patients were selected by the senior most emergency physician available on duty.

The ABG/VBG samples were estimated in the Emergency immediately after collection from a non-heparinized 2 cc syringe using a 22 gauge needle and were analyzed in epoc blood gas analyzer which is a cartridge based point of care device whichcalibres itself automatically prior to the introduction of sample and gives reports in approximately 30 seconds after sample introduction. The peripheral venous samples were collected simultaneously and analyzed in the central laboratory either in Siemens

Dimension RxL Max Integrated chemistry analyzer or in Johnson & Johnson chemistry analyzer model number 51 FS using the indirect ISE method.

All blood samples were taken by senior nursing staff in the ED. The venous blood samples were sent within 30 minutes of the collection in the central laboratory through the pneumatic chute system for serum electrolytes estimation. The results of serum electrolytes were transferred to a patient file through computer and then we had entered these results in our data collection form.

We included only adult patients (both sexes), 18years or older who required a VBG/ABG and venous samples for clinical management purposes for admission from the ED during a period of study.

We Aim to analyzethefollowing aspects in this study

- Distribution of serum and point of care (POC) electrolytes variables
- Correlation of serum and POC electrolytes
- t-test of serum and POC electrolytes
- Any misclassification of electrolyte categories by POC vis a serum test
- Deming Regression, Normal regression, Regression equation of serum from POC test

- Bland Altman test, graphs, n stats of the two methods.

All samples are independent in our article with no repeated measures for any patients.

Results

We collected 60 convenience paired samples from critically ill patients who presented in the ED and requiring ABG/VBG sampling and electrolytes measurements. The mean age was 55.3 years. There were 37 males and 23 female patients in the study. The mean level of sodium in ABG analyzer and central lab sodium were 130.2mmol/L and 130.5mmol/L respectively. A difference above the CLIA criteria was noted for 10 pairs in point of care sodium value[10,14] variation of +/- 4 mmol/L.

A strong correlation has been shown by boxplot view (fig. 3.1) and by regression line for serum and point of care sodium. For comparison of distribution, we had used skewness which showed sodium values are relatively skewed (Tab 3.1). We used the Wilcoxon signed-rank test which showed P-value equals to 0.4114. This suggests that there is no statistically significant difference between serum sodium and point of care sodium.

The correlation coefficient (r2 value) for sodium is 0.9214 and adjusted r2 value is 0.92 which showed a positive correlation between central lab sodium and point of care sodium values. However, the Bland-Altman plot (fig. 3.8 & fig. 3.7) showed the limit of the agreement were minus 5.93 to 6.66 mmol/L though mean bias is less than 0.36, the 95% CI crossed allowed limit of +/- 4.

The mean level of potassium in point of care analyzer and central lab was 4.013mmol/L and 4.255mmol/L respectively. There were 07 samples in the study which has crossed the acceptable variation of up to 0.5 mmol/L as per CLIA recommendation for potassium.[10,14]

The boxplot view showed that serum potassium (fig. 3.3) values are slightly higher the POC potassium. The regression line showed a good correlation between serum and POC potassium. Skewness showed a value closed to zero implies symmetrical distribution between serum and point of care potassium.

The correlation coefficient (the r2 value for potassium) is calculated as 0.822 and adjusted r2 value as 0.818 which also showed a good correlation between two potassium values.Lastly, the Bland-Altman plot for potassium [fig 3.8] showed a mean bias of 0.24mmol/L, the 95%

CI crossed allowed limit of +- 0.5mmol/L.

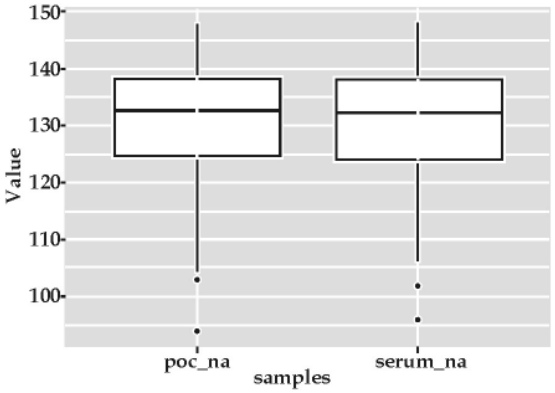

Fig 3.1: Boxplot view of Sodium.

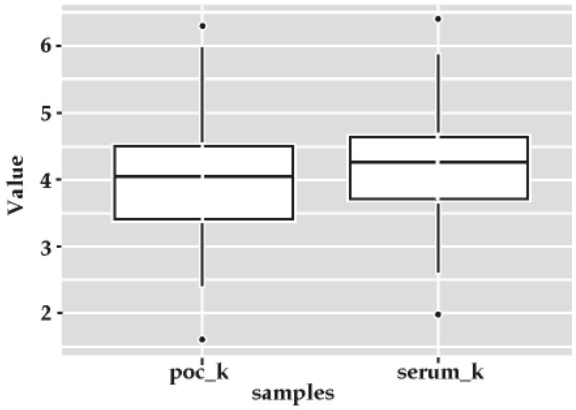

Fig 3.2: Boxplot view of potassium.

We can see serum potassium is slightly higher than POC potassium.

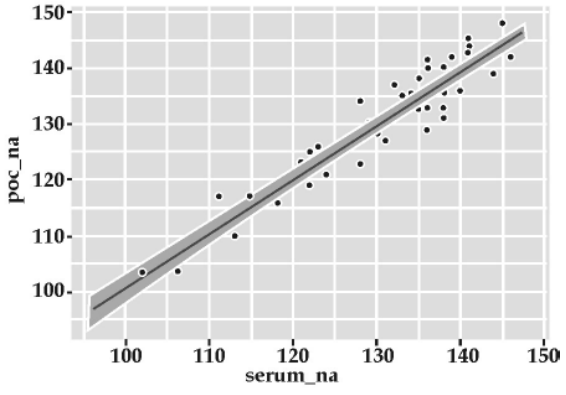

Fig. 3.3: Scatterplot with regression line for sodium.

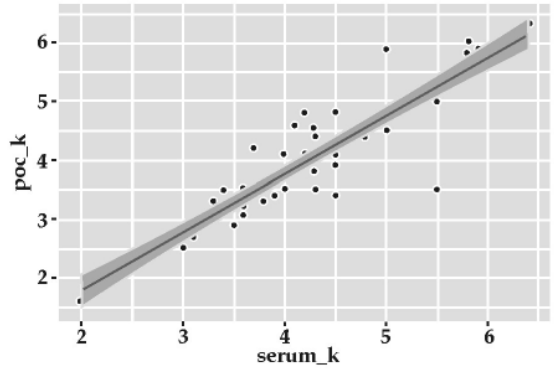

Fig. 3.4: Scatterplot with regression line for potassium.

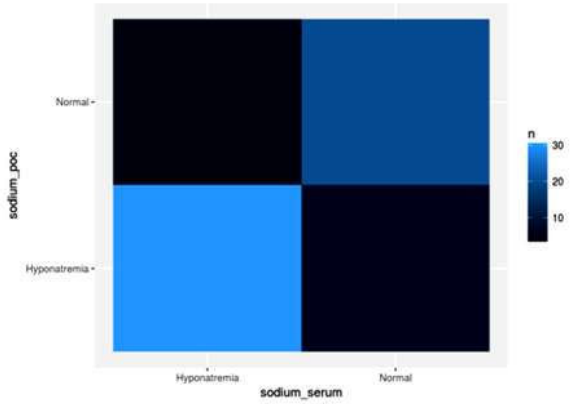

Fig 3.5: Heat maps of Serum Sodium.

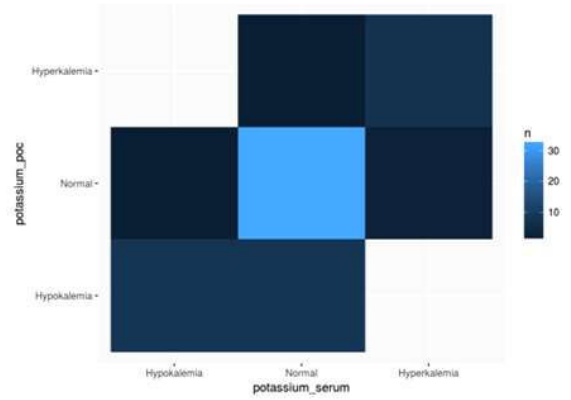

Fig. 3.6: Heat maps of potassium.

Table 3.1: First test of skewness. Sodium data is relatively Skewed.

Serum Sodium	-0.925739
POC Sodium	-0.9389183
Serum Potassium	0.1768452
POC Potassium	0.3294308

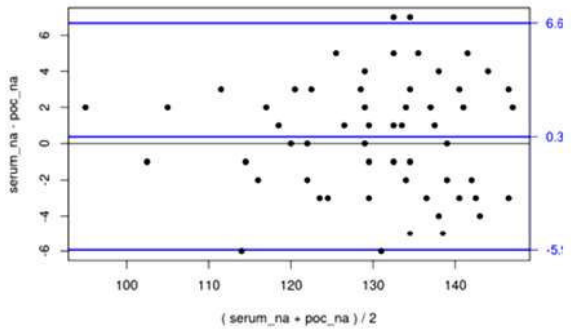

Fig. 3.7: Bland Altman Plot and statistics for sodium.

Limits of agreement

## serum_Na - poc_Na	2.5% limit	97.5% limit	SD(diff)
## 0.3666667	-5.9360545	6.6693878	3.1513606

Thus, for sodium, Serum sodium is higher than POC test by 0.36 and 95% C.I is likely to be between - 5.93 to 6.66, It should be kept in mind that limit of allowable bias for sodium is 4 meq/L.

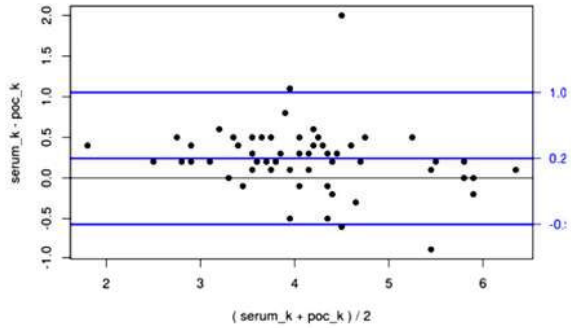

Fig. 3.8: Bland Altman Plot and statistics for potassium.

Limits of agreement.

## serum_k - poc_k	2.5% limit	97.5% limit	SD(diff)
## 0.2416667	-0.5703546	1.0536879	0.4060106

Thus, for potassium, Serum potassium is higher than POC test by 0.24 and 95% C.I is likely to be between - 0.57 to 1.0, It should be kept in mind that limit of allowable bias for sodium is 0.5 meq/L.

Discussion:

In our study mean differences of sodium and potassium values was -0.3 mmol/L and -0.242 mmol/L respectively which showed insignificant differences between the point of care sodium and potassium values as compared with central lab values. According to the US

Clinical Laboratory Improvement Amendment (USCLIA), sodium and potassium biases should be

within +-4mmol/L and +- 0.5 mmol/L respectively are acceptable. [8, 12] In our study, a difference above the CLIA criteria was noted for 10 pairs in sodium and 07 pairs in potassium. Wilcoxon and paired t-test also showed a good correlation between the sodium and potassium values between the point of care device and central lab autoanalyzer. Both values had shown a good correlation coefficient. Our study showed serum potassium is slightly higher than the point of care potassium which is shown bythe boxplot view most likely because of the release of potassium from platelets during clotting which can increase its levels in serum9the point of care measured potassium on average was 0.24mmol/L lower than the central lab and this was within the USCLIA cut off +- 0.5mmol/l, the 95% limits of agreement were -0.57 to 1.0.

There are many studies done for the estimation of sodium and potassium between the point of care device and autoanalyzer from different hospitals. Most of the studies showed serum electrolytes are more reliable.Studies like Chhapola V and by Shalini G suggested to avoid use of point of care device for electrolytes measurements in clinical practice and should be interpreted cautiously. Both the studies showed statistically significant bias between sodium and potassium values, most probably because they used heparin flushed sampling in point of care devices which could lead to the dilution of the sample volume and can lead to underestimation of sodium and potassium in point of care devices.

Critical decisions can be made for clinical decision-making in trusting the values obtained from point of care device and can be used to guide clinical care before the laboratory reports become available. In our hospital, the average time needed to obtain central lab electrolyte value is about 1-2 hours and some small setup hospitals in India it could be extended to 3-4 hours which can impair the clinician to make some critical decisions.

Conclusion

Point of care device sodium and potassium levels can be taken as a reference in Emergency department for critical decision making. This kind of comparative study should be done in several hospitals because there are different instrument types available and it may differ among hospitals. Therefore, it would be useful to carefully evaluate the clinical significance of any differences between the values obtained by point of care devices versus the central laboratory. There should be regular audit to ensure that mean difference of sodium and potassium values between the two machines do not vary over the course of time. Serum electrolytes should be crossed checked once it's available and treatment should be adjusted if required. We also need to keep in our mind that point of care testing is generally costlier than traditional laboratory-based testing.

Finally, we would like to emphasize that the results that we have obtained are specific to Machines which we used in our study and cannot imply to other machines.

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