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Comparative study of Serum Electrolytes Analyzed on Electrolyte Analyzer and Auto Analyzer in an Emergency Laboratory of Postgraduate Institute of Medical Sciences located in North India

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Abstract

Our aim is to determine whether the serum electrolytes (Sodium and Potassium) measured by two different methods on two different equipments are equivalent or not. This retrospective study was conducted over three months period (June 2017-August 2017). A total number of 300 patients from intensive care unit or in the different wards with a variety of diagnoses were enrolled in this study. Analysis of sodium and potassium levels in their serum was carried out using an electrolyte analyzer and an auto-analyzer. Statistical measures were applied using students paired t-tests. The Mean level (± standard deviation) of sodium measured by electrolyte analyzer was statistically significantly higher than the auto-analyzer values (139.99 ± 7.48 mmol/l and 137.15 ± 7.66 mmol/l respectively; P<0.0001). Regarding the potassium levels, the Mean level (± standard deviation) measured by electrolyte analyzer was statistically significantly greater than that of potassium measured by auto-analyzer (4.290 ± 0.743 mmol/l and 4.147 ± 0.738 mmol/l respectively; p<0.0001). Our results showed that serum electrolytes levels measured by electrolyte analyzer were higher than those measured by auto-analyzer. Differences obtained were statistically significant.

Keywords: Sodium; Potassium; Auto-analyser

Introduction

The importance of accurate measurement of electrolytes like Na^+, K^+, Ca^{++}, etc can never be overemphasized in terms of their critical role in clinical practice. So, measurement of the electrolytes in serum is one of the most frequently performed tests in any clinical setting. Electrolyte abnormalities can represent significant risks to life [1]. Two methods of electrolyte assay, one direct and one indirect, both employing ion-sensing electrodes (ISEs), are currently in use in most hospitals [2]. These two methods can also be used in critical care units. The indirect assay features pre-analytic dilution and is often employed in high-throughput central hospital laboratories running automated analyzers [2]. In the direct ISE method, the electrode surface contacts a complete undiluted blood sample; this approach is employed by Electrolyte Analyzer [2]. Indirect ISE devices use diluted plasma (or serum) samples [3]. Studies have reported difference of results between direct and indirect ISE. However in case of indirect ISE one study [4] performed the tests and found out that there was a marked difference in the direct ISE results and indirect ISE results.

Our hospital was equipped with the Eschweiler Combiline electrolyte analyzer and Roche Cobas C Autoanalyser. Combiline electrolyte analyzer works on direct ISE method where as Cobas auto analyzer works on indirect ISE method which involves predillution of specimen. Previous studies shown that even when identical analyzers, identical methods and the same study population was used Point-of-care testing i.e electrolyte analyzer yields different results [5]. Other authors also have suggested that the bias relates to the fact that the POC and laboratory tests involve two different machines, which necessitate the use of different methods and sample types [2,6]. In the present study we explored whether sodium and potassium ion concentrations measured with an Electrolyte analyzer and auto analyzer were equivalent or not.

Materials and Methods

In this retrospective study, 300 patients from intensive care unit or in the different wards with a variety of diagnoses hospitalized in the duration of 3 months (June 2017-August 2017) were enrolled in this study. Standard ethical principles were followed: The study in no way interfered with case management of the subjects who agreed or refused to participate in the study. The sample size was calculated with the formula in the medical statistics textbook as follows.

$N= [(\mu\alpha+\mu\beta)\sigma/ç]2$

Blood samples (4 ml) received from different wards and ICU's were already collected in plain tubes. After clot formation samples were centrifuged at 3,000 RPM for 5 minutes. After serum separation, serum was collected in sample cups and finally run in Cobas Auto analyzer for Serum electrolyte determination. Rest of the serum left in plain tubes was utilized for serum electrolyte measurement by Combiline electrolyte analyzer. According to the hospital policy, daily internal quality control was done for both analyzers to perform accurate testing.

Statistical Analysis

The simultaneously measured Serum Sodium and Serum Potassium concentrations obtained by electrolyte analyzer and auto analyzer were compared using student's paired t-tests. P value of <0.0001 was taken as statistically significant.

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Results

The mean and SD of Serum electrolytes of 300 patients is represented in Table 1.

Analyte (mmol/l)	Electrolyte Analyzer	Auto analyzer	P value
	Mean ± SD (n=300)	Mean ± SD (n=300)	
Sodium	139.99 ± 7.48	137.15 ± 7.66	<0.0001***
Potassium	4.290 ± 0.743	4.147 ± 0.738	<0.0001***

Table 1: Mean ± SD of electrolytes in electrolyte analyzer and ABG analyser. *** Statistically significant.

The above table shows that Mean and SD of Sodium measured by electrolyte analyzer was 139.99 ± 7.48 mmol/l and Potassium was 4.290 ± 0.743 mmol/l which was slightly greater than the Mean and SD of Sodium and Potassium measured by Autoanalyzer i.e 137.15 ± 7.66 mmol/l and 4.147 ± 0.738 mmol/l respectively. The difference obtained was statistically significant ($p<0.0001$).

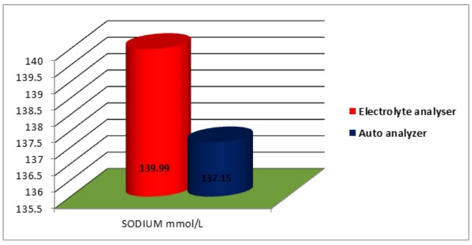

Figure 1: Graphical representation of sodium measurement by electrolyte analyzer and auto analyzer.

Figure 1 shows the comparison of Na values between Electrolyte analyser and Autoanalyser which depicts that Na values measured by electrolyte analyser are extremely significantly higher than Na values measured by Auto analyser.

Figure 2 shows the comparison of K values between electrolyte analyser and autoanalyser which depicts that K values measured by electrolyte analyser are extremely significantly higher than K values measured by auto analyser.

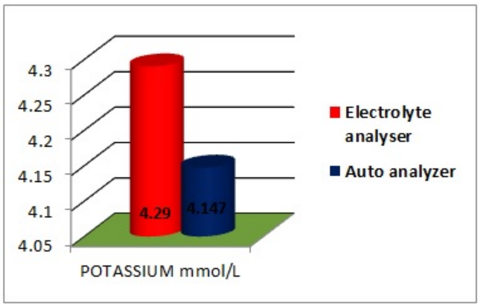

Figure 2: Graphical representation of potassium measurement by electrolyte analyzer and auto analyser.

Discussion

In the present study we investigated whether Sodium and Potassium levels measured using different methods and equipment, namely an electrolyte analyzer and an auto analyzer, were equivalent or not. If so, the electrolyte analyzer results could be employed interchangeably in routine practice. Estimation of serum electrolytes by Combiline electrolyte analyzer was speedier and with less amount of serum sample when compared to COBAS auto analyzer which requires more serum sample and may take much time [7]. To ensure the accuracy of test results, our emergency laboratory (employing an Auto analyzer) participates in an external quality assessment (EQAS) program; both electrolytes were assayed with reasonable accuracy during the study period. Calibrators used for Quality control testing were provided by Eschweiler Combiline system for electrolyte analyser while ISE Standards (Low and High) provided by Roche Diagnostics for auto analyser. However, the accuracy of Electrolyte analyzer was also evaluated via EQAS program; This is an important feature of the present study. One of the limitations of this study was also that there were many factors of biases like all age groups were included in this study which caused measurement errors which are also taken into account.

Accurate and immediate results at or near the site of patient care without spending much time is helpful for physicians working in emergency medicine or areas of critical care. This is primarily needed to act in a life-threatening crisis or to provide counsel in the ongoing management of a chronic disease [8]. According to the instruction manual of the COMBILINE electrolyte analyzer, 4 variables in a serum sample can be measured within 35 seconds. By contrast, to measure serum electrolyte levels using COBAS auto analyzer, time is lost in accumulation of many samples for batch analysis and waiting for the auto analyzer results

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 [9]. In our present study; the mean difference between the two sodium measurements was 2.84 mmol/l; this was under the acceptable value of 4 mmol/l .The mean between-assay difference in K^+ levels was 0.14 mmol/l. Thereby the mean difference between the results of the two Potassium measurements was within the range given by the US CLIA1988 guidelines [9],

In research on the comparison of laboratory electrolyte and blood gas electrolyte results, 200 samples were compared, and no statistically significant difference was found between blood gas K^+ values and laboratory K^+ values. On the other hand, there was a significant difference between Na^+ values. It was concluded that critical treatments could be carried out based on arterial blood gas K^+ results [9]. In our study we have found statistically significant higher values of electrolytes analyzed on electrolyte analyzer when compared to electrolytes analyzed on auto analyzer.

Previous studies have compared Direct ISE i.e. electrolyte analyzer with Indirect ISE i.e. auto analyzer where some studies have shown no similarity between parameters and some showed similarity with potassium but not for other [10] as both principles employed in analysis for electrolyte measurement were different so results in each study differed. But in our study we have observed that there are significant differences in the values in all the ranges. Former studies showed that electrolyte analyzers do not measure electrolytes accurately but in our study we created same environment for both the machines. Strengths of our study are (a) standard practice has been maintained in our study, serum sample was analyzed at the electrolyte analyzer and the same serum sample was analyzed in the auto analyzer in emergency laboratory; (b) The statistical tools that were used in our study to compare the two methods were more appropriate than simple comparisons using the paired t-test.

Conclusion

Our study illustrated that the serum electrolyte values (Sodium and Potassium) obtained by Combiline electrolyte analyzer were statistically significantly higher than the values obtained by Cobas auto analyzer. But they are under acceptable range as mentioned earlier in this study. So, their results can be interchangeably used in clinical practice, which may be more time saving and somehow lifesaving for critically ill patients.

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