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CONCORDANCE OF SERUM ELECTROLYTES ON TWO DIFFERENT LAB EQUIPMENTS –DRY CHEMISTRY VS. ABG AND ITS IMPORTANCE IN PATIENT CARE

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ABSTRACT

Analyzing values of two different machines for the same parameter allocates clinician's discretion for medical decisions and important tool for method validation. Electrolyte samples of 635 patients were measured using ABG and Dry chemistry analyzer. The Mean for Sodium by Dry chemistry analyzer was 134.6 (±7. 59) and by ABG analyzer 134.1 (±7. 57), that of Potassium 3.7 (±0. 7) and 3.5 (±0. 67) and for Chloride 100.4 (±8. 63) and 100 (±8. 79) respectively, showing no difference in Mean. The Bland Altman analysis with the 95 % limit of agreement between methods range from -3.4 to 4.2 (Sodium), -0.3 to 0.7 (Potassium) and -6.2 to 7 (Chloride), providing similar clinically relevant measures. The Deming regression curve showed intercept zero and slope one with (95%CI)3%, 0.5%and 4% CV for sodium, potassium and chloride respectively. Passing and Bablok regression with 95% CI has an intercept zero and slope one showing no systematic and proportional difference. The 95%of random differences are -3.6 to 3.6 (sodium), -0.4 to 0.4 (potassium) and -4.7 to 4.7 (chloride) are small, shows both methods are comparable. The values obtained by two different machines are in concordance and therefore interchangeable, hence can improve the turnaround time.

KEYWORDS: **Serum electrolytes, Bland Altman, ABG Analyzer, Turnaround time, dry chemistry, ISE**

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INTRODUCTION

The balance of the electrolytes in our body is essential for normal function of our cells and our organs. Electrolyte abnormalities can precipitate life-threatening events by derangements in its metabolic process or as a consequence of an underlying disease. Rapid and accurate assessment of electrolyte abnormalities, in emergency conditions is necessary to enable the institution of focused therapies. Electrolytes are usually measured in serum by auto analyzer available in central laboratories. The rapidity of such assessment, particularly in developing countries, is often limited by the delay in transporting samples to the central laboratory, either due to lack of sufficient numbers of human couriers or the absence of rapid transit systems (RTS). This often results in a long turnaround time (TAT) for the measurement of electrolytes in central laboratories[1]. These delays could unfavorably impact outcomes. Point of Care Testing (POCT) is diagnostic testing performed at or near the site of patient Care[2]. The result of the test in action leads to an improved health outcome. POCT has been increasingly used in the emergency department (ED) and the intensive care unit (ICU) to enable the rapid assessment of electrolyte and arterial blood gas (ABG) abnormalities. POCT and main lab machines are used interchangeably depending on the urgency of the report or for cross checking report of one machine or the other or for confirmation of the values when they seemingly do not correlate with the clinical condition of the patient. So, it becomes a very valid issue to have an agreement between the machines to rely on the values generated by each. Clinical Laboratory Improvement Amendment (CLIA) proficiency testing criteria for acceptable analytical performance accepts difference of ±4mmol/L from target value for Sodium, ±0.5 mmol/L from target value for potassium and ±5% from target value for chloride[3].In our present study we have assessed concordance between the values of serum sodium, potassium and chlorides obtained from two different analyzers and verified their interchangeability. Our study had a null hypothesis that there is no significant difference between the electrolytes measured on two machines.

MATERIALS AND METHODS

A Cross sectional study of patients admitted to the critical care units of Nizam's Institute of medical sciences was done. Paired arterial and venous blood samples of 635 patients admitted in critical care units were collected during a study period of one month duration. Heparinized arterial samples were analyzed immediately in an automatic blood gas system ABL basic 800 analyzer. Serum electrolytes were analyzed in department of biochemistry lab by VITROS 350 Dry chemistry auto analyzer. Principle of method employed in analysis of both the machines is Direct Ion Selective Electrode (Direct ISE). Internal quality control samples were run on ABL analyzer using the instruments controls supplied by the machine manufacturer; all the three levels of controls are run daily and are within their range. In VITROS 350 Quality control has been run using routine controls and values are within their target range. Computation and statistics analysis were made using MedCalc statistics software Version 12.3. Bland-Altman assessment for agreement was used to compare the two methods for sodium, potassium and chloride. The Bland-Altman is a graphical method to compare two measurements techniques. In this graphical method the differences (or alternatively the ratios) between the two techniques are plotted against the averages of the two techniques[4]. Limit of agreement was defined as mean bias ± 2SD.Mountain plot was used to compare different distributions in between methods. A mountain plot is created by computing a percentile for each ranked difference between a new method and a reference method. The mountain plot is a useful complementary plot to the Bland & Altman plot. Deming regression was used for taking measurement errors for both methods in to account. Deming regression is an extension of simple linear regression to handle random measurement errors in X as well as Y variables[5]. So Deming regression considers both X and Y to be subject to measurement error, whereas simple regression allows only the Y variable to be measured with error. Passing and Bablok plot was used for calculating regression equation line from the two data sets and to check for systematic difference, proportional difference and linear model validity. Passing and Bablok regression analysis is a statistical procedure that allows valuable estimation of analytical methods agreement and possible systematic bias between them. It is robust, non-parametric and not sensitive to distribution of errors and data outliers[6].

RESULTS

The mean and SD of 635 patients is represented in table1.

Table 1
Mean±SD of Electrolytes in dry chemistry and ABG analyzer

Analyte(mmol/L)	Dry chemistry Mean±SD	ABG analyzer Mean±SD	p Value
Sodium	134.6±7.59	134.1±7.57	0.26
Potassium	3.7±0.7	3.5±0.67	0.09
Chloride	100.4±8.63	100±8.79	0.18

All the three analyses mean and SD were similar between two analyzers and there is no statistical significant difference between two groups.

1 BLAND – ALTMAN ANALYSIS
Bland –Altman plot

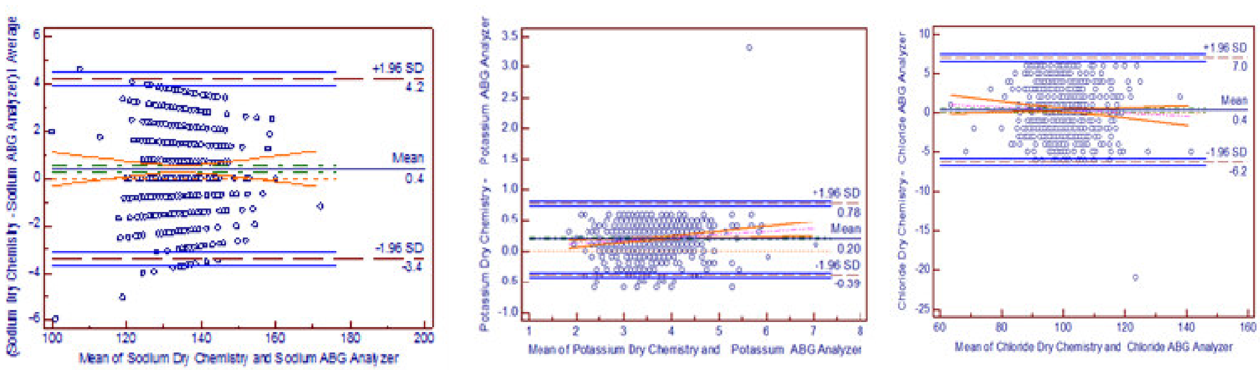

Figure 1
Bland Altman Plot of sodium, potassium and chloride with its LOA

The Bland Altman analysis(Fig 1) with 95% limit of agreement between two methods range from -3.4 to 4.2 for sodium, -0.3 to 0.7 for potassium and -6.2 to 7 for chloride. The two methods consistently provide similar measures which are clinically relevant and within the CLIA total allowable error limits.

2. MOUNTAIN PLOT OF ELECTROLYTES

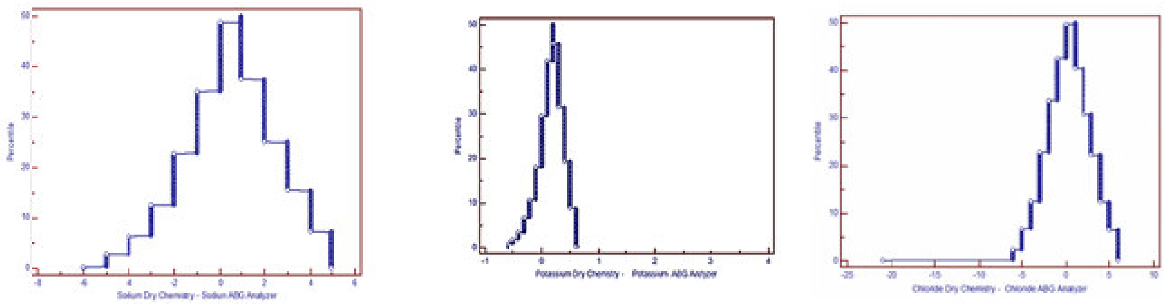

Figure 2
Mountain plot of the electrolytes

The Mountain plot (Fig 2) showed the two assays are unbiased with respect to each other for all the three parameters because zero is in Centre with no long tails.

3. DEMING REGRESSION

The Deming regression curve shows intercept having zero and slope having one with 95%CI with 3% CV for sodium, 0.5% CV for potassium and 4% CV for CHLORIDE

4. Passing and Bablok regression analysis

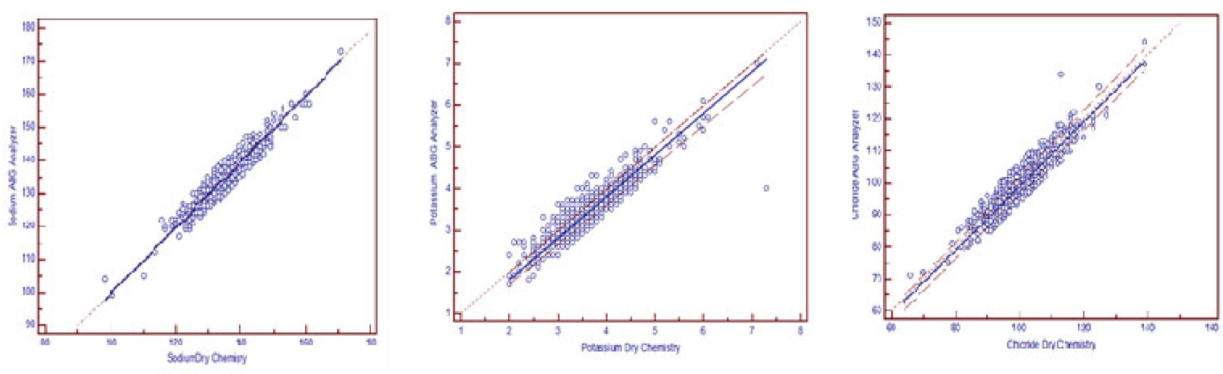

Figure 3
Passing and Bablok regression analysis of three parameters

Passing and bablok regression with 95% CI has intercept of zero showing there is no systematic differences and slope one showing there is no proportional difference (Fig 3). The 95%of random differences is -3.6 to 3.6 for sodium, 0.4 to 0.4 for potassium and -4.7 to 4.7 for chloride which are small showing that both methods are comparable. The Cumulative sum test for linearity shows the p value 0.87 for sodium, 0.5 for potassium and 0.5 for chloride indicting there is no significant deviation from linearity between the methods.

DISCUSSION

Worldwide, one of the fastest growing aspects of clinical laboratory testing is POCT, estimated to be increasing at least 10-12% per year overall and upwards to 30% per year in some testing areas. It is increasingly seen as a complementary or alternate type of testing that meets specific care needs and is an integrated part of clinical laboratory services. POCT should be considered as a part of the continuum of the clinical laboratory's contribution to healthcare and a fundamental responsibility of laboratory services. It needs to be regarded with the same expectations of quality involving the total testing process, covering the pre-, intra-, and post-analytic phases of testing. As healthcare reform changes the perspective from fee for service to the optimization of overall patient care, POCT is a critical factor in streamlining and improving laboratory services. The difference between whole blood and serum electrolyte estimations is described[7] and known for a long time, there are several aspects to this observation which make this study important in the current day critical care milieu. Our study demonstrates that concordance between serum and whole blood electrolytes is uniform across the entire range of values. There is no statistically significant difference between the electrolytes measured on ABG machine and Dry chemistry analyzer. Direct ion-selective electrodes measure the activity of ions in the plasma water, which is directly proportional to their concentration .Point of care analyzers 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 these areas[8-10]. The difference between the two machines is turnaround time to get the results. The blood gas analyzers are unaffected by serum protein levels in their electrolyte measurement is an added advantage of using them in critically ill patients[11-12] for immediate assessment. Previous studies have compared Direct ISE i.e. POCT with Indirect ISE i.e. autoanalyzer where some studies have shown no concordance between parameters and some showed concordance with potassium but not for other[13]as both principles employed in analysis for electrolyte measurement were different so results in each study differed. But in our study we have employed same principle i.e. Direct ISE at both POCT and autoanalyzer in the central lab so there is no significant difference in the values in all the ranges. Previous studies showed that ABG 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, the whole blood sample(arterial sample) was analyzed at the point of care and the serum sample was analyzed in the central 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 illustrates the importance of determining the concordance between electrolyte values obtained by POCT and those obtained in the central laboratory for each individual hospital. The values obtained by Direct ISE method by instrument ABG analyzer and dry chemistry analyzer are in concordance and therefore the two instruments are interchangeable in our institute.

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