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ORIGINAL RESEARCH

Validation of a New Cartridge based ISE Electrolyte Analyzer for Serum Electrolyte measurement: A Comparative Study

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ABSTRACT

Introduction: Elevated morbidity and mortality are linked to electrolyte imbalance (EI), which is prevalent in both hospitalized patients and the general population. According to reports, the frequency of hyponatremia in the emergency department (ED) ranges from 2.3% to 44%, whereas the prevalence of hypernatremia is between 1.4% and 4.4%, hypokalemia is between 10.2 and 39%, hyperkalemia is between 0.8 and 13%, and albumin-corrected hypercalcemia is between 0.7 and 7.5%. Measurement of Serum Electrolytes play a very vital role in diagnostics & treatment of patients. For many years, electrochemical sensors—ISEs in particular—have been widely employed for environmental and clinical investigation. Newer variants of ISEs are coming in market to minimize problems usually encountered in conventional ISEs. These machines have advantages over conventional ISEs. Authors, in this study compared to validate one new Cartridge based Ion Selective Electrode analyzer(Instrument A) with an existing conventional ISE analyzer(Instrument B). **Material & methods:** Thirty Five (35) numbers of Serum samples were selected, Analysis of Electrolytes done in both the instruments i.e. Instrument A &Instrument B. On Second Day Instrument A&B were compared by analysis of fluids with known Control values. **Results:** Linear Regression & Bland Altman plots were made from the results for Serum Sodium & Serum Potassium by the values obtained by Instrument A & B. **Discussion:** Linear Regressions shows positive correlation in both the instruments A & B. Both the Instruments showing Acceptable Values in respect to 2024 CLIA Acceptance Limits for Proficiency Testing by Westgard norms. **Conclusion:** It is concluded that Instrument A is non inferior to Instrument B.

Keywords: ISE, Electrolytes, Cartridge based Analyzer, Non Inferior, Bland Altman, Hypokalemia, Hyponatremia, Hyperkalemia.

INTRODUCTION

Elevated morbidity and mortality are linked to electrolyte imbalance (EI), which is prevalent in both hospitalized patients and the general population. According to reports, the frequency of hyponatremia in the emergency department (ED) ranges from 2.3% to 44%, whereas the prevalence of hypernatremia is between 1.4% and 4.4%, hypokalemia is between 10.2 and 39%, hyperkalemia is between 0.8 and 13%, and albumin-corrected hypercalcemia is between 0.7 and 7.5%.[1]So, Measurement of Serum Electrolytes play a very vital role in diagnostics & treatment of patients.For measuring Serum Electrolytes many methods are used like Flame Photometer, Ion Selective Electrodes based analyzers, Arterial Blood Gas analyzer etc.Among the methods for analysing serum electrolytes, the ISE (Ion Selective Electrodes) based analyzer is the most commonly used & preferred in Clinical Chemistry labs during recent times.For many years, electrochemical sensors—ISEs in particular—have been widely employed for environmental and clinical investigation. Most frequently, ISEs are employed for measurements in carefully monitored lab environments, such mainframe clinical analyzers. [2]With the advances of Science newer variants of ISEs are coming in market to minimize problems usually encountered in conventional ISEs.There comes Cartridge based ISEs. These newer ISEs have certain advances like less sample volume, less analysis time, on board Quality

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Control system. One of the best advantage is no need of double distilled water as these are cartridge based. Here, no need of recurrent consumables like tubings& other liquid consumables. Committed number of testsas cartridge based. So, many Clinical Chemistry labs these days are going toward these cartridge based ISE analyzers.

Authors, in this study compared to validate one new Cartridge based Ion Selective Electrode analyzer*(Instrument A)*with an existing conventional ISE analyzer*(Instrument B)*.

OBJECTIVE

To Compare &Validate a Cartridge based Ion Selective Electrode analyzer with a conventional ISE analyzer.

MATERIAL & METHODS

In order to Validate this Cartridge based Ion Selective Electrode analyzer*(Instrument A)* Authors carried out series of drill on Two separate days.On First day, Thirty Five (35) numbers of Serum samples were selected randomly which came for analysis in Biochemistry Service lab of Agartala Government Medical College& GBPHospital.Samples were taken from patients of Age group 18 years to 60 years. Males were 20 in numbers & Females were 15 in numbers.3 ml of Blood sample was collected in plain Serum / Clot Activator Vacutainer by Venepuncture according to standard protocol. Samples were then sent to the Biochemistry Service Laboratory & centrifuged for 5 minutes at3000 rpm. The supernatant Serum was collected in Aliquot.Lipemic or Haemolysed samples were not used for analysis in this study.Serum was used for analysis of Electrolytes in both the instruments i.e. *Instrument A* &*Instrument B*.All the samples were analyzed on the same day of collection within Two (02) hours of collection.

On the First day,Analysis of Serum Sodium &SerumPotassium was done for these Thirty Five (35) serum samples in both the instruments namely *Instrument A & B*.

On the Second Day *Instrument A*&*B* were compared by analysis of fluids with known Controlvalues i.e.*External Control(Third Party control)*&*Ringer Lactate solution.*

RESULTS

Bland Altman plots were made from the results for Serum Sodium *(Fig: 1)*& Serum Potassium *(Fig: 2)* by the values obtained by *Instrument A & B*.

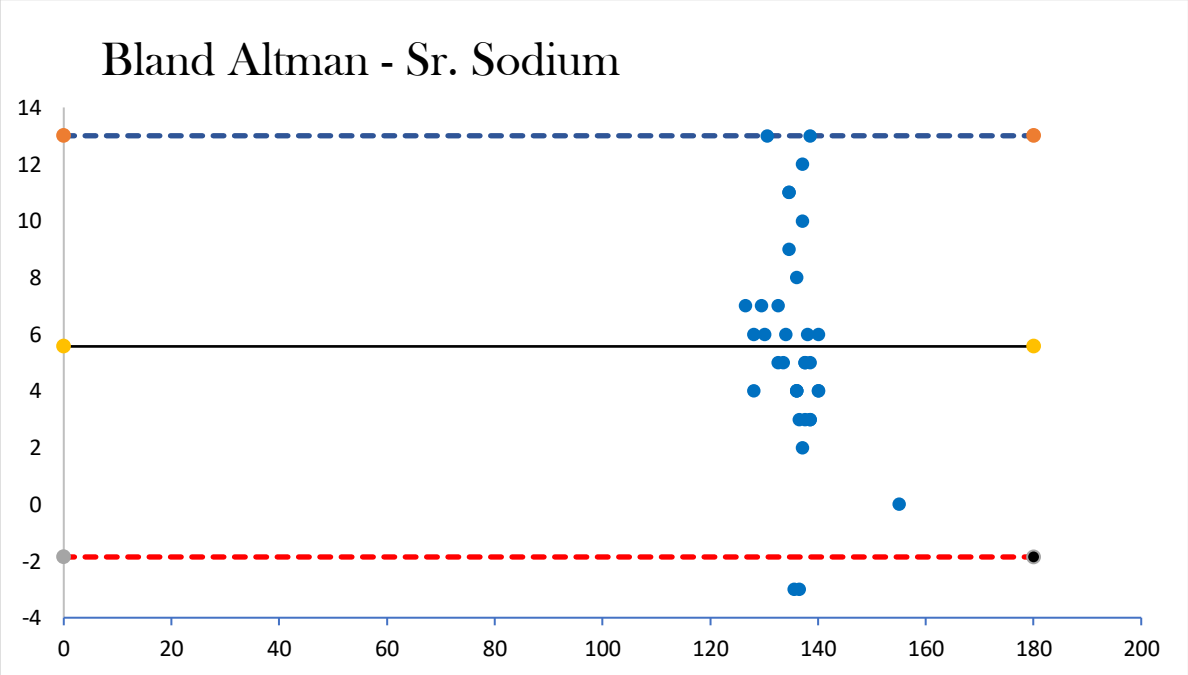

Fig 1: Bland Altman plot - Sr. Sodium

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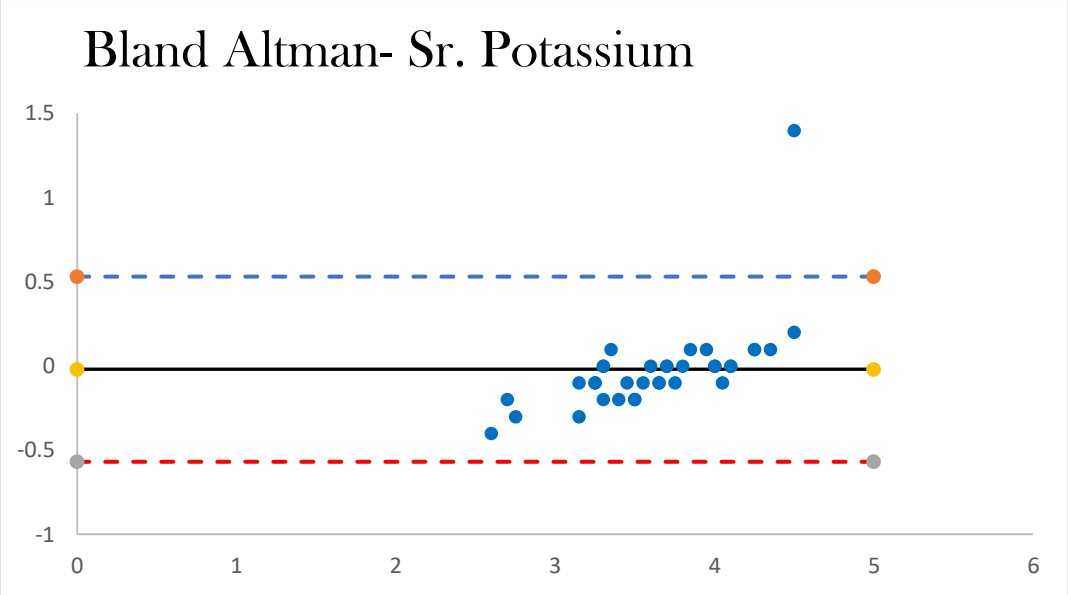

Fig 2: Bland Altman- Sr. Potassium

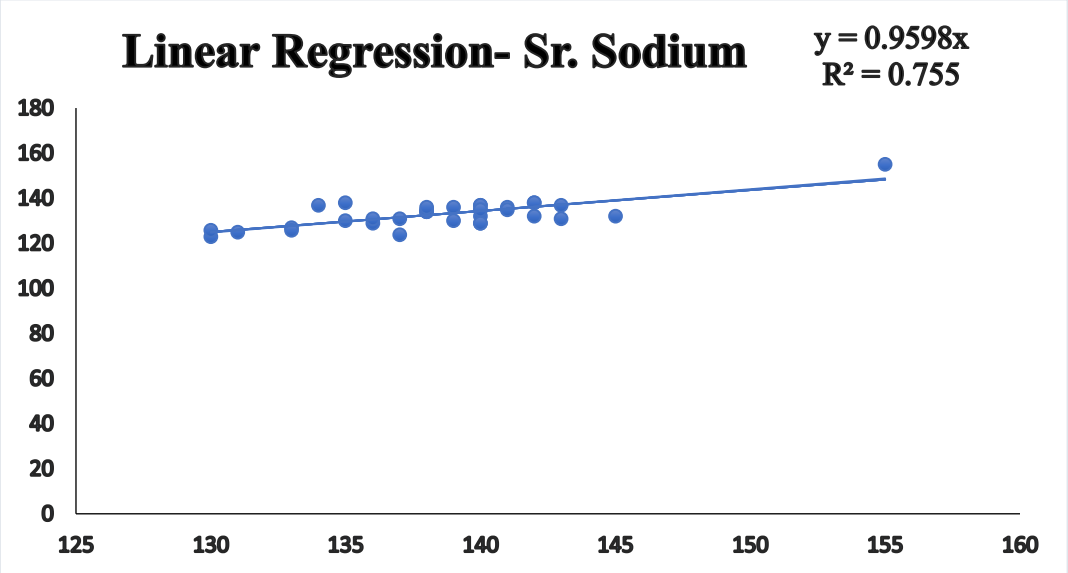

Fig 3: Linear Regression - Sr. Sodium

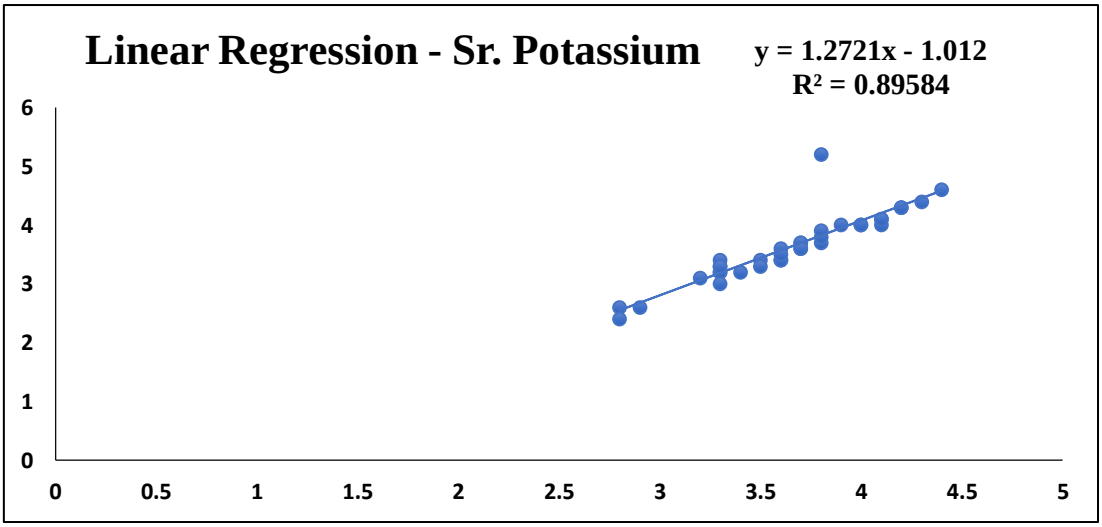

Fig 4: Linear Regression - Sr. Potassium

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Control values were compared for External Control*(Table 1)*& Ringer Lactate*(Table 2)*& evaluated on the basis of 2024 CLIA Acceptance Limits for Proficiency Testing by Westgard norms.

Table 1

Comparison with External Control Level 3					
Parameter	***Instrument A***	***Instrument B***	**Accepted Range**	**2024 CLIA Acceptance Limits for Proficiency Testing by Westgard norms**	**Remarks**
Serum Sodium ($Sr.Na^+$)	117.5	120.6	110-120	TV ± 4 mmol/L	Acceptable
Serum Potassium ($Sr.K^+$)	2.96	2.95	2.4 - 3.0	TV ± 0.3 mmol/L	Acceptable

Table 2

Comparison with External Control Level 3					
Parameter	***Instrument A***	***Instrument B***	**Value mmol/L**	**2024 CLIA Acceptance Limits for Proficiency Testing by Westgard norms**	**Remarks**
Serum Sodium (Sr. Na^+)	131.8	129.4	131	TV ± 4 mmol/L	Acceptable
Serum Potassium (Sr. K^+)	5.09	5.07	5.0	TV ± 0.3 mmol/L	Acceptable

DISCUSSION

Fig 1: Bland Altman plot for Sr. SodiumshowingLow level of Bias with Broad limit of Agreement with Instrument B.

Fig 2: Bland Altman plot for Sr. Potassium showingGood Correlation, No Bias and Narrow limit of Agreement
with Instrument B.

Fig 3: Linear Regression plot for Sr. Sodium showing Positive Correlation.

Fig 4: Linear Regression plot for Sr. Potassium showing Positive Correlation.

On the Second day, Instruments were compared with the External Control & Ringer Lactate solution& the results were evaluated with reference of 2024 CLIA Acceptance Limits for Proficiency Testing by Westgard norms.

Table 1 showing comparison with External Control. Both the Instruments showing Acceptable Values.

Table 2 showing comparison with Ringer Lactate. Both the Instruments showing Acceptable Values.

CONCLUSION

In this study Authors compared these Two Instruments by various means. On the second Day Instruments were comparedon the basis of values obtained by analysis of fluids with known Control values i.e.*External Control(Third Party control)*&*Ringer Lactate solution.*Assessment was done according to 2024 CLIA Acceptance Limits for Proficiency Testing by Westgard norms. Both the Instruments showed results in acceptable range.

So, it is concluded that***Instrument A*** is non inferior to ***Instrument B***.

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