Section: Biochemistry

Original Research Article

COMPARABILITY ASSESSMENT OF SERUM ELECTROLYTES ON DIFFERENT AUTOANALYSERS WORKING ON THE SAME PRINCIPLE

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ABSTRACT

Background: Serum electrolyte analysis is a vital component of clinical diagnostics, providing essential information about a patient's metabolic status and guiding therapeutic decisions. Modern analyzers often utilize direct Ion-Selective Electrode (ISE) technology for rapid and precise measurements of key electrolytes—sodium (Na^+), potassium (K^+), and chloride (Cl^-). However, variations in analyzer performance may impact result comparability, raising concerns about their interchangeability in clinical practice. This study aimed to evaluate the comparability of serum electrolyte measurements between two analyzers operating on the direct ISE principle: the Nova Stat Profile Prime Electrolyte Analyzer and the Vitros XT 7600 Auto Analyzer. The specific objectives were:1. To compare sodium, potassium, and chloride measurements obtained from both analyzers. 2. To determine the extent of agreement between the analyzers for assessing their reliability and interchangeability. **Materials and Methods:** This prospective comparative study analyzed serum samples from 130 patients at the Central Biochemistry Laboratory of ESIC Medical College and Hospital, Faridabad, India. Serum electrolytes (Na^+, K^+, Cl^-) were measured using the Nova and Vitros analyzers. Statistical analyses included descriptive statistics, correlation coefficients, Bland-Altman plots for agreement, and significance testing, with a p-value <0.05 considered statistically significant. **Result:** Sodium and potassium measurements from the two analyzers showed strong agreement, with mean values of 139.43 ± 3.72 mEq/L (Nova) vs. 139.42 ± 3.92 mEq/L (Vitros) for sodium, and 4.41 ± 0.64 mEq/L (Nova) vs. 4.40 ± 0.61 mEq/L (Vitros) for potassium. Correlation coefficients were 0.882 and 0.961, respectively, with narrow Bland-Altman limits of agreement (LoA), indicating high reliability and interchangeability. For chloride, however, significant discrepancies were observed. Mean chloride values were 109.11 ± 3.63 mEq/L (Nova) and 103.34 ± 4.42 mEq/L (Vitros), with a broader LoA of 1.9 to 9.64 (p = 0.0000). This variability underscores the need for caution when interpreting chloride results from these analyzers. **Conclusion:** Sodium and potassium measurements from the Nova and Vitros analyzers demonstrate high consistency, supporting their interchangeability in clinical practice. However, chloride measurements exhibit notable variability, highlighting the importance of standardization and calibration efforts to ensure reliable results. These findings emphasize the need for careful interpretation of chloride levels and further research to address discrepancies, improving the overall quality of patient care.

INTRODUCTION

Serum electrolyte analysis is a cornerstone of clinical diagnostics, providing critical insights into a patient's metabolic status and guiding therapeutic interventions. Electrolytes such as sodium (Na^+), potassium (K^+), and chloride (Cl^-) are essential for maintaining fluid balance, nerve function, and acid-base equilibrium. The accuracy and reliability of serum electrolyte measurements are paramount in

clinical decision-making, particularly in emergency medicine, critical care, and nephrology.[1]

Serum electrolyte assessment is frequently requested for critically ill patients in emergency and intensive care units. These assessments are often obtained on an emergency basis from Point of Care (POC) electrolyte analyzers or processed through laboratory autoanalyzers. Accurate, precise, and quick evaluation of serum electrolytes is crucial not only for providing specific diagnoses but also for guiding therapies aimed at maintaining vital organ function.[2]

Modern laboratories employ automated analyzers to ensure rapid and precise electrolyte analysis. While these analyzers often operate on the same fundamental principle—such as ion-selective electrode (ISE) technology—variations in their calibration protocols, reagent formulations, and technical specifications may influence the results. This raises concerns regarding the comparability of results obtained from different analyzers, even within the same institution or healthcare network.

Assessing the comparability of serum electrolyte measurements across multiple autoanalyzers is critical for ensuring consistency in patient care. Inconsistent results can lead to diagnostic errors, inappropriate therapeutic interventions, and compromised patient safety. Furthermore, as healthcare systems increasingly adopt centralized laboratory services and electronic health records, standardization across platforms becomes essential for seamless data integration and interoperability.

This study aims to evaluate the comparability of serum electrolyte measurements obtained from different autoanalyzers operating on the same principle. By systematically assessing the degree of agreement and potential biases, this investigation seeks to provide insights into the reliability of these instruments and their interchangeability in clinical practice.

Objectives

- To compare the results of serum electrolytes (Sodium, Potassium, Chloride) measured on two different analyzers operating on the same principle of direct Ion Selective Electrode (ISE) technology.
- To determine the extent of agreement between the analyzers to evaluate their reliability and interchangeability in clinical practice.

MATERIALS AND METHODS

Study Design

This prospective comparative study was conducted using serum samples collected from patients at the Central Biochemistry Laboratory of ESIC Medical College and Hospital, Faridabad, India. The study involved 130 patient samples analyzed for serum electrolytes—sodium (Na^+), potassium (K^+), and chloride (Cl^-).

Instrumentation

- Nova Stat Profile Prime Electrolyte Analyzer
- Vitros XT 7600 Auto Analyzer

Both analyzers operate on the principle of direct Ion Selective Electrode (ISE) technology, which is widely used for precise and rapid measurement of electrolyte concentrations.

Sample Collection and Preparation

Serum samples were obtained following routine biochemical testing protocols to ensure sample integrity. Samples were processed as per standard laboratory guidelines to minimize pre-analytical variations.

Statistical Analysis

1. **Descriptive Statistics**
   - The mean and standard deviation (SD) of sodium, potassium, and chloride measurements were calculated for both analyzers to assess central tendency and variability in the data.
2. **Correlation Analysis:**
   - The correlation coefficient (r) was computed to evaluate the strength and direction of the linear relationship between the results from the two analyzers.
3. **Agreement Analysis**
   - **Bland-Altman Plots:** Bland-Altman analysis was performed to visually and quantitatively assess the agreement between the two analyzers. The differences between the paired measurements were plotted against their average. The mean difference (bias) and the 95% limits of agreement (mean ± 1.96 SD) were determined. These limits indicated the range within which most differences between the measurements from the two analyzers would fall.
4. **Statistical Significance Testing:**
   - A p-value of <0.05 was set as the threshold for statistical significance. This indicates that observed differences or correlations were unlikely to have occurred by chance.

Ethical Considerations

The study followed ethical guidelines for laboratory research, ensuring that patient data were anonymized and samples were used solely for the intended research purposes.

RESULTS

The study's approach facilitated a detailed comparison of the analyzers' performance, highlighting potential biases, variability, and the extent of agreement. These findings are crucial for determining the interchangeability of these analyzers in clinical practice.

Table 1: Mean and Standard Deviation of Electrolyte Values Measured by Nova and Vitros Analyzers

Electrolyte	Nova Analyzer (Mean ± SD)	Vitros Analyzer (Mean ± SD)
Sodium (mEq/L)	139.43 ± 3.72	139.42 ± 3.92
Potassium (mEq/L)	4.41 ± 0.64	4.40 ± 0.61

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Chloride (mEq/L)	109.11 ± 3.63	103.34 ± 4.42

Table 2: Correlation Coefficient of Electrolyte Levels Between Nova and Vitros Analyzers

Electrolyte	Correlation Coefficient (r)	p-Value
Sodium (mEq/L)	0.882	<0.05
Potassium (mEq/L)	0.961	<0.05
Chloride (mEq/L)	0.897	<0.05

Table 3: The Limits of Agreement (LoA) from Bland-Altman Plots and p-Value

Parameter	Limits of Agreement (LoA)	p-Value
Sodium	-0.94 to 3.77	0.9554
Potassium	-0.17 to 0.39	0.6207
Chloride	1.9 to 9.64	0.0000

The Bland- Altman plot was used to compare the results of two different assays and to quantify the limit of agreement (LoA) in Fig1,2,3.

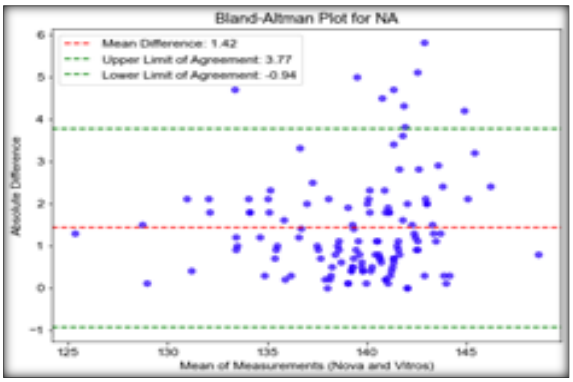

Figure 1: Bland- Altman plot for Sodium ion

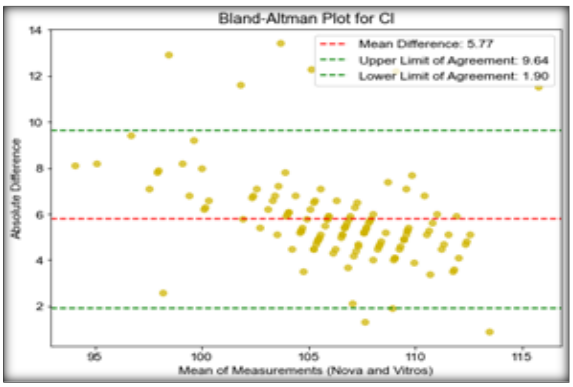

Figure 2: Bland- Altman plot for Chloride ion

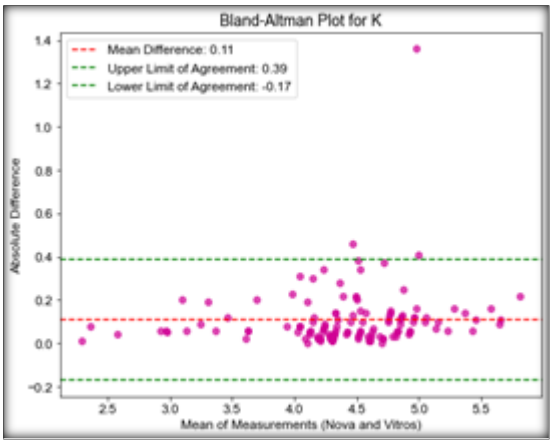

Figure 3: Bland- Altman plot for Potassium ion

DISCUSSION

This study aimed to assess and compare the performance of the Nova and Vitros analyzers in measuring key electrolytes (sodium, potassium, and chloride) in clinical practice. The results, analyzed through statistical tools including mean values, standard deviations, correlation coefficients, and Bland-Altman plots, revealed the performance characteristics of these analyzers. The key findings suggest that sodium and potassium measurements from the Nova and Vitros analyzers are highly consistent, while chloride measurements show significant discrepancies. These results have crucial implications for clinical practice, potential sources of variability, and recommendations for future research.

Sodium Measurement

The sodium levels obtained from the Nova and Vitros analyzers were nearly identical, with a mean value of 139.43 ± 3.72 mEq/L for the Nova analyzer and 139.42 ± 3.92 mEq/L for the Vitros analyzer. The correlation coefficient of 0.882 ($p < 0.05$) indicates a strong positive relationship between the two devices, and the Bland-Altman analysis revealed limits of agreement (LoA) ranging from -0.94 to 3.77, which are clinically acceptable. These findings suggest that the Nova and Vitros analyzers provide comparable sodium measurements, allowing them to be used interchangeably in clinical settings.

In comparison to previous studies, such as Jain A et al,[3] which reported significant discrepancies between sodium values measured by POC Blood Gas Analyzers (BGAs) and laboratory autoanalyzers, our results demonstrate that, in this study, the Nova and Vitros analyzers offer similar and reliable sodium measurements. Jain A et al,[3] and other studies found substantial measurement discrepancies between POC devices and laboratory analyzers, emphasizing the need for caution when using POC sodium values for clinical decisions. However, our study's findings align more closely with Zhang JB et al,[4], who reported that sodium values measured using POC BGAs remained within acceptable bias limits according to US CLIA standards, suggesting that such devices may be used for initial decision-making in critical care environments.

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Potassium Measurement

Potassium measurements were also highly consistent across the Nova and Vitros analyzers, with means of 4.41 ± 0.64 mEq/L for the Nova analyzer and 4.40 ± 0.61 mEq/L for the Vitros analyzer. The correlation coefficient of 0.961 ($p < 0.05$) demonstrates a very strong positive relationship, and the Bland-Altman LoA between -0.17 and 0.39 suggests minimal differences between the two devices. This is consistent with studies such as Sanakal DB et al,[5] which found variability in potassium measurements between different analyzers. Our study, however, demonstrated that the Nova and Vitros analyzers provide highly reliable potassium measurements that can be used interchangeably, unlike the differences observed in other studies.

The findings in this study indicate that both the Nova and Vitros analyzers can be confidently used for potassium measurement in clinical settings, particularly in critical environments such as intensive care units (ICUs) or emergency departments, where potassium imbalances can have significant clinical consequences. The reliability of these analyzers for potassium measurement suggests their utility in initial clinical decision-making, with subsequent confirmation from laboratory analyzers when required.

Chloride Measurement

In contrast to sodium and potassium, chloride measurements showed significant discrepancies between the two analyzers. The Nova analyzer reported a mean chloride value of 109.11 ± 3.63 mEq/L, while the Vitros analyzer measured 103.34 ± 4.42 mEq/L. The correlation coefficient for chloride was 0.897 ($p < 0.05$), indicating a strong positive relationship, but the Bland-Altman LoA was much wider, ranging from 1.9 to 9.64 ($p = 0.0000$). This wide LoA suggests that chloride measurements from the two analyzers may not be interchangeable and should be interpreted with caution.

These findings are consistent with previous studies, including those by Budak YU et al,[6] Gupta S et al,[7] and others, which have reported significant differences in chloride measurements between POC BGAs and laboratory autoanalyzers. Variability in chloride measurements across different analyzers is a known challenge and may be attributed to differences in calibration protocols, reagent formulations, and the methods used for measurement. As chloride plays a critical role in acid-base balance and anion gap calculations, these discrepancies may lead to misinterpretation of patient conditions, particularly in critically ill patients.

Given the wide LoA for chloride measurements, clinicians should be cautious when interpreting chloride results obtained from the Nova and Vitros analyzers. In cases where abnormal chloride values are observed, confirmation through laboratory autoanalyzers or additional diagnostic methods is recommended to ensure accurate clinical decision-making.

Implications for Clinical Practice

- **Sodium and Potassium**: The high degree of agreement between the Nova and Vitros analyzers for sodium and potassium measurements indicates that these devices can be considered interchangeable in clinical practice. Both analyzers provide reliable and consistent results, making them suitable for use in diverse healthcare settings, including emergency departments and intensive care units. In these environments, where rapid and accurate electrolyte assessments are critical, clinicians can rely on either analyzer for initial decision-making, with subsequent confirmation from laboratory autoanalyzers if necessary.
- **Chloride**: The observed bias and broader LoA for chloride measurements present challenges in using these analyzers interchangeably. Discrepancies in chloride values could result in errors in the interpretation of acid-base balance or anion gap calculations, which are crucial for diagnosing and managing critical conditions. To mitigate these risks, standardization efforts or calibration adjustments are necessary to harmonize chloride measurements across analyzers. Ensuring consistency in chloride measurement will improve diagnostic accuracy and enhance patient care.

Potential Sources of Variability

- **Instrument-Specific Factors**: Differences in calibration protocols, reagent formulations, and technical specifications between the Nova and Vitros analyzers likely contributed to the observed variability, particularly for chloride measurements. These factors can introduce systematic biases or errors that affect the accuracy and comparability of results.
- **Pre-analytical Variations**: Despite adherence to standard protocols, factors such as sample handling, storage conditions, and timing of analysis may have introduced variability. These factors are known to influence the accuracy of electrolyte measurements and could contribute to the observed differences between the analyzers, particularly for chloride.
- **Biological Factors**: Inter-patient biological variability, such as differences in plasma proteins or lipid content, may also affect the performance of electrolyte analyzers. Such variability can lead to differential interference in measurements, particularly for chloride, which may explain the broader LoA observed for this electrolyte.

Recommendations for Future Research

1. **Standardization**: Developing unified calibration protocols and reference standards for direct ion-selective electrode (ISE) analyzers could reduce variability and improve comparability of electrolyte measurements across different devices.

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2. **Methodological Improvements**: Larger, multi-center studies involving diverse patient populations are needed to validate these findings and explore the impact of pre-analytical and analytical variables on the accuracy of electrolyte measurements.
3. **Inter-Analyzer Validation**: Comparative studies incorporating additional analyzers would provide a broader understanding of performance variability and establish benchmarks for instrument reliability in clinical practice.

Chloride Measurement: Focused investigations into the biases observed in chloride measurements are essential to identify the underlying causes of discrepancies and develop corrective measures to enhance the accuracy of chloride testing, ensuring that it is reliable for clinical decision-making

CONCLUSION

This study highlights the importance of understanding the performance characteristics of different analyzers used for electrolyte measurement in clinical practice. Sodium and potassium measurements from the Nova and Vitros analyzers demonstrated high agreement and can be used interchangeably in most clinical settings. However, chloride measurements exhibited significant discrepancies, highlighting the need for caution in their interpretation. Standardization efforts, methodological improvements, and further research into the sources of variability are essential to ensure the reliability and accuracy of electrolyte measurements in clinical practice, ultimately improving patient care.

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