

Interchangeability of the I-STAT Point of Care Analyzer With Central Laboratory Testing in an Emergency Department Setting

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Abstract

Background: The i-STAT point of care blood analyzer is a handheld device used for a variety of laboratory analyses in medical settings. Significant research has been performed to evaluate its validity, but it has not been tested in the emergency department, despite its increasingly popular use in such settings.

Research Question: We evaluated the interchangeability of the i-STAT device and central laboratory testing on four lab tests: sodium, potassium, bicarbonate, and chloride. Testing was performed under emergency department conditions.

Methods: We retrospectively examined medical records at the Maricopa Integrated Health Systems Emergency Department to find 100 instances in which a patient had electrolyte testing performed on both the i-STAT and in the central laboratory within a 60 minute timeframe. These data were examined using variance of means and Bland-Altman graphing for equivalency.

Results: We were unable to show equivalency within a 5% deviation from mean normal value for sodium, potassium, bicarbonate and chloride tests. In addition, all electrolytes tested showed small but significant bias between the i-STAT and the central laboratory. Re-examination of the data excluding all measurements more than 15 minutes apart showed similar findings.

Conclusions: More research is needed, but at this time we cannot show equivalency between the i-STAT device and the central laboratory when used under real-life emergency department conditions.

Introduction

Point of care testing (POCT) blood analyzers such as the i-STAT system manufactured by Abbott Laboratories have become increasingly common in emergency department settings. These devices allow common blood tests to be performed at the bedside instead of in the central hospital laboratory which has the potential to improve efficiency and therefore reduce patient wait times and associated costs. Despite their widespread use in such settings, they have not been extensively tested under real-life conditions. We attempted to establish equivalency between the i-STAT system and the central laboratory on four common blood tests: sodium, potassium, bicarbonate, and chloride under emergency department conditions.

Methods

We performed a retrospective review of all patients who presented to the Maricopa Medical Center Emergency Department between February 2014 and September 2014 and identified all who had sodium, potassium, bicarbonate, and chloride lab values drawn using the i-STAT system. We then identified which patients also had the same labs tested using the central laboratory within 60 minutes of the i-STAT test. 100 such patients were identified, which was our target sample population. The lab values for each test were compared using Bland-Altman equivalency graphs, which plot the difference between the i-STAT and the central lab vs the mean of the two measurements. This is a well accepted method of establishing equivalency between two testing methodologies. Two methods are considered equivalent if the 95% confidence interval of the difference between their results is less than a predetermined clinical equivalency threshold.

We assigned the clinical equivalency threshold for each lab to be 5% of the midpoint of the normal range. For example, the midpoint of the normal range of sodium at our central lab is 141. Thus, we declared two results clinically equivalent if they differed by less than 5% of that value, or less than 7. Therefore, if the difference between the i-STAT value and the central laboratory value is less than 7 for 95% of our patients we can declare the i-STAT to be equivalent to the central lab on this test. The full set of clinical equivalencies is shown in Table 1.

We also repeated our equivalency testing excluding all patients with more than a 15 minute time difference between the i-STAT and central laboratory testing. This reduced our sample size to 70, but reduced the potential for error due to medical intervention during the lag between the two tests.

Test	Normal Range	Midpoint	Equivalency Threshold
Potassium	3.5 – 5.1	4.30	0.215
Sodium	137 – 145	141	7.05
Bicarbonate	22 – 30	26	1.30
Chloride	98 – 107	103	5.15

Table 1: The clinical equivalency thresholds are set at 5% of the midpoint of the normal range for each lab.

Results

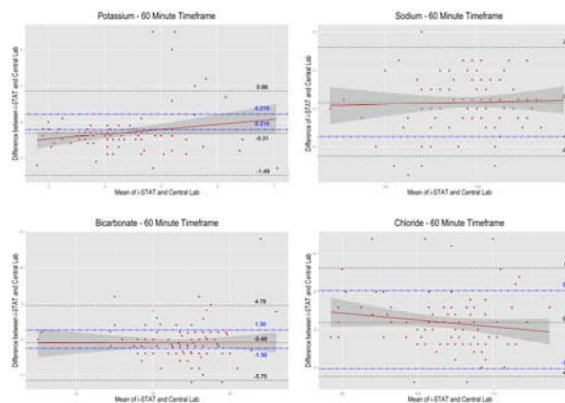


Figure 1: Bland Altman equivalency plots comparing the i-STAT POCT results for Potassium, Sodium, Bicarbonate and Chloride with those from the central laboratory. All labs were drawn within a 60 minute timeframe. These graphs show difference vs mean between the two methodologies. The red line shows correlation surrounded by a shaded area representing its 95% confidence interval. The black lines show mean difference as well as upper and lower 95% confidence intervals. The blue lines show the bounds of clinical significance: two methodologies are clinically equivalent if the 95% confidence interval is contained within the bounds of clinical significance. None of the results meet criteria for equivalence.

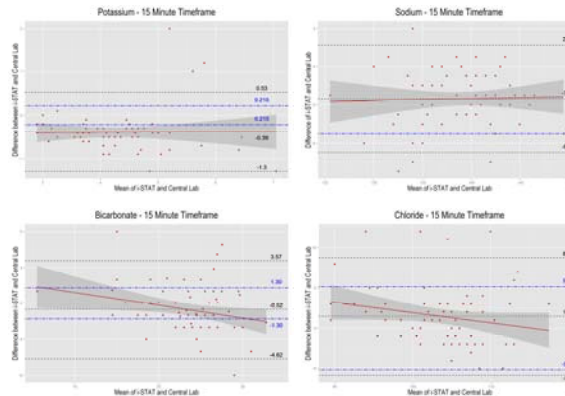


Figure 2: Bland Altman equivalency plots comparing the i-STAT POCT results for Potassium, Sodium, Bicarbonate and Chloride with those from the central laboratory. All labs were drawn within a 15 minute timeframe. These graphs show difference vs mean between the two methodologies. The red line shows correlation surrounded by a shaded area representing its 95% confidence interval. The black lines show mean difference as well as upper and lower 95% confidence intervals. The blue lines show the bounds of clinical significance: two methodologies are clinically equivalent if the 95% confidence interval is contained within the bounds of clinical significance. None of the results meet criteria for equivalence.

Discussion and Conclusions

No laboratory test has a 95% confidence interval which is contained within our previously established threshold of clinical equivalency. Therefore we are unable to claim equivalency between the i-STAT system and the central laboratory on any of four lab tests that we analyzed. In addition, all four tests show small but significant bias between the i-STAT and the central lab. This bias is present across the entire range of lab values, as shown in Figures 1 and 2 by the correlation regression. Given these significant differences between the i-STAT and the central laboratory values, we can not recommend that the i-STAT be used for clinically important decision making at this time.

Further research is needed to corroborate these findings in other emergency departments. It would also be useful to re-examine these data using a categorical interpretation of clinical significance instead of the absolute definition we assigned. Instead of assigning an upper limit on the acceptable difference between the two methodologies, it would be useful to assign bins for the results, (e.g. critically low, low, normal, high, and critically high). The two methods would then be considered equivalent if 95% of their values fell within the same bin. This would more closely represent the most common use of the i-STAT as a screening tool in the emergency department.

Acknowledgements

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