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Accuracy of bedside point of care testing in critical emergency department patients☆

Braden W. McIntosh, MD [a], Jerina Vasek, RN [b], Maria Taylor, RN [a], Deborah Le Blanc, RN [a], Henry C. Thode, PhD [a], Adam J. Singer, MD [a,*]

[a] Department of Emergency Medicine, Stony Brook University, Stony Brook, NY, United States
[b] Department of Clinical Pathology, Stony Brook University, Stony Brook, NY, United States

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ABSTRACT

Background: Point-of-care (POC) testing reduces laboratory turn-around having the potential to improve timely diagnosis and management. We compared the accuracy of nurse performed POC and core laboratory testing and determined whether deviations between the two were clinically meaningful.
Methods: We performed a prospective, observational study on a convenience sample of 50 critical care ED patients in whom a POC chemistry and hematocrit was ordered. Blood samples were divided into 2 aliquots; one sample was tested by the treating nurse using a handheld POC device and the other sample was tested in the core laboratory. Paired comparisons of test results were performed using Pearson's correlation coefficients, Lin concordance coefficients, and Bland Altman plots.
Results: Mean patient age was 67, 50% were male, 82% were admitted. Pearson's correlation and Lin concordance coefficients were excellent (0.84–1.00) for all 8 analytes. Mean (95%CI) paired differences between POC and core laboratory measurements were Na^+ 0.30 (−0.22 to 0.82) mmol/L, K^+ −0.12 (−0.14 to - 0.09) mmol/L, Cl^- 2.10 (1.41 to 2.78) mmol/L, TCO_2–1.68 (−2.06 to −1.30) mmol/L, glucose 2.46 (1.46 to 3.46) mg/dL, BUN, 1.69 (0.95 to 2.42) mg/dL, creatinine 0.13 (0.08 to 0.17) mg/dL, and hematocrit −0.39 (−0.93 to 0.15) %. In 3 of 400 measurements, the difference between POC and core lab exceeded the maximal clinically acceptable deviation based on physician surveys.
Conclusions: Bedside POC by ED nurses is reliable and accurate and does not deviate significantly from core laboratory testing by trained technicians.

1. Introduction

A significant proportion of clinical decisions are made based on the results of laboratory testing [1]. While all analytes are important, acute disturbances in potassium (K^+) levels have the greatest potential to cause patient harm. Thus, use of analytical methods that minimize errors in measuring K^+ levels is of major concern. A large number of rapid point-of-care (POC) tests and devices are now available, which have the potential to significantly reduce test turn around times and emergency department (ED) length of stay [2,3]. However, some health care practitioners may be skeptical about the results of bedside POC testing, and hesitate acting on them without confirmation using core laboratory testing.

Rapid measurement of analytes using whole blood specimens is fast and convenient. However, a major disadvantage of using whole blood samples is the inability to detect hemolysis. A study of 610 blood samples found mild hemolysis in 18%, moderate hemolysis in 3.6%, and severe hemolysis in 0.4% [4]. In this study, Hawkins estimated that the difference in K^+ measurement attributable to hemolysis was >0.5 mmol/L in 8% of the samples. A prior study by the same author estimated a hemolysis rate of 3.4% [5]. As a result, when measuring analytes such as K^+ using whole blood samples, there is a risk of obtaining an artificially elevated K^+ level that can lead to misdiagnosis and inappropriate treatment.

Mechanical forces leading to hemolysis include use of tourniquets, small gauge needles, and fist clenching to name but a few. Other causes of spuriously elevated K^+ levels (pseudohyperkalemia) include excessive numbers of platelets or neoplastic WBCs. These same factors that lead to pseudohyperkalemia may also sometimes mask hypokalemia [6].

The objective of the present study was to determine the reliability of a whole blood based POC device in measuring eight commonly measured analytes in critically ill or injured emergency department patients. We hypothesized that the correlations between POC and core lab results would be excellent and that the bias (the difference between the two measurements) would not be clinically meaningful.

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* Corresponding author at: Department of Emergency Medicine, HSC-L4-080, 8350 SUNY, Stony Brook, NY 11794-8350, United States.
E-mail address: adam.singer@stonybrook.edu (A.J. Singer).

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2. Methods

2.1. Study design

We conducted a prospective, observational, study to test the study hypothesis. Waiver of informed consent was obtained from our Institutional Review Board.

2.2. Patients and setting

The study was conducted at a tertiary care, suburban, academic medical center with an annual ED census of approximately 110,000. Fifty consecutive critically ill or injured adult patients in whom a physician ordered a POC (i-STAT, Abbott Point of Care, Princeton, NJ) limited metabolic panel and hematocrit level (requiring a CHEM8 + cartridge) were enrolled.

2.3. Blood samples and measurements

Venous blood samples were collected from patients using a vacutainer and placed in blood collection glass tubes containing lithium heparin. The blood samples were split into two aliquots, one of which was analyzed by a trained clinical nurse at the bedside using the POC device. The other sample was transported to the core lab for further testing. The remaining aliquot was centrifuged at 3000 $\times g$ for 15 min at 4 °C to harvest plasma. The plasma sample was then analyzed by a trained laboratory technician using core laboratory devices (Roche COBAS 6000 [Roche Diagnostics USA, Indianapolis, IN] and Sysmex XN [Sysmex America, Inc., Licolnshire, IL] for metabolic panel and hemoglobin respectively).

2.4. Physician surveys

A convenience sample of 25 emergency physicians were asked to indicate the maximal clinically acceptable deviation between POC and core laboratory results that would maintain their confidence in the POC results in ED patients for each of the eight analytes (Na+, K+, Cl^-, TCO_2, BUN, creatinine, glucose, and hematocrit).

2.5. Data analysis

Continuous data are summarized as means and 95% confidence intervals (CI). Binary data are summarized as numbers and percentages frequency of occurrence. Regression plots and Pearson's correlation coefficients were used to measure the agreement between paired POC and core laboratory results. The differences (bias) between paired measurements were then determined by Bland-Altman plot analysis [7]. Lin's concordance correlation (p_c) that describes the relationship between paired measurements was also used [8]. Unlike the Pearson correlation, which measures the strength of a linear relationship but may not pass through the origin and have a slope not equal to unity, p_c compares agreement (between two sets of measurements) by assessing the variation from the 45° line through the origin.

The number of test results in which the difference between paired samples was greater than the median minimal clinically acceptable deviation based on physician surveys was also determined.

Assuming a correlation of 0.90 between pairs of measurements and a standard deviation (SD) of 0.6 for each type of measurement (POC or core lab), then the SD of the difference is 0.27. A sample size of 29 patients would be needed to have a confidence interval of the difference of ±0.1 around the point estimate.

3. Results

Samples from 50 ED critical care patients were analyzed. Mean patient age (range) was 67 (24–97) years, 50% were male, 82% were admitted, and of those, 30% went to the intensive care unit (ICU). General categories of patient chief complaints leading to an ED visit included 14 cardiac (chest pain or arrhythmia), 12 neurological (possible stroke or seizure), 11 traumatic (motor vehicle collision or fall), 5 altered mental status, and 5 miscellaneous.

The Pearson's correlation coefficients between paired samples, one measured with the POC device and the other measured with the core laboratory device, ranged from 0.84 to 0.99 (Table 1), and were lowest for Cl^- (0.89) and Na^+ (0.84). Lin concordance coefficients ranged from 0.82 to 0.99 (Table 1), and were lowest for Cl^- (0.82) and Na^+ (0.84).

The mean (range) paired differences between the POC and core laboratory samples were Na^+ 0.30 (−6 to 4) mmol/L, K^+ −0.12 (−0.40 to 0.15) mmol/L, Cl^- 2.10 (−3 to 10) mmol/L, TCO_2 1.68 (−4 to 2) mmol/L, glucose 2.46 (−9 to 9) mg/dL, BUN, 1.69 (−4 to 9) mg/dL, creatinine 0.13 (−0.1 to 0.9) mg/dL, and hematocrit −0.39 (−7.2 to 4.2) % (Table 1). The Bland-Altman plots are presented in Fig. 1.

The mean and median maximal clinically acceptable deviations between POC and core laboratory results that would not impact clinical diagnosis and management based on physician surveys is presented in Table 2. The number of test results in which the difference between POC and core laboratory results exceeded the median clinically acceptable difference were TCO_2 none, Cl^- none, K^+ none, BUN one (27 vs. 18 mg/dL), creatinine one (5.5 vs. 4.6 mg/dL), glucose none, hematocrit one (35 vs. 42%), and Na^+ one (133 vs. 139 mmol/L). Thus, only in 4 out of 400 paired samples did the difference exceed the clinically acceptable deviation. In all four cases, these differences did not alter clinical management.

4. Discussion

In this observational study of 50 critically ill or injured ED patients, there was high to excellent correlation between paired measurements of POC and core laboratory tests for all eight of the tested analytes. Excellent correlations were seen both with the Pearson's and the Lin concordance tests. The bias between the two tests was generally small, with the 95% CIs falling within the maximal clinically acceptable deviations according to the physician surveys. In addition, the differences between the two tests rarely exceeded the maximal clinically acceptable deviation that would be considered to effect clinical diagnosis and management. These findings suggest that rapid beside POC testing using the i-STAT device can be used interchangeably with core laboratory testing. This should give clinicians confidence when making clinical decisions based on POC testing results alone. As always, whenever a laboratory result does not make clinical sense, it should be repeated. This is true for all laboratory tests, regardless of the device or platform used including POC and traditional core laboratory tests.

Table 1
Agreement between point of care and core laboratory results.

	Pearson's correlation coefficient	Mean (95%CI) paired difference	Lin concordance coefficient
TCO_2	0.94	−1.68 −2.06–1.30	0.86
Cl^-	0.89	2.10 1.41–2.78	0.82
K^+	0.999	−0.12 −0.14–0.09	0.97
BUN	0.96	1.69 0.95–2.42	0.94
Creatinine	0.999	0.13 0.08–0.17	0.98
Glucose	0.999	2.46 1.46–3.46	0.999
Hematocrit	0.95	−0.39 −0.93–0.15	0.95
Na^+	0.85	0.30 −0.22–0.82	0.84

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