THE USE OF THE ISTAT PORTABLE ANALYZER IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS

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ABSTRACT. Objective. To evaluate the utility of the iSTAT blood analyzer, a bedside device for hematocrit, sodium, potassium, and glucose measurement during cardiopulmonary bypass (CPB). **Methods.** Forty patients scheduled for elective CPB were evaluated prospectively. In addition to using the iSTAT analyzer, blood samples were analyzed at four time points: following induction of anesthetic, 10 min. after initiation of CPB, 60 min. after initiation of CPB, and following heparin neutralization by protamine. Blood glucose concentration was measured by the hospital laboratory using a Kodak Analyzer and by a glucose meter, electrolytes were evaluated by the Kodak Analyzer and BGE (a device which is commonly used for "satellite laboratory" determinations of electrolyte and blood gas results), and hematocrit samples were measured by the hospital laboratory using an NE 8,000 and a centrifuge. The means and standard deviations of the differences between the methods were calculated. **Results.** The hematocrit values determined by the iSTAT machine, when adjusted for the level of total protein (according to manufacturer's directions), differed from the laboratory values by 0.53 ± 1.46 percentage points. An alternative to measuring total protein and making the adjustment is simply adding 1% to the hematocrit in the pre-CPB period and 3% on-CPB or post-CPB, which we found to yield values that differed from the laboratory by 0.52 ± 1.42 percentage points. For all four tests (hematocrit, sodium, potassium, and glucose) the iSTAT had a similar relationship to the laboratory values as did the other commonly used means (centrifuge, BGE, and glucose meter) of clinical evaluation. **Conclusion.** In summary, we found that in patients undergoing CPB, the iSTAT values agreed sufficiently well with standard laboratory values and that the iSTAT instrument can be relied upon for bedside measurements.

KEY WORDS. Surgery: cardiopulmonary bypass; Analyzers: glucose meter; iSTAT; Laboratory: electrolyte; hematocrit.

INTRODUCTION

The iSTAT machine, a hand-held blood analyzer, has recently been introduced into our clinical practice to circumvent the delay in obtaining results from the hospital laboratory. This device determines hematocrit, serum sodium, potassium, and glucose concentrations within two minutes using a drop of blood. Initiation of CPB causes hemodilution and reduces the circulating levels of total protein. The effect of hemodilution on the accuracy of iSTAT measurements is not known. This study was undertaken to compare the iSTAT values to both standard laboratory values as well as to other commonly used means of measurement before, during, and after CPB.

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METHODS AND MATERIALS

Prior to the investigation, Institutional Review Board approval was obtained. Forty adult patients scheduled for elective CPB were evaluated prospectively. CPB prime consisted of 1700 ml Plasma-Lyte, 250 ml 25% albumin, and 25 gm mannitol. Blood samples were analyzed at four time points: following anesthetic induction, 10 min. after initiation of CPB, 60 min. after initiation of CPB, and following heparin neutralization by protamine. Blood samples were obtained from an arterial catheter. A 10 ml "waste" syringe was first filled and then a single non-heparinized 20 ml syringe was filled for all the evaluations. Simultaneous evaluation of serum glucose was performed using the iSTAT analyzer(iSTAT, Inc., Princeton, New Jersey), standard laboratory method (Kodak Analyzer, Kodak, Inc., Rochester, NY), and glucose meter (Life Scan, Johnson and Johnson, Inc., Milpitas, CA). Serum electrolytes were evaluated by the iSTAT analyzer, standard laboratory method, and BGE machine (Blood Gas, Electrolytes, Instrumentation Laboratory, Inc., Lexington, MA). Hematocrit samples were determined by the iSTAT analyzer, standard laboratory method (NE 8,000, Sysmex, Japan), and centrifuge. For the centrifuge method, two capillary tubes sealed with clay were spun for 5 minutes and the average of the two values obtained from these tubes was used for the study. The iSTAT manufacturer supplies an empirical algorithm for adjusting the iSTAT hematocrit based on the measured level of total protein. Total protein was measured in the laboratory and the iSTAT hematocrit results were adjusted according to this algorithm. An empiric adjustment of +1% pre-CPB, and +3% post-CPB was evaluated as a more convenient method of correction.

The mean difference between the iSTAT, laboratory, and centrifuge results were determined for hematocrit, and are expressed as mean ± SD. Linear regression and correlation were used to compare the hematocrit corrected for measured serum protein with the simple hematocrit correction pre- and post-CPB. The mean difference between the iSTAT, laboratory, and glucose meter results were determined, and are expressed as mean ± SD. The mean difference between the iSTAT, laboratory, and BGE results were determined for sodium and potassium, and are expressed as mean ± SD. Bland-Altman style plots are included to demonstrate the limits of agreement.

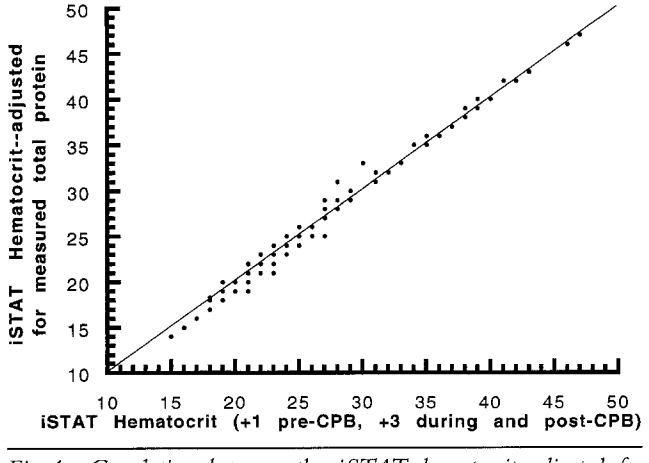

Fig 1. Correlation between the iSTAT hematocrit adjusted for measured total protein (y axis) and the iSTAT hematocrit adding an integer (x axis; +1 pre-CPB, +3 during or post-CPB; $r^2 = 1$).

RESULTS

Patients' ages were 63 ± 11 yr., heights were 66 ± 4 in, and weights were 85 ± 17 kg. The mean duration of CPB was 150 ± 51 min.

The total protein (g/dl) prior to CPB was 6.2 ± 0.5, 10 minutes on CPB was 4.5 ± 0.4, 60 minutes on CPB was 4.3 ± 0.6, and following protamine neutralization was 4.4 ± 0.5.

Hematocrit

Hematocrits measured in the laboratory ranged from 13.5–43.2%. The iSTAT hematocrit values, when adjusted for levels of total protein by the algorithm supplied by the manufacturer, correlated well with the standard laboratory values ($r^2 = 1$) and centrifuged hematocrit ($r^2 = 0.9$). From the first 10 patients, we determined that the iSTAT values were, on average, 1 point lower than laboratory values in the pre-CPB period, and 3 points lower during and post-CPB. We then attempted to determine if simply adding 1 point pre-CPB or 3 points post-CPB would yield results with similar accuracy to the cumbersome method of adjusting for total protein. The correlation between the iSTAT hematocrits adjusted for level of total protein ("hematocrit-adjusting"), and those resulting from simply adding an integer ("hematocrit-adding"; 1 in the pre-CPB period and 3 during and post-CPB) are shown in Figure 1 ($r^2 = 1$). The difference between these two iSTAT hematocrit values was 0.02 ± 0.79%. The differences for all the time periods between the iSTAT, laboratory, and centrifuged values are shown in Table 1. The difference between the iSTAT value for hematocrit and the laboratory value was similar to the difference be-

Table 1. The mean and standard deviation of differences between the various determinations for hematocrit, sodium, potassium, glucose, and glucose levels below 200 mg/dl. For each of the tests, three means of determination were used. Two of these were the laboratory and the iSTAT machine. The additional methods were: centrifuge (hematocrit); BGE (sodium and potassium); and glucose meter (glucose).

	Mean	± SD
Hematocrit (Range 13.5–43.2%)		
iSTAT (adding) - Laboratory	0.52	1.42
iSTAT (adjusting) - Laboratory	0.53	1.46
Centrifuge - Laboratory	0.80	1.21
iSTAT (adding) - Centrifuge	−0.27	1.65
iSTAT (adjusting) - Centrifuge	−0.26	1.82
Sodium (range 126–146 mmol/l)		
iSTAT - Laboratory	1.29	2.15
BGE - Laboratory	−0.99	2.61
iSTAT - BGE	2.28	2.37
Potassium (range 2.9–8.5 mmol/l)		
iSTAT - Laboratory	0.12	0.19
BGE - Laboratory	0.23	0.29
iSTAT - BGE	−0.17	0.20
Glucose (range 82–482 mg/dl)		
iSTAT - Laboratory	30.2	18.9
Glucose meter - Laboratory	14.7	22.9
iSTAT - Glucose meter	15.5	25.6
Glucose (range 82–200 mg/dl)		
iSTAT - Laboratory	18.8	13.7
Glucose meter - Laboratory	10.7	12.9
iSTAT - Glucose meter	8.0	18.6

tween the centrifuged value and the laboratory value. The relationship between the simple correction of iSTAT hematocrit values ("hematocrit-adding") and laboratory values (Fig 2), using the method described by Bland and Altman [1] is shown. These two figures, over the range of laboratory hematocrits, graphically show the iSTAT and centrifuge results relate similarly to the laboratory values. The limits of agreement are −3.36 to +2.33 over the range of hematocrits studied.

Glucose

The range of laboratory values for glucose was 82–482 mg/dl. The mean differences and standard deviations between the iSTAT, laboratory, and glucose meter values are shown in Table 1. The mean difference between iSTAT values and laboratory glucose levels was 30 mg/dl with limits of agreement from −8 to +68 (Fig 3). The mean difference between the iSTAT glucose values and

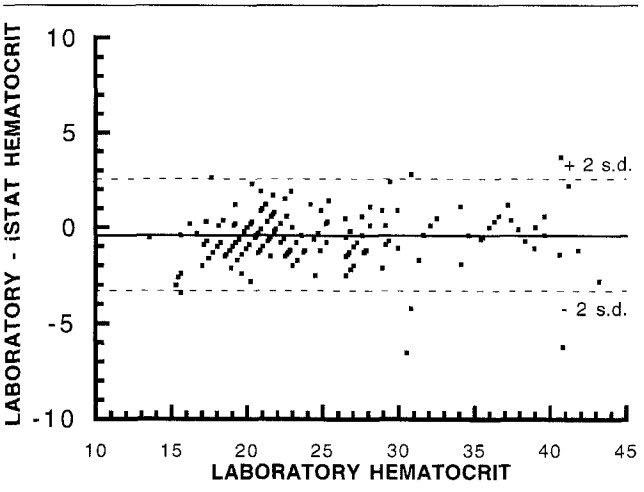

Fig 2. The difference between the laboratory and iSTAT hematocrit adjusted for total protein by the "adding method" (Y axis) over the range of laboratory values (X axis). The solid line represents the mean and the hashed lines represent 2 SD.

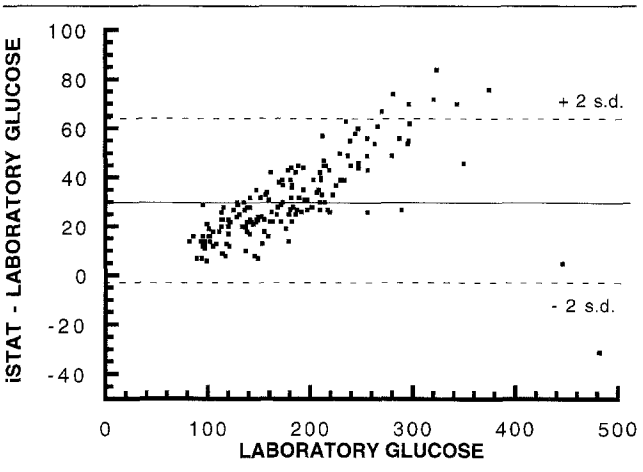

Fig 3. The difference between the laboratory and iSTAT glucose values (mg/dl) (Y axis) over the range of laboratory values (X axis). The solid line represents the mean and the hashed lines represent 2 SD.

the laboratory values was greater than the difference between the glucose meter and laboratory values. However, when only glucose levels below 200 mg/dl are considered, the limits of agreement between the iSTAT and laboratory values were much smaller.

Electrolytes

The range of laboratory sodium values was 126–146 mmol/l. The range for the potassium was 2.9–8.5 mmol/l. The limits of agreement between iSTAT values

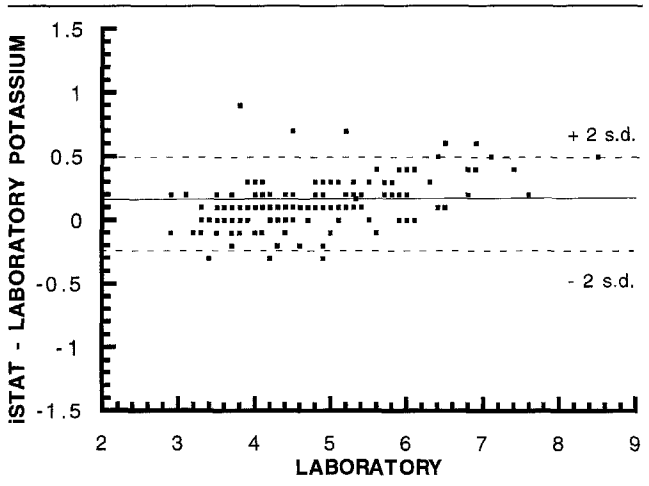

Fig 4. The difference between the laboratory and iSTAT potassium determinations (mmol/l) (Y axis) over the range of laboratory values (X axis). The solid line represents the mean and the hashed lines represent 2 SD.

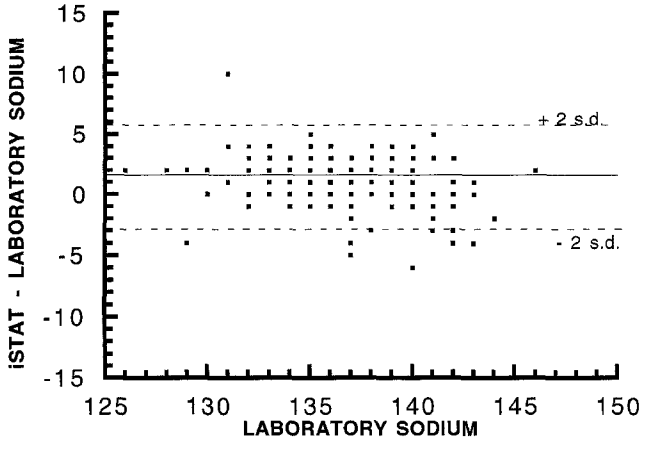

Fig 5. The difference between the laboratory and iSTAT sodium determinations (mmol/l) (Y axis) over the range of laboratory values (X axis). The solid line represents the mean and the hashed lines represent 2 SD.

and laboratory values for potassium and sodium were −0.26 to +0.50 and −3.0 to +5.6, respectively (Figs 4 and 5). The mean differences and standard deviations between the iSTAT, laboratory, and BGE for electrolyte values are shown in Table 1. The iSTAT electrolyte results varied from the laboratory values to a similar degree compared to the BGE results.

DISCUSSION

Conductivity-based methods of hematocrit determination have been shown to be reliable although the accuracy can be altered by plasma dilution [2–5]. The manufacturer of the iSTAT device recommends that the hematocrit value be adjusted by measuring total protein. This adjustment is undesirable, however, since measuring the total protein level and adjusting iSTAT values based on these results reduces the utility of point-of-care testing. Our results indicate that adding 1% to the iSTAT-measured hematocrit in the pre-CPB period, and 3% during or post-CPB values is a clinically acceptable approximation to the laboratory value.

We also determined that the sodium and potassium concentrations determined by the iSTAT machine in patients undergoing CPB are reliable within the clinically acceptable range. The iSTAT machine showed a similar mean difference from the laboratory results as did the BGE machine (see Table 1). The BGE machine is utilized in many hospitals in a "satellite" laboratory situation, thus, these are the results which many clinicians accept in practice. The iSTAT results for glucose showed good correlation with the laboratory results, however as shown in Figure 4, at higher glucose levels (>200 mg/dl), the discrepancy between the iSTAT and laboratory values increased.

Federal C.L.I.A. 88 guidelines (Clinical Laboratory Improvement Act-1988) mandate a certain level of laboratory precision. These are: hematocrit −6% variation; sodium ±4 mmol/l; potassium ±0.5 mmol/l; and glucose ±10%. Laboratories which are C.A.P. accredited (College of American Pathologists) must meet C.L.I.A. guidelines. For hematocrit, this translates into a hematocrit value within ±2.4 hematocrit percentage points of the true value. The mean difference of the iSTAT and centrifuge values determined in the present study relative to the laboratory are within this range. Similarly, for sodium and potassium, the iSTAT machines yielded results within the C.L.I.A. range of variation for laboratory results. The iSTAT glucose results were not within the acceptable range. When evaluating glucose levels below 200 mg/dl, the mean iSTAT results better approximated the laboratory results, but was still not within this 10% range.

When comparing the iSTAT analyzer to standard laboratory testing procedures, a number of advantages become apparent. The iSTAT system processes a sample at the bedside in under 2 minutes, thus eliminating the lengthier processing times of conventional laboratory results. This allows the clinician to make immediate management decisions based upon current and perhaps rapidly changing conditions. Furthermore, it has been shown that clinicians are easily able to operate the iSTAT machine producing reliable and accurate results [6].

In patients requiring frequent or serial laboratory determinations, the iSTAT analyzer offers an advantage

in that the volume of blood required for each panel of tests is minuscule (60 µl). This advantage is also readily apparent in the pediatric population, where the problems associated with frequent phlebotomy may be significant.

Finally, the iSTAT system may offer an economic advantage. The cost to our hospital of an iSTAT cartridge which performs hematocrit, sodium, potassium and glucose measurement is $ 4.25. The costs of testing with the iSTAT analyzer need to be compared to all of the costs of a traditional "stat" laboratory (tubes, messenger, laboratory technicians, reagents, equipment, etc.).

In summary, although the hemodilution associated with CPB has the potential to influence iSTAT measurements, especially hematocrit, we found acceptable agreement between the iSTAT and laboratory values for sodium, potassium, and hematocrit corrected for the change in serum protein. The glucose values did not agree sufficiently with the laboratory results to act as a substitute for the laboratory; however this difference is probably within a clinically acceptable range. We have also shown that the inconvenience of measuring serum protein can be avoided by simply adding 1 to the iSTAT hematocrit measured pre-CPB and adding 3 to the post-CPB measurement to correct the iSTAT hematocrit values. When used correctly, the iSTAT device is an acceptable tool for bedside measurement of hematocrit, glucose, and electrolytes during CPB.

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