

Evaluation of the i-STAT Point-of-Care Analyzer in Critically Ill Adult Patients

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Abstract: Point-of-care analyzers may benefit therapeutic decision making by reducing turn-around-time for samples. This is especially true when biochemical parameters exceed the clinical reference range, in which acute and effective treatment is essential. We therefore evaluated the analytical performance of the i-STAT point-of-care analyzer in two critically ill adult patient populations. During a 3-month period, 48 blood samples from patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) and 42 blood samples from non-cardiac patients who needed intensive care treatment were analyzed on both the i-STAT analyzer (CPB and non-CPB mode, respectively) and our laboratory analyzers (RapidLab 865/Sysmex XE-2100 instrument). The agreement analysis for quantitative data was used to compare i-STAT to RapidLab for blood gas/electrolytes and for hematocrit with the Sysmex instrument. Point-of-care electrolytes and blood gases had constant deviation, except for pH, pO₂, and hematocrit. A clear linear trend in deviation of i-STAT from

RapidLab was noticed for pH during CPB ($r = 0.32, p = .03$) and for pO₂ > 10 kPa during CPB ($r = -0.59, p < .0001$ when $10 < pO_2 < 30$ kPa) and in the intensive care unit ($r = -0.61, p < .001$ when $10 < pO_2 < 30$ kPa). In the normal pO₂ range ($10.6 < pO_2 < 13.3$ kPa), the performance of the i-STAT was comparable to the RapidLab. In contrast to hematocrit measured during CPB, hematocrit using the non-CPB mode in the non-cardiac intensive care population showed an underestimation up to 2.2% ($p < .0001$) in the hematocrit range below 25% ($n = 11$) using the i-STAT. The i-STAT analyzer is suitable for point-of-care testing of electrolytes and blood gases in critically ill patients, except for high pO₂. However, the discrepancy in hematocrit bias shows that accuracy established in one patient population cannot be automatically extrapolated to other patient populations, thus stressing the need for separate evaluation. **Keywords:** point-of-care testing, conductivity-based hematocrit, intensive care, cardiopulmonary bypass. *JECT. 2008;40:57–60*

Point-of-care testing has been developed to provide improvement in convenience, patient care, and turn-around time (1–5). The availability of faster test results expedites diagnosis and the initiation of treatment. For this reason, point-of-care analyzers are an attractive therapeutic instrument in acute patient care. Such point-of-care analyzers allow clinicians and nurses to perform the assays, providing real-time laboratory information at the patient's bedside.

During cardiopulmonary bypass (CPB) for cardiac surgery and on the intensive care unit (ICU) where hemodynamic changes need to be closely monitored, clinicians are particularly interested in blood gases, electrolytes, and he-

matocrit values. These analyses can easily be performed on the i-STAT point-of-care laboratory system (Abbott Point of Care, East Windsor, NJ). The i-STAT is a portable hand-held blood analyzer that uses different cartridges for simultaneous measurement of a variety of biochemical parameters. Furthermore, hematocrit measured during acute hemodilution, as present during CPB, is adjusted for the estimated level of total protein using the so-called CPB-mode of the i-STAT. Therefore, manual correction of the conductivity-based measurement for shifted levels of total protein in the patient's blood caused by hemodilution is no longer necessary (6).

High correlation between the i-STAT measurements and conventional methods has been reported (7–12). However, the patient populations in these studies are not comparable with our ICU or CPB patients, where the laboratory parameters can be far beyond the normal range. In addition, different parameters are used in the published studies.

Biochemical evaluation is an essential component of the total patient care. Therefore, when using point-of-care

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analyzers for therapeutic decision making, accuracy of the measurements (especially in the critical area) need to be equivalent to those obtained on conventional laboratory analyzers.

The purpose of this study was to evaluate the analytical performance of the i-STAT point-of-care analyzer in patients undergoing CPB for elective cardiac surgery and non-cardiac ICU patients.

MATERIALS AND METHODS

Study Design

Whole blood was taken from the arterial line of patients undergoing CPB for elective cardiac surgery or non-cardiac critically ill patients from the ICU. Samples were split and measured on the i-STAT and our laboratory analyzers. Samples from cardiac surgery patients were measured using the CPB-mode on the i-STAT, and samples from ICU patients were measured in the non-CPB mode.

Institutional approval was received for this evaluation. Because this quality control evaluation did not influence the frequency or volume of blood withdrawn from the patient or the routine care of the patient, informed to consent was deemed unnecessary.

Patient Specimens

Whole blood samples, obtained from the patient arterial line, were collected in a heparinized syringe (Portex; Smiths Medical, Keene, NH) for both the i-STAT and the laboratory blood gas measurement. A tri-potassium ethylenediaminetetraacetic acid collection tube (0.072 mL of 15% wt/vol; Becton Dickinson Vacutainer Systems, Plymouth, UK) was used for the laboratory hematology measurement.

Instrumentation

The i-STAT point-of-care laboratory system (Abbott Point of Care) uses a single-use disposable cartridge containing micro-fabricated sensors. The entire fluid path and

the calibration solution are stored in a sealed pouch. The calibration solution is automatically released, and a one-point calibration is performed just before sample analysis. We used the EG6+ cartridge measuring sodium, potassium, pH, pCO₂, pO₂, and hematocrit during cardiac surgery and the EG7+ cartridge measuring the same parameters as the EG6+ plus ionized calcium in the ICU patients. The results are available in 130–200 seconds.

Laboratory testing was performed on the RapidLab 865 (Siemens Medical Solutions Diagnostics, Los Angeles, CA) for blood gas and electrolyte measurement, whereas the automated Sysmex XE-2100 (Sysmex, Kobe, Japan) was used to determine the hemoglobin concentration and hematocrit.

Quality control of both instruments met the Dutch Accreditation Board for Medical Laboratories guidelines, which contain all of the criteria from ISO 15189.

Statistics

Data from both patient populations were separately compared with the corresponding results of the RapidLab and Sysmex using Bland-Altman agreement analysis (13). In a Bland-Altman plot, the deviation is plotted against the average, which allows a visual and statistical assessment of the deviation over the measured range. Trends in the bias of the i-STAT were studied using linear regression. A *p* value <.05 was taken to indicate statistical significance.

RESULTS

Bland-Altman plots showed that the deviation of the i-STAT from the laboratory was constant for all measured blood gas parameters, with the exception of pH and pO₂ (Table 1). The blood gas parameters showed for both patient populations, CPB and ICU, a similar bias (Table 1).

During CPB, pH (*r* = 0.32, *p* = .03) and pO₂ (*r* = -0.59, *p* < .0001 when 10 kPa < pO₂ < 30 kPa) and pO₂ in

Table 1. Systematic bias (mean of differences) and Bland-Altman's limits of agreement for blood gases, hematocrit (hct), Na⁺, and K⁺.

		Range	<i>n</i>	Systematic Bias	95% CI Systematic Bias	LOA
pH	ICU	7.2–7.5	42	0.005 ± 0.004	-0.003–0.012	-0.045 to 0.054
pCO ₂ (kPa)	CPB	4.25–6.78	48	-0.01 ± 0.04	-0.10 to 0.07	-0.60 to 0.60
	ICU	3.05–8.05	42	-0.16 ± 0.04	-0.23 to -0.08	-0.65 to 0.34
Na (mmol/L)	CPB	129–141	48	1.0 ± 0.3	0.4–1.6	-3.1 to 5.2
	ICU	132–158	42	1.3 ± 0.3	0.6–1.9	-2.9 to 5.5
K (mmol/L)	CPB	2.60–5.90	48	-0.03 ± 0.01	-0.05 to -0.01	-0.18 to 0.11
	ICU	3.1–5.2	40	-0.02 ± 0.01	-0.05 to -0.0005	-0.19 to 0.13
Hct (%)	CPB (Hct ≤ 25%)	17.5–25.0	24	0.3 ± 0.3	-0.3 to 0.8	-2.3 to 2.8
	CPB (Hct > 25%)	25.5–42.0	24	0.5 ± 0.4	-0.2 to 1.2	-3.0 to 4.0
	ICU (Hct ≤ 25%)	16.0–24.0	11	-2.2 ± 0.3	-2.8 to -1.6	-4.3 to -0.1
	ICU (Hct > 25%)	25.5–45.0	31	-0.7 ± 0.5	-1.8 to 0.3	-6.6 to 5.2

Note: The 95%-confidence intervals (CI) for the systematic bias are shown. The limits of agreement (LOA) indicate the range in which 95% of the differences between the i-STAT and the laboratory analyzer are expected. The range of measurement is estimated by taking the minimum and maximum of the average measurements of the i-STAT the laboratory analyzer.

ICU patients ($r = -0.61, p < .001$ when $10 \text{ kPa} < pO_2 < 30 \text{ kPa}$) showed a clear linear trend in the deviation between i-STAT and RapidLab. The minimal and maximal bias of these two parameters is shown in Table 2. Partial pressure O_2 values between 10.6 and 13.3 kPa (normal range) are depicted separately. The negative minimal bias for pO_2 in the CPB group is more profound and can be ascribed to the high pO_2 values in this group compared with the ICU group (range from 10.7 to 53.7 and 3.8 to 43.7 kPa, respectively). Figures 1 and 2 show the Bland-Altman plots of the pO_2 measurements in the CPB and ICU group, respectively.

With respect to hematocrit measurements, a difference between the two patient populations was noticed. Measured hematocrit values were divided in two groups, $>25\%$ and $\leq 25\%$, where the latter is the range that is clinically relevant for transfusion of packed red cells in our clinical practice. The CPB group showed a non-significant small bias (Table 1) between i-STAT and Sysmex. However, the ICU group showed a substantial and statistically significant negative bias ($-2.2\%, p < 0.0001$) for hematocrit values obtained by i-STAT compared with Sysmex in the clinically relevant range of hematocrit $\leq 25\%$ ($n = 11$), see Figure 3.

Table 2. The minimal and maximal bias of the measurements showing a trend.

		Range	n	Minimal Bias	Maximal Bias
pH	CPB	7.33–7.51	48	-0.04	0.03
pO_2 (kPa)	CPB (overall)	10.7–53.7	48	-12.6	+1.8
	CPB ($10.6 \leq pO_2 \leq 13.3$)	10.7–13.2	6	-1.2	+1.8
	ICU (overall)	3.8–43.7	42	-2.8	+0.3
	ICU ($10.6 \leq pO_2 \leq 13.3$)	10.8–13.0	9	-0.8	-0.2

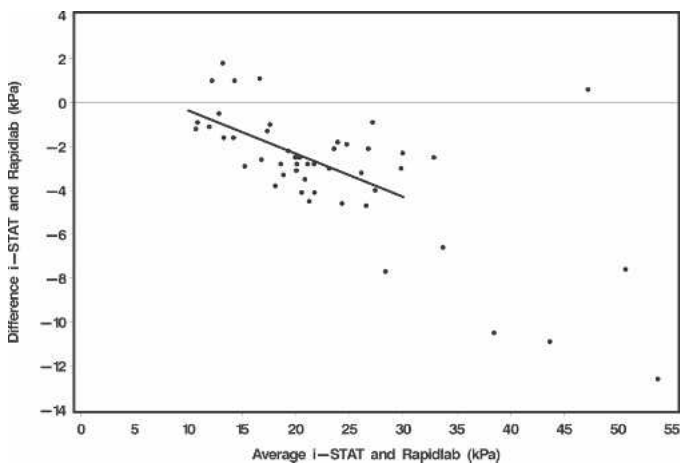


Figure 1. Bland-Altman plot showing the difference vs. the average of paired pO_2 measurements in CPB patients ($n = 48$) on the i-STAT and the RapidLab.

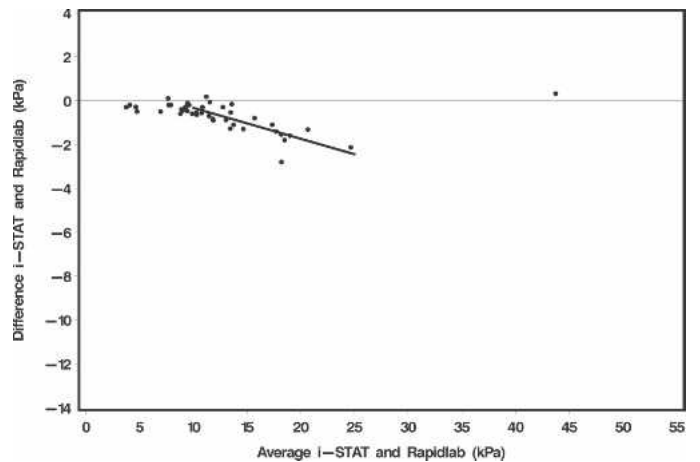


Figure 2. Bland-Altman plot showing the difference vs. the average of paired pO_2 measurements in ICU patients ($n = 42$) on the i-STAT and the RapidLab.

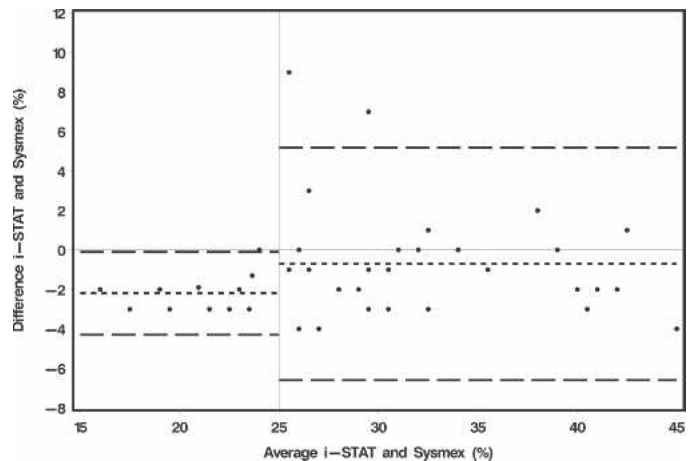


Figure 3. Bland-Altman plot showing the difference vs. the average of paired hematocrit (Hct) measurements in ICU patients ($n = 42$) on the i-STAT and the Sysmex.

DISCUSSION

Measurement of various laboratory parameters is part of clinical routine during CPB and in the intensive care unit and is important in the treatment of critically ill patients. Respiratory, circulatory, and metabolic therapeutic interventions are all supported by blood test results. Therefore, when using point-of-care analyzers for therapeutic decision making, accuracy and precision of the measurements, especially in the critical area, need to be equivalent to those obtained using conventional laboratory analyzers.

Several studies have established the reliability and reproducibility of the i-STAT point-of-care analyzer using samples mainly derived from patients during physiologically normal conditions (7–12). However, we performed our study in critically ill ICU patients or CPB patients, where the physiologic measurements are far beyond the

normal range. Large ranges of hematocrit levels and blood gas values are observed during CPB and in mechanically and artificially ventilated patients, because hemodilution and high oxygen fractions are often used.

Our blood gas results underline the close agreement between the i-STAT measurements and the reference methods. However, pH in CPB patients and pO₂, both in CPB and ICU patients, showed a statistically significant trend. Concerning pH, the difference between the two methods was not clinically significant. With respect to high pO₂ values, a clear trend toward underestimation was observed in both patient populations, but differences remained <13 kPa. This study shows, just like the study performed by Sediame et al. (6), a difference in bias between low and high pO₂ measurement. In general, accuracy of pO₂ is mainly important in the low range, but the impact of underestimation in the high pO₂ range should be judged with respect to local clinical practice. In addition, it is important to point out that in the normal physiologic range (10.6–13.3 kPa), the i-STAT and RapidLab pO₂ measurements were almost identical, with the largest observed difference being +1.8 and –0.9 kPa in the CPB and non-CPB population, respectively.

Our findings concerning the accuracy in the low range hematocrit underline those in a previous evaluation study of the i-STAT (14). In contrast to the hematocrit measured during CPB, the hematocrit using the i-STAT non-CPB mode in the non-cardiac intensive care population showed an underestimation of up to 2.2% in the hematocrit range below 25%. This observation may affect therapeutic transfusion decisions (15). The use of the non-CPB mode in intensive care patients with moderate hemodilution and with shifting electrolyte concentration therefore needs to be reconsidered. An obvious solution to this bias would seem to use the CPB mode, which corrects for protein dilution. However, without further research, we feel that using the CPB function in ICU patients is a delicate matter. The general ICU population is more heterogeneous than the population of patients during CPB and differs from the CPB population in terms of the level of dilution and the mix of plasma expanders used (colloids and electrolytes). In a previous study (16), we found that colloids cause an upward bias and crystalloids a downward bias in the conductivity method as used by the i-STAT. Therefore, the correction needed would most probably need to take into account more factors than only protein dilution.

CONCLUSION

From our results, the i-STAT analyzer is suitable for point-of-care testing of electrolytes and blood gases in critically ill patients, except for high pO₂. However, the

discrepancy in hematocrit bias shows that accuracy established in one patient population cannot be automatically extrapolated to other patient populations, thus stressing the need for separate evaluation.

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