Accuracy of the i-STAT^{TM} bedside blood gas analyser

S. Sediame, F. Zerah-Lancner, M.P. d'Ortho, S. Adnot, A. Harf

Accuracy of the i-STAT^{TM} bedside blood gas analyser. S. Sediame, F. Zerah-Lancner, M.P. d'Ortho, S. Adnot, A. Harf. ©ERS Journals Ltd 1999.
ABSTRACT: The performance of the i-STAT portable clinical analyser for measuring blood gases and pH was evaluated with reference to a conventional blood gas analyser (ABL520 Radiometer).

Ninety-two samples from the routine blood gas analysis laboratory were chosen according to a wide distribution of partial pressure of carbon dioxide (Pa,CO_2), partial pressure oxygen (Pa,O_2) and pH and then analysed. All measurements were performed in duplicate by trained technicians from the central hospital laboratory.

Differences between duplicate measurements were computed for Pa,CO_2: (1.2 *versus* 0.4%), Pa,O_2 (1.7 *versus* 1.1%) and pH (0.06 *versus* 0.02%), for the i-STAT and ABL520, respectively. pH and Pa,CO_2 values measured with the i-STAT were very close to those obtained with the ABL520, the difference (mean±SD) being 0.006±0.018 and -0.13±0.17 kPa, respectively. Statistical analysis showed that the differences between analysers did not depend on values of pH or Pa,CO_2. The performance of the analysers depended on the level of $P$$O_2$. Below 15 kPa (n=48), the two systems gave nearly identical values, the mean difference was 0.01±0.37 kPa. Between 16 and 55 kPa (n=44), there was a systematic but small (-0.69±0.67 kPa) underestimation of Pa,O_2 measured with the i-STAT (p<10^{-8}).

In conclusion, this study shows that blood gas analysis using the i-STAT portable device is comparable with that performed by a conventional laboratory blood gas analyser.
Eur Respir J 1999; 14: 214–217.

Service de Physiologie-Explorations Fonctionnelles, and Institut National de la Santé et de la Recherche Médicale U492, Hôpital Henri Mondor, AP-HP, Créteil, France.

Correspondence: A Harf
Service de Physiologie-Explorations Fonctionnelles
Hôpital Henri Mondor
94010 Créteil
France
Fax: 33 149812667

The development of so-called "point-of-care" (POC) devices for blood or urine analysis has resulted in many systems that are widely used at home or at the bedside [1, 2]. These devices have been developed to provide improvement in convenience, patient care, and turn-around time. Most of these devices are dedicated to glucose analysis, but increasing attention has been paid in recent years to the development of bedside systems capable of a wider spectrum of analyses. Improvements in biosensor technology have permitted the production of various devices that detect and quantify electrolytes and other analyses. More recently, blood gas analysis has become available with such systems. Such POC systems allow operators without technical training to perform the assays.

The i-STAT portable clinical analyser (HPM3600A i-STAT hand-held blood analyser; Hewlett Packard, Les Ulis, France) is a hand-held analyser that performs simultaneous blood measurements of sodium, potassium, chloride, glucose, urea, nitrogen, haematocrit, partial pressure of oxygen ($P$$O_2$), partial pressure of carbon dioxide ($P$$CO_2$) and pH, in <2 min. Both the i-STAT and the conventional blood gas analyser (ABL520; Radiometer, Copenhagen, Denmark) are designed to measure $P$$CO_2$ and $P$$O_2$ in any biological fluid. Such a system is now used on a routine basis in a number of hospitals. Intensive care units are particularly interested in such systems which allow real-time laboratory information at the patient's bedside.

Such POC systems have to achieve accuracy and precision of measurements equivalent to those obtained in the clinical laboratory. Surprisingly few data are available to evaluate the i-STAT system for performance in measuring blood gas analysis, *i.e.*, pH, $P$$O_2$ and $P$$CO_2$. A high correlation between i-STAT measurements and conventional methods has been reported [3, 4]. However, no systematic evaluation of patient's samples from intensive care units showing a wide range of pH, $P$$O_2$ and $P$$CO_2$, has been performed. In this study, i-STAT measurements for low and high values of $P$$CO_2$, $P$$O_2$ and pH were evaluated.

Materials and methods

Description of the system

The i-STAT system is composed of two main parts, the portable hand-held analyser and disposable cartridges.

The i-STAT weighs ~500 g and is powered by two 9-V alkaline batteries. It consists of a mechanical system that controls the flow of calibration solution and samples in the cartridges, an electrical connector to receive signals from the cartridges, an electronic system that measures and monitors signals from the biosensors of the cartridges, and a liquid crystal screen that displays prompts, messages and test results.

The cartridges contain a series of biosensors, which are thin-film electrodes microfabricated on silicon chips. $P$$CO_2$

and pH measurements are made by ion-selective electrodes showing Nernstian behaviour. P_{O_2} is measured amperometrically; the oxygen sensor is similar to a conventional Clark electrode. Before use, cartridges are removed from the refrigerator and allowed to reach room temperature after which they can be kept at room temperature for 14 days.

The whole-blood specimen (~65 µL) is introduced into the cartridge using a capillary tube or syringe. The cartridge is then inserted into the analyser, which is automatically activated. Patient and operator identification numbers can be entered using the numeric keypad. Each cartridge contains a sealed foil pack of calibration solution. During the testing cycle, the pack is ruptured and the calibration solution is automatically transported over the biosensors. The signals produced by the biosensors in response to the calibration solution are conducted from contact pads on the cartridge to the analyser, where they are processed and stored. When this process is complete, the analyser automatically displaces the calibration solution and moves the sample over the sensors. The result is obtained by comparing the sensor response to the sample with that of the calibration solution. The complete test lasts ~90 s.

When the analysis is complete, the results are displayed on screen together with the patient identification, time and date of the assay. The analyser is capable of storing 50 patient's records. Results are transmitted by use of infrared signals to an adjacent printer (HP 82240B Infrared Printer; Hewlett Packard).

One cartridge is used for each specimen and is then discarded. The specimen is contained in the cartridge and does not come into contact with the analyser at any time. In all experiments, the cartridges were used with strict adherence to the recommended procedure. i-STAT control solutions (aqueous) were used to check the cartridge batch as recommended by the manufacturer.

Experimental procedure

Ninety-two samples from the routine blood gas analysis laboratory were investigated, over a nine-day period. Samples were collected in 3 mL lithium heparinized plastic syringes (Drihep-Plus® Kit; Becton Dickinson, Franklin Lakes, NJ, USA). These specimens were obtained from the intensive care units of the authors' hospital. Measurements were performed with the conventional blood gas analyser (ABL520; Radiometer, Copenhagen, Denmark), and with the i-STAT system. All measurements were performed in duplicate, with half of the samples undergoing the sequence i-STAT -ABL520 -i-STAT -ABL520, and the other half the sequence ABL520 -i-STAT -ABL520 -i-STAT. All measurements were performed in the central laboratory, by trained technicians.

Statistics

As recommended by BLAND and ALTMAN [5] for the comparison of a new method to an established one, i-STAT and conventional blood gas analyses were compared by plotting the difference between the methods against their mean. The limits of agreement are computed as the mean of the differences $\pm 2\text{SD}$. To test whether the mean of the differences was significantly different from zero, a paired t-test was used.

Results

Differences between duplicates (expressed as a percentage of the mean of the two values) were computed for the 92 samples. These differences (mean$\pm$SD) were as follows: P_{a,CO_2} 1.2$\pm$1.1 *versus* 0.4$\pm$0.3%, P_{a,O_2} 1.7$\pm$1.1 *versus* 1.1$\pm$1.0% and pH: 0.06$\pm$0.06 *versus* 0.02$\pm$0.03%, for the i-STAT and ABL520, respectively. In the following analysis, only the first measurements of the two duplicates, for each system, was considered.

The pH measured with the i-STAT was very close to the measurement obtained with the ABL520. Although the paired t-test was significant (p<0.001), the difference was clinically irrelevant, (0.006$\pm$0.018 (mean$\pm$SD)). The Bland and Altman analysis showed that this difference remained stable, independently of the pH values (fig. 1 and table 1).

P_{CO_2} measured with the i-STAT was also very close to the measurement obtained with the ABL520. Although the paired t-test was significant (p<10^{-10}), the difference was clinically irrelevant (-0.13$\pm$0.17 kPa (mean$\pm$SD)). The Bland and Altman analysis showed that this difference remained stable, independently of the P_{a,CO_2} values (fig. 1 and table 1).

P_{a,O_2} measured with the i-STAT was evaluated at two sets of values. Below 15 kPa, the two systems gave nearly identical values, as shown in figure 1, the mean difference being 0.01$\pm$0.37 kPa (paired t-test, NS). Between 15 and 55 kPa, there was a systematic but small (-0.69$\pm$0.67 kPa) underestimation of P_{a,O_2} measured with the i-STAT (p<10^{-8}) (fig. 1).

Discussion

Decentralization of laboratory services is likely to gain great importance in the future, since financial pressures will demand a more efficient delivery of health care. In the early 1990s, the i-STAT Corporation (Princeton, NJ, USA) introduced a hand-held chemistry analyser for which a number of studies have proved the reliability of the system for measurements of sodium, potassium, chloride, urea, glucose and haematocrit [6–9]. Ionized calcium can also be determined.

More recently, blood gas analysis became available with the i-STAT analyser. Surprisingly, only a few data are available to evaluate the performance of the i-STAT in measuring blood gases. MUELLER-PLATHE *et al*. [3] in adults and MURTHY *et al*. [4] in neonates showed high correlations between i-STAT measurements and conventional blood analysis. However, it has been shown that a correlation analysis is inappropriate to compare a new measurement technique with an established one, since it measures the strength of a relation between two variables and not the agreement between them [5]. In addition, i-STAT analysers are often used in intensive care units, where a large range of P_{O_2}, P_{CO_2} and pH can be observed. Special care was taken to examine the accuracy of the measurements for low pH and high P_{CO_2} which are now observed in mechanically ventilated patients with
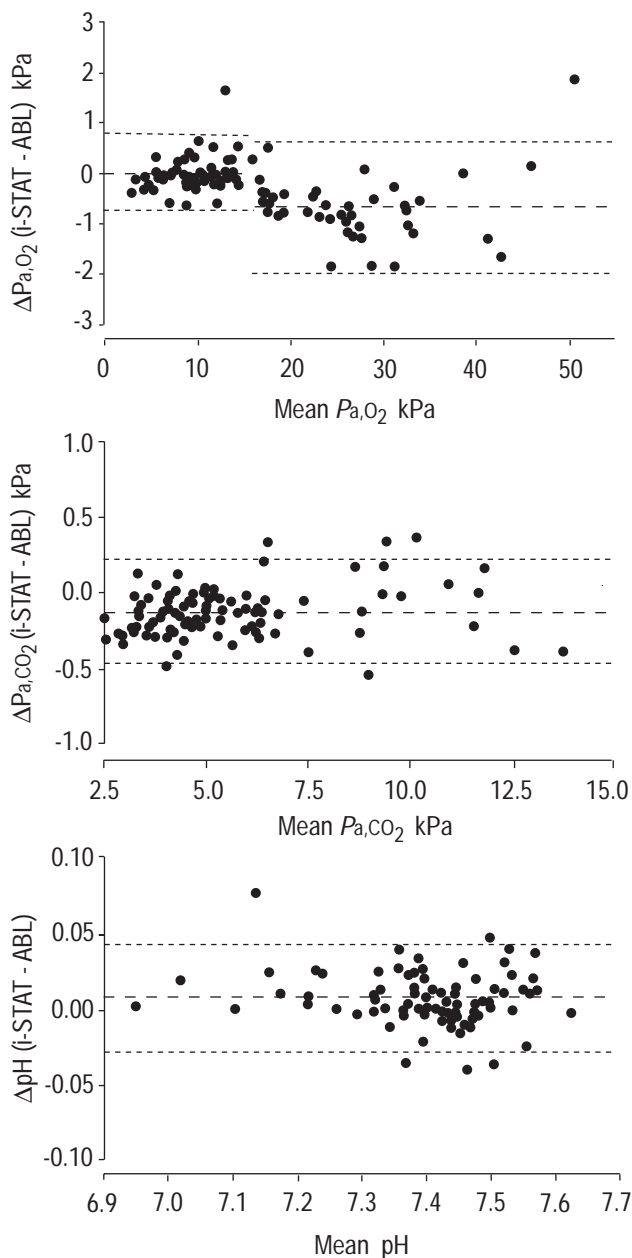
Fig. 1. – Conventional blood gas analysis (ABL520, Radiometer) and i-STAT were compared by plotting the differences in arterial oxygen tension (Pa,O$_2$), arterial carbon dioxide tension (Pa,CO$_2$) and pH between the methods against their means for 92 blood samples. The limits of agreement were computed as the mean of the differences (– – –) $\pm$2sd (- - -). For Pa,O$_2$ <15 kPa, the two systems gave nearly identical values. For Pa,O$_2$ >15 kPa, i-STAT systematically underestimated Pa,O$_2$ (p<10^{-8}). Pa,CO$_2$ and pH measurements were very similar for the two systems.

Table 1. – Comparison of blood gases and pH measurements in 92 samples using the i-STAT and the Radiometer ABL520

Range	Mean difference	SD	Measurements n
pH			
<7.35	0.01	0.02	20
7.35–7.45	0	0.01	38
>7.45	0	0.01	34
Pa,CO$_2$ kPa			
<4.5	-0.17	0.14	38
4.5–6.0	-0.12	0.10	24
>6.0	-0.08	0.23	30
Pa,O$_2$ kPa			
<15	0.01	0.37	48
15–55	-0.69	0.67	44

Pa,CO$_2$: arterial carbon dioxide tension; Pa,O$_2$: arterial oxygen tension.

negligible. For PCO$_2$, a 0.5 kPa difference can be occasionally observed. It is important to point out that even very high PCO$_2$-values are accurately measured with the i-STAT system. The i-STAT and ABL520 measurements of PO$_2$ in the range up to 15 kPa are almost identical, most of the differences being <0.5 kPa. In the higher range of PO$_2$, an underestimation of PO$_2$ measured with i-STAT was observed, but the differences remained <10%.

Hand-held portable clinical analysers for POC tests may help to provide better patient care in a number of atypical situations such as in a moving ambulance [9] or in a helicopter [10]. Such analysers are also routinely used in a number of hospitals, especially in neonatal and paediatric intensive care units [4] as a means of providing a patient′s results more rapidly and effectively, by decreasing test turnaround time [6, 11]. However, it should be carefully evaluated whether improvement in the overall turnaround time of the test results affects the decision time of the care giver and whether it has any effect on the outcome for the patient (length of stay, hazards, complications, etc) [12, 13].

The cost effective nature of POC testing is still a matter of debate. It has been questioned whether implementing such testing *versus* centralized testing is cost effective [14–16]. On the other hand, when taking into account the cost per panel, nursing time spent and overall turnaround time, a reduction of cost with the i-STAT system has been shown in a recent study [17]. Further studies are clearly needed to evaluate the cost effective nature of POC testing, depending on the site where it will be used.

In conclusion, this study shows that blood gas analysis with the i-STAT portable analyser is comparable to traditional blood gas analysis. This study was performed in the laboratory with a methodology which followed precisely the recommendations of the manufacturer. The use of such a system at the bedside would require careful operation according to these recommendations. This study indicates that, if practical or economic considerations lead to the use of this system, the results are reliable.

permissive hypercapnia, and in a wide range of PO$_2$ values, since high oxygen fractions are often used in the intensive care unit.

The results obtained underline the close relationship between the i-STAT measurements and a reference method. For pH, the difference between the two methods is well below the clinical significance, since the largest difference in pH is 0.08, and most of the values are <0.05. Even for very low pH, the difference between the two methods is

References

1. Salem M, Chernow B, Burke R, Stacey JA, Slogoff M, Sood S. Bedside diagnostic blood testing. Its accuracy, rapidity, and utility in blood conservation. *JAMA* 1991; 266: 382–389.
2. Zaloga GP. Evaluation of bedside testing options for the critical care unit. *Chest* 1990; 97: 185S–190S.
3. Muller-Plathe O, Ginzbourg J, Rudolph S. Evaluation of the i-STAT portable blood gas and electrolyte analyser. *J Lab Med* 1997; 21: 325–331.
4. Murthy JN, Hicks JM, Soldin SJ. Evaluation of i-STAT portable clinical analyzer in a neonatal and pediatric intensive care unit. *Clin Biochem* 1997; 30: 385–389.
5. Bland MJ, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; 8: 307–310.
6. Mock T, Morrison D, Yatscoff R. Evaluation of the i-STAT system: a portable chemistry analyzer for the measurement of sodium, potassium, chloride, urea, glucose and hematocrit. *Clin Biochem* 1995; 28: 187–192.
7. Jacobs E, Vadasdi E, Sarkozi L, Colman N. Analytical evaluation of i-STAT portable clinical analyser and use by nonlaboratory health care professionals. *Clin Chem* 1993; 39: 1069–1074.
8. Woo J, McCabe JB, Chauncey D, Schug T, Henry JB. The evaluation of a portable clinical analyzer in the emergency department. *Am J Clin Pathol* 1993; 100: 599–605.
9. Tortella BJ, Lavery RF, Doran JV, Siegel JH. Precision, accuracy and managed care implications of a hand-held whole blood analyzer in the prehospital setting. *Am J Clin Pathol* 1996; 106: 124–127.
10. Burrit MF, Santrach PJ, Hankins DG, Herr D, Newton NC. Evaluation of the i-STAT portable clinical analyzer for use in a helicopter. *Scand J Clin Lab Invest* 1996; 56: Suppl. 224, 121–128.
11. Erickson KA, Wilding P. Evaluation of a novel point of care system, the i-STAT portable clinical analyzer. *Clin Chem* 1993; 39: 283–287.
12. Kendall J, Reeves B, Clancy M. Point of care testing: randomised controlled trial of clinical outcome. *BMJ* 1998; 3: 1052–1057.
13. Kilgore ML, Steindel SJ, Smith JA. Evaluation stat testing options in an academic health center: therapeutic turnaround time and staff satisfaction. *Clin Chem* 1998; 44: 1597–1603.
14. Jatlow P. Point of care laboratory testing in the emergency department. *Am J Clin Pathol* 1993; 100: 591.
15. Nosanchuk JS, Keefner R. Cost analysis of point of care laboratory testing in a community hospital. *Am J Clin Pathol* 1995; 103: 240–243.
16. Parvin CA, Lo SF, Deuser SM, Weaver LG, Lewis LM, Scott M. Impact of point-of-care testing on patient′s length of stay in a large emergency department. *Clin Chem* 1996; 42: 711–717.
17. Bailey TM, Thopham TM, Wanz S, Grant M, Jones D, Zerbe TT. Laboratory process improvement through point-of-care testing. *J Qual Impr* 1997; 23: 362–380.