J Anesth (2004) 18:14–17
DOI 10.1007/s00540-003-0209-1

Journal of
Anesthesia

Accuracy of a point-of-care blood gas analyzer in gastric tonometry measurements of intramucosal pH (pHi) and P_{CO_2} gap

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Abstract
Purpose. We assessed the accuracy of a point-of-care blood gas analyzer in providing data from saline samples obtained by gastrointestinal tonometry (Tonometrics Catheter; Tonometrics Division, Instrumentarium, Helsinki, Finland) for the calculation of intramucosal pH (pHi) and the P_{CO_2} gap (intramucosal P_{CO_2} − Pa_{CO_2}).
Methods. We compared the point-of-care analyzer (Opti; AVL Medical Instruments, Schaffhausen, Switzerland; "Opt") with a conventional analyzer (Compact 2 AVL Medical Instruments, Schaffhausen; "Elect") in a clinical study (Elect being taking as the standard). In an in vitro study, P_{CO_2} data of tonometer saline (Pr_{CO_2}) from Opt and Elect were compared with P_{CO_2} data from a continuous air tonometer (Tonocap Tonometrics Division, Instrumentarium) for a bottle containing a mixed P_{CO_2} gas. Data were evaluated by the Bland-Altman method.
Results. In the clinical study, the bias (B) and precision (P) were: B = 0.223 and P = 0.056 for pHi, B = −14.0 and P = 2.43 (mmHg) for Pr_{CO_2}, and B = −16.7 and P = 2.6 (mmHg) for the P_{CO_2} gap (n = 27). In the in vitro study, the bias between the two values (Pr_{CO_2} and bottle P_{CO_2}) was −1.98 mmHg and precision was 1.23 mmHg for Elect, but for Opt, these values were −22.09 mmHg and 3.15 mmHg, respectively (n = 18).
Conclusion. Opt is not suitable for measuring pHi and the P_{CO_2} gap because it does not provide an accurate P_{CO_2} for tonometry saline.

Key words Intramucosal pH (pHi) · Blood gas analyzer · Point-of-care · Accuracy

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Part of this study was presented at the 20th International Symposium on Intensive Care and Emergency Medicine (Brussels, March, 2000).
Received: December 7, 2002 / Accepted: October 31, 2003

Introduction

Measurement of intramucosal pH (pHi) and the P_{CO_2} gap (intramucosal P_{CO_2} minus Pa_{CO_2}) by tonometry requires the use of a blood gas analyzer, and the values obtained are used in evaluating the oxygen metabolism and general state of critically ill patients. However, some limitations have been pointed out [1,2], one of which is the accuracy of the particular kind of gas analyzer used [3]. Recent advances in medical technology have made it possible for us to carry out blood gas analysis at the bedside, using so-called point-of-care analyzers. Because little has been known about the accuracy of point-of-care analyzers in relation to their use in the monitoring of pHi and the P_{CO_2} gap, we evaluated one of these machines to assess its suitability for this purpose.

Subjects, materials, and methods

A point-of-care blood gas analyzer (Opti; AVL Medical Instruments, Schaffhausen, Switzerland; hereafter called "Opt") was the focus of this study. Opt employs a disposable single-use cassette and fluorescence for measuring purposes. It uses three different optode sensors for pH, P_{O_2}, and P_{CO_2} measurements. To compare the accuracy of Opt with that of a conventional machine, we used a blood gas analyzer that uses electrodes for measurement purposes: namely, the Compact-2 (AVL Medical Instruments; hereafter called "Elect"). In the in vitro setting, we also studied the accuracy of Opt and its suitability for tonometry. To this end, in the clinical study we took the data obtained from the conventional analyzer (Elect) as the standard, while in the in vitro study we took the P_{CO_2} of the environmental gas measured by a continuous air tonometer (Tonocap, Tonometrics Division, Instrumentarium, Helsinki, Finland) as the standard.

Clinical study

This study was approved by the Ethics Committee for Human Subjects, and patients gave their informed consent. In each of ten patients who were scheduled for semitotal esophagectomy, a gastrointestinal tonometer (Tonometrics Catheter; Tonometrics Division, Instrumentarium) was inserted and located within the rolled stomach during the operation. The measurements were made in the intensive care unit (ICU) after the patient's operation had finished. The position of the sigmoid catheter was confirmed in the ICU by checking X-ray films. For each reading, we infused 2.5 ml of normal saline into the balloon. After a 60-min equilibration time, the saline was withdrawn, and its P_{CO_2} (Pr_{CO_2}) measured. Each sample was divided into two parts, one for each analyzer (Opt and Elect). For each sample, the infusion into the two analyzers was completed within 5 min. At the same time as we made these measurements, we withdrew and analyzed arterial blood for $H_{CO_3^-}$ and Pa_{CO_2}. Then, pHi and the P_{CO_2} gap were calculated, as follows:

$$pHi = 6.1 + \log A$$
$$A = H_{CO_3^-}/(0.03 \times 1.19 \times Pr_{CO_2})$$
$$P_{CO_2}\ Gap = Pr_{CO_2} - Pa_{CO_2}$$

The value 1.19 is the correction factor for a 60-min dwelling time, as shown in the manufacturer's manual.

In vitro study

Three tonometer balloons were placed in a bottle (height, 120 mm; diameter, 93 mm; volume, 355 ml). The bottle had a tap through which the three tonometer balloons were inserted. Oxygen (6–91·min^{-1}) and CO_2 gas (0.2–0.31·min^{-1}) were allowed to flow into the bottle, and P_{CO_2} was determined from the flow rates of the two gases. The gas was assumed to be mixed well in the line because the flow rate of oxygen (61·m^{-1} to 91·m^{-1}) was much larger than that of CO_2 (0.2 to 0.31·min^{-1}). The CO_2 concentration was set to approximately 40 mmHg by changing the flow of the two gases. A Tonocap was connected to the bottle, and the value shown as PEI_{CO_2} on the Tonocap window was considered to represent the P_{CO_2} of the gas in the bottle (P_{CO_2}-B). One of the tonometer catheters was connected to the Tonocap and used for measuring Pr_{CO_2} using the Tonocap's internal system. The other two tonometers were used to measure Pr_{CO_2} by two saline methods using Opt and Elect. The bottle was placed in a water bath, and was kept at a temperature of 37°C by regulating the temperature of the surrounding water.

Statistical analysis

Data values were expressed as means ±SD. We calculated the bias (the mean difference between paired values) and the precision (SD of the difference) using the Bland-Altman method [4]. For differences between groups, we used a paired *t*-test. For these analyses, we used Statview 5.0 (SAS Institute, Cary, NC, USA) for Apple Computers (Apple Computers, Cupertino, CA, USA).

Results

Clinical study

Twenty-seven pairs of pHi and P_{CO_2} gap values were obtained in the clinical study.

Pa_{CO_2}

Mean Pa_{CO_2} (mmHg) was 42.6 ± 5.9 (range, 34.7–58.1) by Elect and 45.3 ± 5.8 (36.3–61.0) by Opt. The Bland-Altman plot of difference against average for the pairs of values obtained for Pa_{CO_2} using Opt and Elect revealed good precision (P) and only a small bias (B): P = 1.15 mmHg and B = 2.75 mmHg.

Pr_{CO_2}

Mean Pr_{CO_2} (mmHg) was 44.1 ± 7.0 (range, 32.2–59.1) by Elect and 30.7 ± 7.0 (range, 21.0–44.0) by Opt. These data did not show acceptable bias: B = −14.0 mmHg; P = 2.43 mmHg.

pHi

Mean pHi was 7.305 ± 0.056 (7.172–7.401) by Elect and 7.542 ± 0.089 (7.334–7.656) by Opt. The values obtained from the Bland-Altman analysis for bias and precision were B = 0.223; $P = 0.056$ (Fig. 1), and there was a significant relationship between the average and the difference: Y = −3.408 + 0.49X (X, average of paired averaged data and Y, difference between paired data).

P_{CO_2} gap ($Pr_{CO_2} - Pa_{CO_2}$)

Mean values for the P_{CO_2} gap (mmHg) were +1.49 ± 3.9 (−5.1 to 10.2) mmHg by Elect and −15.2 ± 4.4 (−24.0 to −6.0) mmHg by Opt. When the data from Opt and Elect were compared, a statistically significant difference was observed ($P < 0.0001$; paired *t*-text). The Bland-Altman plot gave values for bias and precision as follows: B = −16.7 mmHg; P = 2.57 mmHg (Fig. 2), showing that there was a large bias between the data obtained by the two methods.

In vitro stud

Eighteen pairs of Pr_{CO_2} and P_{CO_2}-B values were obtained. In the case of Elect, the bias between the two

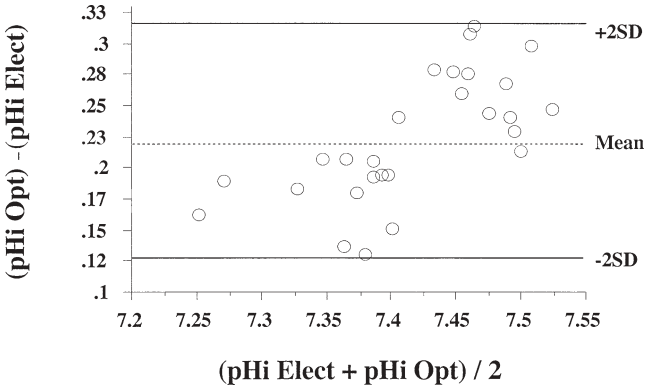

Fig. 1. Intramucosal pH (pHi) in clinical study. Differences between the paired values obtained using a point-of-care analyzer (*Opt*) and a conventional analyzer (*Elect*) were plotted against the average of each pair of values. The values obtained from the Bland-Altman analysis for bias (B) and precision (P) were B = 0.223; P = 0.056. *Opt*, Opti (AVL Medical Instruments); *Elect*, Compact-2 (AVL Medical Instruments); *pHi-Opt*, pHi obtained from Opti; *pHi-Elect*, pHi obtained from the conventional analyzer, Compact-2

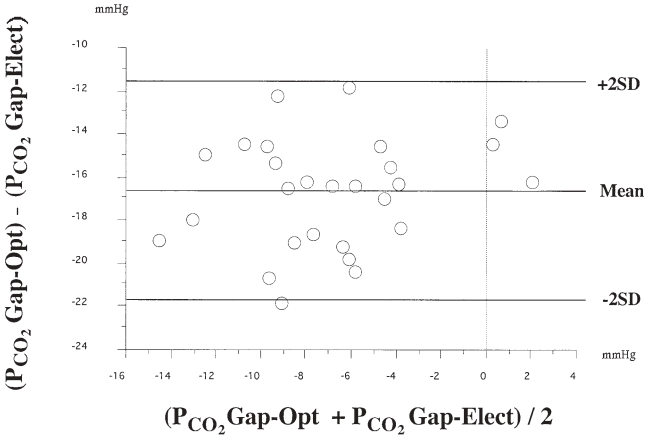

Fig. 2. P_{CO_2} gap in clinical study. Differences between the paired values obtained using Elect and Opt were plotted against the average for each pair of values. B = −16.7 mmHg; P = 2.57 mmHg. *Opt*, Opti; *Elect*, Compact-2

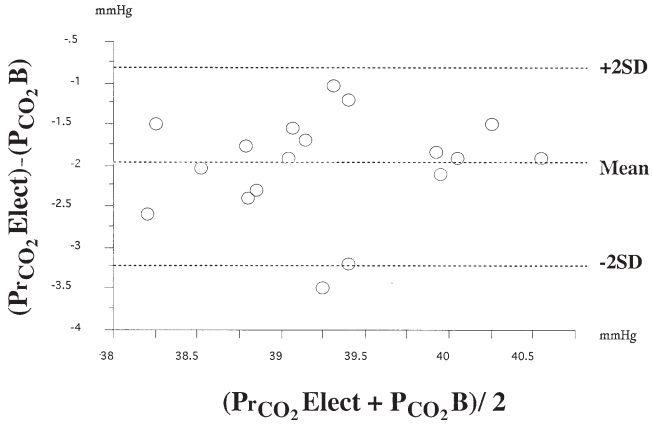

Fig. 3. Pr_{CO_2} in vitro study (Elect vs P_{CO_2}-B). Differences between the paired values obtained using mean Pr_{CO_2} and P_{CO_2}-B were plotted against the average of each pair of values. B = −1.98 mmHg, P = 1.23 mmHg. *Elect*, conventional analyzer (Compact-2); P_{CO_2}-*B*, the P_{CO_2} of the gas in the bottle

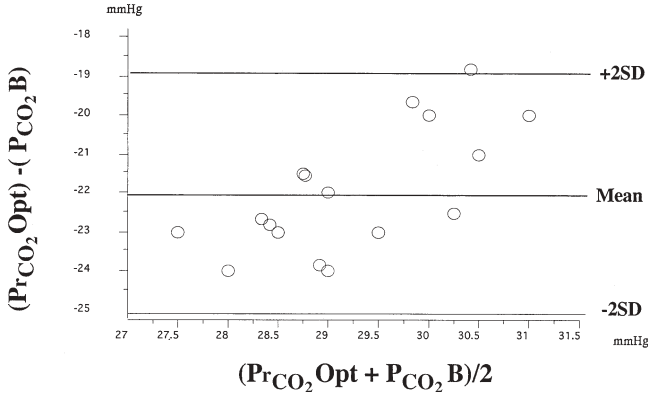

Fig. 4. Pr_{CO_2} in vitro study (Opt vs P_{CO_2}-B). Differences between paired values obtained using Opt and P_{CO_2}-B were plotted against the average of each pair of values. B = −22.09 mmHg; P = 3.15 mmHg. P_{CO_2}-*B*, the P_{CO_2} of the gas in the bottle; *Opt*, Opti

values (Pr_{CO_2} and P_{CO_2}-B) was −1.98 mmHg, and precision was 1.23 mmHg (Fig. 3). However, in the case of Opt, the bias was −22.09 mmHg and precision was 3.15 mmHg (Fig. 4). There was a significant relationship between the average and the difference only in the case of Opt: Y = −55.931 + 1.16X ($r2$ = 0.466) (Y, difference; X, average).

Discussion

In the present study, Opt showed large discrepancies in the values measured using saline, rather than blood samples, compared with those obtained using a conventional analyzer (Elect). These discrepancies were seen in both the clinical and in vitro studies. On the basis of these results, we should say that Opt is not suitable for making accurate measurements using saline samples obtained from a tonometer. The PHi and P_{CO_2} gap values play important roles in the evaluation of critically ill patients, because they allow us to assess the patient's peripheral oxygen metabolism [5,6]. However, the values obtained differ according to the kind of analyzer used, a point that needs to be borne in mind when we use these indices [3]. Moreover, other factors are thought to induce bias [2]; one of these is the time-lag involved in measuring arterial blood gases (ABG). This time-lag has also been said to induce errors in precision [7]. However, avoiding delay can be difficult in some

situations. The handy type of analyzer has the advantage that, because it can be used at the bedside, it should reduce the delay between sampling and measurement.

It has been asserted that point-of-care analyzers are sufficiently accurate for the purposes of blood gas analysis in the clinical setting, and, indeed, data derived from such machines have been used to provide an indication for treatment. Opt has three integral optode sensors for measuring pH, P_{O_2}, and P_{CO_2}. It actually measures changes in the intensity of the light passing through the optode sensor, and then calculates the values of the above three variables. In contrast, most conventional analyzers use electrodes for measuring these three values (three-electrode system).

It has been said that in measuring P_{CO_2} in normal saline in a tonometer, bias can occur even with conventional machines, and that this can lead to there being differences in pHi values between two machines [2]. Such bias was also detected in the present study. The difference between the two mechanisms (optodes versus electrodes) might have been responsible for the differences in results between the two kinds of machines.

In the present clinical comparison of Opt with Elect, we saw a large bias in the saline Pr_{CO_2} value obtained using Opt, and also in the values derived from it (pHi and P_{CO_2} gap). The errors in pHi and the P_{CO_2} gap would appear to be too large for us to be able to use Opt with confidence for this purpose in clinical applications. In this study, the P_{CO_2} gap values obtained using Opt were negative. In general, the P_{CO_2} value is higher in all tonometer saline than in arterial blood. This negative value seems to indicate that Opt does not provide data reflecting the state of peripheral oxygen metabolism. On the basis of the above points, we think that Opt is not an adequate substitute for conventional analyzers in the analysis of tonometry samples (in spite of its usefulness and accuracy in measuring blood samples).

Opt uses a cartridge employing a light-detection system in performing gas analysis, while the conventional machine uses electrodes. In the conventional machine, a change in Pr_{CO_2} is converted into a change in voltage, and this is detected by the electrode. The different mechanisms employed might have made a difference to the values obtained.

We could not find any reported data about taking measurements from saline using Opt. As this analyzer was less accurate when used for making measurements from saline samples, it may be that Opt needs to be recalibrated in order to measure the P_{CO_2} of saline accurately. Possibly, this could have been a significant factor in creating the observed differences between the two machines. Solutions other than normal saline have been reported to be more suitable for measurements of pHi and the P_{CO_2} gap, but such substitute solutions are not yet in clinical use. So, in measuring Pr_{CO_2} we have to employ normal saline when using machines such as Elect and Opt. As mentioned above, one of the potential advantages of point-of-care testing is the ability to obtain results rapidly, and in calculations of pHi and the P_{CO_2} gap, this should greatly reduce the errors resulting from time delay. This would appear to be a reason for advocating the use of point-of-care analyzers in providing the data needed to calculate pHi and the P_{CO_2} gap. However, the bias levels seen in the present study do not support the use of this particular handy type of analyzer for such a purpose.

In conclusion, despite its undoubted convenience and adequate reliability in arterial blood gas analysis, the present point-of-care blood analyzer (Opti) proved not to be suitable for the measurement of pHi and the P_{CO_2} gap because it did not provide an accurate P_{CO_2} value of the saline used for gastrointestinal tonometry.

Acknowledgments. We thank Dr. Robert Timms for revising the English.

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