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Clinical evaluation of a new continuous intraarterial blood gas monitoring system in the intensive care setting

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Abstract: The present study was designed to evaluate a new continuous intraarterial blood gas monitoring system under routine clinical intensive care conditions. Nine mechanically ventilated adult patients were enrolled in this study. A multiparameter intravascular sensor was inserted into the radial or dorsalis pedis artery through a 20-gauge cannula in each patient. The accuracy of the sensor for pH, Pco_2, and Po_2 values was evaluated by comparing the data simultaneously obtained from the monitoring system and from conventional blood gas analysis. Measurements were performed for 3 days for each sensor. A total of 62 blood samples were obtained for comparison. The ranges of measured variables were: pH 7.185–7.602, Pco_2 28.8–68.5 mmHg, and Po_2 45.2–542.4 mmHg. The overall bias ± precision values were 0.002 ± 0.018 for pH units, 0.53 ± 2.04 mmHg for Pco_2, and −1.62 ± 20.00 mmHg for Po_2. In clinically important ranges of Po_2, less than 200 mmHg in particular, the bias and precision values were −2.25 ± 6.48 mmHg in the range of less than 100 mmHg, and 0.98 ± 14.38 mmHg in the range of 100–200 mmHg. Variations of sensor accuracy as a function of elapsed time were within the clinically acceptable range throughout the study period. These findings suggest that this new device is sufficiently useful for routine clinical settings.

Key words: Intraarterial blood gas monitoring, Blood gas analysis, Critical care, Intensive care unit

Introduction

The advantages of continuous intraarterial blood gas monitoring systems were discussed by Shapiro [1] in 1992. He summarized that these systems (a) provide a proactive monitor with alarms for early warning of significant changes, perhaps leading to therapeutic intervention prior to significant physiologic disruption; (b) furnish immediate and continuing blood gas trends, allowing for more rapid and precise adjustment of respiratory supportive therapy; (c) reduce blood loss incident to obtaining data; (d) reduce the risks of nosocomial infection; and (e) reduce the exposure of hospital personnel to the patient's blood.

In this paper, we evaluate the clinical accuracy and efficacy of a new continuous intraarterial blood gas monitoring system, Paratrend 7, developed by Biomedical Sensors (Highwycombe, UK) in the routine intensive care setting.

Materials and methods

The monitor and sensor assembly used in this study are illustrated in Fig. 1. After obtaining informed consent, nine adult patients with various diagnoses who received mechanical ventilation in our intensive care unit (ICU) were enrolled in this study. Patient selection was based on the expected clinical necessity of frequent blood gas analysis. A 20-guage, custom-made intraarterial cannula (Radial Artery Catheterization Set, Arrow International, Reading, PA, USA) was inserted into the radial or dorsalis pedis artery of each patient. The multiparameter intravascular sensor was inserted into the artery through the cannula at about 4 cm depth, and fixed with Luer-lock connectors and sticking plasters. The sensor used in this study was 0.4–0.5 mm in outer diameter, so it can be inserted through a 20-gauge cannula without any difficulty.

The sensor consists of two optical fibers for the measurement of pH and Pco_2, one miniaturized Clark electrode for Po_2, and a thermocouple for blood temperature, which is connected to the monitor itself via a flexible cable (Fig. 1). The same principle of measurement of pH and Pco_2 is used in this sensor. The space

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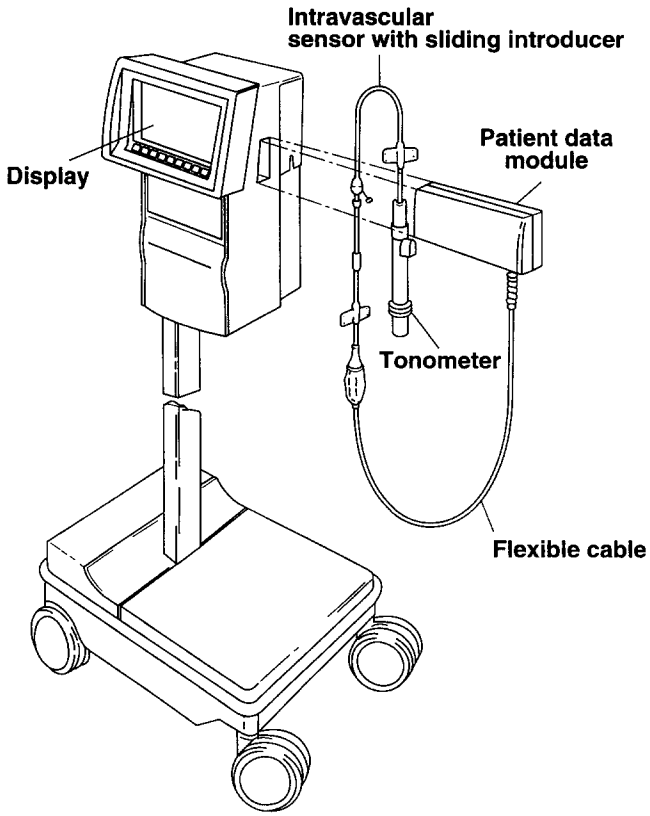

Fig. 1. Monitor and sensor assembly

between sensors is filled with acrylamide gel containing phenol red dye, and the measuring beam is absorbed in passage through this dye gel. The dye gel changes color and hence its degree of light absorption as the hydrogen ion concentration changes.

Tethered to the monitor side of the cable is the patient data module, which is detachable from the monitor. The display screen can show either the current numerical values or real-time graphic trends for pH, Pco_2, and Po_2. The outer surface of the sensor is heparin-coated to reduce fibrin deposition and thrombus formation. At the middle portion of the sensor system, a Y-piece is incorporated to allow arterial blood pressure tracing and blood withdrawal. The arterial cannula and the sensor system were connected to a pressure transducer (Life Kit, Ohmeda, Singapore) from this portion for routine blood pressure monitoring (Lifescope 12, Nihon-Kohden, Tokyo, Japan), and heparinized saline was continuously infused through the sensor system and cannula.

Prior to insertion into the artery of the patient, in vitro calibration of the sensor was performed by passing three precision gas mixtures in sequence through the tonometer under microprocessor control. The pH and Pco_2 elements have three calibration points (7.83, 7.43, and 7.13 for pH; 14.3, 35.7, and 71.3 mmHg for Pco_2) and the Po_2 sensor has one (107 mmHg). This calibration requires about 30 min.

After insertion of the sensor and system stabilization, a blood sample was drawn for the first conventional blood gas analysis. Then the data of the monitoring system were corrected to these values at 37°C. After this first correction of the data of the monitoring system to the results of the conventional blood gas analyzer, there was no data correction throughout the study. A 278 Blood Gas System (Ciba-Corning, Medfield, MA, USA) located in the ICU was used in this study for conventional blood gas analysis (values corrected to 37°C) as the criterion standard. The pH, Pco_2, and Po_2 values obtained from the conventional blood gas analysis were compared with the values from the monitoring system at the moment of blood withdrawal. Blood was drawn for blood gas analysis when clinically indicated or the sensor showed a clinically important change in one of three variables. The accuracy of the thermocouple was not examined in this study. Measurements were performed for 3 days for each sensor.

All paired measurements from the monitoring system and the blood gas analyzer were subjected to statistical analysis by calculation of least squares linear regression and correlation coefficients. In addition, the method of Bland and Altman [2] was used to calculate bias and precision for comparison. According to this method, the bias was calculated as the mean of the differences between the monitoring system and the blood gas analyzer, while the precision was calculated as the standard deviation of these differences.

Results

Measurements were carried out in 9 adult mechanical ventilated patients (6 male, 3 female). The average age of these patients was 62.8 (range 46–72) years.

Nine sensors were tested for 3 days and no failures of the sensor nor of the monitoring device occurred. There were no difficulties with blood sampling from the arterial cannula with the sensor in situ. No adverse effects due to sensor insertion were observed.

A total of 62 blood samples were obtained for comparison. The ranges for measured variables were: pH 7.185–7.602, Pco_2 28.8–68.5 mmHg, and Po_2 45.2–542.4 mmHg.

Figure 2 shows scatterplots of all data obtained by the monitoring system over the results of the conventional blood gas analyzer, as well as the results of the linear regression analysis.

Table 1 shows the bias and precision for all variables. Figure 3 shows the differences between the monitoring system and the blood gas analyzer plotted against the

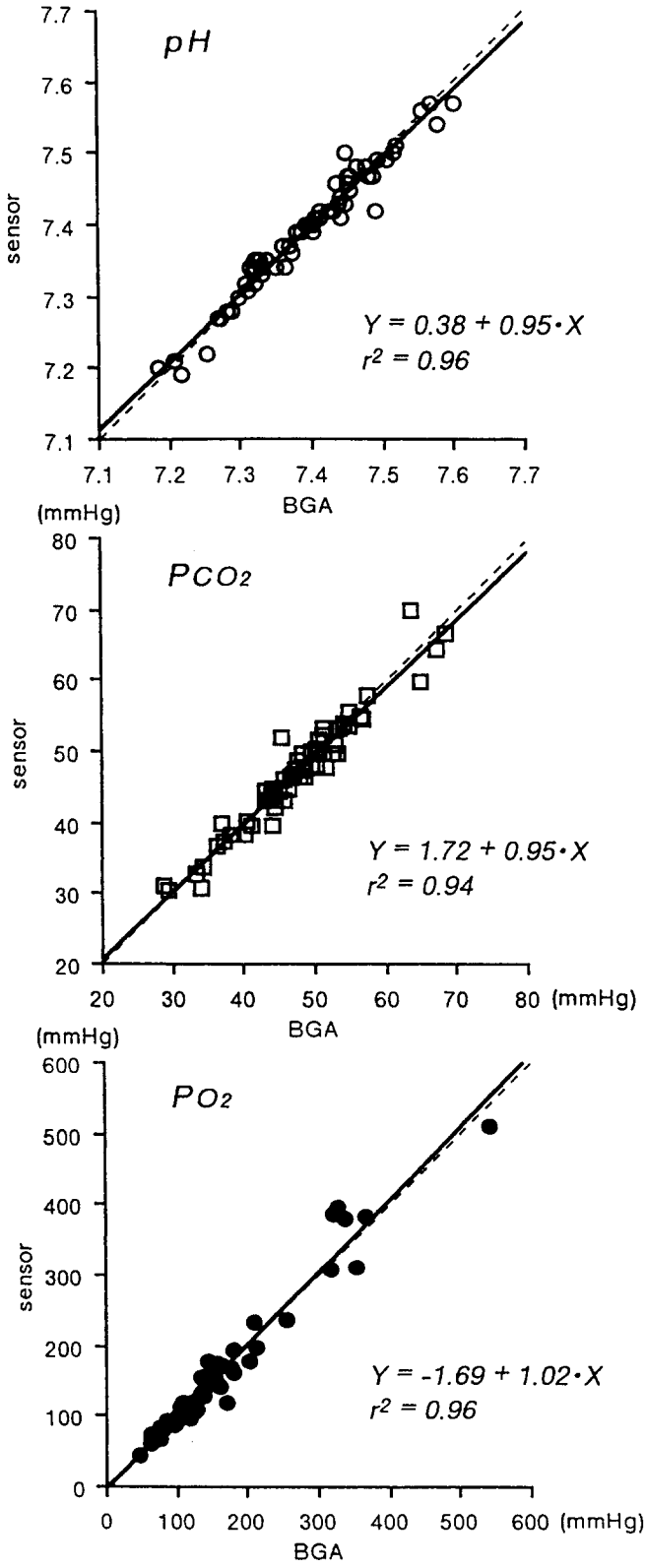

Fig. 2. Scatterplots of the monitoring system sensor values of pH, Pco_2, and Po_2 with conventional blood gas analysis (*BGA*). *Solid lines*, regression analysis lines; *dashed lines*, line of identity

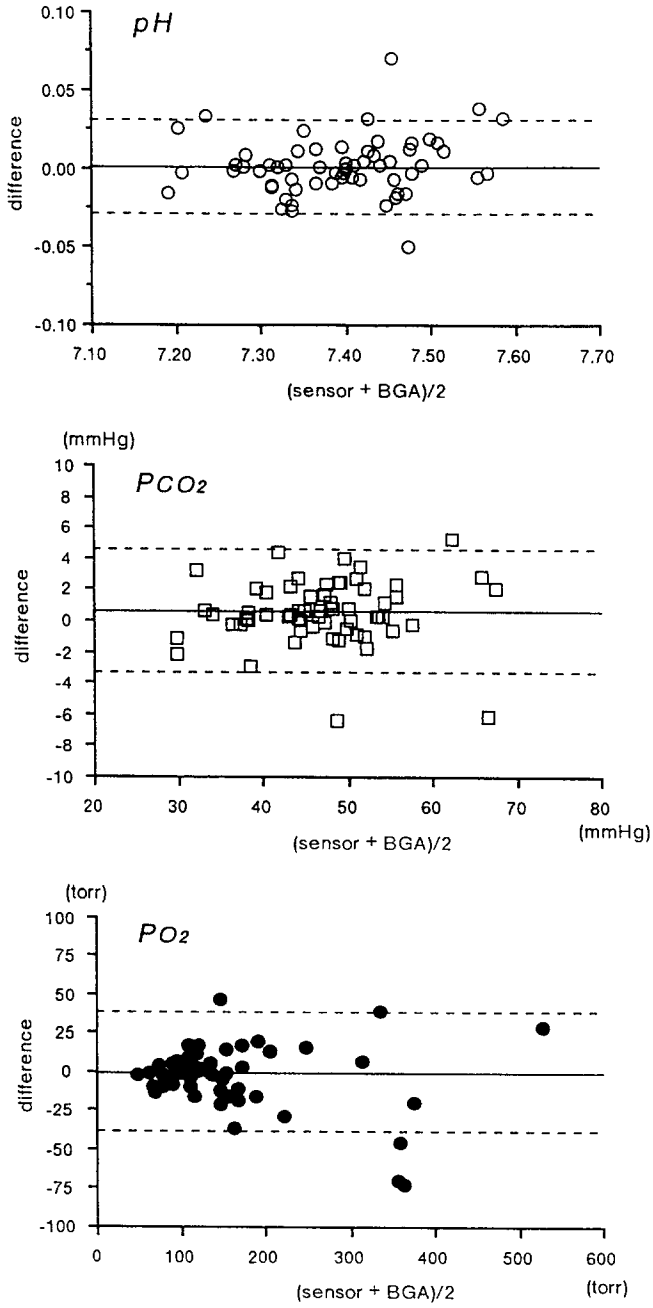

Fig. 3. Differences between the monitoring system sensor values and the conventional blood gas analysis (*BGA*) plotted against the mean value of these methods. *Solid lines*, bias (mean difference); *dashed lines*, 95% confidence range for agreement (±2 SD of mean difference)

Table 1. Bias and precision for all variables

	pH (pH unit)				Pco_2 (mmHg)				Po_2 (mmHg)			
	Overall	<7.35	7.35 to 7.45	>7.45	Overal	<35	35 to 45	>45	Overall	<100	100 to 200	>200
Bias	0.002	−0.004	0.002	0.010	0.53	0.20	0.38	0.65	−1.62	−2.25	0.98	−9.35
Precision	0.018	0.015	0.016	0.023	2.04	2.05	1.52	2.28	20.00	6.48	14.38	39.44

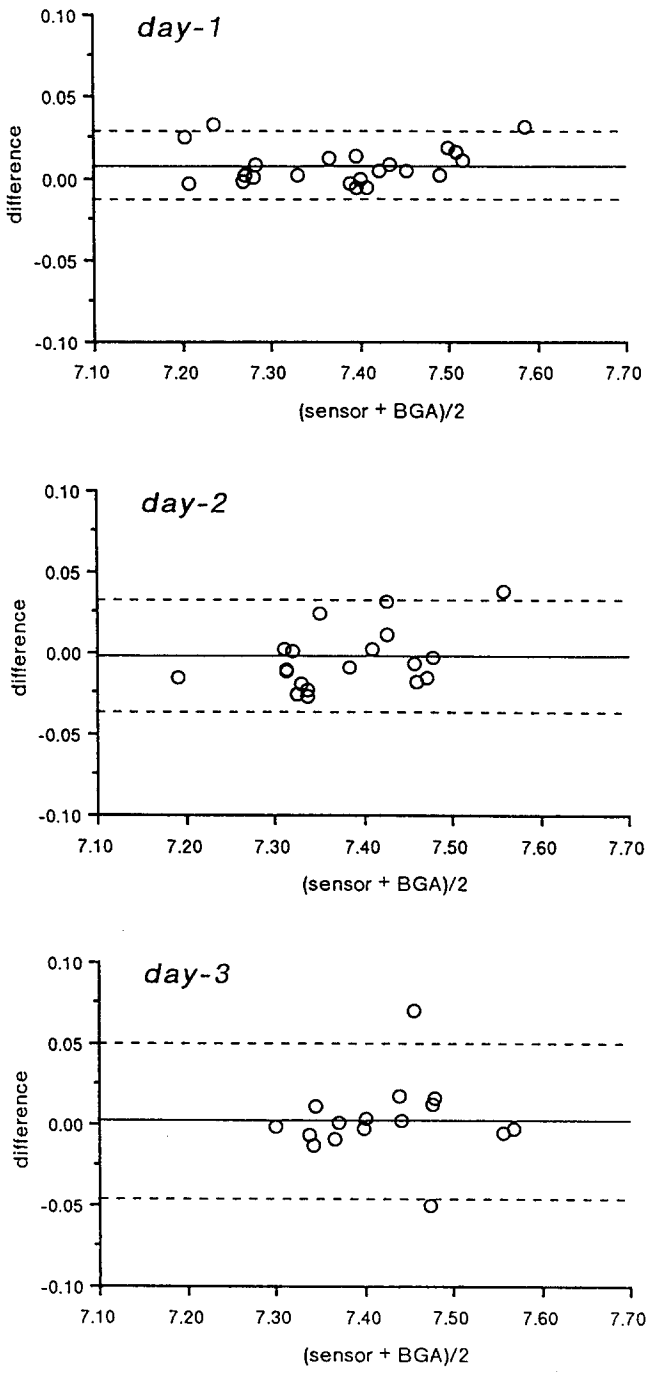

Fig. 4. Daily variations in accuracy of the monitoring system sensor for pH. *Abbreviations and lines*, see Fig. 3

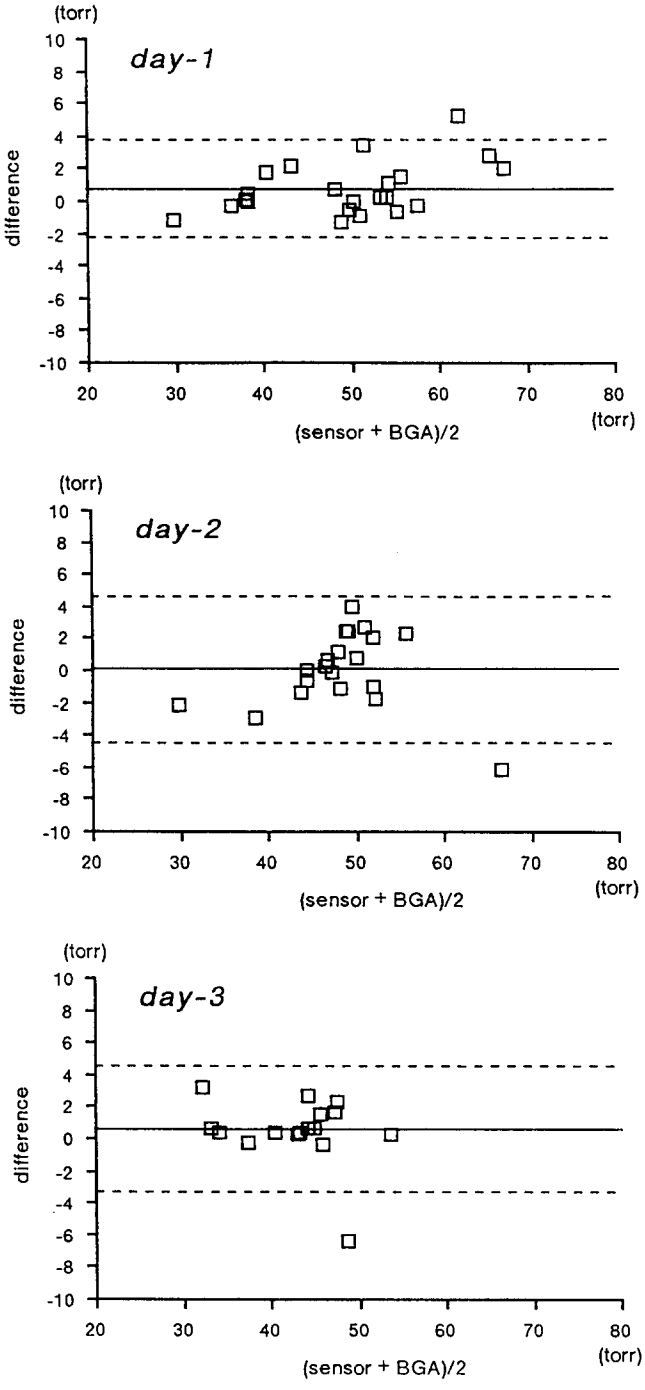

Fig. 5. Daily variations in accuracy of the monitoring system sensor for Pco_2. *Abbreviations and lines*, see Fig. 3

Table 2. Daily variations in sensor accuracy

	pH (pH unit)			Pco_2 (mmHg)			Po_2 (mmHg)		
	Day 1	Day 2	Day 3	Day 1	Day 2	Day3	Day 1	Day 2	Day3
Bias	0.008	−0.004	0.003	0.74	0.06	0.52	4.70	−4.57	−3.70
Precision	0.011	0.018	0.024	1.59	2.37	2.12	18.68	17.12	24.20

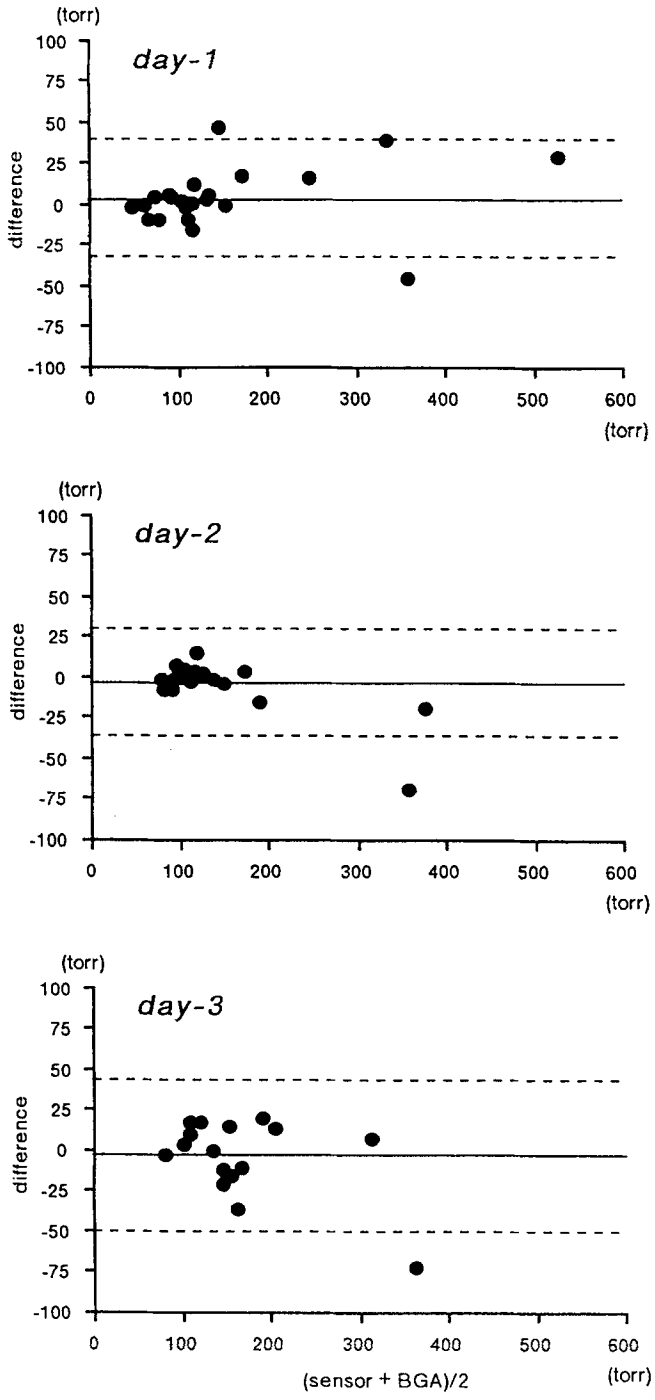

Fig. 6. Daily variations in accuracy of the monitoring system sensor for Po_2. *Abbreviations and lines*, see Fig. 3

average of two paired values according to the method of Bland and Altman [2].

Daily variations in sensor accuracy for pH, Pco_2, and Po_2 are presented in Figs. 4–6 and Table 2.

Discussion

The present study was designed to evaluate a new continous intraarterial blood gas monitoring system under routine clinical ICU conditions. Other reports of three monitoring systems including the one used in this study in similar situations have recently been published [3–5]. The bias and precision of these reports are shown in Table 3.

The results of the measurement of pH and Pco_2 demonstrated a high clinically acceptable accuracy throughout the range studied in this trial (Figs. 2, 3). The overall bias and precision of each measurement in our trial were 0.002 ± 0.018 units for pH and 0.53 ± 2.04 mmHg for Pco_2, and these findings are within the range reported by others (Tables 1, 3).

The Po_2 values measured in our trial also showed good agreement with the conventional blood gas analyzer in the range of less than 200 mmHg. In the range of less than 100 mmHg in particular, the closest correlation and low levels of bias and precision between the monitoring system and the blood gas analyzer were seen (Fig. 3). The bias and precision were −2.25 ± 6.48 mmHg in the range of less than 100 mmHg, and 0.98 ± 14.38 mmHg in the range of 100–200 mmHg (Table 1). In these clinically important ranges of Po_2 less than 200 mmHg, these findings are acceptable enough to use in clinical ICU settings. On the other hand, in the range of over 200 mmHg, some differences in Po_2 between the monitoring system and the blood gas analyzer were found to be larger. The largest difference was 71.2 mmHg (the monitoring system was 398 mmHg, when the blood gas analyzer was 326.8 mmHg), and the bias and precision was −9.35 ± 39.44 mmHg in this range. Fortunately, however, the risk of overlooking severe hypoxemia of the patient in this high Po_2 range may be negligible, even if the differences are up to 100 mmHg.

These large differences in Po_2 between the monitoring system and the blood gas analyzer in the high Po_2

Table 3. Comparison with other reported data

Investigator	Samples	pH (pH unit) Bias ± precision	P_{CO_2} (mmHg) Bias ± precision	P_{O_2} (mmHg) Bias ± precision
Zimmerman and Dellinger [3]	104	−0.021 ± 0.037	1.74 ± 6.06	−5.89 ± 13.19
Haller et al. [4]	487	−0.04 ± 0.02	−1.9 ± 3.0	−2.3 ± 6.4
Venkatesh et al. [5]	158	0.01 ± 0.06	1.4 ± 4.8	2.8 ± 25.6
Present study	62	0.002 ± 0.018	0.53 ± 2.04	−1.62 ± 20.00

range are due to the composition of the calibration gases. Three precision gas mixtures for in vitro calibration are: 2% CO_2, 15% O_2, balance N_2; 5% CO_2, 15% O_2, balance N_2; and 10% CO_2, 15% O_2, balance N_2. These gas mixtures enabled the pH and CO_2 sensor to use a three-point calibration, while the Clark electrode for P_{O_2} measurement was calibrated at only one point (15% O_2 = 107 mmHg). If we used a slightly higher concentration of O_2 for calibration. such as 30% O_2, we might get smaller differences in P_{O_2} between the monitoring system and the blood gas analyzer in the high P_{O_2} range.

The sensors are approved for 3-day use by the manufacturer, and our data also show sufficient accuracy throughout the stdy period (Figs. 4 to 6 and Table 2). Although the precision of pH and P_{O_2} at only the 3rd day tended to be slightly large, they seemed to be within the clinically acceptable range.

The patient data module, incorporated into this monitoring system, contains a nonvolatile memory to retain the calibration and patient data, and can be detached from the monitor itself. When the need for patient transportation from the ICU occurred, such as for diagnostic computed tomography scans, the sensor was left in place during the transportation. After the transportation, monitoring can be resumed immediately by plugging the module back into the monitor.

Finally, the system used in this study also has the advantages of a useful flexible cable, a sliding sensor introducer system, and a somewhat flexible sensor itself. These improvements were effective to maintain the device in the patient for 3 days. No sensor malposition nor "wall effect" due to patient movement was observed in this trial.

Pulse oximetry is a noninvasive and reliable method to detect hypoxemia. However, neither changes in P_{aCO_2} and pH nor changes in oxygenation in the range of high or subnormal values can be accurately detected by this method [4].

The most effective application of this kind of device in the ICU seems to be for monitoring the minute-by-minute changes of the blood gases, such as in NO inhalation or surfactant therapy for acute lung injury, in the prone position or positional drainage for gravity-dependent lung disease, and in tracheal toiletting by suctioning or flexible bronchoscopy for the patient under high positive end-expiratory pressure. These are all conditions requiring frequent blood gas analysis to confirm the effect of therapy or to prevent hypoxemia. It is a relief to have access to real-time blood gas data, not only P_{O_2} but also pH and P_{CO_2} at the moment of the procedure, in addition to being able to monitor blood pressure simultaneously.

Aberrant values due to electrical noises were not observed in this ICU trial, and we have no experience in using this system during electrosurgery. But this may be an important consideration when using this device in an operating room. Further study is needed in this point.

As this system is designed to use in conjunction with a 20-gauge arterial catheter or larger, small children or infants may be precluded from treatment using this system for practical reasons. Furthermore, the manufacturer recommends the use of a custom-made intraarterial cannula (Radial Artery Catheterization Set, Arrow International) to assure adequate transmission of the blood pressure waveform. We have already confirmed the sensor accuracy and adequate waveform transmission with a 20-gauge Surflo (Terumo, Tokyo, Japan) (unpublished data).

Although this kind of device may not be inexpensive enough for widespread use throughout the country at present, lots of advantages, especially the ability to monitor minute-by-minute blood gas changes in critically ill patients as well as simultaneously monitoring blood pressure without any blood loss, are very attractive for us. This device is on the market at the price of ¥6.5 million per monitor and ¥60000 per sensor in Japan. Medical insurance is available for this sensor only for use during differential lung ventilation.

In conclusion, this new continuous intraarterial blood gas monitoring system is sufficiently accurate for routine clinical use when compared with conventional blood gas analysis. Intensivists now have a new, useful, and safe method at their disposal in the management of critically ill adult patients.

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