

## Accuracy and clinical performance of a continuous intra-arterial blood-gas monitoring system during thoracoscopic surgery†

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### Summary

Accuracy and performance of the only currently available intra-arterial blood-gas monitoring system (Paratrend 7, PT7) were assessed in 23 patients during thoracoscopic surgery using one-lung ventilation. Over a wide range of values for arterial  $P_{O_2}$  (6.1–61.1 kPa),  $P_{CO_2}$  (4.1–9.5 kPa) and pH (7.19–7.50), 138 arterial blood-gas values obtained by PT7 were compared with corresponding *in vitro* laboratory blood-gas measurements. We found good clinical performance with the PT7 and good agreement between PT7 values and *in vitro* measurements for arterial  $P_{O_2}$  (bias (1.96 SD) = 0.38 (9.52) kPa),  $P_{CO_2}$  (0.31 (0.76) kPa) and pH (–0.017 (0.065)). Also, the bias for sequential changes between two consecutive times was not significantly different from the ideal value of 0. We conclude that the PT7 is helpful in monitoring patients during thoracoscopy. (*Br. J. Anaesth.* 1997; 79: 47–52).

### Key words

Measurement techniques, gass exchange. Equipment, blood-gas monitors. Surgery, thoracic. Ventilation, one-lung.

Video-assisted thoracoscopic surgery is used widely for an increasing number of diagnostic and therapeutic procedures in patients with compromised lung function. Additionally, one-lung ventilation (OLV) is necessary to provide a collapsed lung on the side of operation, and this is often associated with significant changes in arterial blood-gas tensions. Oxygenation may be impaired by significant intrapulmonary shunting, and carbon dioxide removal may be impaired by increased deadspace ventilation. Furthermore, lateral positioning of patients is usually necessary for an optimal surgical approach and may contribute further to ventilation-perfusion mismatch resulting in compromised gas exchange. In order to prevent hypoxaemia and hypercapnia, repeated *in vitro* (laboratory) blood-gas analyses are performed frequently during OLV to control and adjust ventilation and oxygenation of the lungs. Continuous intra-arterial blood-gas monitoring would be advantageous because changes in oxygenation and carbon dioxide elimination can be recognized and treated immediately.<sup>1</sup>

The Paratrend 7 (Biomedical Sensors Ltd, Pfizer Hospital Products Group, High Wycombe, UK) is a fast-response intra-arterial blood-gas monitoring system which may be suitable for detection of rapid changes in arterial  $P_{O_2}$ ,  $P_{CO_2}$  and pH values during thoracic surgery with OLV. It is currently the only commercially available intravascular blood-gas sensor system. The Paratrend 7 system (PT7), however, has been validated by only one group of authors in an experimental animal study<sup>2</sup> and, for limited  $P_{O_2}$ ,  $P_{CO_2}$  and pH ranges, in the intensive care unit and during cardiac surgery.<sup>3–5</sup>

This study was performed to evaluate prospectively the clinical accuracy and performance of the Paratrend 7 intra-arterial blood-gas monitoring system during thoracoscopy over a wide range of  $P_{O_2}$ ,  $P_{CO_2}$  and pH values.

### Patients and methods

Twenty-three patients undergoing elective thoracoscopic surgery gave their written informed consent to participate in this study, which was approved by the local Ethics Committee.

### INTRAVASCULAR BLOOD-GAS SENSOR

The Paratrend 7 (PT7) is a multi-parameter sensor system incorporating four different sensors:  $P_{O_2}$  is measured by a miniaturized Clark electrode,  $P_{CO_2}$  and pH are measured by Optodes, and blood temperature is determined by a thermocouple. The four sensor elements are housed in a heparin-coated microporous polyethylene tubing of approximately 0.5 mm in diameter, suitable for insertion through a 20-gauge or larger size catheter. The tip with the sensor elements, approximately 4 cm in length, has to float freely in the arterial lumen. The device with the blood-gas sensor incorporates a tubing system enabling simultaneous continuous intravascular arterial pressure measurement and intermittent

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blood aspiration via a sideport for repeated *in vitro* laboratory blood-gas measurement. The disposable sensor is sealed by the manufacturer within a tonometer containing buffer solution, which maintains hydration and serves as a calibration medium. Before insertion into the patient, the sensor is calibrated under microprocessor control by the PT7 monitor using three precision gases bubbled through the tonometer. The calibration procedure takes 30 min. According to the manufacturer's guidelines, the sensor should be inserted into the artery within 8 h thereafter. Later, re-calibration of the system using the values of *in vitro* laboratory blood-gas determinations as a reference is only recommended every 12 h. After insertion of the calibrated sensor, the PT7 monitor provides continuous graphical and numerical display of the measured values  $P_{O_2}$ ,  $P_{CO_2}$ , and pH. Temperature and calculated values  $SO_2$ ,  $HCO_3^-$  and BE are displayed numerically.

Patients received oral premedication with midazolam 3.75–7.5 mg, 30–45 min before transfer to the operating theatre. After insertion of an 18-gauge i.v. cannula (Adsyte, Becton Dickinson Vascular Access Inc., UT, USA), a radial artery (left/right = 16/7) was cannulated under local anaesthesia using a 5.1 cm long, 20-gauge catheter (Insyte, Becton Dickinson Vascular Access Inc., Sandy, UT, USA). A pressure transducer (Uniflow 43–600F, Baxter, Bentley Laboratories Europe, Uden, The Netherlands) was connected to the sideport of the previously calibrated PT7 sensor system for continuous intra-arterial pressure measurement. The pressure transducing tubes were pre-filled with a solution of normal saline containing heparin 2 u. ml<sup>-1</sup>. While flushing continuously from a pressurized flush bag, the sensor was inserted through the radial cannula, advanced to a depth of 15 cm and attached to the skin with adhesive tape. Any movements of the hand were prevented to avoid kinking of the PT7 sensor. The arterial pressure waveform was displayed on a Hellige monitor (VICOM-SM SMU 612, PPG Hellige, Freiburg, Germany) and the continuous intra-arterial blood-gas measurements displayed on the PT7 monitor. Additional routine monitoring of patients consisted of five-lead ECG, pulse oximetry, rectal temperature measurement and measurements of end-tidal concentrations of carbon dioxide and inhalation anaesthetics (all VICOM-SM SMU 612, PPG Hellige, Freiburg, Germany). Anaesthesia was induced using thiopentone and fentanyl i.v. Neuromuscular block was produced with suxamethonium. Left endobronchial intubation was performed with a double-lumen tube (Sher-I-Bronch, Sheridan Catheter Corp., Argyle, NY, USA) under fibreoptic control. Enflurane in oxygen and air, fentanyl and pancuronium were used for maintenance of anaesthesia and neuromuscular block. Volume-controlled ventilation was used (Siemens Servo 900 D ventilator, Siemens Life Support Systems, Solna, Sweden), and ventilatory patterns were adjusted by an experienced anaesthetist tailored to the individual patient. Positioning of patients was performed according to surgical needs (left lateral 14 patients; right lateral eight patients; supine one patient). To provide a collapsed

lung on the side of operation, OLV with an inspired oxygen fraction of 1.0 was induced on the contralateral side before skin incision for introduction of the trocar through the seventh or eighth intercostal space, and maintained throughout thoracoscopy. At the end of surgery a drainage tube was inserted and the collapsed lung was again ventilated.

#### DATA COLLECTION

The PT7 sensor was inserted immediately after the initial calibration procedure was completed in all cases, and was not re-calibrated thereafter. Data were obtained after induction of anaesthesia, 5, 10, and 20 min after the onset of OLV, before the end of OLV, and 10 min after two-lung ventilation was re-established. Provided that system stability was indicated by the PT7 computer according to the manufacturer's manual, arterial blood-gas values displayed on the PT7 monitor were stored at these times. Simultaneously, a 1-ml blood sample was obtained for *in vitro* blood-gas analysis from the radial artery cannula using a pre-heparinized syringe (QS 50, Radiometer Medicals, Copenhagen, Denmark). *In vitro* measurement was performed within the next 2 min (IL 1400 BGE-analyzer with IL 482 co-oximeter, Instrumentation Laboratory, Milano, Italy) by a laboratory technician who was unaware of the *in vivo* PT7 values. Both PT7 and blood-gas analysis values were determined at 37 °C and thus no temperature correction was performed. Rectal and PT7 temperature readings were also recorded.

#### DATA ANALYSIS

All results were analysed using StatView 4.1 software (Abacus Concepts, Inc., Berkeley, CA) on an Apple Macintosh computer. Data are presented as mean (SD). Bias (mean of the differences PT7–blood-gas analysis (BGA)) and precision (1.96 SD of these differences) were calculated<sup>6</sup> for arterial pH,  $P_{O_2}$ ,  $P_{CO_2}$ ,  $SO_2$ ,  $HCO_3^-$ , BE and temperature. Simple linear regression analyses were performed for arterial  $P_{O_2}$ ,  $P_{CO_2}$ ,  $SO_2$ ,  $HCO_3^-$ , BE and temperature, but not for pH because of its logarithmic scale. The pH values, instead, were converted to  $[H^+]$ , and linear regression analysis and calculation of bias and precision were performed. Furthermore, sequential changes in arterial  $PO_2$ ,  $P_{CO_2}$ , pH and  $[H^+]$  between two consecutive times ( $\Delta PO_2$ ,  $\Delta P_{CO_2}$ ,  $\Delta pH$ ,  $\Delta [H^+]$ ) were calculated for PT7 and BGA. Bias and precision of these changes were calculated for  $\Delta PO_2$ ,  $\Delta P_{CO_2}$ ,  $\Delta pH$  and  $\Delta [H^+]$ , and linear regression analyses were performed for  $\Delta PO_2$ ,  $\Delta P_{CO_2}$  and  $\Delta [H^+]$ . One-sample Sign tests were used to compare biases with the hypothesized ideal value of 0.  $P < 0.05$  was considered statistically significant.

#### Results

All 23 patients were studied (mean age 55 (range 20–76) yr; male/female ratio 17/6; ASA grade I, two patients, grade II, 12 patients, grade III, eight

**Table 1** Arterial blood-gas values obtained by the Paratrend 7 monitor (PT7) and by simultaneous *in vitro* blood-gas analysis (BGA). Arterial  $PO_2$ ,  $PCO_2$  and pH were measured by both systems,  $HCO_3^-$  and BE were calculated by both systems,  $SO_2$  was measured by the co-oximeter and calculated by the Paratrend 7.  $n = 138$

|                                       | Mean (SD)   |             | Minimum |      | Maximum |      |
|---------------------------------------|-------------|-------------|---------|------|---------|------|
|                                       | PT7         | BGA         | PT7     | BGA  | PT7     | BGA  |
| $PO_2$ (kPa)                          | 24.3 (15.8) | 24.0 (14.5) | 5.7     | 6.1  | 72.9    | 61.1 |
| $PCO_2$ (kPa)                         | 6.0 (0.8)   | 5.7 (0.9)   | 4.5     | 4.1  | 9.9     | 9.5  |
| pH                                    | 7.37 (0.06) | 7.39 (0.05) | 7.19    | 7.19 | 7.47    | 7.50 |
| $HCO_3^-$ (mmol litre <sup>-1</sup> ) | 25.9 (2.1)  | 25.6 (1.4)  | 21.4    | 21.3 | 33.5    | 28.8 |
| BE (mmol litre <sup>-1</sup> )        | 0.6 (2.7)   | 1.0 (1.5)   | -6.2    | -4.5 | 8.6     | 3.7  |
| $SO_2$ (%)                            | 97.0 (4.1)  | 95.3 (4.9)  | 78.7    | 73.8 | 99.9    | 99.7 |

**Table 2** Results of comparisons between Paratrend 7 readings and simultaneous *in vitro* blood-gas determinations. Arterial  $PO_2$ ,  $PCO_2$  and pH were measured by both systems,  $HCO_3^-$  and BE were calculated by both systems.  $SO_2$  was measured by the co-oximeter and calculated by the Paratrend 7.  $[H^+]$  was calculated from the pH values measured by both systems to allow linear regression analysis.  $n = 138$ . \* $P < 0.05$ , \*\*\* $P < 0.0001$ , compared with hypothesized ideal value of 0. Regression line equation  $y = a + b \times x$ :  $y =$  Paratrend 7 readings,  $x =$  *in vitro* blood-gas determinations,  $a =$  axis intercept,  $b =$  regression coefficient (slope),  $r =$  correlation coefficient

|                                       | $a$   | $b$  | $r$  | Bias      | Precision |
|---------------------------------------|-------|------|------|-----------|-----------|
| $PO_2$ (kPa)                          | -0.64 | 1.04 | 0.95 | 0.38      | 9.52      |
| $PCO_2$ (kPa)                         | 1.04  | 0.87 | 0.90 | 0.31***   | 0.76      |
| pH                                    | —     | —    | —    | -0.017*** | 0.065     |
| $HCO_3^-$ (mmol litre <sup>-1</sup> ) | 9.73  | 0.63 | 0.43 | 0.3*      | 3.9       |
| BE (mmol litre <sup>-1</sup> )        | -0.36 | 1.00 | 0.56 | -0.4      | 4.4       |
| $SO_2$ (%)                            | 25.4  | 0.7  | 0.82 | 1.7***    | 5.5       |
| $[H^+]$ (nmol litre <sup>-1</sup> )   | 4.69  | 0.93 | 0.84 | 1.76***   | 6.62      |

**Table 3** Temperature obtained by the Paratrend 7 sensor in the radial artery (Temp PT7, °C) and by simultaneous rectal temperature measurement (Temp rect, °C).  $n = 138$ . \*\*\* $P < 0.0001$  compared with hypothesized ideal value of 0. Min/Max = Minimum/maximum values. Regression line equation  $y = a + b \times x$ :  $y =$  Paratrend 7 radial temperature measurement,  $x =$  rectal temperature measurement,  $a =$  axis intercept,  $b =$  regression coefficient (slope),  $r =$  correlation coefficient

|           | Mean (SD)  | Min/Max   | $a$  | $b$  | $r$  | Bias    | Precision |
|-----------|------------|-----------|------|------|------|---------|-----------|
| Temp PT7  | 35.9 (0.9) | 32.0/37.2 | 9.55 | 0.72 | 0.48 | -0.5*** | 1.6       |
| Temp rect | 36.1 (0.6) | 34.5/37.5 |      |      |      |         |           |

**Table 4** Sequential changes in arterial blood-gas tensions between two consecutive times (delta  $PO_2$ , delta  $PCO_2$ , delta pH): results of comparisons between Paratrend 7 readings and simultaneous *in vitro* blood-gas determinations. Delta  $[H^+]$  was calculated from the pH values measured by both systems to allow linear regression analysis.  $n = 115$ . No significant differences from the hypothesized ideal value of 0. Regression line equation  $y = a + b \times x$ :  $y =$  Paratrend 7 readings,  $x =$  *in vitro* blood-gas determinations,  $a =$  axis intercept,  $b =$  regression coefficient (slope),  $r =$  correlation coefficient

|   | $a$   | $b$  | $r$  | Bias   | Precision |
|---|-------|------|------|--------|-----------|
| Delta $PO_2$ (kPa)                        | 0.27  | 1.03 | 0.97 | 0.28   | 9.04      |
| Delta $PCO_2$ (kPa)                       | -0.01 | 0.87 | 0.87 | 0.01   | 0.59      |
| Delta pH                                  | —     | —    | —    | -0.001 | 0.035     |
| Delta $[H^+]$ (nmol litre <sup>-1</sup> ) | 0.06  | 0.93 | 0.87 | 0.08   | 3.52      |

patients, grade IV, one patient). The operations performed were: lung resection (14), pleurectomy (six), bullectomy (two) and sympathectomy (one). Duration of anaesthesia was 220 (68) min, duration of operation was 106 (61) min and duration of OLV was 99 (58) min. All PT7 sensors calibrated and inserted into a radial artery measured intra-arterial blood-gas tensions throughout the study and there were no technical failures. According to the study design, six measurements in 23 patients were performed, producing 138 PT7 readings with corresponding blood-gas analysis values. Positioning of patients and diathermy did not affect sensor

function. No complications attributable to the sensor were observed.

On average, near normal arterial  $PCO_2$  and high  $PO_2$  values were found (table 1). However, extreme blood-gas values were observed during thoracoscopic surgery and OLV, which offered the opportunity to study the accuracy of the PT7 over a wide range of blood-gas analysis values (table 1). PT7- $PO_2$  corresponded very well with BGA- $PO_2$ , as evidenced by non-significant bias (0.38 kPa) and a correlation coefficient of 0.95 (table 2, fig. 1). Also, PT7- $PCO_2$  corresponded well with BGA- $PCO_2$ , as documented by a bias of 0.31 kPa ( $P < 0.0001$ ) and a correlation

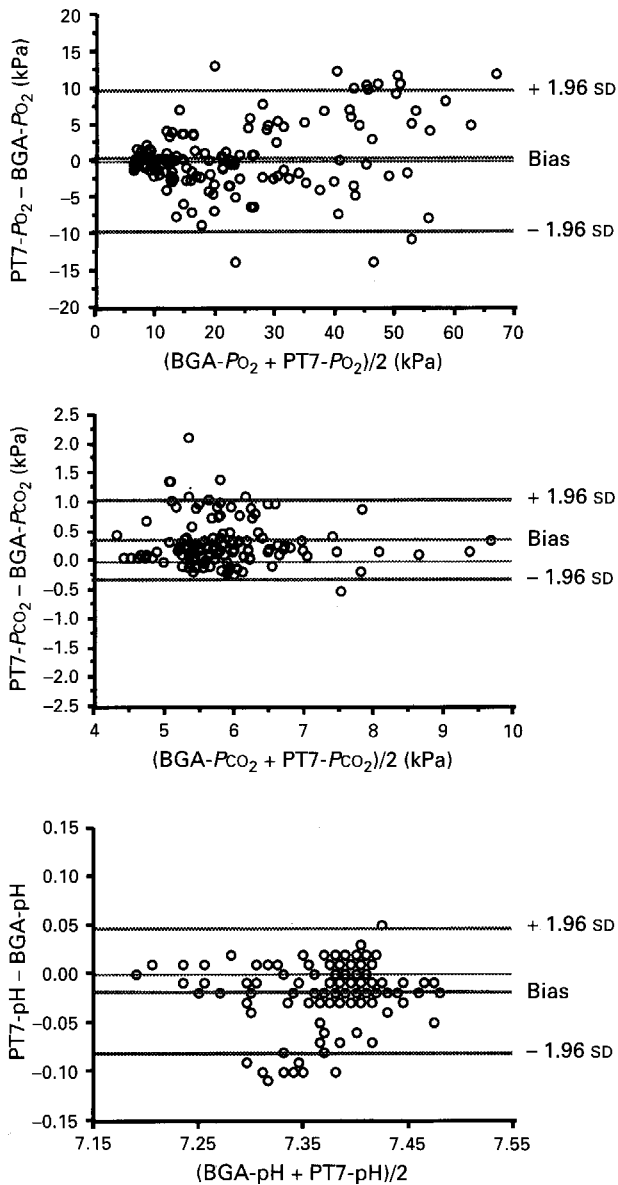


Figure 1 Bland Altman plots<sup>6</sup> showing bias (mean of differences) and precision (1.96 SD of these differences) vs mean values of arterial  $P_{O_2}$ ,  $P_{CO_2}$  and pH obtained by Paratrend 7 (PT7) compared with values obtained by *in vitro* blood-gas measurement using a co-oximeter (BGA).  $n = 138$ .

coefficient of 0.90 (table 2, fig. 1). Furthermore, the calculated  $[H^+]$  concentrations derived from the PT7-pH values correlated well with those derived from BGA-pH (correlation coefficient 0.84) (table 2). Bias between PT7-pH and BGA-pH was relatively small ( $-0.017$ ;  $P < 0.0001$ ) (table 2, fig. 1). However, agreement of the calculated values  $HCO_3^-$  (0.43) and BE (0.56) was relatively poor (table 2). Mean PT7 radial temperature values were lower than those recorded rectally (table 3). The bias of the sequential changes between two consecutive times ( $\Delta P_{O_2}$ ,  $\Delta P_{CO_2}$ ,  $\Delta pH$ ,  $\Delta [H^+]$ ) was not significantly different from the hypothesized ideal value of 0 (table 4), and a good correlation coefficient between BGA and PT7 was found for the values  $\Delta P_{O_2}$  (0.97),  $\Delta P_{CO_2}$  (0.87) and  $\Delta [H^+]$  (0.87) (table 4, fig. 2).

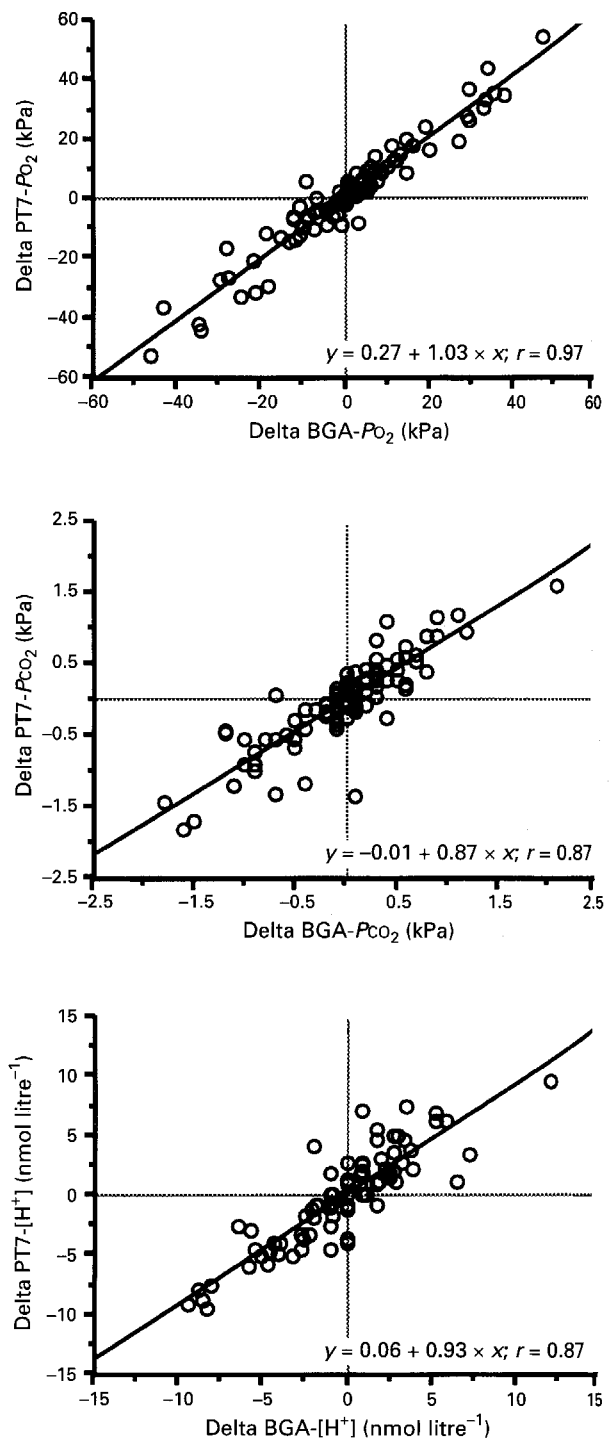


Figure 2 Linear regression analysis plots showing sequential changes in arterial  $P_{O_2}$ ,  $P_{CO_2}$  and  $[H^+]$  between two consecutive times ( $\Delta P_{O_2}$ ,  $\Delta P_{CO_2}$ ,  $\Delta [H^+]$ ) obtained by Paratrend 7 (PT7) vs corresponding changes obtained by *in vitro* blood-gas measurement using a co-oximeter (BGA).  $n = 115$ .

## Discussion

The results of this study indicate good clinical performance of the Paratrend 7 multi-parameter sensor. In all patients the sensor was inserted into the radial artery catheter without difficulties and accurately measured arterial blood-gas tensions continuously during thoracoscopy over a wide range of  $P_{O_2}$ ,  $P_{CO_2}$  and pH values (see tables 1 and 2; fig. 1).

The correlation of  $So_2$  values calculated by the PT7 compared with *in vitro* values determined by the co-oximeter was also satisfactory (table 2). However, radial PT7 temperature compared with rectal temperature (table 3), and values of  $HCO_3^-$  and BE calculated by and displayed on the Paratrend 7 monitor showed poor correlation with those calculated from the *in vitro* blood-gas determinations (table 2).

Thoracoscopy necessitates OLV with close monitoring of arterial blood-gas tensions. Intermittent blood-gas measurement is currently standard care and insertion of an intra-arterial catheter is usually required. Although this represents a "continuously invasive" method, blood-gas determination is still only intermittent. Recently, serious shortcomings of conventional intermittent blood-gas analyses have been discussed.<sup>7-10</sup> The most obvious disadvantage is the dependence on clinical judgement as to when blood samples should be obtained. Adequate and immediate detection of serious events by the anaesthetist is presumed, blood has to be sampled in time and the results should be available rapidly. In many critical situations, however, blood sampling, transport and laboratory analysis is only possible with a considerable delay, and sampling rate is inherently limited. Thus intermittent blood-gas measurement represents a "snapshot" of a continuous physiological variable and is frequently obtained after a critical event has already occurred.<sup>7</sup> Continuous intra-arterial blood-gas monitoring, on the other hand, provides relevant physiological information on-line, including display of trends of measured variables. Furthermore, alarm limits for the variables may be defined. Continuous intra-arterial blood-gas monitoring is therefore desirable, provided that such a system is accurate.

Several clinical studies on the performance of intravascular sensor systems have been published<sup>3-5 9-16</sup> and the results have been reviewed recently.<sup>17 18</sup> None of these systems, however, is available commercially, except for the PT7. Unfortunately, the PT7 system has been validated clinically by only one team of investigators in collaboration with the manufacturer.<sup>3-5</sup> Assessing accuracy and clinical performance of the PT7 system independently is therefore important. In thoracoscopy, using OLV, we had the opportunity to assess the accuracy of the PT7 system over a wide range of arterial  $PO_2$  (6.1–61.1 kPa),  $PCO_2$  (4.1–9.5 kPa) and pH (7.19–7.50) values. We found good agreement of PT7 values and *in vitro* blood-gas analysis values for arterial  $PO_2$ ,  $PCO_2$  and pH (fig. 1, table 2). This is in keeping with previous studies in intensive care medicine<sup>3</sup> and cardiac surgery.<sup>4,5</sup> Furthermore, comparison of sequential changes between two consecutive times ( $\Delta PO_2$ ,  $\Delta PCO_2$ ,  $\Delta pH$ ) showed good agreement (table 4, fig. 2), and no clinically relevant changes in PT7 values compared with changes in blood-gas analysis values were observed. This is of the utmost importance for a continuous monitoring system, as it is designed primarily to accurately reflect trends in measured variables.

Radial PT7 temperature was significantly lower

than rectal temperature (table 3). This is not surprising as the radial artery may be considered an intermediate or even a peripheral temperature measuring site: core temperature is reflected more accurately by rectal rather than axillary temperature measurements during anaesthesia.<sup>19</sup> Therefore, both PT7 and blood-gas analysis values were determined at 37°C in this methodological study. The PT7 system, however, offers the choice between measurement of blood-gas tensions at 37°C (as performed in this investigation) and at patient (intravascular) temperature. Comparison of the two methods was not the object of this study.

Comparing PT7 and laboratory blood-gas analysis results is difficult because laboratory blood-gas analysis measurement is fraught with a variety of problems: samples for blood-gas analysis may easily be handled incorrectly by sample dilution, excess heparinized saline,<sup>20 21</sup> delays in analysis with the sample being stored at room temperature,<sup>20 22</sup> oxygen consumption from metabolism by leucocytes and other cells contained in the sample,<sup>23</sup> diffusion of gases through the plastic wall of syringes<sup>24-26</sup> and pressure of air bubbles in the samples,<sup>22 26 27</sup> particularly during transport.<sup>28</sup> In addition, the accuracy and variability of laboratory blood-gas analysers are applied in a recent evaluation of blood-gas analysers<sup>29</sup>: in the  $PO_2$  range of 4–20 kPa and  $PCO_2$  range of 2.7–10.6 kPa, respectively, 95% of measurements should be within  $\pm 7.5\%$  or  $\pm 0.6$  kPa of a reference; for  $PO_2 > 20$  kPa and  $PCO_2 > 10.6$  kPa, respectively, 95% of measurements should be within  $\pm 12.5\%$  of a reference; pH accuracy cannot be tested because there is no reference method.<sup>29</sup> Differences between PT7 and laboratory blood-gas values thus cannot *a priori* be considered to represent variability in the new method, that is the PT7, but may also result from errors in laboratory blood-gas analysis or in both of these methods.

The observed variability of PT7  $PO_2$ ,  $PCO_2$  and pH measurements is acceptable for clinical decision making, and PT7 is a reliable trend indicator of arterial blood-gas tensions. During thoracoscopy with OLV, in selected cases, continuous intra-arterial blood-gas monitoring is therefore helpful in monitoring oxygenation and carbon dioxide. However, cost effectiveness and influence on outcome of this particular technology must be examined.<sup>30 31</sup> Whether the good clinical performance will translate into improved long-term outcome has not yet been investigated and requires further study.<sup>32-34</sup>

In summary, we found good accuracy and good clinical performance of the Paratrend 7 sensor system when used in patients during thoracoscopy. It appears to be a helpful tool in monitoring patients during surgical procedures associated with large variations in arterial blood-gas tensions, such as thoracoscopy with OLV.

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