Anesthesiology
81:543–552, 1994

Multisite Evaluation of a Continuous Intraarterial Blood Gas Monitoring System

C. Philip Larson, Jr., M.D., Jeffrey Vender, M.D.,† Adam Seiver, M.D., Ph.D.‡*

Background: **We compared the performance of a new, continuous intraarterial blood gas (CIABG) monitor with arterial values obtained periodically and analyzed by conventional equipment.**

Methods: **A CIABG monitoring system consisting of a sterile, disposable, fiberoptic sensor and a microprocessor-controlled monitor with a self-contained calibration unit and detachable display panel was used. The sensor was inserted through a 20-G radial artery cannula. Light was transmitted from the monitor to the sensor tip where it reacted with fluorescent dyes sensitive to oxygen or hydrogen ions (analytes). The change in the intensity of the photoluminescent radiation caused by the analytes was measured every 20 s and derived blood gas values were displayed. Twenty-nine sensors were evaluated in 29 surgical or intensive care unit patients at one of three institutions (Stanford University Hospital, Evanston Memorial Hospital, and the Palo Alto Veterans Administration Hospital). The duration of study averaged 6 h (5–8 h) in the operating room, and 46 h (7–121 h) in the intensive care unit. A total of 552 values were compared with those obtained at regular intervals and analyzed in the hospital blood gas laboratory. Average bias (mean difference between lab value and CIABG), precision (SD of difference), and drift (change in the bias with time were determined.**

Results: **At arterial oxygen tension (P_{O_2}) values of 32–528 mmHg, the average bias was −1% meaning that the average CIABG monitor values were 1% lower than those obtained by conventional equipment. The precision was 15%. At arterial P_{O_2} values of 32–99 mmHg, average bias and precision were −0.3 ± 8.9 mmHg. At arterial carbon dioxide tension (P_{CO_2}) values of 24–54 mmHg, average bias and precision were 1.3 ± 3.3 mmHg, and at *p*Ha values of 7.23–7.57, average bias and precision were 0.01 ± 0.04. Observed drift per day was −1.2% for arterial P_{O_2}, 0.3 mmHg for arterial P_{CO_2}, and 0.01 for *p*H. Bias and precision for samples compared in two pairs of like-model *in vitro* blood gas analyzers were 0.4 ± 4.6% for arterial P_{O_2} over the full range, and 0.4 ± 3.7 mmHg for values less than 100 mmHg, −0.5 ± 1.8 mmHg for arterial P_{CO_2}, and 0.01 ± 0.01 for *p*Ha. Although the occasional marked discrepancies between one or more CIABG and *in vitro* values could sometimes be corrected by flushing the arterial catheter or repositioning the sensor, usually we could not determine the cause of the discrepancy or which values were the more accurate.**

Conclusions: **Over the range of values and under the clinical conditions studied, CIABG monitoring provides immediate blood gas results and trend information with sufficient agreement with *in vitro* results to be reliable for decision making in most clinical circumstances. Generally, the differences in the values between the two methods of analysis were the result of the combination of the inherent errors of each method. Additional studies need to be undertaken to evaluate the performance of the CIABG monitor across wider ranges of blood gas values, especially for arterial P_{O_2} values less than 60 mmHg and arterial P_{CO_2} values greater than 50 mmHg. (Key words: Equipment: blood gas monitors. Monitoring: blood gases.)**

THE current standard of blood gas and *p*H assessment in patients involves procurement of an arterial blood sample that is analyzed at the point of care or in a central laboratory with a commercial blood gas analyzer. Although this approach has been exceedingly valuable in patient care, it has serious shortcomings.[1] Most importantly, sampling is intermittent and depends upon the judgment of the caregiver to determine when a measurement is needed. Consequently, sampling may not be done when it is needed, or the timing of the sampling may be inappropriate. As a result, clinically important changes in patient blood gas status may go undetected or may occur after a sample has been drawn, while it is being analyzed. Alternatively, excessive and unnecessary analyses may be performed.

These problems would be eliminated by use of an indwelling, continuously monitoring arterial blood gases and *p*H sensor. Over the past 30 yr, attempts have been made to develop a continuous blood gas monitoring system using electrochemical,[2–5] mass spectrometry,[6] gas chromatography,[7] and optical technol-

* Professor of Anesthesia and Neurosurgery, Stanford University.

† Associate Professor, Clinical Anesthesia, Northwestern University School of Medicine.

‡ Clinical Assistant Professor of Surgery, Stanford University.

Received from the Departments of Anesthesia, Neurosurgery, and Surgery, Stanford University School of Medicine, Stanford, California, and the Department of Anesthesia, Evanston Memorial Hospital and Northwestern University School of Medicine, Evanston, Illinois. Accepted for publication April 4, 1994. Supported in part by Puritan-Bennett Corporation, Overland Park, Kansas. C.P.L. is a member of the Board of Directors of Puritan-Bennett Corporation.

Address reprint requests to Dr. Larson: Department of Anesthesia, H-3584, Stanford University School of Medicine, Stanford, California 94305.

ogies.[8-10] Although many variations of optically based continuous blood gas monitoring systems have been evaluated in clinical trials,[11-17] only recently have such systems become commercially available.

We evaluated the accuracy, repeatability, and drift of a prototype continuous intraarterial blood gas (CIABG) monitoring system in patients by comparing its values with those obtained by periodically sampling arterial blood and analyzing it using conventional laboratory blood gas analyzers.

Materials and Methods

The CIABG monitoring system (3300 Intraarterial Blood Gas Monitoring System, Puritan-Bennett, Carlsbad, CA) continuously measures and displays arterial blood values for *p*H, carbon dioxide tension (P_{CO_2}), and oxygen tension (P_{O_2}). The system consists of a sterile, disposable, fluorescent-based, 10-foot fiberoptic sensor with a 10-cm invasive portion, and a microprocessor-controlled monitor with a self-contained calibration unit, and detachable display and control panel. The sensor has an external diameter of 0.55 mm and readily fits inside a 20-G vascular cannula provided with the sensor (Becton-Dickinson, Sandy, UT) having an internal diameter of 0.84 mm. The design of the sensor is based on oxygen- or *p*H-sensitive fluorescent dyes immobilized at the end of optical fibers. Three fibers, one each for sensing *p*H, P_{O_2}, and P_{CO_2} are integrated along with a thermocouple for measuring temperature to create the final sensor. Short-wavelength (360–480-nm) light is periodically launched from the monitor and used to excite the dyes. The dyes fluoresce, emitting light in a longer, visible wavelength (515–540 nm). The degree of emission is modified by the amount of analyte (hydrogen ions or oxygen) at the tip of the optic fiber. The carbon dioxide sensor uses a *p*H-sensitive dye dissolved into a bicarbonate buffer solution. The dye–buffer mixture is contained within an ion-impermeable, carbon dioxide–permeable polymer layer on the outer surface of the fiber. Changes in blood carbon dioxide are reflected by changes in the *p*H of the dye–buffer mixture, which can be detected by the *p*H-sensitive dye. The ratio of the excitation to emission signals is processed by the monitor and displayed as patient values. The temperature measurement is used to correct for the temperature sensitivity of the dyes, and to correct the CIABG values to 37°C using the Severinghaus algorithm.[18] New CIABG values are measured every 20 s and updated on the screen. Response time of the sensors is approximately exponential with 90% response times of 48 s for P_{O_2}, 84 s for P_{CO_2}, and 130 s for *p*H. The manufacturer recommends sensor use to 72 h, but the monitor will continue to measure and display values for as long as the sensor is left *in vivo*. In this study, the same sensor was used for as long as 121 h. Sterile sensors are supplied in a calibration cuvette containing *p*H buffer solution. Before insertion, the sensors were automatically calibrated at two known values of *p*H, P_{CO_2}, and P_{O_2} by tonometering the *p*H buffer solution with two precision-mixed calibration gases. Calibration takes approximately 15 min, and no further calibrations were performed during the use-life of the sensors. A Y-port is built into the sensor to permit arterial blood pressure monitoring and blood sampling.

The studies were conducted at three sites: Stanford University Hospital, Evanston Memorial Hospital, and the Palo Alto Veterans (VA) Administration Hospital. After local institutional review board approval and informed consent had been obtained, 31 sensors were required to monitor 29 patients, with two sensors failing to calibrate and not used. In each patient a 20-G, 4.5-cm cannula (Becton-Dickinson) was placed in a radial artery, and a calibrated sensor was inserted through the cannula about 5.5 cm into the free-flowing arterial blood stream. A blood pressure monitoring system was connected to the Y-port of the sensor, and a heparin solution (1 U/ml) was continuously infused through the cannula at a rate of 3 ml/h.

In 12 of the patients the sensor was inserted in the operating room before surgery. Monitoring continued postoperatively in the intensive care unit in 11 patients. In 17 patients the sensor was inserted in the intensive care unit postoperatively. The patients were 23 men and 6 women aged 29–85 yr and ASA physical status 2–4 (because of preexisting heart or lung disease[19]) who were undergoing neurosurgery (aneurysm clipping or tumor or arteriovenous malformation resection) or open heart surgery with cardiopulmonary bypass. The average number of comparative analyses per patient was 18 (range 2–57), and the total number of analyses was 552. The duration of study was 4.5–8 (mean 6) h in the operating room and from 7–121 (mean 46) h in the surgical intensive care unit. Twenty sensors were used for more than 24 h, and 12 were used for more than 48 h. The *in vitro* laboratory values were 7.23–7.57 for *p*H, 24–54 mmHg for P_{CO_2}, and 32–528 mmHg for P_{O_2}.

Three-milliliter samples of arterial blood were drawn at predetermined intervals (immediately after sensor

insertion, each hour for 3 h, and once every 3 h thereafter) into 5-ml heparinized syringes from a stopcock located on the arterial flush line. Occasionally, additional samples were drawn when the monitoring system indicated the occurrence of untoward values for any of the variables. Sample time averaged 20 s. The samples were iced and analyzed within 5 min in the hospital blood gas laboratory. Analyses were performed at Stanford University Hospital with a Corning 178 analyzer (Ciba Corning Diagnostics, Medfield, MA); at Evanston Memorial Hospital with a Radiometer ABL3 analyzer (Radiometer America, Westlake, OH); and at the Palo Alto VA Hospital with a Ciba Corning 288 analyzer. The laboratory analyzers were operated according to the procedures in common use in each institution. All of the laboratories participate regularly in either the College of American Pathologists or the American Thoracic Society proficiency surveys, and all were found to have acceptable performance over the time frame of this study. To evaluate the agreement between laboratory blood gas analyzers, 3-ml samples were analyzed in duplicate using two identical analyzers. At the Palo Alto VA Hospital, 142 sample pairs were analyzed using two Corning 278 analyzers; at Evanston Memorial Hospital, 169 sample pairs were analyzed using two Radiometer ABL3 analyzers.

Data Analysis

The agreement between the CIABG monitor and the blood gas laboratory was determined by the calculation of bias, precision, drift rate, and drift corrected precision (see Appendix for details). Bias is a systematic error between two methods, and is defined as the average difference between two methods. Precision is a measure of the random error of the difference and is defined as the standard deviation of the difference between two methods. The larger the precision value, the greater the random error or variability in the measurement.

The data are presented graphically according to the method described by Bland and Altman[20] by plotting the difference between the two methods against the mean value of the two methods. Bias and precision were also determined for duplicate measurements of the same blood samples analyzed in two *in vitro* blood gas analyzers.

The use of bias and precision as measures of agreement assumes that the agreement remains essentially constant during the time that the sensor is studied. If agreement between the methods changes with time, then bias and precision values will depend upon how long the sensor is used, and on the sampling frequency. To assess the change in agreement over time it is helpful to consider several other calculated values. If the agreement between the CIABG and *in vitro* measurements changes systematically over time, then bias may be thought of as having two components. The initial bias is the systematic difference between the two methods when the first *in vivo* measurement is made, and drift is the systematic change in the agreement of the two methods over time. If a CIABG sensor drifts, then the bias becomes a time dependent function. In this drift model, the drift rate is assumed to be constant, and the bias may be estimated as bias at time (t) = initial bias + (drift rate $\times$ t) where t = elapsed time since sensor calibration. We calculated drift rate and initial bias for each sensor by a least-squares linear regression analysis of the differences between the methods *versus* elapsed time (days) since calibration. The drift rate for each sensor was calculated as the gradient, or regression coefficient of the least squares regression line. Initial bias is defined as the intercept of the regression line. A new drift-corrected precision is defined as the square root of the residual variance of the regression line. The combined study drift rate and initial bias were calculated as the sample-weighted average of the individual drifts, and initial biases for all sensors monitored at least 24 h. The combined drift corrected precision was calculated by pooling the individual drift corrected precision values in the same way the precision values were pooled. Sensors used less than 24 h were excluded from the calculation of the combined drift statistics because of the difficulty in obtaining reliable drift measurements over shorter time frames.

Results

The means and standard deviations of the *in vitro* samples and corresponding CIABG results for each institution and for all three institutions combined are shown in table 1. The values are similar among institutions except for the lower values for arterial P_{O_2} at the Palo Alto VA Hospital because comparisons were made only in the intensive care unit. The bias and precision values for all three sites combined are 0.01 $\pm$ 0.04 for *p*H, 1.3 $\pm$ 3.3 mmHg for P_{CO_2}, and -1.0% $\pm$ 15% for P_{O_2} respectively (figs. 1–4 and table 2). The P_{O_2} bias and precision at values less than 100 mmHg were -0.3 $\pm$ 8.9 mmHg. The *p*H and P_{CO_2} biases did

Table 1. Blood Gas Values Measured by *In Vitro* Analysis and the Continuous Intraarterial Blood Gas Monitoring System at Three Study Sites and Combined

		*p*Ha	Pa_{CO_2} (mmHg)	Pa_{CO_2} (mmHg)
Stanford (no. of comparisons 122; no. of sensors studied 7; monitored hours 43 ± 14)	*In vitro* results	7.41 ± 0.07	345 ± 4	138 ± 74
	CIABG results	7.38 ± 0.08	38 ± 5	142 ± 83
Evanston (no. of comparisons 177; no. of sensors studied 11; monitored hours 44 ± 25)	*In vitro* results	7.39 ± 0.06	38 ± 5	136 ± 96
	CIABG results	7.40 ± 0.07	40 ± 6	132 ± 98
Palo Alto VA (no. of comparisons 253; no. of sensors studied 11; monitored hours 44 ± 35)	*In vitro* results	7.38 ± 0.05	38 ± 4	86 ± 19
	CIABG results	7.41 ± 0.07	38 ± 5	78 ± 19
Combined (no. of comparisons 552; no. of sensors studied 29; monitored hours 44 ± 28)	*In vitro* results	7.39 ± 0.06	37 ± 5	113 ± 71
	CIABG results	7.40 ± 0.07	39 ± 6	113 ± 73

not vary with the patient values. When normalized as a percent of the mean of the two methods, the P_{O_2} bias also did not vary over the range of values seen. The variations in bias and precision among hospitals were small with the exception of *p*H, for which the biases ranged from −0.03 at Stanford University Hospital to 0.03 at the Palo Alto VA Hospital. Drift analysis showed little change in the agreement between the methods over time (table 3). The combined daily drift rates were 0.01 for *p*H, 0.3 mmHg for P_{CO_2}, and −1.2% for P_{O_2}. Because the drifts were so small, the initial bias and drift corrected precision were very close to the bias and precision.

The bias values between like-model *in vitro* analyzers were similar to those between the CIABG monitors and *in vitro* analyzers, whereas the precision values between *in vitro* analyzers were much smaller than those between the CIABG monitor and *in vitro* analyzers.

Samples where the absolute difference between the CIABG monitor and the *in vitro* results exceeded 2.5 standard deviations of the bias were identified as outliers. When an outlier was observed, a second sample was drawn for laboratory analysis to confirm its existence (in two instances a third sample was drawn), and these data are included in the results. Twenty eight outliers were identified involving 13 sensors. The most common differences affecting eight samples from four sensors was a pattern of low monitor *p*H and P_{O_2} values along with high monitor P_{CO_2} values relative to the *in vitro* values. In three of these four sensors agreement between the CIABG monitor and the laboratory values was restored by flushing the arterial line or rotating the sensor inside the arterial cannula. Ten other samples from five sensors showed very low monitor P_{O_2} values without large *p*H or P_{CO_2} differences. Six samples from three sensors showed high monitor P_{CO_2} values without corresponding P_{O_2} or *p*H bias. Two samples in one sensor showed a low monitor P_{CO_2}, and *p*H differences greater than 0.13.

The placement of the sensor in the arterial cannula did not significantly alter the blood pressure waveform nor did it impair sampling of arterial blood from the Y-port of the sensor. No patient sustained any observed injury from use of the CIABG monitor.

Table 2. Bias and Precision of the CIABG Monitoring System at Three Study Sites and Combined

	*p*Ha	Pa_{CO_2} (mmHg)	Pa_{O_2} (%)	Pa_{O_2} < 100 (mmHg)
Stanford				
Bias	−0.03	2.7	1.6	2.3
Precision	0.04	2.7	13	5.7
Evanston				
Bias	0.01	1.7	−4	−3.6
Precision	0.03	3.6	13	11.9
Palo Alto				
Bias	0.03	0.3	−0.3	0.5
Precision	0.03	3.3	16	8.0
Combined				
Bias	0.01	1.3	−1.0	−0.3
Precision	0.04	3.3	15	8.9

Pa_{O_2} over the entire range of values is expressed as a percentage of the mean of the two methods for each sample, whereas values less than 100 are expressed as mmHg.

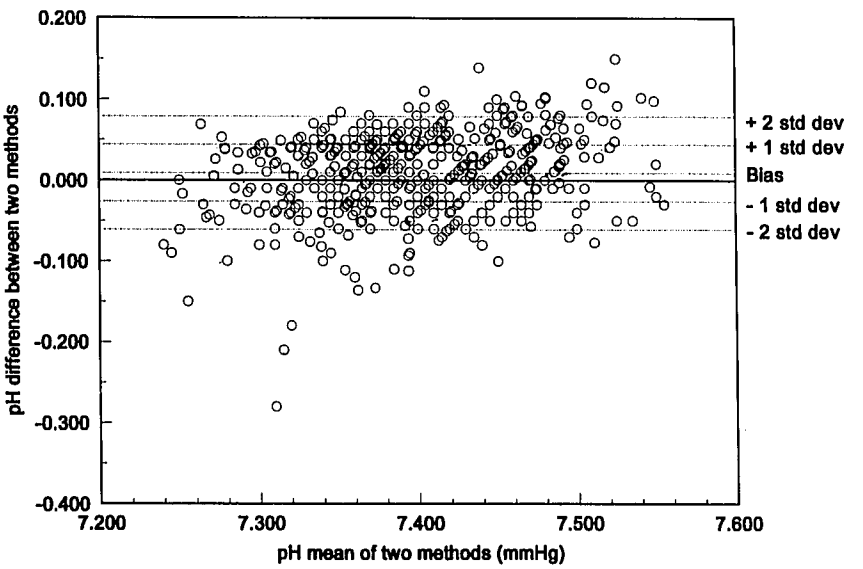

Fig. 1. Difference in *p*Ha measured by *in vitro* analysis and a continuous intraarterial blood gas monitor plotted against the mean of *p*Ha results by the two methods for 552 samples. The bias (mean of the differences) ± 1 and 2 standard deviations of the bias is also shown.

Discussion

The potential benefits of continuous blood gas monitoring are well described.[1,12,15,16] They include elimination of turn-around time and expedition of care, decreased dependence on clinical judgment as to when samples should be drawn, and earlier detection and subsequent intervention during life-threatening events. Other advantages include the elimination of preanalytic variables as sources of error, decreased exposure of healthcare workers to blood, decreased blood loss because of sampling, and decreased risk of nosocomial infection. Before any of these potential benefits can be realized, however, accurate, precise, and reliable devices must be made available and their performance validated.

In the assessment of blood gas monitoring systems, *in vitro* analysis should not be considered a "gold standard." *In vitro* analyzers, when well maintained, generally provide results that are accurate and precise within clinically useful limits, although significant biases are common between widely used *in vitro* analyzers.[21-25] In our study we observed that there were bias values between two laboratory analyzers testing the same sample (table 4), which were similar to the combined bias values between the CIABG and laboratory analyzers (table 2). Lack of precision, or reproducibility also existed between laboratory analyzers (table 4), although the imprecision was two to three fold greater between the CIABG monitors and the laboratory analyzers (table 2).

It is expected that there would be greater imprecision between CIABG monitoring and *in vitro* values than between a sample analyzed in two like analyzers, because the variability in the former comparison results from the combined effects of all of the inaccuracies of each method relative to the true patient values. In addition to variations in values between like analyzers, there are preanalytic variables that affect *in vitro* blood samples. These include errors resulting from contamination of samples by variable quantities of air, which in routine practice is virtually impossible to eliminate; a decrease in oxygen content from metabolism during sample transport; and the dilution effect of anticoagulant.[26-30,§] Also, at high patient arterial P_{O_2} values the nonlinear response of oxygen electrodes contributes to errors in *in vitro* analysis.[31]

Other factors that affect the agreement between the CIABG monitor and the laboratory values include the uncertainty in the relative timing of the *in vitro* samples with the CIABG readings. During the time needed for an *in vitro* sample to be withdrawn, the CIABG monitor may have made more than one reading. Even in clinically stable patients, blood gas values may vary appreciably over short intervals,[32] and this problem is magnified if the patient's blood gas values are unstable. Thus it is sometimes difficult to know which of the CIABG values recorded during that time should be used

§ Eichhorn J, Moran RF, Cormier AD: Blood gas pre-analytical considerations. Document C-27T. Villanova, PA, National Committee for Clinical Laboratory Standards, 1989.

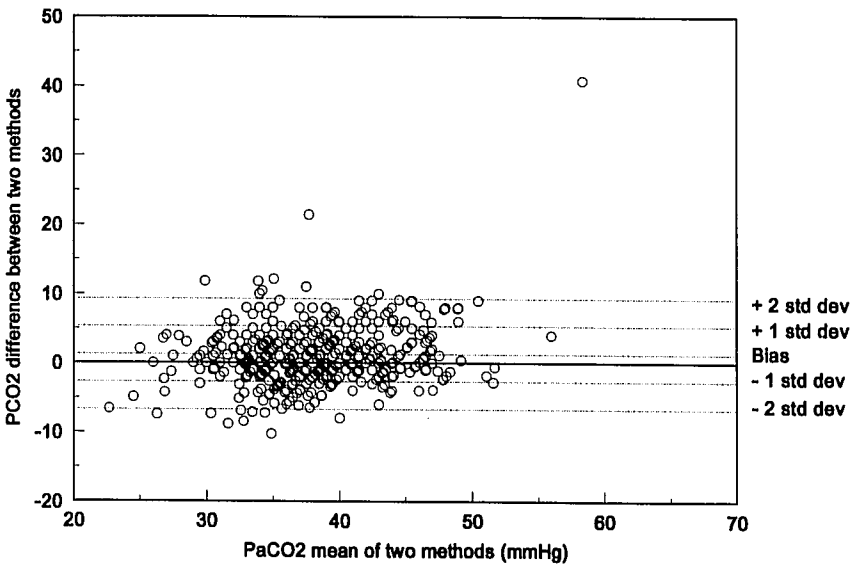

Fig. 2. Difference in arterial carbon dioxide tension (P_{CO_2}) measured by *in vitro* analysis and a continuous intraarterial blood gas monitor plotted against the mean of the arterial P_{CO_2} results by the two methods for 552 samples. The bias (mean of the differences) ± 1 and 2 standard deviations of the bias is also shown.

for comparison. This effect may be further aggravated by the response times of the sensors. Physiologic artifacts may also affect the values reported by the CIABG monitor.

The two most common patterns of disagreement seen in the outlier samples mirror those described by Mahutte *et al.*[12] for a prototype design of an intraarterial blood gas sensor in the radial artery. Mahutte *et al.*[12] described a "down–up–down" pattern of difference in which the *p*H and P_{O_2} values reported by the monitor were depressed and the P_{CO_2} values elevated. This effect was attributed to the formation of clots covering the sensor tip. This pattern was observed in four sensors in our study, although no other signs of a clot were seen. The possibility that clots caused these large differences is supported by the fact that in three instances in which this pattern was observed, agreement was restored by flushing or repositioning the sensor. Mahutte *et al.*[12] also described a "down" pattern in which monitor P_{O_2} values were depressed relative to *in vitro* values, while good agreement was maintained for both *p*H and P_{CO_2}. Mahutte *et al.*[12] attributed this pattern to

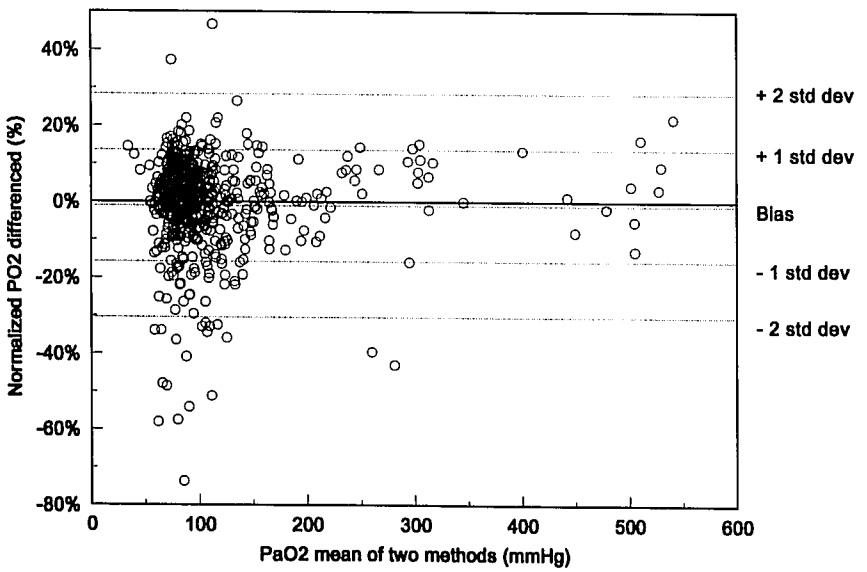

Fig. 3. Normalized difference in arterial oxygen tension (P_{O_2}) measured by *in vitro* analysis and a continuous intraarterial blood gas monitor plotted against the mean of arterial P_{O_2} results by the two methods for 552 samples. The differences are normalized as a percentage of the mean of the two methods for each sample. The bias (mean of the normalized differences) ± 1 and 2 standard deviations of the bias is also shown.

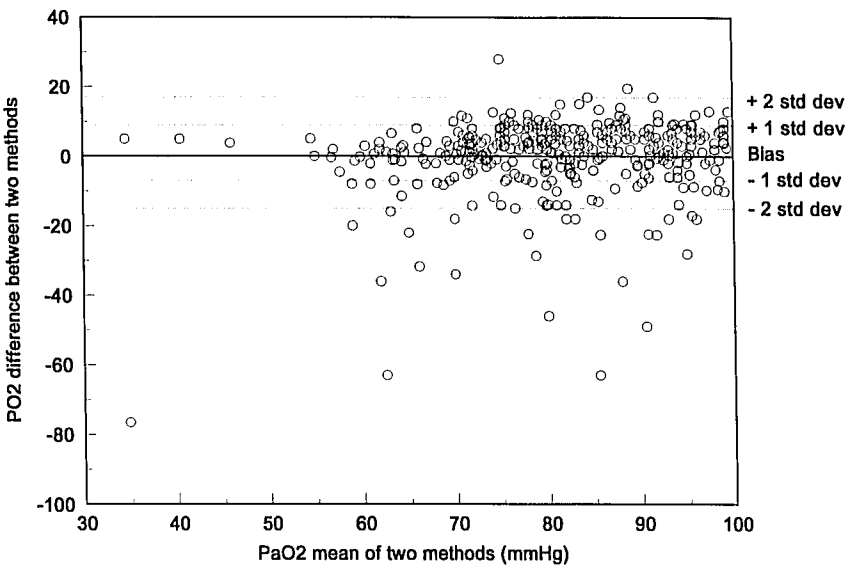

Fig. 4. Difference in arterial oxygen tension (P_{O_2}) measured by *in vitro* analysis and a continuous intraarterial blood gas monitor plotted against the mean of the arterial P_{O_2} results by the two methods for 344 samples. All samples have a arterial P_{O_2} < 100 mmHg as determined by the mean of the two methods. The bias (mean of the differences) ± 1 and 2 standard deviations of the bias is also shown.

the sensor's being pushed against the arterial wall or decreased blood flow near the sensor tip. This pattern was observed as outlier in five sensors in our study.

Bland and Altman[20] defined "limits of agreement" in the comparison of two methods of measuring an unknown quantity. The limits of agreement are calculated as the bias plus or minus twice the precision. These limits define a range of values encompassing approximately 95% of the differences between the two methods. The limits of agreement between the CIABG monitor and *in vitro* analysis are calculated to be −0.06 + 0.08 for *p*H, −5 + 8 mmHg for P_{CO_2}, and −30 + 28% for P_{O_2} over the full range and −18 + 18 mmHg for P_{O_2} values less than 100 mmHg. The clinical requirements for accuracy in the measurement of blood gases is subjective and dependent on the clinical scenario,[33] and no consensus exists for appropriate limits of agreement between blood gas monitors and *in vitro* analysis. With the exception of P_{O_2} precision, the bias and precision values observed in this study are similar to those reported in recently published evaluations of other continuous blood gas monitors. In these evaluations the authors concluded that monitor performance was comparable to values obtained from blood gas analyzers.[15,16] The P_{O_2} precision values obtained in this study are higher (*i.e.*, less precise or more variable) than the published results. Most of this variability can be attributed to the outlier samples exhibiting the down–up—down and down patterns. In a study of sensors in five patients using 104 comparative samples, Zimmerman and Dellinger reported bias ± precision values of −0.21 ± 0.037 for *p*H, 1.7 ± 6.1 mmHg for P_{CO_2}, and −5.9 ± 13.2 mmHg for P_{O_2}.[15] In 14 surgical patients Barker and Hyatt evaluated a prototype system and showed bias ± precision values of −0.032 ± 0.042 for *p*H, −3.8 ± 4.7 mmHg for P_{CO_2}, and −6.2% ± 10% for P_{O_2}.[13] Using a system in which the sensors are not inserted into an artery and blood is periodically with-

Table 3. Initial Bias Drift Rate per 24 Hours and Drift Corrected Precision

	*p*H	P_{CO_2} (mmHg)	P_{O_2} (%)
Stanford			
Initial bias	−0.036	2.1	5.3
Drift rate/24 h	0.003	0.2	−0.9
Drift corrected precision	0.042	2.6	12.5
Evanston			
Initial bias	0.004	1.5	−4.9
Drift rate/24 h	0.01	0.0	1.2
Drift corrected precision	0.028	3.7	10.7
Palo Alto			
Initial bias	0.010	−0.3	1.5
Drift rate/24 h	0.01	0.6	−3.0
Drift corrected precision	0.031	3.1	15.2
Combined			
Initial bias	−0.005	0.8	0.5
Drift rate/24 h	0.01	0.3	−1.2
Drift corrected precision	0.033	3.1	13.4

Values are derived from 21 sensors, which were used *in vivo* for longer than 24 h.

Table 4. Range, Bias, and Precision of Two Pairs of Like-Model *in Vitro* Blood Gas Analyzers on Replicate Measurements of the Arterial Blood Samples and the Combined Bias and Precision

	*p*Ha	Pa_{CO_2} (mmHg)	Pa_{O_2}	$Pa_{O_2} < 100$ (mmHg)
Evanston* (n = 169; n_a = 74)				
Range	7.41 ± 0.06	37 ± 6	136 ± 96 mmHg	79 ± 11
Bias	0.016	−1.4	−0.3%	−0.3
Precision	0.012	1.6	5.6%	5.1
Palo Alto VA† (n = 142; n_a = 115)				
Range	7.40 ± 0.06	38 ± 4	87 ± 23 mmHg	78 ± 10
Bias	0.002	0.6	1.3%	0.8
Precision	0.012	1.3	2.7%	2.2
Combined (n = 311; n_a = 189)				
Range	7.40 ± 0.06	38 ± 5	112 ± 77 mmHg	79 ± 10
Bias	0.010	0.5	0.4%	0.4
Precision	0.014	1.8	4.6%	3.7

n = no. of samples; n_a = no. of samples for which the mean of the results of the two methods is less than 100 mmHg.

* Radiometer ABL3 blood gas analyzer.

† Ciba-Corning 278 blood gas analyzer.

drawn into an external sensor cuvette for analysis, Shapiro *et al.* showed bias ± precision values of −0.004 ± −0.027 for *p*H, −0.8 ± 2.4 mmHg for P_{CO_2}, and −2.2 ± 8.3% for P_{O_2}.[16] A major difference between the CIABG system evaluated in this study and the published results for most other systems was the use of periodic *in vivo* recalibrations. These recalibrations used the results of periodic *in vivo* analysis to adjust the system's calibration every 8–24 h.[12,15–17] No *in vivo* recalibrations were performed in this study.

Limits used in blood gas proficiency testing have been cited as appropriate goals for acceptable performance of continuous blood gas monitors.[9,11,13,16] Proficiency testing assesses the reliability of a blood gas analyzer by measuring the agreement between the analyzer and the pooled results of a "peer group of similar analyzers" measuring a common sample.‖ Level of acceptable agreement between a given *in vitro* blood gas analyzer and the pool results have been set by the Health Care Financing Administration as 0.04 for *p*H and 5 mmHg for P_{CO_2}.#

The limit of acceptable P_{O_2} agreement is three standard deviations of the pooled results. Using the *in vitro* data from table 3, we calculated a target P_{O_2} of 12.9%. The combined CIABG precision compared favorably with the Health Care Financing Administration limits, falling within the limits for *p*H and P_{CO_2}, and falling just out of the limits for P_{O_2}. Shapiro *et al.* also suggested acceptable bias limits of 0.05 for *p*H, 3 mmHg for P_{CO_2}, and 5 mmHg for P_{O_2}.[16] Again our combined CIABG results are within these limits.

In conclusion, we believe that the CIABG monitoring system provides continuous, and generally reliable and clinically useful blood gas data. The system is stable with no clinically significant drift in results over the course of patient monitoring. Although differences between CIABG and *in vitro* values do arise, these disparities do not necessarily mean that the CIABG monitor is reading inaccurately. Our data do not allow us to conclude which method most accurately measures the "true" patient values, although this is the ultimate goal for either method. When outlier values appear on the CIABG monitor, they are almost invariably readily apparent as such in the form of a sudden change in trend data with no change in patient status. In addition, when the P_{O_2} sensor gave outlier values from sensor malfunction, they were always lower than the *in vitro* values. Consequently, decisions based on a falsely low arterial P_{O_2} until it can be checked are not likely to be harmful to patients. Finally, additional studies should be undertaken to evaluate the performance of the CIABG monitor across wider ranges of blood gas values,

‖ 1992 Interlaboratory Comparison Surveys Program Manual: Section III. Clinical Chemistry. College of American Pathologists, Northfield, 1992, pp 28–29.

Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88). Federal Register, Vol 57 (40), February 28, 1992, p 7008.

especially for arterial P_{O_2} values less than 60 mmHg and arterial P_{CO_2} values greater than 50 mmHg.

References

1. Shapiro BA: *In vivo* monitoring of arterial blood gases and pH. Resp Care 37:165–169, 1992

2. Conway M, Durbin GM, Ingram D, McIntosh N, Parker D, Reynolds EOR, Soutter LP: Continuous monitoring of arterial oxygen tension using a catheter-tip polarographic electrode in infants. Pediatrics 57:224–250, 1976

3. Coon RL, Lai NCJ, Kampine JP: Evaluation of a dual function pH and $PaCO_2$ *in vivo* sensor. J Appl Physiol 40:625–629, 1976

4. Rithalia SVS, Bennett PJ, Tinker J: The performance characteristics of an intra-arterial oxygen electrode. Intensive Care Med 7: 305–307, 1981

5. Nilsson E, Edwall G, Larsson R, Olsson P: Continuous intra-arterial PO_2 monitoring with a surface heparinized catheter electrode: A study of conformity in conventional blood gas analysis and of long-term electrode function in the non-heparinized dog. Scand J Clin Lab Invest 42:331–338, 1982

6. Wald A, Hass WK, Siew FP, Wood DH: Continuous measurement of blood gases *in vivo* by mass spectrography. Med Biol Eng 8:111–128, 1970

7. Richman KA, Jobes DR, Schwalb AJ: Continuous *in vivo* blood gas determination in man: Reliability and safety of a new device. ANESTHESIOLOGY 52:313–317, 1980

8. Peterson JI, Fitzgerald RV: Fiber optic probe for *in vivo* measurement of oxygen partial pressure. Anal Chem 56:62–67, 1984

9. Gehrich JL, Lubbers DW, Opitz N, Hansmann DR, Miller WW, Tusa JK, Yafuso M: Optical fluorescence and its application to an intravascular blood gas monitoring system. IEEE Trans Biomed Eng 33:117–132, 1986

10. Hui HK, Divers GA, Lumsden TJ, Wallner TG, Weir CS: An accurate, low-cost, easily-manufacturable oxygen sensor. Proceedings of the Society of Photo-Optical Instrumentation Engineers–International Society of Optical Engineers (Chemical, Biochemical and Environmental Fiber Sensors) 172:233–238, 1989

11. Miller WW, Yafuso M, Yan CF, Hui HK, Arick S: Performance of an in-vivo, continuous blood-gas monitor with disposable probe. Clin Chem 33:1538–1542, 1987

12. Mahutte CK, Sassoon CS, Muro JR, Hansmann DR, Maxwell TP, Miller WW, Yafuso M: Progress in the development of a fluorescent intravascular blood gas system in man. J Clin Monit 6:147–157, 1990

13. Barker SJ, Hyatt J: Continuous measurement of intraarterial pH, $PaCO_2$ and PaO_2 in the operating room. Anesth Analg 73:43–48, 1991

14. Greenblott GB, Tremper KK, Barker SJ, Gerschultz S, Gehrich JL: Continuous blood gas monitoring with an intraarterial optode during one lung anesthesia. J Cardiothorac Vasc Anesth 5:365–367, 1991

15. Zimmerman JL, Dellinger RP: Initial evaluation of a new intra-arterial blood gas system in humans. Crit Care Med 21:495–500, 1993

16. Shapiro BA, Mahutte CK, Cane RD, Gilmour IJ: Clinical performance of a blood gas monitor: A prospective multicenter trial. Crit Care Med 21:487–494, 1993

17. Lemus JF, Kearney T, Margulies DR, Mackenzie DJ, Leyerle BJ, Shabot MM: Continuous intra-arterial oxygen monitoring: Accuracy and reliability in the surgical intensive care unit. Am Surg 58:740–742, 1992

18. Kellman GR, Nunn JF: Nomograms for correction of blood PO_2, PCO_2, pH and base excess for time and temperature. J Appl Physiol 21:1484–1490, 1966

19. Keats AS: The ASA classification of physical status: A recapitulation. ANESTHESIOLOGY 49:233–236, 1978

20. Bland JM, Altman DG: Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1:307–310, 1986

21. Lodegard-Pederson HJ: Accuracy and reproducibility of arterial blood gas and pH measurements. Acta Anaesthesiol Scand 67(suppl): 63–65, 1978

22. Hansen JE, Feil MC: Blood gas quality control materials compared to tonometered blood in examining for interinstrument bias in PO_2. Chest 94:49–54, 1988

23. Hansen JE, Jensen RL, Casaburi R, Crapo RO: Comparison of blood gas analyzer biases in measuring tonometer blood and a fluorocarbon-containing proficiency-testing material. Am Rev Resp Dis 140:403–409, 1989

24. Salem M, Chernow B, Burke R, Stacey J, Slogoff M, Sood S: Bedside diagnostic blood testing: Its accuracy, rapidity and utility in blood conservation. JAMA 226:389–392, 1991

25. Scuderi PE, MacGregor DA, Bowton DL, Harris LC, Anderson R, James RL: Performance characteristics and interanalyzer variability of PO_2 measurements using tonometered human blood. Am Rev Resp Dis 147:1354–1359, 1993

26. Biswak CK, Ramos JM, Agroyannis B, Kerr DS: Blood gas analysis: The effect of air bubbles in the syringe and delay in estimation. Br Med J 284:923–927, 1982

27. Madiedo G, Sciacca R, Hause L: Air bubbles and temperature effect on blood gas analysis. J Clin Pathol 33:864–867, 1980

28. Hutchinson AS, Ralston SH, Dryburh FJ, Small M, Fogelman I: Too much heparin: Source of error in blood gas analysis. Br Med J 287:1131–1132, 1983

29. Anderson OS: Sampling and storing blood for determination of acid-base status. Scand J Clin Lab Invest 13:196–204, 1961

30. Bagent RA: Variations in arterial blood gas measurements due to sampling techniques. Resp Care 20:565–570, 1975

31. Andersen PK, Brinklov WM, Stokke DB, Hole P, Rosendal T: Inaccuracy of oxygen electrodes at high blood oxygen tensions. ANESTHESIOLOGY 49:61–62, 1978

32. Thorson SH, Marini JJ, Pierson DJ, Hudson LD: Variability of arterial blood gas values in stable patients in the ICU. Chest 84:14–18, 1983

33. Clausen JL, Murray KM: Clinical applications of arterial blood gases: how much accuracy do we need? J Med Tech 2:19–22, 1985

Appendix

Agreement statistics were calculated as follows, where BGA = conventional blood gas analyzers; k = the three institutions; i = the sensors; m_k = the sensors evaluated at each institution; j = individual comparative samples; n_i = number of comparative samples drawn for each sensor; m = total number of sensors evaluated; and n = the total number of samples used. For each sensor an individual bias was calculated:

$$\text{bias}_i = \frac{\sum_{j=1}^{n_i} (\text{CIABG}_{ij} - \text{BGA}_{ij})}{n_i} \quad (1)$$

For each hospital a weighted bias was calculated from the m_k sensors evaluated at that site:

$$\text{hospital bias}_k = \frac{\sum_{i=1}^{m_k} n_i \text{ bias}_i}{\sum_{i=1}^{m_k} n_i} \quad (2)$$

and a combined study bias was calculated:

$$\text{study bias} = \frac{\sum_{i=1}^{m} n_i \times \text{bias}_i}{\sum_{i=1}^{m} n_i} \quad (3)$$

A precision was calculated for each sensor studied:

$$\text{precision}_i = \sqrt{\frac{\sum_{j=1}^{n_i} ([\text{CIABG}_{ij} - \text{BGA}_{ij}] - \text{bias}_i)^2}{n_i - 1}} \quad (4)$$

A pooled institutional precision was calculated for each institution and for all three hospitals combined:

$$\text{hospital precision}_k = \sqrt{\frac{\sum_{i=1}^{m_k} ([n_i - 1] \times \text{precision}_i^2)}{\sum_{i=1}^{m_k} n_i - m_k}} \quad (5)$$

$$\text{study precision} = \sqrt{\frac{\sum_{i=1}^{m} ([n_i - 1] \times \text{precision}^2)}{\sum_{i=1}^{m} n_i - m}} \quad (6)$$