

Clinical Evaluation of the On-Line Sensicath™ Blood Gas Monitoring System

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ABSTRACT

Background: Blood gas analysis is an integral part of the management of open heart surgery and post-surgical intensive care patients. This study was conducted to compare the results of on-line blood gas analysis using the new Sensicath™ (SC) optical sensor technology against standard blood gas assay.

Methods: Comparative blood gas analysis was performed on 45 postoperative cardiovascular surgical patients and 5 patients during cardiopulmonary bypass. Simultaneous samples were obtained. One sample was sent to the central hospital laboratory for measurement using a Radiometer ABL 500 blood gas analyzer and the second sample was drawn past the optical sensor. Comparisons between the two methods for pH, pO₂ and pCO₂ were analyzed using linear regression and the method of Bland and Altman for the intensive care unit samples (N = 451) while the T test was used to compare data points obtained during cardiopulmonary bypass (N = 57). Bias, accuracy and precision were also calculated.

Results: The regression lines (r²) for pH, pO₂, and pCO₂ and were 0.69, 0.94, and 0.68 with slopes of 1.000, 0.0957, and 1.052 respectively for postoperative surgical patients. During cardiopulmonary bypass, the T test did not show any significant difference between the Sensicath™ and the reference values for the arterial and venous pH, pO₂ and pCO₂.

Conclusions: In summary, this study found the Sensicath™ to be an accurate, useful tool which permits immediate blood gas analysis without blood exposure and constitutes an advance in the field of intensive care monitoring.

INTRODUCTION

Blood gas analysis is an important means of monitoring a patient's progress in the operating room and intensive

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care unit. Currently, an arterial blood sample is drawn from the patient and sent to a distant laboratory, analyzed and returned. This process can be time consuming as well as requiring multiple levels of personnel for analysis, transportation, and documentation. Each step exposes these personnel to a potential blood borne hazards.

The Sensicath™ (Optical Sensors, Minneapolis, MN) device is a closed system designed to obviate these issues by permitting rapid on-line determination of blood gas values. The Sensicath™ system (SC) consists of a fiber optic sensor attached to the arterial catheter which detects optical changes produced in circulating blood caused by the measured gasses. These optical changes are analyzed by custom software utilizing an OpticalCAM monitor with immediate results and feed back. The device does not require recalibration between samples. These tests may be conducted without limitation at the point of contact by nursing, operating room, or perfusion personnel.

The current study was undertaken to determine comparative measurements between blood gases analyzed in the standard fashion versus those analyzed by the Sensicath™ optical sensor system.

MATERIALS AND METHODS

Instrumentation

The Sensicath™ system consists of patented fiber optic technology in a sensor which attaches directly to the patient's arterial line (see Figure 1, ⊙). ABGs are obtained by simply drawing a blood sample into the sensor. After a 60 second measurement time, the blood is returned to the patient and the line is flushed. The sensor transmits data through an optic cable to a microprocessor-based module. The sensor contains three optical fibers with fluorescent chemistries for sensing pH, pCO₂ and pO₂, and can measure 100 blood gas samples over 72 hours after a single calibration. The sensor housing is a molded plastic shell compatible with standard arterial line, pressure monitoring tubing and stopcocks. It does not disrupt the pressure waveform or interfere with fluid delivery.

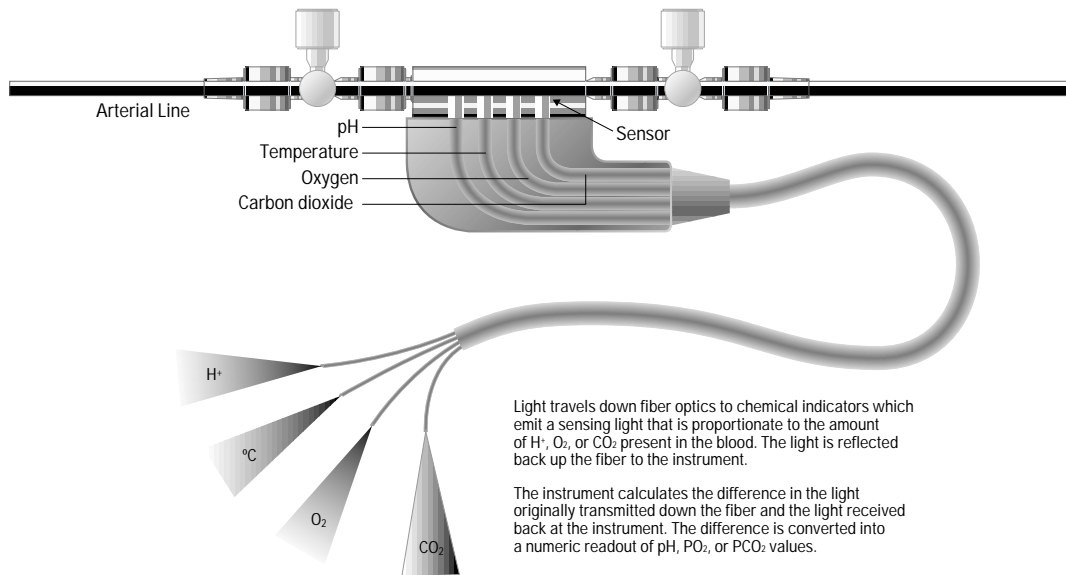


Figure 1.

The sensor emits two signals with different analyte sensitivities. The system uses the two signals in a radiometric measurement approach to compensate for common mode disturbances in optical signals whether induced in the optical train or in the sensor itself. Sensor response time is sufficiently fast to provide results in 60 seconds not only for pH, pO₂ and pCO₂, but for calculated bicarbonate, oxygen saturation and base excess as well. [Venkatesh 1995]

Study Design

A clinical study was undertaken to determine the accuracy of blood gasses determined by the fiber optic sensor method versus those obtained by standard laboratory analyzers (Radiometer ABL 500). After obtaining informed consent, 45 surgical patients in the Intensive Care Unit (ICU) underwent blood gas analysis using the Sensicath™ system as well as conventional means. In 5 other patients, samples were obtained during cardiopulmonary bypass (CPB). Only arterial samples only were obtained from the ICU patients, while both arterial and venous samples were obtained from the CPB patients. Glass test tubes were used to store the samples which were transported to the central laboratory in a plastic bag with ice. In ICU patients, blood samples were withdrawn from an indwelling arterial catheter. In the CPB patients, the Sensicath™ device was integrated into the CPB circuit with a three-way stopcock. The placement of the sensor was such that one sensor could be used to perform both arterial and venous samples. Data from samples were analyzed using linear regression and the method of Bland and Altman assessing two different methods of clinical measurement. Accuracy (mean difference) and precision (standard deviation difference) were also calculated. The CPB data were also compared using the T test for small samples. Back sample served as its own control.

RESULTS

Forty-five intensive care patients underwent a total of 451 comparative arterial blood gas samples using both techniques of analysis. The result of are shown in Table 1.

The regression lines (r²) for pH, pO₂, and pCO₂ and were 0.69, 0.94, and 0.68 with slopes of 1.000, 0.0957, and 1.052 respectively. The linear regression analysis is shown in the Figure 2 (⊙), Figure 3 (⊙) and Figure 4 (⊙) respectively.

In the CPB samples, the T test for venous pH, pO₂ and pCO₂ were 1.33, 1.72 and 0.13 respectively and for arterial samples were 2.01, 1.89 and 0.03 respectively. This test with a p value for established degree of freedom did not show a significant difference between the SC and the reference values. Comparative results are shown in Figure 5 (⊙), Figure 6 (⊙), and Figure 7 (⊙) respectively.

There were no untoward effects to the patients related to blood draws through the Sensicath™ device, reinfusion or radial artery pressure monitoring.

Table 1. Blood Gas Analyzer vs. Online ABG Monitoring System

	pH	pCO ₂	PO ₂
Samples	451	451	451
Range	7.15-7.54	26-64	57-245
r ²	0.69	0.78	0.94
Slope	1.000	1.052	0.957
Accuracy	0.022	1.0	-4.4
Precision	0.035	3.5	8.9

Accuracy (mean difference) and precision (standard deviation difference) determined by the fiber optic sensor method versus those obtained by standard laboratory analyzers (Radiometer ABL 500).

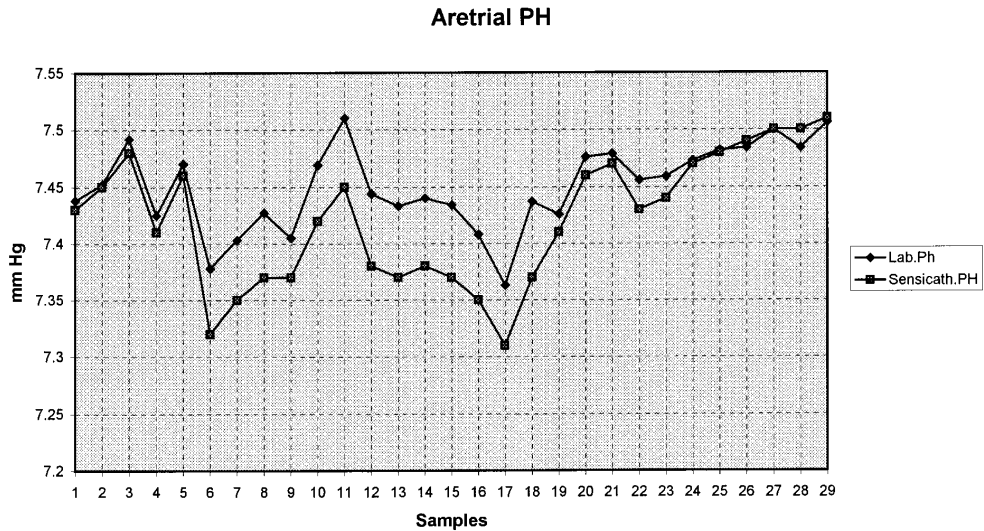


Figure 2. pH Determination
 Linear Regression Analysis of arterial blood gas samples using the Sensicath™ and Radiometer ABL 500

DISCUSSION

Continuous monitoring of blood gases and pH could add substantially to patient safety, reduced costs, and reduced exposure hazards to personel [Phillip 1992]. The application of fiber optic sensors has proved that in vivo monitoring of blood gasses is truly feasible [Mora 1995]. Fiber optic sensors have been used in the aviation, automotive and petroleum industries to sense impurities in fluids rapidly and accurately. The Sensicath™ system is a specialized medical application of this technology using patented sensors and analysis equipment.

During cardiac surgery, frequent blood gas monitoring is necessary to detect disorders of gas exchange and acid-base

status occurring during cardiopulmonary bypass. In this study, attention was directed to the accuracy of fiber optic sensing for continuous monitoring of arterial and venous pH, pO2, and pCO2 using the Sensicath™ system. For all measured samples, the correlation with standard gas analysis was very close. This raises the possibility of using the Sensicath™ to augment or replace standard blood gas sampling during CPB. This fiber optic technology can allow accurate and instantaneous results of key gas values during CPB which in turn can guide therapeutic decisions regarding changes in oxygenator performance, mechanical ventilation, and drug administration. Further studies may show that this technique is cost effective when compared to cur-

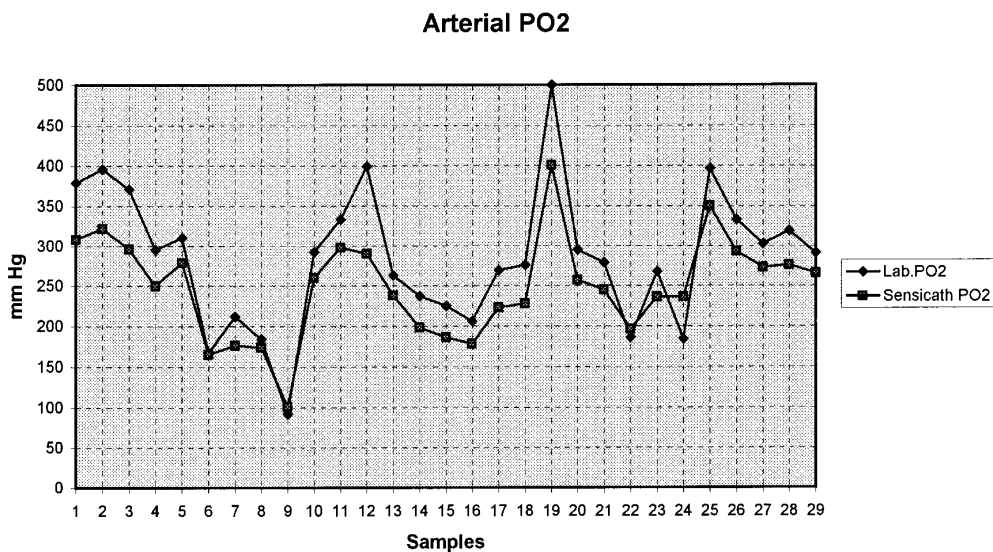


Figure 3. pO2 determination
 Linear Regression Analysis of arterial blood gas samples using the Sensicath[tm] and Radiometer ABL 500

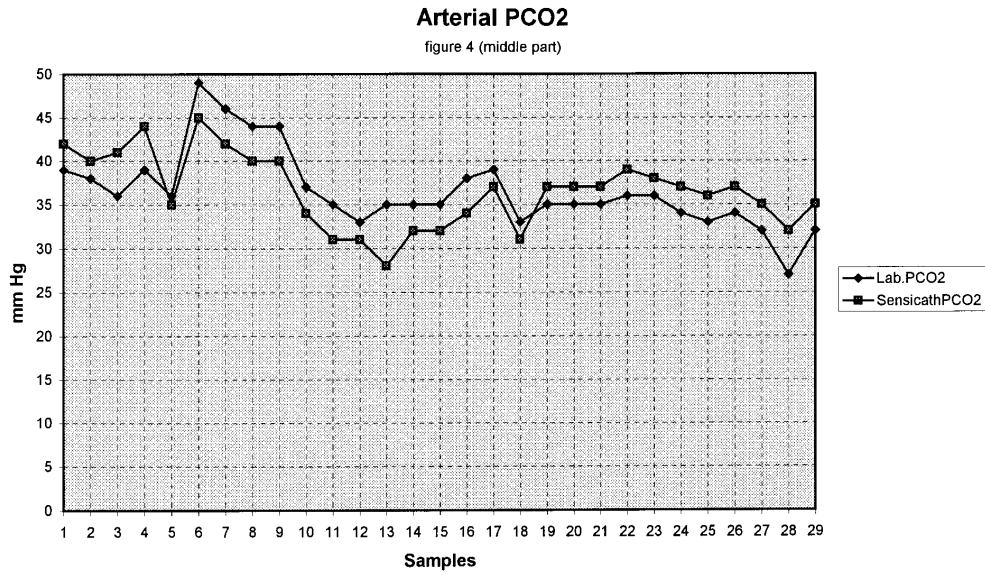


Figure 4. pCO₂ determination
Linear Regression Analysis of arterial blood gas samples using the Sencath[tm] and Radiometer ABL 500

rent gas analysis techniques. [Halbert 1990, Haller 1994, Couser 1996]

A major challenge in critical-care medicine is the need to manage precipitous changes in a patients status. The results determined in this study show that arterial gas analysis in ICU patients using the Sencath™ system correlated extremely well with the values obtained from standard hospital laboratory analyzers. In addition, no blood exposure or transportation of blood products is

required. Health care workers are not exposed to a biologic hazard. The blood is flushed back to the patient, eliminating the risk of iatrogenic blood depletion, especially in pediatric patients.

Results are immediately obtained for required therapeutic intervention. As a closed system, it does not break sterility because there is no need of draw the samples from a port or an arterial line, decreasing a possible source of infection.

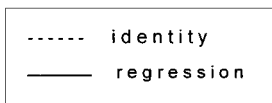
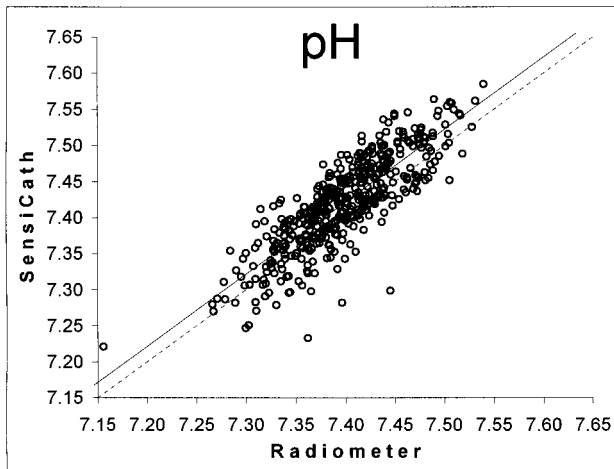


Figure 5. pH Determination on CPB
Comparative results between the Sencath[tm] and the reference value.

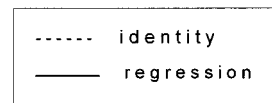
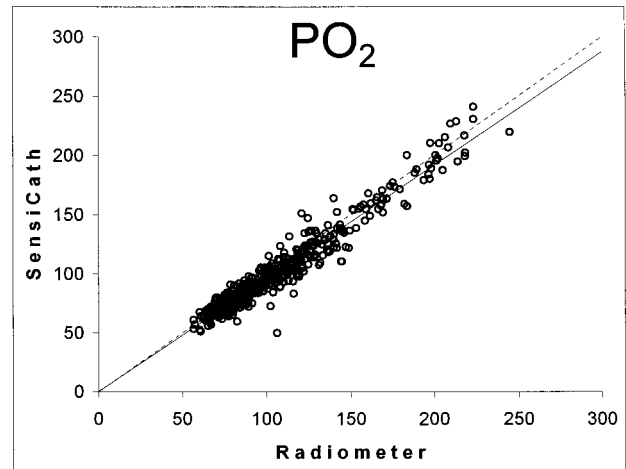


Figure 6. pO₂ Determination
Comparative results between the Sencath[tm] and the reference value.

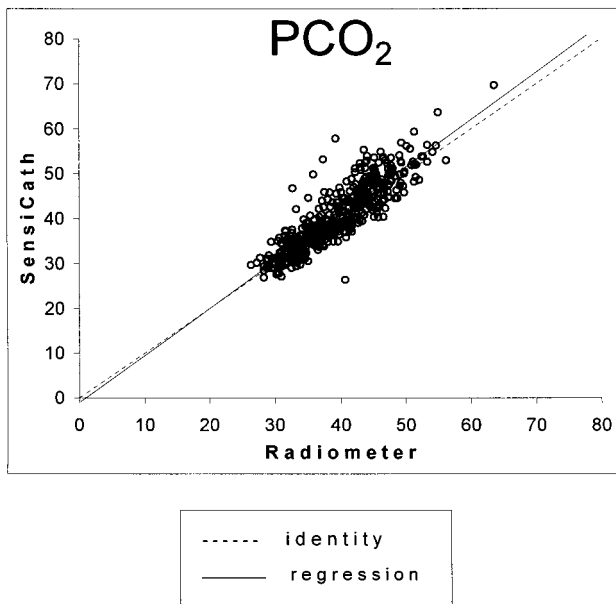


Figure 7. pCO₂ Determination
Comparative results between the Sensicath™ and the reference value.

In conclusion, on line blood gas monitoring is accurate and a potentially valuable tool in the management of critically ill patients and during cardiopulmonary bypass.

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