Early Clinical Experience with Gas-STAT™

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Keywords: Gas-STAT™, continuous blood gas/pH monitoring, blood gas/pH, monitoring accuracy

Abstract

The purpose of this study was to evaluate and report on the Gas-STAT™ continuous blood gas and pH monitoring system. This system was tested for accuracy, stability and reproducibility during extracorporeal circulation when compared to intermittent blood gas sampling. The Gas-STAT was used in conjunction with 44 clinical cardiopulmonary bypass procedures. There were 261 arterial and 259 venous blood samples obtained for analysis.

Early results comparing Gas-STAT versus intermittent samples analyzed on an IL813 blood gas analyzer[b] showed less than ideal correlation. With continued clinical experience and further system refinements, data agreement improved substantially. This system provides valuable information to the perfusion team. Continuous blood gas and pH readings give the perfusionist immediate visualization of the effects of therapeutic interventions. Changes in gas flows and mixtures, blood flow, perfusate temperatures, hemodilution and the effects of pharmacologic agents all can affect the acid base and blood gas status of the patient. This system can be calibrated and employed without any substantial increase in time required by the perfusionist.

Introduction

The Gas-STAT System is designed to provide continuous arterial and venous pH, pCO_2, pO_2 and perfusate temperatures. It utilizes a technology termed optical fluorescence microsensing to measure the pH and gas values. A thermistor is used for direct temperature measurement at sensor level in the extracorporeal circuit. The instrument sends light signals down the fiberoptic bundles to the fluorescent material in the sensor. The intensity of light returning from the sensor is proportional to the level of either oxygen, carbon dioxide or hydrogen ions present at the sensor. The returning light is filtered, measured and converted to a digital display. The time constant of the system is nominally three minutes.

The Gas-STAT System is composed of the instrument itself with its fiberoptic cables and cable connectors, the disposable flow-through cells, and disposable sensor in its calibrating cuvette.

Calibration of the system is accomplished by using the calibrating device supplied with the instrument. This device contains two disposable gas cylinders with tonometered gas levels of pO_2 and pCO_2. The first cylinder has a pO_2 of 74 mmHg and a pCO_2 of 18.5

Presented at AmSECT's 22nd International Conference, May 20-23, 1984, Las Vegas, NV.

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mmHg. The second cylinder has a pO_2 of 224 mmHg and a pCO_2 of 59.5 mmHg. During calibration the gas bubbles through a buffer solution in the sensor cuvette to establish the two-point gas calibration curve. The pH calibration points are determined by the level of carbon dioxide and the buffer composition in the sensor cuvette. Both sensors are calibrated simultaneously prior to their insertion in the flow-through cells.

Preclinical testing and the development of the Gas-STAT System reported on by Dyson, et al.[1] at the AmSECT National Meeting in 1983. Their study concluded that the Gas-STAT System and its technology had developed enough to be acceptable for clinical trials and evaluation.

It was understood that the system would need additional refinements and improvements which could only be identified through clinical experience. Because of this, our test protocol included an agreement that no therapeutic interventions would be made based on the data displayed by the instrument. Perfusion management followed our normal protocol which includes intermittent pH and blood gas sampling.

Materials and Methods

During the period of March 1983 to December 1983, the Gas-STAT Monitoring System was utilized in conjunction with 44 clinical cardiopulmonary bypass procedures. There were 26 hollow fiber membrane oxygenators and 18 bubble oxygenators used. Perfusion time ranged from 27-210 minutes with an average of 108.2 minutes. Blood flow ranged from 1.9-5.0, liters per minute. Hypothermia was employed in all cases and samples were obtained over a perfusate temperature range of 15.0 °C-40.3 °C, allowing data comparison during cooling, hypothermia, rewarming and normothermia. Gas-STAT displays were compared to 261 arterial blood samples and 259 venous blood samples that were analyzed on a IL813 blood gas analyzer. Average time between blood samples was 15.7 minutes. Our first blood sample was taken ten minutes after the initiation of cardiopulmonary bypass with additional samples drawn every 15 minutes thereafter. Our sampling protocol was based on a time interval; thus, we did not allow time for circuit stabilization after therapeutic interventions such as gas or blood flow changes or temperature changes.

The cardiopulmonary bypass circuit consisted of either a hollow fiber membrane or bubble oxygenator, filtered cardiotomy reservoir, 20 micron arterial filter, and a 0.5 micron prebypass filter. The priming solution consisted of 2 liters of a pH adjusted isotonic solution. Pharmacologic agents included in the prime were an antibiotic, steroid and a multi vitamin concentrate. The arterial filter was purged with 100% carbon dioxide prior to recirculation. The cases in which a hollow fiber membrane oxygenator was utilized included a 100% carbon dioxide purge of the entire circuit. Gas-STAT flow-through cells were inserted in the arterial line proximal to the arterial filter and in the venous line just proximal to the venous inlet of the oxygenator. All blood samples were obtained using a manifold system. Sample lines were connected to the purge port of the arterial filter to obtain the arterial blood samples, and proximal to the venous inlet of the oxygenator for venous blood samples. The venous saturation was monitored using the Bentley Oxy-Sat® * meter[a].

Results

We divided the 44 clinical cases into two groups. The first group consisted of cases 1-29; the second group consisted of cases 30-44. This was done because of refinements in the system prior to the 29th case. The refinements are as follows:

The temperature sensitivity of the individual sensors was identified and a correction factor was incorporated into the software of the instrument.

A pH sensor offset seen between human and bovine blood was identified and corrected. This offset was present in the System as a result of the early developmental work utilizing bovine blood.

An altitude adjustment was added to the System to compensate for the effects of altitude on the partial pressure of the gases and pH.

A temperature correction algorhythm was added to the system which allows for the display of pH and blood gases at either the actual perfusate temperature or calculated to 37 °C.

The actual perfusate temperature measurement was refined.

We also discovered that a carbon dioxide purge in acetate containing primes had the potential to permanently damage the CO_2 sensor of the Gas-STAT. The acetate, in combination with high levels of carbon dioxide in a nonventilated circuit, drives the pH to low levels. The acetate is converted to acetic acid which

enters the CO_2 sensor of the System creating a permanently high CO_2 offset. This problem was eliminated by ventilation of the circuit during recirculation after CO_2 flush and debubbling, prior to the senor insertion.

Figures 1 through 3 show the correlation between the Gas-STAT and the blood gas analyzer. Figure 1 shows the arterial and venous pH. In cases 1-9 the correlation coefficient is 0.5146. In cases 30-44 the correlation coefficient is 0.8173. Figure 2 shows the arterial and venous pCO_2. In cases 1-29 the correlation coefficient is 0.4873 and in cases 30-44 the correlation coefficient is 0.8803. Figure 3 shows the arterial and venous pCO_2. In cases 1-29 the correlation coefficient is 0.9441. In cases 30-44 the correlation coefficient is 0.9131.

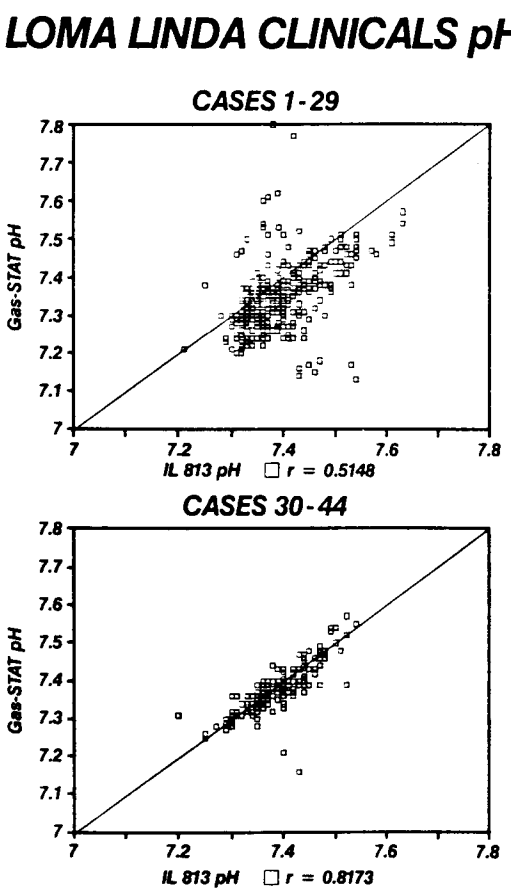

Figure 1: correlation of pH values between Gas-STAT and IL813 cases 1-29 and cases 30-44.

Discussion

Since the blood gas analyzer is the currently accepted standard for measurement of pH and gases, management of our clinical perfusion is determined by data obtained from intermittent blood sampling. Even through the correlation for the pO_2 values were high, we observed discrepancies between the Gas-STAT and the blood gas analyzer when the pO_2 value was greater than 150 mmHg and during hypothermia when temperature corrections were utilized. Because of this, we felt it necessary to determine the reason for this disagreement. One method of determining accuracy for any blood gas measuring device is by using a tonometered blood circuit. Absolute values for carbon dioxide and oxygen are known by the percentage of gas introduced into the circuit. Barometric pressure is measured and used to calculate the absolute partial pressure of these gases. A bovine test circuit was established and oxygen concentrations were introduced to yield pO_2s of approximately 150 mmHg, 200 mmHg and 400 mmHg. The tonometered circuit was stabilized at 37 °C and samples were drawn for measurement on a blood gas analyzer. Comparison was then made between the blood gas analyzer results and the Gas-STAT readings.

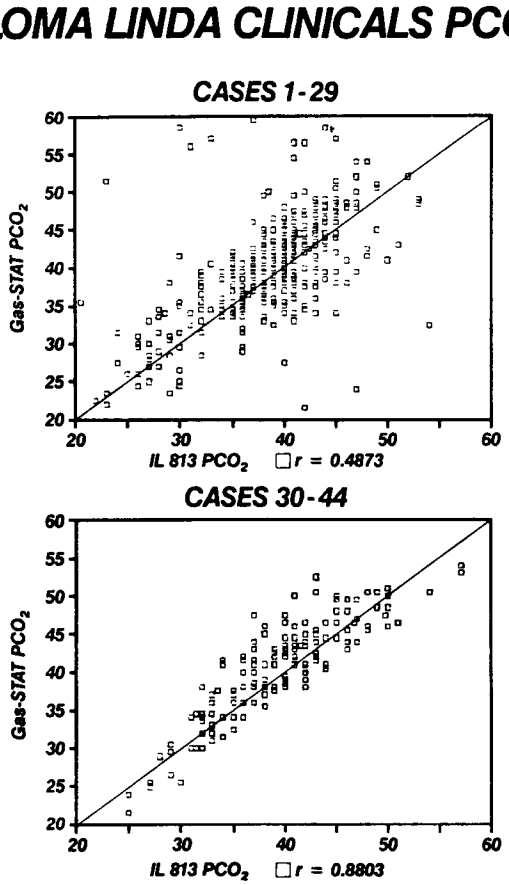

Figure 2: Correlation of pCO_2 values between Gas-STAT and IL813 cases 1-29 and cases 30-44.

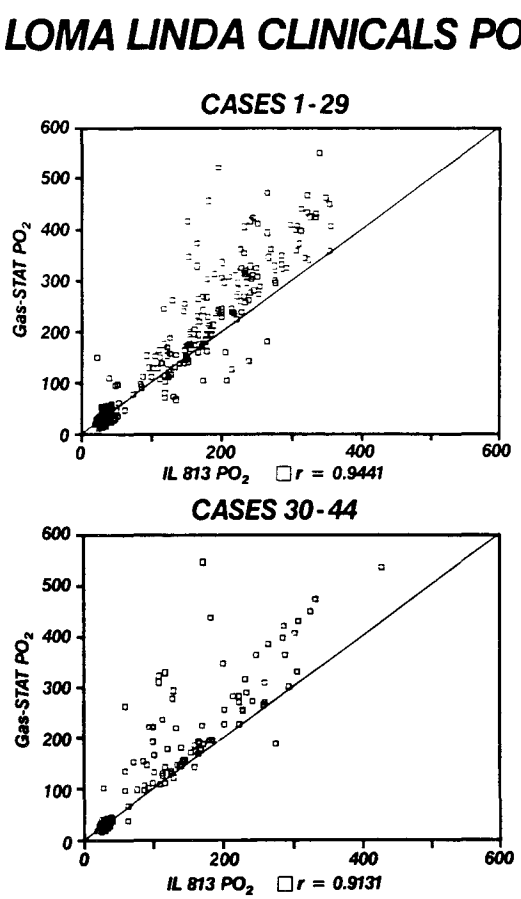

Figure 3: Correlation of pO_2 values between Gas-STAT and IL813 cases 1-29 and cases 30-44.

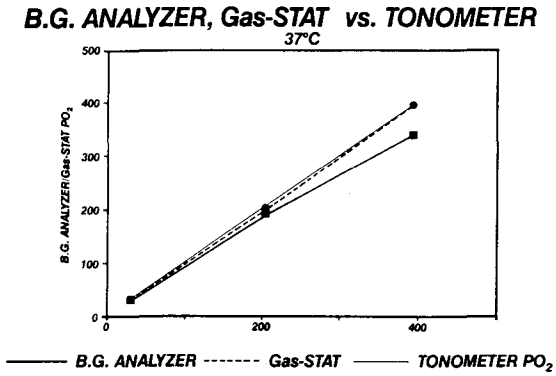

Figure 4: Comparison of blood gas analyzer and Gas-STAT to tonometered blood circuit at 37 °C at a pO_2 of 100 to 400mmHg.

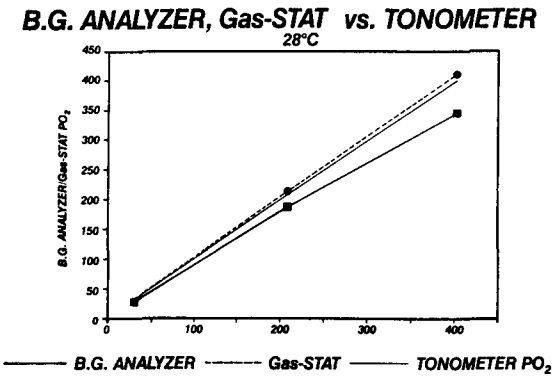

Figure 5: Comparison of blood gas analyzer and Gas-STAT to tonometered blood circuit at 28 °C at a pO_2 100 to 400mmHg.

Figures 4 and 5 show the correlation. Figure 4 shows that with a pO_2 value of 150 mmHg, there is good agreement between the blood gas analyzer and the Gas-STAT as compared to the tonometered value. At a pO_2 of 200 mmHg the blood gas analyzer understates the tonometered value by approximately 5% or a mean of -10.7 mmHg. The Gas-STAT Monitor was within approximately 1.5% or a mean of -3.2 mmHg. At a pO_2 of 400-mmHg the blood analyzer understated tonometered circuit was cooled and stabilized at 28 °C. Figure 5 shows that a pO_2 of 150 mmHg there is again, good agreement between both the blood gas analyzer and the Gas-STAT as compared to the tonometered value. At a pO_2 of 200 mmHg the blood gas analyzer understates the tonometerd value by approximately 10% or a mean of 20.5 mmHg while the Gas-STAT remained within 2% or a mean of 4.5 mmHg. At a pO_2 of 400 mmHg, the blood gas analyzer understated the tonometered value by approximately 14% or a mean of -56 mmHg while the Gas-STAT remained within 2% or a mean of 4.5 mmHg.

Most blood gas analyzers are calibrated to a high pO_2 point of either 85 or 150 mmHg. In addition, when temperature corrections are desired the blood gas analyzer uses a temperature correction algorhythm to calculate the pO_2 for the temperature other than 37 °C. There is also the potential for sample handling errors when using In Vitro blood gas analyzers.[2]

The results from our tonometered bovine test circuit showed that there was an understatement of the pO_2 by the blood gas analyzer at levels above physiologic range and when temperature correction is employed.

Although there is disagreement between the IL813 and the Gas-STAT during hypothermia or nonphysiologic PaO_2s, we have no reason to believe that this is clinically significant.

Part of our evaluation was to determine if the Gas-STAT Monitoring System could be incorporated into

our routine prebypass preparation without adding a substantial amount of time. The total elapsed time of the calibration procedure is approximately 17-18 minutes. Because the system has an automated calibration feature in the software of the instrument, the actual perfusionist dedicated time is approximately 2-3 minutes. A small amount of additional time is required to incorporate the system into the extracorporeal circuit, however, we found this additional time to be acceptable.

During the clinical evaluation the arterial and venous flow-through cells were inserted into both the arterial and venous lines. In the future, these cells can be supplied as part of a custom tubing pack, eliminating this step. Once the cells were in line, the circuit was primed, recirculated and debubbled. The sensors were then inserted into the cells after completion of the calibration procedure. Following this, the fiberoptic cables were connected to the flow-through cells and sensors. The instrument then began displaying the pH and gases of the circuit perfusate.

In conclusion, we feel that the Gas-STAT correlates well with the blood gas analyzer, provides continuous data, gives rapid response to therapeutic interventions which affect blood gases and pH, and required minimal dedicated perfusionist time for calibration and setup.

By utilizing the Gas-STAT we feel that we have improved our perfusion management due to the continuous display of pH and blood gas values. This system has also improved our ability to evaluate cardiovascular products in our extracorporeal circuit. We have also found it to be an excellent teaching aid because extracorporeal circulation is a dynamic environment subject to frequent changes in the pH and blood gas parameters.

References

1. Dyson, C.W. et al. Preclinical Evaluation of the Gas-STAT, *AmSECT Proceedings*, AmSECT 21st International Conference, April 11-13, 1983, New Orleans, LA.
2. C.K. Biswas, J.M. Ramos, B. Agroyannis, and D.N.S. Kerr. Blood Gas Analysis: Effect of Air Bubbles in Syringe and Delay in Estimation. *Brit. Med. J.* Volume 204, 27, March 1982.