Clinical Accuracy of Continuous Hemoglobin Oxygen Saturation Monitoring Devices

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Abstract

Three devices used to measure hemoglobin oxygen saturation in the extracorporeal circuit were studied and compared to a control. The Baxter Bentley OxySat, Oximetrix Accusat, and the Radiometer ABL4 blood gas monitor were compared to a control, the IL 282 Co-Oximeter. Fifty-one sample points were obtained during all phases of cardiopulmonary bypass with results as follows:

<table>
<thead>
<tr>
<th></th>
<th>DIFF</th>
<th>SD</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCUSAT</td>
<td>0.94</td>
<td>-0.6</td>
<td>3.2</td>
</tr>
<tr>
<td>ABL-4</td>
<td>0.93</td>
<td>-1.7</td>
<td>3.3</td>
</tr>
<tr>
<td>OXYSAT</td>
<td>0.87</td>
<td>-6.8</td>
<td>4.4</td>
</tr>
</tbody>
</table>

Table 1. Comparison of Oxygen Saturation Devices.

The Accusat was found to be a statistically more accurate means of monitoring hemoglobin oxygen saturations during cardiopulmonary bypass than the ABL4 and the OxySat. All devices had significant correlation with the control and with each other.

Introduction

A fundamental goal during extracorporeal circulation (ECC) is to increase organ survival by supplying an adequate amount of oxygen to meet tissue demands. The use of continuously measured mixed venous oxygen saturation (SvO2) is one way to monitor the extent to which oxygen supply meets the oxygen demand during cardiopulmonary bypass (CPB)(1). SvO2 recordings may be used with arterial/venous blood gas analyses and hemodynamic indices to estimate the patient's oxygen supply/demand status. With continuous SvO2 as a monitor of overall tissue oxygenation of the patient, recognition and management of episodes of oxygen deficiency may be accomplished earlier in the course of the patient's care (1).

In most cases, the estimates of cell demand for oxygen can be made by calculating the amount of oxygen consumed by the tissue. If the amount of oxygen supply is known and if the amount of oxygen that is returned unused in the venous blood is also known, the difference represents tissue oxygen consumption (VO2) (2,3,6,7,12).

Equation 1

\[
\text{O}_2 \text{ supply} - \text{O}_2 \text{ return} = \text{O}_2 \text{ consumption}
\]

\[
\text{CO} (1.34 \times \text{Hgb} \times \text{SaO}_2) - \text{CO} (1.34 \times \text{SvO}_2) = \text{VO}_2
\]

\[
\text{SvO}_2 = \text{SaO}_2 - \text{VO}_2
\]

\[
\text{CO} \times \text{Hgb} \times 13.4
\]

Equation 1 - VO2 equation rearranged to reflect the determinants of SvO2. CO=Pump Output, Hgb = Hemoglobin, SaO2 = Arterial Oxygen Saturation, SvO2 = Venous Oxygen Saturation

When oxygen demands by the cells increase, cellular consumption of oxygen must increase accordingly. A fall in the partial pressure of oxygen, (PO2), within the cell widens the oxygen diffusion gradient to hasten the movement of dissolved oxygen out of solution within the capillary. If the diffusion gradient is not sufficiently maintained, reduced capillary PO2 prompts oxyhemoglobin desaturation as reflected by a falling SvO2.

If the supply fails to meet the need for dissolved oxygen and if

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the use of the second defense, the venous oxygen reserve, 
(12,18) fails to preserve a capillary PO2 of 20 mmHg (with a 
corresponding SvO2 of 30%, at 37°C.). The reduced diffusion 
gradient cannot move oxygen in sufficient quantity to meet cell 
demands (19, 20). The inability of cells to receive an adequate 
amount of oxygen defines the point at which anaerobic 
metabolism will occur (3, 7, 18). Anaerobic metabolism results 
in lactic acid production, a progressively more acidic cellular 
environment, and ultimately in cell injury or death.

Once cell death occurs (or any cellular event that 
prohibits cell use of available oxygen, such as cyanide toxicity 
(21), increased capillary density, increased arteriovenous 
shunting, or hemoglobinopathies (23)) a less than normal fall in 
oxygen tension in the accompanying capillary bed results. 
Consequently, higher capillary PO 2 requires less dissociation 
of oxygen from hemoglobin. Elevated SvO2 may then signify that 
even though oxygen may be adequately supplied, cell 
dysfunction is so severe that the available oxygen is not being 
used.

Cardiac disease patients in various stages of anemia, low 
cardiac output syndrome, ischemia, and acid-base imbalance 
have compensated for their inadequate tissue perfusion by 
decreasing hemoglobin affinity for oxygen (22). This 
decreasing hemoglobin affinity results in a increased PsO value, 
(normal PsO = 27 mmHg), which results in a rightward shift in 
the oxygen dissociation curve (ODC). A rightward shift in the 
ODC makes it possible to meet a greater oxygen demand with 
same tissue PO2.

The early innovation by Brinkman, et al. in 1944 (24) yielded 
an instrument called "Cyclops" by which reflection from the 
forehead was analyzed to obtain SaO2 noninvasively. Following 
this innovation, various instruments have been devised to 
noninvasively obtain arterial or tissue SO2. It was 1962 when 
the basis of modern reflection oximetry was established by 
Polanyi and Hehir (13) who used fiber optics to guide the light 
at specific wavelength into the blood stream and to measure 
SO2 in vivo. In 1972, Johnston et al (4) devised a solid state 
fiber-optic oximeter, and catheter tip hybrid type systems which 
were further developed by Yee et al (5) and Schmitt et al (14). 
For application to CPB, Vurek et al (15) constructed a dual 
wavelength oximeter whose sensor was mounted in-line to 
continuously monitor the adequacy of oxygenation by the 
artificial lung.

In deriving SO2 from the optical reflection measurement in 
whole blood, Polanyi and Hehir computed the ratio of the 
reflectance at two specific wavelengths, one in the red and the 
other in near infrared regions, to approximate SO2 using the 
following relationship:

\[
SO2 = A + B \times \frac{R805}{R665}
\]

where R805 and R665 are the reflectance at the wavelength of 
805 and 665 nm, A and B are the constants that depend on the 
characteristic of the blood and sensor. However, due to the 
nonlinear effect of light scattering occurring at the interface of 
plasma and red blood cells, this method may yield errors unless 
the correction is made as the hematocrit variation occurs (9). 
Also, the nonlinear relationship between reflectance ratio and 
SO2 at the lower SO2 values may add errors in this method. In 
order to minimize errors due to hematocrit variation, Pitman 
and Duling (8) employed a third wavelength at the isosbestic 
region in transmission measurement.

The purpose of this study is to analyze three devices used to 
measure or estimate SvO2 during CPB and to compare these 
results to a control. The Baxter Bentley OxySata, Oximetrix 
Accusatb, and the Radiometer ABL4 blood gas monitor (c) 
were compared to the Instrumentation Laboratory (IL) 282 Co- 
Oximeter (d) as the control.

The Bentley OxySat oxygen saturation monitor is a small, 
noninvasive, electronic, digital, battery operated, dual 
wavelength optical device (7). An infrared (905 nm) light 
emitting diode (LED) and a red (655 nm) LED that alternately 
illuminates blood as it flows through a plastic cuvette. The ratio 
of the infrared to the red signal received by the photo 
transistor is computed by a single electro-optical feedback circuit. The 
ratio is linearly related to the blood oxygen saturation over the 
range of 40% to 100%. Oxygen saturation can be monitored by 
attaching probes to cuvettes mounted in the CPB line. The 
cuette is a plastic, straight through connector with a window in 
it through which the optical coupling is made. The OxySat 
allows for high speed, on-line, full flow SO2 measurement with 
a 30 second response time (17).

The Oximetrix Accusat monitoring system facilitates the use 
of the Oximetrax Shaw Catheter system. The system is a special 
purpose reflection spectrophotometer which provides 
continuous noninvasive monitoring of the SO2 without blood 
sampling or electrical connection to the patient. The Accusat 
contains fiber optics for light transmission through the Accusat 
Light Pipe, which is connected to the OS/1271, Optical Module. 
The Optical Module contains three solid-state LED in the red 
and infrared light spectrum, and a solid state light detector. 
Light from the LED is transmitted through the light pipe fiber 
optics and through a window in the optical "T" connector to 
illuminate blood flowing past. The optical "T" connector is 
placed in the CPB line. The reflected light signals are then 
converted into electrical signals and then amplified for 
transmission to the OS/1270A Processor. The Oximetrix 
OS/1270A Processor computes SO2 values based on the 
electrical signals transmitted from the Optical Module. These 
values are continuously displayed in numerical form. The 
Processor also displays a reflected light intensity signal which 
provides an indication of whether or not the Lite Pipe is 
properly positioned and the system is functioning properly. The 
three wavelength technology results in more sensitivity to 
changes in the hematocrit, blood pH, blood flow, and 
temperature (25). The microprocessor interprets the signal and 
then averages the computed mean SO2 digitally (11).

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b. Oximetrix Inc., Mountainview, CA 94013
c. Radiometer America Inc., Westlake, OH 44145
d. Instrumentation Laboratories Inc., Lexington, MA 02173
OXYGEN SATURATION MEASUREMENT ACCURACY
HEMATOCRIT EFFECT ON DIFFERENCE

OXYGEN SATURATION MEASUREMENT ACCURACY
TEMPERATURE EFFECT ON DIFFERENCE

OXYGEN SATURATION MEASUREMENT ACCURACY
PvO2 EFFECT ON DIFFERENCE
The IL 282 and the ABL4 have shown accuracy and repeatability of \( SO_2 \) values during CPB and are used as the standard for comparison (10, 11, 13). The IL 282 CoOximeter utilizes a thallium/neon hollow cathode lamp, which emits light at the desired four wavelength (353, 585, 594, 626 nm)(10). The ABL4 blood gas monitor analyzes a single anaerobic sample to determine the pH and \( PO_2 \) which are used to estimate the \( SO_2 \) from the results obtained.

Materials and Methods

Fifty one sample points were observed during all phases of CPB on a total of eight male and female adult patients having coronary artery bypass grafts or valve surgery. The IL 282 CoOximeter was used as the control for all \( SO_2 \) readings. The IL 282 was calibrated and the full range of quality control samples were tested daily.

During the circuit set-up, before each clinical case, an Oximetrix Accusat 1/2" Optical "T" tubing connector and a Bentley OxySat 1/2" optical transmission cell (OTC) were placed in the venous tubing of the circuit. The OxySat probes and meter were tested for proper calibration (+/- 2%) using colored calibration cuvettes supplied by the manufacturer. The probes were then attached securely to the OTC. The Accusat Lite Pipe (fiber optics) and the OS/1271 Optical Module were attached to the Oximetrix Opticath OS/1270A Processor and the system was standardized per operating manual. The Accusat system was calibrated after the initiation of CPB by running an anaerobic venous sample in the IL 282 CoOximeter and using that \( SvO_2 \) reading to calibrate the Accusat \( SvO_2 \) reading per operators instructions. The ABL4 Blood Gas Analyzer (c) used for the study had the full range of quality control samples run before each study case and also automatically performed one- and two-point calibration throughout the study.

Anaerobic venous sampling was performed every 20 minutes during the CPB period. The following parameters were measured from or simultaneous to the sampling: venous blood temperature, percent hematocrit (determined by centrifuged method), OxySat \( SvO_2 \), ABL-4 \( SvO_2 \), Accusat \( SvO_2 \), IL 282 Cooximeter \( SvO_2 \), partial pressure of venous oxygen (\( PV_0_2 \)) at 37°C and \( PV_0_2 \) corrected to actual blood temperature.

The results were entered in a computer software file (e) so that graphic and statistical analysis (f) could be performed. The following statistical data were calculated: correlation coefficient (\( r \)), standard error (S.E.), mean difference from control (Diff), and \( p \) value. All P values are significant at \( p<.001 \).

Results

The data which was obtained was entered into the Lotus 123 program and statistical analysis (f) was performed utilizing the BMDP statistical software program. A scatter diagram of the raw data is shown in Figure 1. Measurement accuracy of the ABL4 is depicted in Figure 2. It shows that the ABL4 correlated with the IL 282 was significant (\( r=0.93 \), SD=3.3). Figure 3 depicted the measurement accuracy of the OxySat to the IL 282 and again the correlation was significant (\( r=0.87 \), SD=4.4).

The accuracy of the Accusat, shown in Figure 4, correlated the best with the IL 282 (\( r=0.94 \), SD=3.3). The instruments were tested for the affect of hematocrit on the measurement accuracy and as seen in Figure 5, there was no significant affect. The affects that temperature had on the devices are shown in Figure 6, there was no significant affect. The affect of changing \( PV_0_2 \) is displayed on Figure 7, which shows relatively no change with changing \( PV_0_2 \). Statistical comparison of the oxygen saturation devices to the IL 282 is depicted in Table 1.

Discussion

The continual monitoring of venous oxygen saturation is a practice that is now being embraced by many perfusionists during CPB. This information allows the perfusionist to insure that the patient is being sufficiently perfused by supplying an adequate amount of oxygen to meet tissue demands (l). The value of a continuous determination of mixed venous saturation depends on how accurately the \( SvO_2 \) approximates measured saturation under adverse physiological condition. The Fick equation (equation 1) describes the relationship between \( VO_2 \), arterial and venous oxygen content difference (\( AVO_2 \)) and cardiac output (pump output). The relationships between the variables allow for the adjustment of conditions during CPB.

Since the venous saturation is a component of the \( AVO_2 \) difference, the greater this difference the greater the oxygen consumption, providing the pump output remains the same. By rearrangement of this equation, it is found that the \( VO_2 \) is directly proportional and the pump output is inversely proportional to the \( AVO_2 \) difference.

Equation 3

\[
VO_2 = AVO_2 
\]

pump output

During CPB if the pump output is decreased and the \( VO_2 \) still remain unchanged, this will be recognized as a decrease in the venous saturation. The perfusionist may then increase the pump output. The in-line devices allow immediate access to this information.

Chung, et al. demonstrated that the cardiac output early after CPB can be reliably predicted by a plot of venous oxygen saturation at various flow rates on CPB, based on in-line monitoring of venous oxygen saturation (26).

The in-line monitors allow the perfusionist continuous monitoring abilities without increase risk of contamination and distraction while drawing samples. Both the Accusat and OxySat provide indication that proper position is established with the connectors. The advantages of the Accusat system is the ability to adjust the calibration to a known in-vitro \( SO_2 \). The Oximetrix monitor provide continuous visual trending during CPB. Visual and audible, upper and lower limits, \( SO_2 \) alarms can be set via the Oximetrix monitor.

Our results show that neither, the OxySat, Accusat, or ABL4 device were significantly affected by a change in the hematocrit, temperature, or \( PV_0_2 \) in Figures 5, 6, 7. The OxySat, a two wavelength system, consistently showed lower \( SvO_2 \) readings in
Figures 1 and 3. The protocol does not allow one to conclude whether the lower reading observed occurred due to the adverse physiologic conditions, time, or both.

The Accusat, a three-wavelength system, accurately reflects measured $SvO_2$, as illustrated in Figures 1-4, during a wide variety of clinical conditions and a valuable tool for the perfusionist during CPB.

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References