Clinical Evaluation of Cardiomet 4000
Continuous On-Line Blood Gas Analyzer

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Abstract

PURPOSE: Clinically evaluate a new, continuous, on-line blood gas analyzer, Cardiomet 4000, for accuracy, safety, user friendliness.

METHOD: 32 patients undergoing cardiopulmonary bypass were randomly selected. Approximately 105 blood samples were drawn and analyzed by the hospital blood-gas laboratory. The Bentley Gas Stat was used as an on-line reference. The parameters of the C4000 and BGS were recorded simultaneously to the drawing of blood samples. Calibration times and sensor insertion procedures were noted. Lab results were evaluated for bias and precision (B/P). The bias of both in-line systems was subject to a student's t-test analysis for significance.

RESULTS: Significant level = 0.001

<table>
<thead>
<tr>
<th>Device</th>
<th>pH Bias/Precision</th>
<th>pCO2 B/P</th>
<th>pO2 B/P</th>
</tr>
</thead>
<tbody>
<tr>
<td>C4000</td>
<td>0.003/0.028</td>
<td>0.095/2.8 mmHg</td>
<td>-7.1/43.7 mmHg</td>
</tr>
<tr>
<td>BGS</td>
<td><strong>0.28/0.505</strong></td>
<td>0.13/4.4 mmHg</td>
<td><strong>29.5/44.7 mmHg</strong></td>
</tr>
</tbody>
</table>

*not significant  **significant

Daily cal. time C4000 5 min. Full cal. time 15 min. (apx. once/wk.) Design of C4000 connector allows for sensor insertion and removal during CPB.

CONCLUSION: The C4000 demonstrated a clinically acceptable bias and precision in the measured parameters pH, pCO2, pO2 and required minimal calibration and set-up time during daily use. The C4000 stainless steel reinforced gas/ion window design provides a pressure barrier (17PSI) thus: A) allows for sensor calibration verification at any time, B) allows for sensor insertion after onset of CPB in emergency applications, C) eliminates sensor placement as requirement for membrane integrity.

Introduction

The need for automating and centralizing the extracorporeal circuit has been well documented.1,2 One such level of automation/centralization is the use of continuous on-line blood gas analysis. (CLBGA)3,4,5,6

Currently available CLBGA systems have several disadvantages: A) they do not provide the user a means to verify the calibration during operation, B) are sensitive to acetate containing priming solutions at low pH and high pCO2 levels, causing permanent offset of the pCO2 sensor values,7 and C) pose a potential safety hazard in that proper sensor placement is a requirement for gas ion permeable membrane integrity.*

A new CLBGA system, the Cardiomet 4000* (C 4000) from Biomedical Sensors Incorporated was evaluated in the clinical setting for accuracy, safety, reliability and ease of operation. The C4000 pH and pCO2 system is based on absorbance technology. The indicator dye phenol red behaves as a weak acid and exists in two tautomeric forms, each having a different light absorption spectrum. As the pH varies, the relative size of each tautomer's optical absorption peaks varies in proportion to the changing concentrations of the acid and base forms of the dye. Therefore, changes in the optical absorption of the phenol red dye measure changes in pH or pCO2.8 The pO2 sensor of the C4000 uses electrochemical technology (Clark type electrode).3,9

Materials and Methods

Thirty-two patients undergoing cardiopulmonary bypass (CPB) for myocardial revascularization were randomly selected. Patient population consisted of 21 males, 11 females with an average age of 72 (range 63–81) and average weight of 73 kilograms (ranges 47–
Table 1.
Patient Population

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MALES</strong></td>
<td><strong>21</strong></td>
</tr>
<tr>
<td><strong>FEMALES</strong></td>
<td><strong>11</strong></td>
</tr>
<tr>
<td><strong>AVG. AGE</strong></td>
<td><strong>72 YRS.</strong></td>
</tr>
<tr>
<td><strong>(RANGE 63 - 81 YRS.)</strong></td>
<td><strong>72 YRS.</strong></td>
</tr>
<tr>
<td><strong>AVG. WT.</strong></td>
<td><strong>73 kg.</strong></td>
</tr>
<tr>
<td><strong>(RANGE 47 - 92 kg.)</strong></td>
<td><strong>73 kg.</strong></td>
</tr>
</tbody>
</table>

92) (Table 1). The Bentley Gas Statb (BGS) was used as an on-line reference. The C4000 and BGS connectors were placed sequentially in the arterial line just proximal to the arterial line filter. Samples sent to the hospital laboratory were drawn from the purge of the arterial line filter (Diagram 1) and measured on the Corning 178. All results were reported at 37.0°C. Simultaneous to drawing the samples n = 112, values from both systems were recorded. Samples were drawn at predetermined intervals that divide into four groups: stable at 37.0°C., cooling, warming, and stable at less than 32°C. The results were evaluated for bias and precision, and the bias of both systems subjected to a student's t-test analysis for significance. The bias is defined as the mean difference between the CLBGA values and the laboratory reported values.

Results

The recorded values from the C4000 system for pH, pO2 and pCO2 are illustrated in Figure 1. Notably, the bias and precision of the C4000 values for pH, pCO2 and pO2 were within clinically acceptable ranges in all of the subdivided temperature groups, with no intra-group significant variation. Figure 2 reports the cumulative data for the C4000 and BGS. The collective values for pH and pO2 showed statistically significant differences (significance level 0.001) in the C4000 and BGS values, with a significantly lower bias shown by

\[\text{Table 1. Patient Population} \]

\[\begin{array}{|l|l|}
\hline
\text{MALES} & 21 \\
\hline
\text{FEMALES} & 11 \\
\hline
\text{AVG. AGE} & 72 YRS. \\
\text{(RANGE 63 - 81 YRS.)} & 72 YRS. \\
\text{AVG. WT.} & 73 kg. \\
\text{(RANGE 47 - 92 kg.)} & 73 kg. \\
\hline
\end{array} \]

b Bentley Labs, Irvine, CA 92714.
c Corning Medical Instruments, Palo Alto, CA 94306.
**Cooling defined as an active reduction in blood temperature.
***Warming defined as an active increase in blood temperature.
Figure 2.
Accumulative Data for C4000 and BGS

<table>
<thead>
<tr>
<th>N</th>
<th>105</th>
<th>105</th>
<th>105</th>
<th>105</th>
<th>105</th>
<th>105</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVG</td>
<td>7.43</td>
<td>7.46</td>
<td>7.38</td>
<td>7.37</td>
<td>7.00</td>
<td>7.00</td>
</tr>
</tbody>
</table>

*STATISTICALLY SIGNIFICANT SIGNIFICANCE LEVEL = 0.001

Table 2.
Emergency Procedure C4000 Calibrated 24 Hours

<table>
<thead>
<tr>
<th>SAMPLE 1</th>
<th>SAMPLE 2</th>
<th>SAMPLE 3</th>
<th>SAMPLE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CARDIOMET</strong></td>
<td><strong>HOSP. LAB</strong></td>
<td><strong>CARDIOMET</strong></td>
<td><strong>HOSP. LAB</strong></td>
</tr>
<tr>
<td>pH</td>
<td>7.48</td>
<td>7.48</td>
<td>7.44</td>
</tr>
<tr>
<td>PCO₂</td>
<td>40.7</td>
<td>40.0</td>
<td>41.8</td>
</tr>
<tr>
<td>PO₂</td>
<td>208</td>
<td>262</td>
<td>277</td>
</tr>
<tr>
<td>TEMP</td>
<td>37</td>
<td>37</td>
<td>37.5</td>
</tr>
</tbody>
</table>

Diagram 2.
C4000 Connector—Gas/Ion Windows

It has been described that even with a highly trained staff using blood gas analyzers meeting quality control standards, intermittent errors of clinical significance occur, at times frequently. In review, CLBGA provides the perfusionist with real-time, on-line, continuous information, thereby eliminating the potential for laboratory analysis error, and circumvents unnecessary, unwanted time delays in obtaining clinical parameters. Additionally, CLBGA...
allows the perfusionist to maintain blood gas parameters at physiologic levels and avoids the risks of sampling error, contamination of the sampling site, handling error, and receipt of erroneous results.

The data presented in this evaluation shows that the C4000 CLBGA system has a clinically acceptable bias and precision for the measured parameters PH, pCO₂ and pO₂ within the dynamic environment of CPB. The C4000's unique connector design provides stainless steel reinforced gas/ion windows pressure tested to 17 psi. Therefore, single or multi-sensor calibration verification can be performed at any time, and the need for one point calibration to the external laboratory deleted, helping bring complete consolidation of the CPB circuit in view.

Acknowledgement

The authors wish to acknowledge the support of Stan Fink, Ph.D., towards accomplishing this evaluation.

References


Questions from the Audience

Mike Dunaway, San Diego, CA: Question: Could you explain the precision bias to us again and tell us how that is significant to us on a daily basis?
Answer: The bias is the standard deviation of the values being compared and the precision is the spread of those differences. Neither one alone means anything, however an ideal situation is to have a very low bias combined with a low or statistically insignificant precision. I would refer you to a reference in the article by Altman, D.G., Statistics and Ethics in Medical Research, British Medical Journal, 1987, Vol. 33 page 1538.

Question: Did you feel that Gas Stat was acceptable or unacceptable?
Answer: Well, I think it is unfair whether the Gas Stat was acceptable or unacceptable—I think it would be better to evaluate this system solely on its own merit. I believe that the ability to remove the sensor from the connector to verify calibration is a key plus to this particular system. The other system in this case is not able to do that. The recommendation of a one point calibration to the external lab, I think, defeats the whole purpose of what we are trying to accomplish. We all have experienced multiple problems with the external lab... lost blood gases, blood gas results that seemed completely out of proportion to what we expected, etc. So when you want to consolidate a cardiopulmonary bypass circuit, I see no need to be drawing blood to send away.