Clinical Evaluation of the Gas Transfer of the Bentley 10 Plus Bubble Oxygenator during Alpha-Stat Regulated Hypothermic Cardiopulmonary Bypass


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Abstract

The gas transfer performance of the Bentley 10 Plus bubble oxygenator was clinically investigated. 26 consenting adult patients undergoing either Coronary Artery Bypass Grafts (CABG) or valve replacement were perfused using this oxygenating system and moderate hypothermia. Mean body surface area (BSA) was 1.78 square meters ranging from 1.38 to 2.12. During bypass blood flow was maintained at 2.4 l/m²/min. We aimed for an arterial \( \text{pO}_2 \) between 100 and 200 mmHg and an arterial \( \text{pCO}_2 \) between 35 and 45 mmHg. Arterial \( \text{pO}_2 \) was adjusted mainly by the \( \text{pO}_2 \) control valve setting and \( \text{pCO}_2 \) by total gas flow. The blood gas result shows clearly the controllability of the \( \text{PaO}_2 \) and \( \text{PaCO}_2 \). The mean \( \text{PaO}_2 \) for all the procedures was 154 ± 38 mmHg and the mean \( \text{PaCO}_2 \) was 39.7 ± 3.24 mmHg.

The results of this study demonstrate that the correct use of the Bentley 10 Plus bubble oxygenator during alpha-stat regulated hypothermic (26-30°C) CPB allows control of the \( \text{PaO}_2 \) and \( \text{PaCO}_2 \) levels within preset ranges.

Introduction

The actual interest for the new membrane oxygenators does not prevent a large number of perfusionists from remaining in favour of the bubble oxygenators. The use of membrane oxygenators now equals that of bubble oxygenators. The manufacturers of the bubble oxygenators have kept on improving their products. These improvements were mainly directed towards higher oxygenation capacity and gentler blood-handling. Oxygenation and \( \text{CO}_2 \) clearance used to be controlled mainly by total gas-flow with both functions influencing one another.

The new physiological approach to optimal acid-base management during induced hypothermia and the concept of alpha-stat regulation created new demands on \( \text{O}_2 \) and \( \text{CO}_2 \) gas transfer of the oxygenators. The perfusionist not only wants to regulate and continually control both the \( \text{pO}_2 \) and the temperature levels, but also the \( \text{pH} \) and the \( \text{pCO}_2 \) of the arterial blood during CPB.

Bentley has developed the Bentley 10 Plus bubble oxygenator to allow a separate regulation of \( \text{O}_2 \) and \( \text{CO}_2 \) gas transfer by means of a gas valve.

Materials and Methods

Description of the Bentley 10 Plus bubble oxygenator

The Bentley 10 Plus oxygenator is a new oxygenator evolving the basic concepts of the Bentley 10 B. The top of the new oxygenator has a \( \text{pO}_2 \) control valve. The valve has settings from "MAX \( \text{pO}_2 \)," 8, 6, 4, "MIN \( \text{pO}_2 \)." The total gas-flow is directed to the gas diffusor when the \( \text{pO}_2 \) control valve is placed at the "MAX \( \text{pO}_2 \)" position, operating identical to the Bentley 10 B bubble oxygenator. A portion of the gas-flow is diverted from the gas diffusor down the center of the oxygenation column by turning the valve to the "MIN \( \text{pO}_2 \)" position. Setting between "MIN \( \text{pO}_2 \)" and "MAX \( \text{pO}_2 \)" provide different proportions of gas directly bubbled into the blood via the gas diffusor or to the film of blood passively flowing over the heat exchanger. The decreased amount of \( \text{O}_2 \) flowing through the gas diffusor results in a less efficient \( \text{O}_2 \) gas transfer without affecting the \( \text{CO}_2 \) gas clearance controlled by the total gas flow. In the "MIN \( \text{pO}_2 \)" position 15% of the total gas still passes through the diffusor.
**Patients**

The study included 26 patients (7 female—19 male), ASA grades II or III, aged 43–73 yr (mean 59 yr), 8 of them had acquired valvular disease and 18 ischemic heart disease. (Table 1)

**Anaesthesia**

All patients were premedicated with thalamonal, 2 ml (fentanyl, 0.1 mg and droperidol, 5 mg) and scopolamine, 0.5 mg given I.M. 30 minutes before the induction of anaesthesia.

Anaesthesia was induced with fentanyl, 1 mg injected as a bolus, followed by a continuous infusion of fentanyl until a total dose of 100 a 150 μg/kg was infused. Anaesthesia was maintained by supplementary doses of flunizapam or sufentanil at the time of skin incision, sternal split and after weaning off the cardiopulmonary bypass. Neuromuscular blockade was obtained with pancuronium bromide. Ventilation with oxygen and air was adjusted to maintain normoxia and normocapnia, as confirmed by capnography and blood-gas analyses.

Heparin was administered according to a dose-response curve in order to maintain an activated coagulation time above 500 seconds as measured by the Hemochron 400 instrument. After cardiopulmonary bypass, heparin was neutralized with protamine 1000.

Post-operative assisted ventilation was maintained for approximately 20 hours. Preoperative treatment of the coronary patients: calcium antagonists, beta receptors antagonists and nitrates were given up to the operation day.

**Extra-Corporeal Circuit**

The extra-corporeal circuit consisted of a Bentley pre-connected Custom Pack containing a Bentley 10 Plus oxygenator, a BCR 3500 cardiotomy reservoir and an AF-1025C arterial filter. The circuit was mounted on a Stockert pump console. Oxygenator and tubing circuit were flushed with 100% CO₂ and primed with Geloplasma (Gelatina modif. 30 gr, Na, 150 mEq, K, 5 mEq, Mg, 3 mEq, Cl, 100 mEq, lact, 30 mEq per litre) 1600 ml and heparin, 50 mg (5000 I.U.).

**Cardiopulmonary bypass**

During the cardiopulmonary bypass the blood flow was kept at 2.4 l/m²/Min. The patients mean arterial blood pressure was kept between 50 and 70 mmHg. The arterial reservoir level was kept around 1200 ml. The gas flow rate of 100% O₂ and the oxygen control valve setting of the Bentley 10 Plus were manually adjusted. PaO₂ levels were maintained between 100 and 200 mmHg at actual temperature and PaCO₂ levels were maintained between 35 and 45 mmHg at 37°C. Patients undergoing coronary bypass surgery were cooled to 30°C and intermittent cross-clamping technique was used. Patients undergoing valvular replacement surgery were cooled to 26°C and approximately 1600 ml cardioplegic solution was administered. A Gas Statemeter measured continuously inline PaO₂, PaCO₂ and arterial pH during CPB.

**Data Collection**

The following data were collected every 15 min during CPB: blood flow, oxygen gas-flow, O₂ control valve position, oxygenator arterial reservoir level, arterial and venous line temperatures, mean arterial pressure, central venous pressure and oesophageal and rectal temperatures.

Arterial and venous blood samples were drawn every 15 minutes for: blood-gas analyses and serum potassium levels, Hgb and S₀₂.

Blood samples were drawn during CPB, 30 minutes, 24 hours, and 48 hours after CPB for plasma haemoglobin levels measured by the modified benzidine method, and for erythrocyte, leucocyte and thrombocyte counts determined by automatic cell counter.

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**Table 1**

Characteristics of patient group and bypass time.

<table>
<thead>
<tr>
<th>Patients male/female</th>
<th>ASA group</th>
<th>Patient age (yr)</th>
<th>Patient weight (kg)</th>
<th>Patient surface area (m²)</th>
<th>Bypass time (min)</th>
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</thead>
<tbody>
<tr>
<td>19/7</td>
<td>II-III</td>
<td>59</td>
<td>69.9</td>
<td>1.78</td>
<td>81</td>
</tr>
<tr>
<td>Mean:</td>
<td></td>
<td>7</td>
<td>12</td>
<td>0.19</td>
<td>18</td>
</tr>
<tr>
<td>Range:</td>
<td></td>
<td>43-73</td>
<td>47-92</td>
<td>1.38-2.12</td>
<td>50-105</td>
</tr>
</tbody>
</table>

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b Datex Instrumentarium, Teollisuuskatu 27, 00510 Helsinki
c Internat. Technidyne Corp., Nevsky Str. 23, Edison, New Jersey 08820
d Roche Labs.
e Stockert, Osterwaldstrasse 10, 8000 Munchen

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f Cardiovascular Device Inc., 17502 Armstrong Avenue, Irvine, California 92714
g Acid-Base Laboratory 4, Radiometer, Endrupvey 72, DK 2400 Kopenhagen
h Co-Oxymeter 282, Instrumentation Laboratory Inc., 113 Hardwell, Lexington, Massachusetts 02173
i Coulter S+4, Coulter Electronics Limited, Northwell Drive, Beds Lu 3RH, United Kingdom

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The cell counts were corrected for haemodilution (actual count × initial haematocrit value/haematocrit value at the sampling time).

**Results**

The cardiopulmonary bypass procedure and the anaesthesia technique were standardized and all patients had an uncomplicated recovery.

Mean, standard deviation, and ranges of PaO₂, PaCO₂, arterial saturation, venous saturation, Hgb, O₂ transfer, valve setting and total gas-flow/square meter BSA at the different sample times are presented in Table 2.

The results of the pO₂ and pCO₂ changes during hypothermia, 1C to 4C (C stands for cooling, numbers 1 to 4 represent the sample numbers) and during the rewarming phase, 1R to 3R (R stands for rewarming, numbers 1 to 3 represent the sample numbers) are shown in Figure 1. The PaO₂ values are reported corrected to the blood temperature,¹⁴ the PaCO₂ determinations, as read on the blood gas analyser at 37°C.

Figure 2 shows the mean total oxygen gas-flow in liters/square meter of BSA. The figures indicating the mean oxygen valve setting correspond to the mean portion of the total gas-flow diverted from the diffusor as represented by the upper hatched bars. The scattergram (Figure 3) shows the results of the plotting of the PaO₂ and the corresponding PaCO₂ values of all blood samples drawn during cardiopulmonary bypass using the Bentley 10 Plus. Most values of the blood gas levels are concentrated within the desired limits: PaO₂ between 100 and 200 mmHg and PaCO₂ between 35 and 45 mmHg.

The results of the haematological parameters are summarized in Table 3. All data are presented as means ± one standard deviation and the cell counts are corrected for haemodilution. We observed the well known thrombocytopenia, a transient rise of the free plasma haemoglobin level and the post-bypass leucocytosis. The results presented are comparable to those published in similar studies using bubble oxygenators during CPB.¹¹,¹²,¹³

**Discussion**

The achievements of modern cardiac surgery have been made possible since the development of safe hypothermia and reliable extracorporeal circulation techniques.

From the beginning, the problem of the "optimal acid-base management during induced hypothermia in man" had to be solved. The answer is still controversial. In the early years, the pH-stat acid-base management (pH and pCO₂ corrected to body temperature) seemed to offer the most reasonable solution and was therefore generally adopted in open cardiac surgery.⁶ During the last decade however, results of many physiological, biochemical, experimental and clinical research favoured the alpha-stat management (pH and pCO₂ measured at 37°C and not corrected to body temperature)²,⁷,⁹,¹⁰

The alpha-stat strategy has been used in our institution for many years.

### Table 2

<table>
<thead>
<tr>
<th></th>
<th>1C</th>
<th>2C</th>
<th>3C</th>
<th>4C</th>
<th>1R</th>
<th>2R</th>
<th>3R</th>
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</thead>
<tbody>
<tr>
<td>PaO₂ (mmHg):</td>
<td>151</td>
<td>139</td>
<td>141</td>
<td>162</td>
<td>171</td>
<td>156</td>
<td>174</td>
</tr>
<tr>
<td>Range PaO₂ (mmHg):</td>
<td>118-184</td>
<td>113-165</td>
<td>113-169</td>
<td>134-190</td>
<td>115-226</td>
<td>131-180</td>
<td></td>
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<tr>
<td>PaCO₂ (mmHg):</td>
<td>39.7</td>
<td>31.3</td>
<td>21.7</td>
<td>31.6</td>
<td>37.1</td>
<td>31.5</td>
<td>37.1</td>
</tr>
<tr>
<td>Range PaCO₂ (mmHg):</td>
<td>36.5-43</td>
<td>39-43.5</td>
<td>39-45</td>
<td>39-44</td>
<td>34.5-40</td>
<td>35-39</td>
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<tr>
<td>aSAT (%):</td>
<td>97.7</td>
<td>97.7</td>
<td>97.7</td>
<td>97.7</td>
<td>97.4</td>
<td>97.5</td>
<td>98.2</td>
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<tr>
<td>Range aSAT (%):</td>
<td>98.6-96.7</td>
<td>98.3-96.7</td>
<td>98.8-96.9</td>
<td>98.4-96.9</td>
<td>98.1-96.7</td>
<td>98.2-97.0</td>
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</tr>
<tr>
<td>vSAT (%):</td>
<td>81.1</td>
<td>94.6</td>
<td>79.5</td>
<td>80.0</td>
<td>79.7</td>
<td>79.7</td>
<td>81.8</td>
</tr>
<tr>
<td>Range vSAT (%):</td>
<td>90.3-68.4</td>
<td>88.1-70.5</td>
<td>87.4-72.9</td>
<td>86.6-67.8</td>
<td>76.3-48.7</td>
<td>68.2-51.3</td>
<td></td>
</tr>
<tr>
<td>Hgb (mg%):</td>
<td>8.9</td>
<td>8.8</td>
<td>9.0</td>
<td>8.7</td>
<td>8.7</td>
<td>8.7</td>
<td>9.1</td>
</tr>
<tr>
<td>Range Hgb (mg%):</td>
<td>11.0</td>
<td>6.5</td>
<td>11.1</td>
<td>6.5</td>
<td>11.3</td>
<td>7.6</td>
<td>9.9</td>
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<tr>
<td>O₂ transfer (Vol%):</td>
<td>2.4±0.6</td>
<td>2.5±0.6</td>
<td>2.5±0.6</td>
<td>2.6±0.6</td>
<td>4.1±0.8</td>
<td>4.5±0.6</td>
<td>5.9±0.6</td>
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<tr>
<td>Valve Setting:</td>
<td>7±1.9</td>
<td>6±2.1</td>
<td>6±2.5</td>
<td>6±2.5</td>
<td>9±1.8</td>
<td>10±0.8</td>
<td>8±0.8</td>
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<tr>
<td>Range Valve setting:</td>
<td>10-3</td>
<td>10-3</td>
<td>10-2</td>
<td>10-3</td>
<td>10-4</td>
<td>10-7</td>
<td></td>
</tr>
<tr>
<td>Total Gas Flow (l/m²):</td>
<td>1.51±0.25</td>
<td>1.44±0.23</td>
<td>1.6±0.2</td>
<td>1.6±0.23</td>
<td>1.77±0.35</td>
<td>1.99±0.34</td>
<td>1.53±0.6</td>
</tr>
<tr>
<td>Range Gas Flow (l/m²):</td>
<td>2.01-1.06</td>
<td>2.00-0.95</td>
<td>2.00-1.23</td>
<td>2.03-1.31</td>
<td>2.85-1.17</td>
<td>2.68-1.53</td>
<td></td>
</tr>
<tr>
<td>Number of Samples:</td>
<td>26</td>
<td>25</td>
<td>20</td>
<td>9</td>
<td>24</td>
<td>12</td>
<td>1</td>
</tr>
</tbody>
</table>

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Most modern disposable oxygenators have been manufactured to provide optimal oxygenation. Using the pH-stat acid-base management CO₂ gas can be added to the O₂ gas flow in order to keep the pH and the PaCO₂ at normal levels at the patient's temperature. When alpha-stat strategy is adopted, clinical practice shows that most bubblers are such efficient oxygenators that the CO₂ clearance can only be achieved at the expense of very high PaO₂ levels with the potential dangers of gaseous microemboli and O₂ toxicity. ¹⁰

The present study was intended to evaluate the clinical use of the Bentley 10 Plus.¹ This device allows for a separate O₂ and CO₂ gas exchange by means of adjusting the total O₂ gas-flow and the pO₂ control valve position. The results of the study reveal that the mean arterial PaO₂ and PaCO₂ levels could be maintained at the desired levels throughout the cardiopulmonary bypass (Figure 1). The mean total O₂ gas-flow was stable and only slightly increased during the rewarming period (Figure 2). This result confirms that the Bentley 10 Plus is an efficient oxygenator allowing a low gas to blood flow ratio. The mean setting of the pO₂ control valve during hypothermia indicates that approximately 50% of the total gas-flow was diverted from the diffuser to avoid over-oxygenation. CO₂ clearance remained efficient in the film mode of oxygenation because of the very high diffusability of the CO₂ gas.

Adequate PaO₂ values during the rewarming phase were obtained using settings of 9 and "MAX pO₂" on the pO₂ control valve.

The results of the PaO₂ and PaCO₂ levels shown in the scattergram in Figure 3 are similar to the results obtained with membrane oxygenators.¹⁰ This indicates that the Bentley 10 Plus functions as an effective gas exchange device.

The results of erythrocyte, leucocyte, thrombocyte counts and free plasma haemoglobin levels, as summarized in Table 3, show that haemolysis and thrombocytopenia occurred in our patients as expected with the use of a bubble oxygenator during CPB in open-heart surgery.¹¹,¹²,¹³

**Conclusion**

The perfusionist is now able, by correctly using the Bentley 10 Plus during alpha-stat regulated hypothermic CPB (26–30°C) to control separately the PaO₂ and the PaCO₂ levels.
Table 3
Changes in haematocrit, erythrocyte count, leucocyte count, thrombocyte count and plasma free haemoglobin. (mean and SD) Cell counts are corrected to haemodilution. CPB = Cardiopulmonary bypass.

<table>
<thead>
<tr>
<th></th>
<th>Pre-CPB</th>
<th>SD min-CPB</th>
<th>End-CPB</th>
<th>24 Hours</th>
<th>48 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haematocrit L/L</td>
<td>0.370 ± 0.04</td>
<td>0.260 ± 0.039</td>
<td>0.278 ± 0.037</td>
<td>0.345 ± 0.031</td>
<td>0.323 ± 0.037</td>
</tr>
<tr>
<td>Erythrocyte Count (Corrected) 10+12/L</td>
<td>4.11 ± 0.5</td>
<td>4.21 ± 0.5</td>
<td>4.12 ± 0.51</td>
<td>4.14 ± 0.49</td>
<td>4.07 ± 0.46</td>
</tr>
<tr>
<td>Leucocyte Count (Corrected) 10+9/L</td>
<td>5.1 ± 1.4</td>
<td>7.2 ± 3.3</td>
<td>12.1 ± 3.9</td>
<td>16.7 ± 4.1</td>
<td>20.7 ± 5.1</td>
</tr>
<tr>
<td>Thrombocyte Count (Corrected) 10+9/L</td>
<td>231 ± 66</td>
<td>131 ± 66</td>
<td>95 ± 42</td>
<td>123 ± 45</td>
<td>130 ± 43</td>
</tr>
<tr>
<td>Plasma Free Haemoglobin mg/L</td>
<td>70 ± 48</td>
<td>153 ± 78</td>
<td>208 ± 88</td>
<td>41 ± 24</td>
<td></td>
</tr>
</tbody>
</table>

PaCO₂ within preset ranges by means of total oxygen gas-flow and oxygen valve setting.

The haematologic results show that the evolution of erythrocyte, leucocyte, thrombocyte counts and free plasma haemoglobin (before, during and after bypass) fall within the ranges accepted with the use of bubble oxygenators during CPB in open-heart surgery.

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References