The Capiox RX05 oxygenator: pediatric clinical observations

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Terumo Cardiovascular Systems has released the X-Coated™ Capiox® RX05 or Baby RX™ oxygenator. This oxygenator is designed for neonate and infant patient populations. The device was integrated into our current perfusion practice and our clinical observations are described here. The Baby RX™ has a prime volume of 43 mL with a maximum flow of 1.5 L/min. The integrated hardshell venous reservoir has independent venous and cardiotomy filters, as well as a very low minimal operating level of 15 mL. A variety of options provide exceptional versatility for the device. The Baby RX™ proves to be a low-prime, high-flow oxygenator, enabling us to use it on a wide range of pediatric patients. It will be a useful tool for reducing our neonate and infant circuit priming volumes. Perfusion (2003) 18, 321–323.

Introduction

Reducing circuit prime volumes is a persistent challenge within the perfusion community. The need for reduced prime volumes is most evident among the pediatric population and is under continuous examination. The volume of prime in a pediatric circuit has been recognized as fundamentally important and, in most cases, the ratio of a pediatric patient’s blood volume to circuit prime volume does not favor the patient. This hemodilution can adversely affect a patient’s fluid balance and organ function.

During the past five years at our institution, we have seen a 50% increase in the number of patients weighing less than 5 kg. There has also been a 36% increase in patients weighing between 5 and 10 kg. Our trend towards a smaller patient population prompted us to look at a new low-prime, high-flow oxygenator, the Capiox® RX05 (Terumo Cardiovascular Systems Co., Ann Arbor, MI, USA) or Baby RX™. This paper contains our clinical observations of the device. No scientific measurements other than arterial and venous blood gases were done. No statistical analyses were used. Only observations were noted.

Materials and methods

We evaluated the Baby RX™ on a variety of pediatric patients. There were no exclusionary criteria based on diagnosis or repair. Patient demographics and bypass information are shown in Table 1.

We incorporated the device into our existing neonatal and infant circuits. Circuit and oxygenator details are shown in Table 2. The Baby RX™ was set up and primed in accordance with the manufacturer’s instructions. Arterial and venous blood gases were performed during the first 15 min of cardiopulmonary bypass and a minimum of every 30 min thereafter while on bypass. Blood gas analyses were performed on either the iSTAT (iSTAT Corporation, Princeton, NJ, USA) or the Gem Premier Plus (Instrumentation Laboratory, Lexington, MA, USA) blood gas analyzer. Observations were noted on database forms completed by the perfusionist managing the case.

Observations

Gas exchange and heat exchange

Gas and heat exchange for the Baby RX™ performed as expected on all cases, including those in which core temperatures ranged from deep hypothermia at 13°C to normothermia at 36.5°C.

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The Capiox RX05 oxygenator

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Table 1 Patient data

<table>
<thead>
<tr>
<th>n = 40</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>2.0–16.3</td>
</tr>
<tr>
<td>BSA (m²)</td>
<td>0.15–0.70</td>
</tr>
<tr>
<td>CPB time (min)</td>
<td>28–128</td>
</tr>
<tr>
<td>Blood flow (L/min)</td>
<td>0.11–1.60</td>
</tr>
<tr>
<td>Core temperature (°C)</td>
<td>13.0–36.5</td>
</tr>
</tbody>
</table>

BSA, body surface area; CPB, cardiopulmonary bypass.

Table 2 Oxygenator and circuit characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum blood flow (L/min)</td>
<td>1.5</td>
</tr>
<tr>
<td>Static priming volume (mL)</td>
<td>43</td>
</tr>
<tr>
<td>Minimum operating volume (mL)</td>
<td>15</td>
</tr>
<tr>
<td>Connector sizes (in)</td>
<td>3/16 and 1/4</td>
</tr>
<tr>
<td>Neonatal AV loop (in)</td>
<td>3/16 × 1/4</td>
</tr>
<tr>
<td>Infant AV loop (in)</td>
<td>1/4 × 1/4</td>
</tr>
</tbody>
</table>

AV, arterial-venous.

**Priming**
The device primed and debubbled easily. The top- to-bottom blood flow with the integrated purge line was designed to aid in air handling. With 15 mL of crystalloid prime recirculating at a rate of 1.5 L/min, no visible air was seen passing into the arterial line. Please note, however, no scientific measurements were taken to disprove the possibility of microemboli passing to the arterial side.

**Reservoir design**
There was minimal breakthrough time when priming with crystalloid or blood. Independent venous and cardiotomy filters minimize the holdup volume and limit blood exposure to the defoaming agent.

**Versatility**
The device is manufactured with an east and west configuration for use on right- or left-sided pumps. The accessory package contains an additional recirculation line, 3/16-in port adapters, and a 3/8-in port adapter for the venous inlet. The reservoir rotates, as do the sucker and vent ports. The blood inlet rotates 360°.

The bracket for the oxygenator is multipositional and adapts to the larger bracket used by other Capiox® oxygenators.

**Overall design**
The top of the reservoir is so compact that it does get congested when all lines and ancillary equipment are attached. The design of the reservoir inhibits vortexing of the fluid and allows for easy accounting of the reservoir level; however, when the level sensors are placed on the front of the reservoir, in accordance with the manufacturer’s instructions, the view is severely obstructed by the sensors.

The water line connections exit the device at angles that may increase the risk of breaking if inadvertently hit.

**Biocompatible surface coating**
All surfaces of the device are coated with Terumo’s X-Coating™, an amphiphilic, biopassive coating. The coating molecules bind to the surface materials, as well as each other, to reduce protein denaturation and platelet adhesion. No observations were made regarding the efficacy of the X-Coating™ of the oxygenator.

**Discussion**

The effort to decrease the prime volume of pediatric perfusion circuits is ongoing. Products and techniques to reduce hemodilution have been described many times.1,4,5 The introduction of the Capiox® RX05 or Baby RX™ oxygenator with a static priming volume of 43 mL provides a low-prime, high-flow alternative to pediatric oxygenators currently on the market.

We found the device easy to prime. The adaptable bracket eased set up, while the accessories made the device extremely versatile. The versatility and the high flow rate enable us to use the device on pediatric patients weighing up to 15 kg.

The recommended maximum blood flow rate is 1.5 L/min and was challenged to 1.6 L/min during one case without incidence. The longest cardiopulmonary bypass time was 128 min; the device was not tested beyond that length of time.

The Baby RX™ is coated with X-Coating™. Terumo’s amphiphilic, biopassive coating. We did not examine the possibility of any benefits related to the coating and cannot comment on the efficacy of the coating.

The compactness of the device lends to congestion on the top of the reservoir. There is limited space for mounting of the level sensors, which can obstruct the operator’s view of the reservoir level when mounted according to the manufacturer’s recommendations.

Although no specific measurements were taken and no analyses completed, our observations have led us to integrate the Baby RX™ into our current neonatal and infant circuits. The Baby RX™ will be our first step in reducing prime volumes for the majority of our pediatric patient population.
Acknowledgements

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References

