Extended Support With the Terumo BABY-RX™ Oxygenator

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Abstract: The Terumo Baby-RX™, a new-generation low prime oxygenator, recently has entered the perfusion market in North America. This oxygenator is designed exclusively for neonates and infants and has the smallest priming volume of any clinically available oxygenator. The BABY-RX™ also is treated with X Coating™, Terumo’s biocompatible, hydrophilic polymer surface coating that reduces platelet adhesion and protein denaturation. The oxygenator has a blood flow range of 0.1 to 1500 mL/min and operates with a minimum reservoir volume of 15 mL. A 3.2-kg patient, status post-Stage 1 Norwood, Palliation was placed on cardiopulmonary support after thrombus formation within the modified Blalock-Taussig shunt during a general surgery procedure. The extended support circuit incorporated the Baby-RX™ oxygenator for 17.5 hours. The oxygenator performed well over this time period at flows of 600–800 mL/min, sweep rates of 100–300 mL/min, FiO2 of 30–40%, and ACTs of 140–200 seconds. There were no indices of oxygenator failure noted within the time frame of support. After placement of a new systemic to pulmonary shunt, the patient was removed from support and the oxygenator drained of residual blood. No evidence of fiber damage or clot formation was noted. The patient had a successful support run without complications related to cardiopulmonary support.

Keywords: oxygenator, cardiopulmonary bypass, single ventricle, extended mechanical support.

The introduction of therapies such as high frequency oscillatory ventilation, surfactant therapy, and nitric oxide inhalation have lead to a decline in the number of patients receiving extracorporeal membrane oxygenation (ECMO). ECMO currently is used less frequently for respiratory failure than in the past and more frequently for sepsis or pneumonia accompanied by cardiovascular compromise, for patients with decreased cardiac function post cardiomyopathy, and as a bridge to transplant or further intervention (1). During the past decade, no changes seen have been observed in mean gestational age, gender, and age at which ECMO was initiated, in the pH, or in the PaCO2 before initiation of ECMO (2). However, there has been an increase in the amount of time patients are on support, suggesting that the patients currently receiving ECMO may be at an increased risk for morbidity compared with those from a decade earlier (2).

With the increase in use of extended cardiopulmonary support (CPS) as a bridge to transplant or as a bridge to reintervention, many institutions are implementing rapid-deployment CPS systems. These systems typically include a standard hollow-fiber polycarbonate membrane oxygenator instead of the traditional silicone membrane oxygenators (Medtronic Cardiovascular, Minneapolis, MN) because they can be primed more rapidly and easily (3). Although hollow fiber oxygenators typically fail more readily than silicone membrane oxygenators, emergent situations dictate their use. Most clinicians are prepared to change the oxygenator once the patient is stable on support, if oxygenator failure is indicated by poor gas exchange, fiber leak, or clotting within the component.

We present a case in which CPS was instituted emergently with the use of the Terumo Baby-RX™ hollow-fiber membrane oxygenator on a single-ventricle patient whose status was post Norwood Stage 1 Palliation for hypoplastic left heart syndrome (HLHS).

DESCRIPTION

A 3.2-kg, 6-week-old female with HLHS status post Norwood Stage 1 Palliation presented to the general operating room (OR) for fundoplication and feeding gastrostomy. During the procedure, the patient became profoundly cyanotic. Volume in the form of packed red blood cells (PRBCs) was given with no improvement. A trans-thoracic echocardiogram was immediately preformed and...
revealed reduced blood flow through the right modified Blalock-Taussig shunt (RMBTS). Thrombus in the shunt was thought to be the reason for the reduced blood flow. The patient was then given a bolus of both heparin and tissue plasminogen activator (tPA). The patient remained acidic and hypoxic, and there was no noted increase in RMBTS flow.

The patient was transferred to the cardiac catheterization laboratory, where thrombus was confirmed in the RMBTS, and an attempt was made to directly administer tPA into the shunt. The patient continued to have decreased saturations with intermittent episodes of bradycardia, prompting cardiopulmonary resuscitation. The patient never experienced any periods of hypotension or cardiac arrest.

In preparation for the placement of a new shunt, a cardiopulmonary bypass circuit was set up incorporating a 3/16 × 1/4 AV loop (COBE Cardiovascular, Arvada, CO), 3/16 pump boot (COBE Cardiovascular), Terumo Baby-RX™ oxygenator with open venous reservoir (Terumo Cardiovascular, Ann Arbor, MI), Terumo Capiox™ AF02 arterial line filter, and a Terumo CDI 500 arterial gas and venous saturation-hematocrit monitor. The system was then crystalloid primed. The patient became extremely unstable, with critically low saturations. The decision was made to place the patient on support in the catheterization laboratory with the bypass circuit. The patient was heparinized with an activated clotting time of 285 seconds. The bypass circuit was blood primed, and the patient was placed on support through the right carotid artery and right internal jugular vein at 150 mL/kg/min.

The patient’s acid-base status was slowly corrected over an hour, primarily with tris-hydroxymethyl aminomethane and secondarily with sodium bicarbonate. The patient also was placed on bypass initially at an FiO2 of 21% to avoid a large burst of oxygen in an hypoxic and acidic environment and then slowly increased to maintain a patient PaO2 of 75–100 mmHg (4). The patient was to rest on CPS overnight to allow the heart and clotting system to recover and return to the OR the next day for a second shunt placement. The venous reservoir was left in the circuit to keep the heart decompressed. The patient was transferred to the pediatric intensive care unit, and the following parameters were observed: flow 150–175 mL/kg/min, patient PaO2 75–100 mmHg, and PaCO2 40–45 mmHg. A heparin drip with a 60 U/mL concentration was started at 1.6 mL/h (30 U/kg/h) after the ACT fell to less than 200 seconds and titrated to obtain a target ACTs of 150–180 seconds.

Because of the tPA administration and abdominal surgery, bleeding was substantial during the first hours of support. The patient’s platelets and fibrinogen were normalized with donor blood products. Over the course of the CPS, the patient received 7 units of PRBCs, 4 units of FFP, 3 units of platelets, and 9 units of cryoprecipitate before bleeding was controlled and clotting factor levels returned to normal. All clotting factors were given to the patient through peripheral intravenous access.

Three hours after the patient was placed on CPS, we were able to achieve enough hemodynamic stability to start slow continuous ultrafiltration (SCUF) for the removal of lactate and metabolites (5). Blood was removed from a port distal to the oxygenator using a second roller pump, shunted through a hemofilter at a rate of 50 mL/min, and returned to a port in the venous line. By using a second pump for SCUF, blood flow to the patient was always known. PlasmaLyteA and 0.45% normal saline were used during the SCUF procedure for crystalloid replacement. Constant monitoring of the patient’s sodium level during the SCUF period dictated which solution was used. During a 14-hour period, 3 L of PlasmaLyteA and 3 L of 0.45 normal saline were used with approximately 12 L of ultrafiltrate removed, which included blood products and other volume given. The patients initial lactate of 20 decreased to 3.8 during the SCUF period.

The next day, the patient was taken to the OR, where the initial RMBTS was removed and a central shunt was placed from the ascending aorta to the right pulmonary artery through a median sternotomy. The patient was then weaned from CPS after 17.5 hours of support. The circuit was drained into a cell saver, where the PRBCs were washed and salvaged. Upon examination of the oxygenator, after being cleared of residual blood, no thrombus or protein leakage was noted. Examination of the arterial line filter revealed the fibers to be approximately 10% thrombus covered. The patient left the OR in critical but stable condition with the chest left open because of tissue edema. The patient returned to the OR on postop day 13 for chest closure and was transferred out of the pediatric intensive care unit on postop day 28.

**COMMENT**

The decision to use CPS in a patient with single-ventricle physiology is very controversial in regards to patient management while on support. CPS in these patients carries a significant risk of morbidity and prompt initiation of support is one of the only factors able to offset this risk (6,7). Our decision to initiate CPS in the catheterization laboratory with a conventional CPB circuit was crucial when the alternative was to waste precious time in building and priming an extended support system. Once the patient was safely supported and hemodynamically stable, the circuit was analyzed and a plan of action was set for changing out circuit components in the event of failure.

In the presence of postop abdominal surgery and tPA, the decision to keep the ACTs to less than 180 seconds was necessary to stabilize the patient and stop the abdominal hemorrhaging. Reports have suggested that ACTs of
less than 200 seconds for patients on extended support with a coated oxygenator does not increase thrombogenicity (8). Doing so with an open venous reservoir, fiber membrane, and an arterial line filter in the circuit elicited concerns of clotting and yet were necessary to control patient bleeding. The ACT after the initiation of CPS was just less than 1000 seconds and did not fall to less than 200 seconds until after 7 hours on CPS (Figure 1). The initial ACT after CPS initiation was much more elevated than the pre-CPS ACT of 285 seconds. This was probably caused by more adequate mixing of the tPA and presupport heparin boluses once CPS was initiated, not accomplished by the patient in the lower cardiac output state of the pre-CPS time period. Once the ACT fell to less than 200 seconds, the abdominal bleeding decreased significantly and a heparin drip was started. The absence of thrombus in the reservoir and oxygenator was surprising and may be attributed to the Terumo oxygenator and reservoir being X Coated™, Terumo’s biocompatible, hydrophilic polymer surface coating that reduces platelet adhesion and protein denaturation. These were the only coated components of the circuit and therefore we were not surprised to find thrombus in the arterial line filter.

The oxygenator performed very well during the 17.5 hours of CPS, with no plasma leakage noted from the gas exhaust port. The FiO2 remained at 30–35%, with just a brief period at 45% when the patient was anesthetically light, to maintain a patient PaO2 around 100 mmHg (Figure 2). The CO2 removal also was noted to be quite efficient and stable throughout the entire CPS run with sweeps of only 300 mL/min or less (Figure 3).

CONCLUSION

The Terumo Baby-RX™ system performed considerably well for this short-term CPS. The oxygenator may be considered for short term extended support even in the presence of an open reservoir. The user should be prepared to acutely change out the oxygenator at the bedside should there be an indication to do so. Having an open venous reservoir in the system may prove challenging in changing out of components and should be considered when using the oxygenating system in this capacity.

REFERENCES


