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Case Reports

Membrane Oxygenator Heat Exchanger Failure Detected by Unique Blood Gas Findings

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Abstract: Failure of components integrated into the cardiopulmonary bypass circuit, although rare, can bring about catastrophic results. One of these components is the heat exchanger of the membrane oxygenator. In this compartment, unsterile water from the heater cooler device is separated from the sterile blood by stainless steel, aluminum, or by polyurethane. These areas are glued or welded to keep the two compartments separate, maintaining sterility of the blood. Although quality control testing is performed by the manufacturer at the factory level, transport presents the real possibility for damage. Because of this, each manufacturer has included in the instructions for use a testing procedure for testing the integrity of the heat exchanger component. Water is circulated through the heat exchanger before priming and a visible check is made of the oxygenator bundle to check for leaks. If none are apparent, then priming of the oxygenator is performed. In this particular case, this procedure was not useful in detecting communication between the water and blood chambers of the oxygenator. **Keywords:** heat exchanger failure, hypochlorite. *JECT. 2014;46:91–93*

Failure of components integrated into the cardiopulmonary bypass circuit, although rare, can bring with it catastrophic results and the stress of emergent oxygenator or circuit change-out. Fisher et al. noted that the incidence of oxygenator failure for any cause requiring change-out was approximately one in 4000 cases. They also noted that for leaking, the incidence of change-out was one in 15,000 (1). One of the integral components that may fail is the heat exchanger of the membrane oxygenator. In this compartment, nonsterile water from the heater cooler device is separated from the sterile blood by stainless steel, aluminum, or by polyurethane. These areas are glued or welded to keep the two compartments separate, maintaining sterility of the blood (1). Although quality control testing is performed by the manufacturer at the factory level, transport presents the real possibility for damage. Because of this, each manufacturer has included in the instructions for use a testing procedure for testing the integrity of the heat exchanger component. Water is circulated through the heat exchanger before priming and a visual check is made of the oxygenator bundle to check for leaks. If none are apparent, then priming of the oxygenator is performed. In this particular case, this procedure was not helpful in detecting the communication present between the water chamber and blood chambers of the oxygenator (2).

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DESCRIPTION

An infant weighing 4.5 kg with a secundum atrial septal defect (ASD) was scheduled for primary ASD closure. After setup of the oxygenator, water from the Hemotherm Cincinnati subzero (CSZ) (Cincinnati, OH) heater cooler unit was circulated through the oxygenator. After 2–3 minutes of circulation, there were no visible abnormalities observed with the oxygenator, so priming continued. As a result of the child's size and blood volume, the circuit was primed with blood to obtain a predicted hemoglobin level of 10 g/dL during cardiopulmonary bypass. Simplified modified ultrafiltration (SMUF), a technique previously described, was used (3). The circuit was first primed with Plasmalyte A (Baxter Corporation, Mississauga,

Ontario, Canada), then 175 mL packed red blood cells (PRBCs) and 300 mL fresh-frozen plasma are added. The mixture is circulated through the cardiopulmonary bypass circuit and hemoconcentrated through the SMUF system. This ensures washing of the PRBCs normalizing the potassium levels and theoretically removes the 1000 mL Plasmalyte A crystalloid component from the circuit, leaving reconstituted blood and plasma priming the circuit. One thousand units of porcine heparin (Pharmaceutical Partners of Canada, Richmond Hill, Ontario, Canada) were added to the circuit to prevent coagulation; 10 mEq of sodium bicarbonate (Hospira, Montreal, Quebec, Canada) and 150 μg calcium chloride (Hospira) were added to the circuit to correct acid-base balance and ionized calcium levels. Next sweep gas flow is initiated through the oxygenator. This facilitates matching the cardiopulmonary bypass circuit prime values as physiologically as possible to the child's circulating blood values. Next a blood sample is obtained of the prime, and an activated clotting time (ACT) and blood gas analysis are performed on the point-of-care (POC) blood analyzer, Radiometer ABL800 FLEX (Radiometer Medical Aps, Bronshoj, Denmark).

The results of the POC test of the circuit prime noted an ACT that stopped at 900 seconds. However, the blood sent for blood gas analysis was found to contain hypochlorite. The machine displayed the message "hypochlorite detected." No other electrolytes values were made visible by the blood analyzer, and the presence of the hypochlorite disabled the machine. To confirm this, another sample was drawn of the blood prime and sent to the hospital central laboratory for testing. Here testing was performed on a Radiometer ABL800 FLEX (Radiometer Medical Aps). This sample also confirmed the presence of the hypochlorite. At this juncture, it was puzzling as to where this chemical came from. The laboratory technician asked if the sample was in contact with any cleaning agents. It was determined after this discussion that the heater cooler device cleaning procedure involved using bleach as a disinfectant. This was determined to be the only possible source for the hypochlorite. During this period of time, there was no noted change in the oxygenator reservoir level, which would have been expected with significant water to blood leak. This could likely have been related to the higher pressure now present in the blood compartment compared with the water compartment. Although the CDI 500 inline blood gas monitor was not calibrated, the values displayed were within normal expected range for values. At this point, the operation was progressing and sternotomy had been performed, the heparin had been administered, and the surgeon had begun placement of the cannulas. The attending surgeon was immediately made aware of the contamination issue, and an emergent circuit change-out was preformed. The circuit was again primed with the same procedure described earlier. A blood gas was drawn from the circuit and sent to the central laboratory and was found to contain no hypochlorite, so the surgery was then carried out. This situation was a chilling reminder that although the perfusionist follows the pretesting and priming protocols outlined in information for users of manufacturers, an unanticipated incident can still occur. This child's body weight (4.5 kg) was the single rationale requiring addition of blood to the cardiopulmonary bypass circuit prime. If the patient had been larger, potentially no blood would have been required, and a blood gas of the circuit prime would not have been necessary. In this scenario, water to blood leak would have gone undetected.

If the manufacturer's procedure outlined in the information for users for testing water to blood leak failed in this case, is there any other method for checking the heat exchanger for leaks? A literature search was performed and an article by Hamilton et al. was found. This article outlined a novel technique for testing heat exchangers. The described method used air pressure to pressurize the water chamber and to observe a manometer for any fall in pressure. The appealing characteristic of this method is it would allow for detection of a defective heat exchanger before setup and priming (4). This procedure is now incorporated into practice.

As a result of this particular surgery case, the procedure at our hospital requires a blood gas sample be drawn from the blood primed circuit and the results confirmed with the surgical team before initiating bypass. In this case, this action potentially saved this child's life.

COMMENT

Failures of medical devices, although rare and stressful, provide the opportunity to learn detection and prevention strategies to enhance patient safety. In the event of failure of an oxygenator, the causes can never be assumed to always be the same. In the literature, there are reports of electrostatic charge building up from the roller pump creating a spontaneous discharge, which compromised the integrity of the oxygenator fibers. More recently another manufacturer issued a warning noting oxygenators that are primed for a prolonged time period with sodium chloride solution risk developing microholes in the heat exchanger, creating communication between the heat exchanger water path and the blood path (5,6). Therefore, the mechanisms for failure are many.

Another point noted after researching this area was there is variation in the operation of heater coolers. Although heater cooler units all serve the purpose of heating and cooling the blood, how they circulate the water can be different. It is important to point out that some heater coolers draw water into the unit rather than

pump water outward. This action would result in lower water pressures in the heat exchanger and a higher likelihood of blood to water leak as opposed to water to blood leaks. This mode of water circulation could aid in the detection of a leak resulting from the visibility of blood in the circulating water lines. It would also spare the patient from the deleterious effects of unsterile contaminated water entering the bloodstream. The Hemotherm CSZ (Cincinnati, OH) pumps water outward. Our institution now uses a heat cooler system that circulates water by drawing water in rather than pumping it outward (Sorin T-3, Mirandola, Italy).

Although device failure is infrequent, the procedure for reporting of the incident is very important. In this case, the failure was documented first with risk management at the hospital as a patient near miss. Next the suspected device failure was reported to Health Canada, Ottawa, Ontario, Canada. The device was then secured and sent to Health Canada for further testing. At their investigations, laboratory testing confirmed communication between the water and blood compartments. After concluding the investigation of the device, Health Canada then decides if this warrants any further course of action at the industry level such as recalls or investigation of manufacturing methods.

The Health Canada guidance document for mandatory problem reporting for medical devices outlines in detail the procedures to follow in Canada (7). In the United States, reporting sites such as the U.S. Food and Drug Administration, Manufacturer and User Facility Device Experience database and Perfusion Incident Reporting Systems allow for voluntary reporting of problems with medical devices. These databases make information accessible to the greater perfusion community allowing the clinician to be aware of potential product problems. Although reporting procedures vary with governing departments in different countries, it is important for the perfusionist to be aware of the policy and procedures to follow for securing, shipping, and investigation of faulty devices. It is a professional responsibility to report adverse occurrences and ensure follow-up for the safety of our patients.

REFERENCES

1. Fisher AR. The incidence and cause of emergency oxygenator changeovers. Perfusion. 1999;14:207–14.
2. High KM, Bashin G, Kurtz M. Principles of oxygenator function: Gas exchange, heat transfer, and operation. In: Gravalee GP, Davis RF, Kurtz M, Utley JR, eds. Cardiopulmonary Bypass: Principles and Practice. 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2000:49–68.
3. Myers GJ, Leadon RB, Mitchell LB, et al. Simple modified ultrafiltration. Perfusion. 2000;15:447–52.
4. Hamilton C, Stein J, Seidler R, et al. Testing of heat exchangers in membrane oxygenators using air pressure. Perfusion. 2006;21:105–7.
5. Snijders J, de Bruijn P, Bergmans M, Bastianen G. Study on causes and prevention of electrostatic charge build-up during extracorporeal circulation. Perfusion. 1999;14:363–70.
6. Notice safety warning from the Sorin group. Available at: www.scps.org.uk/pdfs/Sorin-12:12:11.pdf. Accessed December 2013.
7. Health Canada. The guidance document for mandatory problem reporting for medical devices. Available at: www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php. Accessed December 2013.