

Case Report

A Novel Method to Detect an Oxygenator Defect Prior to Cardiopulmonary Bypass Initiation

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Abstract: Cardiopulmonary bypass (CPB) is a common practice in our era. The medical technology used for cardiac surgery goes through rigorous testing to ensure its safety. Unfortunately, it is not fail proof. Oxygenator failures are a rare occurrence but may lead to catastrophic events. We present a case where the preparation for initiating CPB was complicated by an oxygenator defect. After thorough examination, the oxygenator was found

leaking from the gas exhaust port suggesting a disruption in continuity of the fibers. This was found by the vigilance of the perfusionist and a creative method to quickly assess the integrity of the oxygenation device. We describe a simple technique to help diagnose an oxygenator leak. **Keywords:** cardiopulmonary bypass, equipment, oxygenator failure, safety, quality assurance. *JECT. 2015;47:180–182*

Since the development and evolution of cardiac surgery, cardiopulmonary bypass (CPB) has proven to be an essential element. As the technology of oxygenators has evolved, so too has their safety. Unfortunately, an equipment failure can still occur despite this technological evolution and the improvement of quality process. In 2014, 180 reports of oxygenator leaks have been filed to the Manufacturer and Users Device Experience website (United States), in which 26 were noticed prior to clinical use (1). We describe the use of a technique to diagnose disruption in continuity of the oxygenator fibers prior to its clinical usage.

DESCRIPTION

A 47-year-old male patient hospitalized with critical aortic stenosis (aortic valve area of .44 cm²) was scheduled for an elective aortic valve replacement. The patient pre-

sented with a bicuspid aortic valve, a dilated left ventricle associated with severe systolic dysfunction and volume overload. His ejection fraction was 28%, had aortic insufficiency three out of four, mitral insufficiency one out of four and normal coronary arteries. His body surface area was 1.86 m². The patient was brought to the operating room on day 8 of his hospitalization and was anesthetized as per the anesthesiologist. The CPB circuit was composed of a Sorin D905 EOS oxygenator (Sorin Group Italia, Mirandola, Italy), Sorin Smart tubing pack (Sorin Group USA, Arvada, CO), consisting of a 3/8" arterial line and 1/2" venous line, and a Medtronic Myotherm XP cardioplegia device (Medtronic Inc., Minneapolis, MN). The CPB circuit was prepared in a routine fashion. Water was circulated for 5 minutes through the heat exchanger of the oxygenator, followed by a visual inspection of the circuit prior to the priming sequence. The initial prime solution was constituted of 2,000 mL of lactated ringer's (Hospira, Montreal, Canada). During the induction process, the prime recirculated in the CPB circuit at a flow rate of three liters per minute (LPM) with a partial clamp positioned distally to the arterial filter, which generated an approximate pressure in the circuit of 110 mmHg measured post-oxygenator but pre-arterial filter. The circuit recirculated in this fashion for about 1 hour. Final inspection of the CPB circuit was

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done in accordance with the pre-bypass checklist. After sternotomy and arterial and venous purse strings installation, the arterial-venous (AV) loop was given to the surgeon. At that moment, the perfusionist observed a small amount of clear fluid on the floor at the level of the oxygenator gas outlet. The gas scavenger was not attached at this time. Feeling that it seemed to be more volume that just from condensation, the perfusionist asked for a second opinion from a colleague. Both perfusionists could not conclusively rule out an oxygenator defect. It was then decided to test the oxygenator by recirculating at a higher pressure (around 180 mmHg) via the circuit's recirculation line, which is installed between the oxygenator and the arterial filter on the arterial line, while isolating the AV loop. Still not being capable to arrive to a conclusion since there was not a frank increase of volume coming out of the oxygenator gas outlet, it was concluded that coloring the prime solution would be advantageous. A 10-mL syringe filled with the patient's blood taken from the central venous catheter by the anesthesiologist was added to the prime and recirculated via the same technique as described previously. A white gauze was installed at the oxygenator gas outlet to verify the change of color of the fluid exiting that site. The fluid seemed to have somewhat changed color but not significantly. It was then decided to clamp the circuit's recirculation line and to open the manufacturer's built-in oxygenator recirculation line and to recirculate at a pressure of around 250 mmHg measured post-oxygenator. After this last step, the fluid exiting the oxygenator gas outlet was frankly pink. It was then decided to electively change out the oxygenator prior to going on CPB. After the change out and priming, the new oxygenator was tested and pressurized to a pressure of 300 mmHg with the residual blood tainted prime solution. The CPB was initiated and the procedure continued with a total prime volume of 1,200 mL. The aortic valve replacement was done without complications. The CPB time was 66 minutes with a cross-clamp time of 52 minutes. The patient was extubated the same day and discharged from the intensive care unit on postoperative day 2.

DISCUSSION

The evolution of medical equipment since the development of CPB has been significant. This has required the industry concomitantly to develop their production and quality control systems to ensure a safe and functional product to the user. Even though safety has increased, incidents still occur. Oxygenator malfunction has been largely described in the literature. In 1998, a questionnaire was sent to 1030 cardiac centers in the United States by Mejak et al. Oxygenator failure was reported in 1 out of 2,459 cases (2), and an oxygenator change out was required in 1 out of

4661 cases. Jenkins et al. (3) in an Australasian perfusion survey have reported a witnessed membrane leak prior or during CPB by 24% of the survey respondents. More importantly, 26% of the respondents have had to change at least one oxygenator during that same time period of 18 months. More recently, Soo et al. (4) have documented reported oxygenator failures in the United States at a frequency of 50 cases in 2009, 101 cases in 2010, and 133 cases in 2011. After interrogation by the authors of the Manufacturer and Users Device Experience website, 180 reports of oxygenator leaks have been filed in the United States (1). We describe a simple method of verifying the oxygenator when there is a concern by the perfusionist prior to initiation of CPB, thus reducing the risks to the patient.

The cause of the oxygenation device damage is unknown in this case. Once the product has been produced and tested at the manufacturing facility, we as the end users, assume that the product is safe to use. Unfortunately, different incidents could have happened between the stage of leaving the quality assurance laboratory and arriving on the shelves in our operating room. Damage could be caused at any stage, from packaging at the manufacturer, shipping, unpacking at the hospital or transportation to the operating room. We do not believe that damage was caused during the stages of setting up the CPB or during priming. As a safety mechanism, we do prime the CPB circuit with the pressure monitor/regulator in function during priming and has a set limit of 300 mmHg, thus avoiding accidental over pressurization of the CPB circuit.

Based on the perfusionist's preference, the gas scavenger line to exhaust volatile agents was not attached prior to connecting the arterial line to the arterial cannula by the surgeon. The authors do believe that if the gas scavenger line had been attached, they would have potentially missed the small amount clear fluid leakage.

Our institution policy required the authors to fill an incident/accident report for equipment defect as a near incident. The company was made aware of the incident and the device was sent back to the manufacturer. The manufacturer did confirm a small rupture of the oxygenator fibers but were incapable of confirming the cause of the damage. In Canada, it is mandatory for the manufacturer or the importer to report incidences causing or potentially causing deterioration in the health of a patient, user or other person, related to medical devices to Health Canada (5). In the United States, there is a similar mandatory reporting of medical devices suspected of device-associated deaths, serious injury, and malfunctions, by the manufactures, importers, and device users facility to the Food and Drug Administration. The reports are housed in a database called the Manufacturer and User Facility Device Experience database available to the public (1). In addition, established by the Australian and New Zealand College

of Perfusionist, to which Canadian Society of Clinical Perfusion collaborates, a Perfusion Incident Reporting System where perfusion-related incidents and accidents are voluntarily reported is available to the international perfusion community (6). With all of these tools available, it is essential to report incidents of equipment malfunction allowing the end user to be aware of potential problems in the goal to ensure an appropriate and safe functioning of all medical equipment, providing the safest possible care to the patient.

The authors decided to change the oxygenator electively prior to initiation of CPB. Not doing so could have increased the risk of having to do an emergency oxygenator change out with all the potential threats that comes with it. The decision of changing the oxygenator prior to CPB carries its own potential risks to the patient, especially in the setting of a critical aortic stenosis with the risk of rapid cardiovascular deterioration (7). We believe that the risks were minimized compared to having to potentially proceed to an emergency oxygenator change out during normothermic open-heart surgery.

CONCLUSION

Patients undergoing CPB for cardiac surgery certainly expect that all elements of the procedure are tested and proven to be safe. Yet, safety can never be proven. Only

failure can be demonstrated through testing (8). In this article, a description of a simplified and costless method to assist in the detection of an oxygenator leak is given. The sole goal as health-care provider is to help treat a patient in the safest possible setting.

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