

Unexplained Obstruction of an Integrated Cardiotomy Filter During Cardiopulmonary Bypass

Cory M. Alwardt, PhD, CCP; Donald S. Wilson, MS, CCP; Octavio E. Pajaro, MD, PhD

Abstract: Cardiopulmonary bypass (CPB) is considered relatively safe in most cases, yet is not complication free. We present a case of an integrated cardiotomy filter obstruction during CPB, requiring circuit reconfiguration. Approximately an hour after uneventful initiation of CPB the integrated cardiotomy filter became obstructed over several minutes, requiring circuit reconfiguration using an external cardiotomy filter to maintain functionality. Following reconfiguration, CPB was maintained with a fully functional circuit allowing safe patient support throughout the remainder of CPB. Postoperatively, there was no sign of thrombus or mechanical obstruction of the filter, which was sent to the manufacturer for analysis. The cause of the obstruction

was unclear even after chemical analysis, visual inspection, and a review of all techniques and products to which the patient was exposed. The patient had a generally routine hospital stay, with no signs or symptoms related to the incident. To our knowledge, this is the first report describing an obstructed integrated cardiotomy filter. An appropriate readiness plan for such an incident includes proper venting of the filter chamber, a method for detecting an obstruction, and a plan for circuit reconfiguration. This case illustrates the need for a formal reporting structure for incidents or “near miss” incidents during CPB. **Keywords:** cardiopulmonary bypass, CPB, filter, cardiotomy, obstruction. *J Extra Corpor Technol. 2017;49:59–63*

Cardiopulmonary bypass (CPB) has become a relatively safe procedure since the first use of modern extracorporeal circulation by John Gibbon in 1953. CPB is not complication free, however, with the reported rate of incidents related to CPB ranging from 1 in 84 cases to 1 in 220 cases (1,2). Not all of these incidents result in patient harm or death with the rate of serious injury or death related to CPB reported as low as 1 in 1,453 (1). Interestingly, it has been reported that the rate of perfusion-related incidents is approximately 10 times higher than incidents occurring in anesthesia (3). In addition, it is likely that the incident rate is underreported since there has been no formal reporting system for incidents or “near misses.”

Historically, the most commonly reported incidents during CPB include heater/cooler failure, air and throm-

bus in the circuit, oxygenator failure, gas supply failure, and mechanical failure of pumps (1–4). We present a unique incident of an integrated cardiotomy filter obstruction during CPB, resulting in the need for circuit reconfiguration.

CASE REPORT

A patient with a history of ischemic cardiomyopathy was implanted with a left ventricular assist device (LVAD) as a bridge to heart transplant. Several months later, an organ donor was found and the patient was brought to the operating room for LVAD removal and heart transplantation. A redo sternotomy was performed when the surgical team received confirmation from the procuring surgeon that the organ was suitable. When the organ was on its way from the donor facility, 300 units per kg of heparin was administered by the anesthesia team before cannulating the patient’s ascending aorta for CPB. The patient was bicavally cannulated for drainage. A blood sample was drawn for measurement of activated clotting time (ACT), which returned a result of >480 seconds with a heparin concentration of 300 IU/kg

Received for publication June 21, 2016; accepted December 22, 2016.
Address correspondence to: Cory M. Alwardt, PhD, CCP, Division of Cardiothoracic Surgery, Mayo Clinic Hospital, 5777 East Mayo Boulevard, Phoenix, AZ. E-mail: alwardt.cory@mayo.edu

The senior author has stated that the authors have reported no material, financial, or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

(Medtronic HMS Plus, Minneapolis, MN). Once the therapeutic ACT was confirmed, full CPB was initiated and LVAD support discontinued. The CPB circuit consisted of a FX25 oxygenator with integrated arterial filter (Terumo Cardiovascular, Ann Arbor, MI), and a custom Terumo X-coated tubing pack with a 3/8" arterial line and 1/2" venous line. The circuit was configured and used in a manner which was compliant with the manufacturer's instructions for use. Roller pumps were used for the main arterial pump and for pump suction. No form of assisted venous drainage was used during CPB. Figure 1 illustrates the basic circuitry used during the initial period of CPB. The circuit prime consisted of 1,100 mL Plasmalyte A, 50 mEq sodium bicarbonate, 10,000 IU heparin, and 50 g of albumin. No other drugs (aside from phenylephrine) were administered through the CPB circuit before the following event.

Several minutes after uneventful initiation of CPB, the aortic cross clamp was placed and the heart was excised in preparation for the donor heart. Approximately an hour after placement of the aortic cross clamp and unremarkable CPB, the perfusionist noticed that the continuous drip rate of phenylephrine that was entering the integrated cardiectomy filter had unexpectedly slowed.

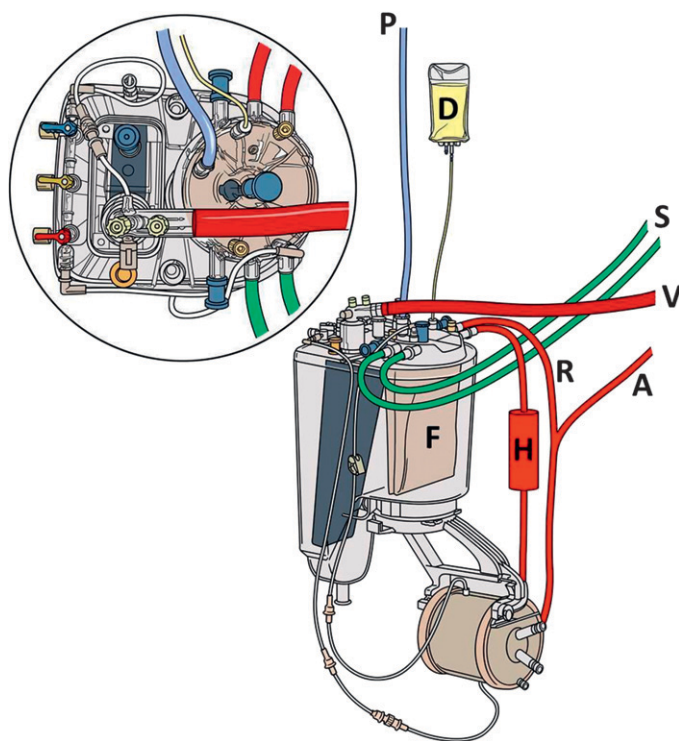


Figure 1. Original circuit configuration. A = patient arterial line, D = phenylephrine drip line, F = integrated cardiectomy filter, H = hemoconcentrator, P = priming line, R = recirculation line, S = pump suction (sucker/vent).

The roller-type clamp on the intravenous (IV) tubing set was adjusted but failed to increase the drip rate. Suspecting an obstruction at the luer connection, the perfusionist then disconnected the IV tubing from the luer connection entering the integrated cardiectomy filter. On disconnection, there was a clear audible indication of pressure release from the cardiectomy filter chamber. The phenylephrine IV tubing was not reconnected, and in addition, the cap was then removed from the vertical port entering the cardiectomy filter to prevent pressurization and allow the filter chamber to equilibrate with atmospheric pressure. The rate of the pump suckers was dramatically reduced and the surgical team was made aware of the incident (while specific data on sucker rates were not available in the electronic chart, typical suction rate in our practice is 1.0–1.5 LPM). The perfusionist conducted a thorough inspection of the circuit and noticed no visual indication of obstruction or thrombus formation. For the next few minutes of CPB, the circuit seemed to function normally, albeit with decreased sucker rates as a precaution. However, approximately 5 minutes later the integrated cardiectomy filter began to fill with blood from the pump suckers, requiring complete termination of sucker flow into the cardiectomy filter. Visual inspection again revealed no apparent cause of the obstruction. At this point, a second perfusionist was called to assemble and prime a backup CPB circuit in case the situation escalated further.

Communication between the surgeon and perfusionist confirmed the surgeon's need for a properly functioning pump sucker and vent, therefore routing sucker/vent blood to a cell salvage reservoir was not appropriate. The perfusionist then retrieved a 4 L hard-shell blood collection reservoir with 40-micron filter (EL404, Medtronic, Minneapolis, MN) and secured it to the heart lung machine just above the level of the main venous reservoir to ensure gravity drainage. This reservoir allowed for appropriate circuit adaptation (Figure 2). The pump suckers were disconnected from the obstructed cardiectomy filter suction ports, extended using 1/4" straight connections and 1/4" tubing, then rerouted to the new reservoir. The prime line, hemoconcentrator shunt, and phenylephrine drip line were also transferred to ensure full functionality of the CPB circuit. The recirculation line was not relocated since it is generally kept clamped throughout CPB. The outlet of the new reservoir was then connected to the 3/8" auxiliary port entering the venous filter to allow drainage into the venous reservoir. The 3/8" tubing between the new reservoir and the auxiliary port was generally kept clamped, and unclamped only when volume had accumulated to prevent excess air from entering the venous filter. Although the phenylephrine drip was transferred and reconnected, dosing was done using a syringe into the venous line via the sampling

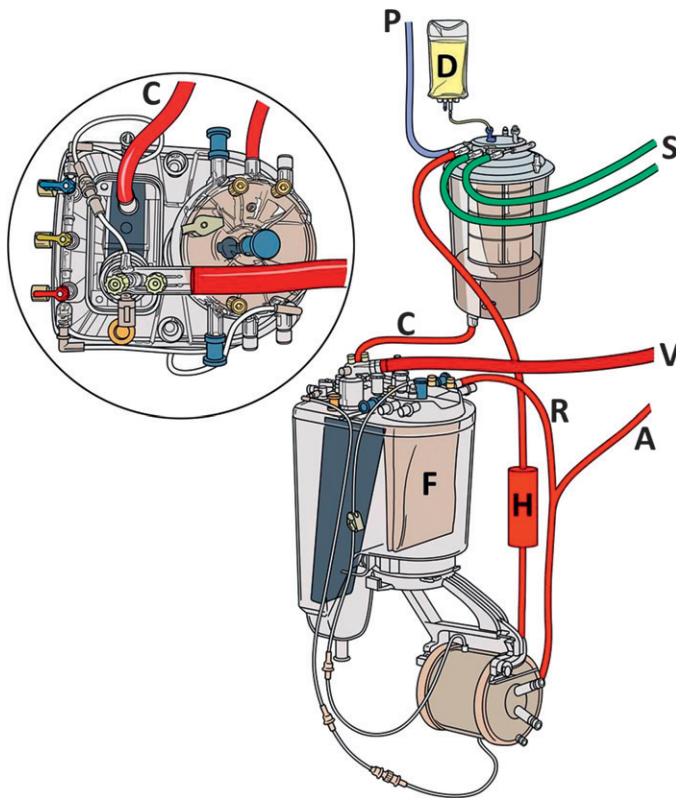


Figure 2. Adapted circuit configuration. A = patient arterial line, C = circuit connection to the external cardiomy reservoir, D = phenylephrine drip line, F = integrated cardiomy filter, H = hemoconcentrator, P = priming line, R = recirculation line, S = pump suction (sucker/vent).

manifold. This configuration successfully bypassed the obstructed filter and allowed the full use of pump suckers, prime lines, and hemoconcentration without introducing excess air into the venous reservoir. CPB was maintained in a normal fashion, aside from the change in configuration. There was never any disruption in support of the patient in terms of blood flow or proper gas exchange throughout the entirety of this incident.

Throughout the entirety of CPB, the arterial pH was between 7.25 and 7.40, the PaCO_2 between 35 and 45 mmHg, the PaO_2 between 140 and 400 mmHg, and the hematocrit between 26% and 30%. The ACT was therapeutic throughout, never falling below 500 seconds. The arterial blood flow was maintained between an index of 1.8 and 2.1 L/min/m² and the SvO_2 was maintained above 60%. Mean arterial blood pressure was maintained between 60 and 80 mmHg, and a total of 5 mg of phenylephrine was used during CPB. The patient remained warm ($>36.0^\circ\text{C}$) throughout CPB. The patient was transferred to the intensive care unit following surgery and was extubated within 24 hours. The patient had a generally routine hospital stay following surgery, and was successfully discharged 2 weeks after transplantation

with no apparent complications related to the incident during CPB.

Following successful completion of the surgery, the problematic reservoir was visually inspected more thoroughly than could be accomplished during CPB. After disassembling the circuit the blood was poured out of the filter (through ports on top of the reservoir) allowing better visualization, but still no clot or visual sign of obstruction was apparent. Water was then poured into the obstructed filter through ports both above and below (inside and outside of the filter), still there was no visual sign of thrombus or blockage and the water was not able to pass through the filter. The perfusionists simply noted a pink tinge to the filter, but no heavy blood stains.

We reported the event to our supply chain management as a medical device failure, which triggered communication with the vendor. The filter was sent to the manufacturer for inspection and analysis. A full report was also sent to the manufacturer, including a redacted CPB record and full list of solutions, supplies, and drugs used during the case for cross referencing and identifying any problematic agents. The manufacturer completed a thorough investigation of the obstructed filter, per our request. None of the items on the list of solutions, supplies, and drugs used during the case were deemed suspicious. In the initial report, it was stated by the manufacturer that the returned cardiomy filter was found to be “blood soaked with an oily/slimy texture on the inside of the filter.” The manufacturer sent the filter to an outside laboratory facility to analyze and identify the properties of the materials within the obstructed filter. None of the materials identified on the filter were considered likely causative agents, as those materials are found either in normal physiology, medications, or CPB circuitry. Ultimately, it is unclear what caused the obstruction, even after laboratory analysis.

DISCUSSION

This report presents a unique case of an integrated cardiomy filter (polyester depth type) obstruction during CPB. Fortunately, the patient was adequately supported throughout the entirety of CPB despite the occurrence, and full functionality was given to the surgeon after a brief period by re-routing circuitry through an alternate cardiomy reservoir. The cause of the obstruction is unknown. Notably, the primary venous filter (a 47-micron polyester, screen-type filter) was seemingly unaffected. Also of note is that the patient had received no blood products during the operation prior to the unexpected filter obstruction, and the ACT was therapeutic (>480 seconds) throughout the entirety of CPB. The patient did receive a number of blood products later

in the procedure (as would be expected following long-term LVAD support), so it is difficult to say whether the small amount of blood lost in obstructed filter was significant in terms of transfusion requirements.

Regarding the configuration of our circuit, it is routine in our practice that the hemoconcentrator shunt enters the cardiomy reservoir directly (Figure 1). Although this configuration results an increased air/blood interface that could theoretically cause increased hemolysis, we prefer the configuration to adding a high-pressure shunt to the venous line as not to interfere in any way with venous drainage. We have used this same configuration over many years with no incidents or notable hemolysis; therefore, it would be unlikely that any sort of increased load on the filter due to the configuration would be to blame for the filter obstruction.

Pressure monitoring of the integrated cardiomy filter chamber is not typically done during CPB. A 2013 survey of pressure monitoring during adult CPB revealed that 72% of centers performing CPB monitor venous circuit pressures when applying vacuum to the venous reservoir (5). Of these centers, 21% measured the negative pressure from the venous line directly while the other 79% measured indirectly from a luer connection on top of the venous reservoir. Although the survey did not specifically address whether the indirect measurements were taken from the main venous reservoir or the integrated cardiomy filter, it is likely that most or all centers were measuring from the main venous reservoir. The survey also did not comment on the number of centers measuring venous circuit pressures when vacuum assisted venous drainage was not being performed. Again, it is likely that monitoring of reservoir pressures is rare when not performing vacuum-assisted venous drainage. In contrast, the survey revealed that 99% of centers monitor arterial line pressures at any one of six locations. Ironically, a survey 33 years prior found that only 72% of perfusionists routinely measured arterial line pressure during CPB (5)—a percentage identical to the number of centers monitoring venous pressure in 2013.

The American Society of Extracorporeal Technology published Standards and Guidelines for Perfusion Practice in 2013 (6). Standard 6 (Safety Devices) states that, “pressure monitoring of the arterial line, cardioplegia delivery systems, and venous reservoir (when augmented venous drainage is used) shall be used during CPB procedures.” Although this standard seems very appropriate, adhering to this standard would not have indicated any sort of problem in the current case report. First, vacuum was not being applied to the venous reservoir to augment drainage and therefore the standard would not apply. Second, even if vacuum were being applied, it is unlikely that the location of pressure monitoring would have revealed a problem in this case.

To our knowledge, this is the first report describing an obstructed integrated cardiomy filter. The fact that no thrombus formation could be visualized makes it even more unique. The Dutch Perfusion Incident Survey in 2010 (4) noted replacement of the venous reservoir twice and replacement of the cardiomy reservoir three times in 23,500 cases, but the causes and details of these failures were not mentioned. It can also be assumed that these cardiomy reservoirs were not integrated with the venous reservoir, since replacement would likely have been counted as a complete venous reservoir replacement.

This case illustrates the need for a formal reporting structure for incidents or “near miss” events during CPB. A formal reporting structure would benefit the community in terms of the awareness and education to shape a clinical response to such an event. The Australian and New Zealand College of Perfusionists implemented a Perfusion Incident Reporting System to increase confidential incident and accident reporting in Australia, New Zealand, and the international perfusion community. However, concerns of potential legal subpoena due to different laws amongst countries have limited international contributions. The Society of Cardiovascular Anesthesiologists’ implemented the Flawless Operative Cardiovascular Unified Systems initiative in 2005 (7) in response to the need to improve quality and safety in the cardiovascular operating room. This is an exceptional effort towards safety, but does not include a means for reporting incidents. In addition, the United Kingdom National Reporting and Learning System (8) was developed in 2003 and represents the largest incident reporting database in the world, with over a million reports generated. Unfortunately, access is limited to centers in England and Wales. In a thorough review of the history and barriers to perfusion incident reporting, Willcox (9) describes the field of perfusion as “a tightly coupled, highly complex system where accidents are inevitable,” and that reporting of near miss events may be of even greater value than reporting actual accidents.

The unique cardiomy filter obstruction in this report is a rare finding in both clinical practice and the literature. An appropriate readiness plan for such an event would include proper venting of the cardiomy filter chamber, a method for detection of an obstructed filter, and a plan for reconfiguration of a circuit. A proper response will contribute to a likely positive outcome for the patient. Also, despite the lack of a formal, public incident reporting system, all perfusionists should be familiar with their institution’s policies and procedures for handling a medical device failure and appropriately communicating with the manufacturers following such failures. Reporting device failures in this manner may assist manufacturers in identifying problematic trends.

REFERENCES

1. Mejak BL, Stammers A, Rauch E, Vang S, Viessman T. A retrospective study on perfusion incidents and safety devices. *Perfusion*. 2000;15:51–61.
2. Stammers AH, Mejak BL. An update on perfusion safety: Does the type of perfusion practice affect the rate of incidents related to cardiopulmonary bypass? *Perfusion*. 2001;16:189–98.
3. Jenkins OF, Morris R, Simpson JM. Australasian perfusion incident survey. *Perfusion*. 1997;12:279–88.
4. Groenenberg I, Weerwind PW, Everts PA, Maessen JG. Dutch perfusion incident survey. *Perfusion*. 2010;25:329–36.
5. Rigg L, Searles B, Darling EMA. 2013 survey on pressure monitoring in adult cardiopulmonary bypass circuits: modes and applications. *J Extra Corpor Technol*. 2014;46:287–92.
6. Baker RA, Bronson SL, Dickinson TA, et al. Report from AmSECT's International Consortium for Evidence-Based Perfusion: American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice: 2013. *J Extra Corpor Technol*. 2013;45:156–66.
7. Barbeito A, Lau WT, Weitzel N, Abernathy JH, Wahr J, Mark JB. FOCUS: The Society of cardiovascular anesthesiologists' initiative to improve quality and safety in the cardiovascular operating room. *Anesth Analg*. 2014;119:777–83.
8. Hutchinson A, Young TA, Cooper KL, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: Results from the National Reporting and Learning System. *Qual Saf Health Care*. 2009;18:5–10.
9. Willcox TW. D'ou Venons-nous/Que Somes Nous/Ou Allons Nous? Accidents are inevitable. *J Extra Corpor Technol*. 2012;44:2–5.