

A Single-Center Experience with Luminal Venous Cannulae Obstruction Caused by Clot Formation during Bypass

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Abstract: Our institution experienced two bypass cases from January through December 2011 in which venous return was significantly variable and at times poor. Luminal clot formation in the venous cannulae was found in each case postbypass. These events were captured and monitored through our institution's Non-Routine Event Reporting Program and eventually reported to the Food and Drug Administration (FDA). We began inspecting all venous cannulae postbypass in December 2011. During a subsequent 9-month surveillance period, we documented 33 venous cannulae in 21 patients with luminal clot formation. Only one cannula during this surveillance period

required change-out on bypass. The manufacturer eventually identified changes in production that likely caused the clotting events. The manufacturer modified their production methods and began supplying cannulae produced under the new method in September 2012. We have experienced only one clotting event with the new cannulae and in that instance, the metal tip was found to be defective. We recommend inspection of all venous cannulae postbypass with internal, manufacturer, and FDA reporting for those noted to have luminal clot formation. **Keywords:** cardiopulmonary bypass, non-routine events, venous drainage, venous cannula. *JECT. 2013;45:55–57*

OVERVIEW

Our institution experienced two bypass cases from January through December 2011 in which venous return was significantly variable and at times poor. The perfusionist in each case verified patency of the venous line while the surgeon repositioned the caval cannulae and ensured there were no other possible causes for the drainage issue. Luminal clot formation in the venous cannulae was found in each case postbypass. These events were captured and monitored through our institution's Non-Routine Event (NRE) Reporting Program (1). We began inspecting all venous cannulae postbypass in December 2011 and worked with the manufacturer to identify the cause for the clots. In early 2012, the manufacturer identified changes in production that likely caused the clotting events. The causative issue has been addressed through an improved production method and the manufacturer's entire line of angled metal-tipped venous cannulae are now produced using the new method. We recommend

inspection of all venous cannulae postbypass with internal, manufacturer, and Food and Drug Administration (FDA) reporting for those noted to have luminal clot formation.

DESCRIPTION

Decreased venous return is readily apparent to the perfusionist running an open reservoir system as the fluid level drops. Sudden and apparent decreased venous return may be the result of many factors including venous line air, cannulae position, external obstruction of the cannula ports, kinking of the venous line, patient blood loss, third spacing of fluid, or internal obstruction of the cannula lumen (2). Venous return that is inadequate needs to be addressed by the surgical team when the desired or required arterial pump flow rate cannot be maintained. Physical causes of decreased return such as internal or external cannula obstruction can be particularly harmful because these causes may lead to increased venous pressure and a decreased arteriovenous pressure gradient. The brain, liver, and kidneys are particularly vulnerable to ischemic damage caused by an acutely elevated venous pressure (3).

Our institution experienced two cases over an 11-month period in 2011 with significantly decreased venous return during bypass, which was ultimately found to be the result of luminal cannula obstruction. Figure 1 shows the obstruction from our first observed case. It was initially surmised

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that these obstructing events were unique and perhaps related to patient hypercoagulability, heparin management, or isolated cannulae production lot events. We were concerned enough after the two initial cases that we began inspecting all venous cannulae postbypass at the end of 2011. We used our NRE monitoring program to document all cases that had venous cannulae luminal obstructions whether venous return was affected on bypass or not. From January through August 2012, we documented partial luminal obstruction of the angled metal tip in 33 cannulae used in 21 patients. We did not experience cannula clotting events in any other venous cannulae used. Only one case, in August 2012, exhibited venous return poor enough to require cannula change-out on bypass. Throughout the venous cannulae monitoring period, we sent several samples of the luminal obstruction to our pathology laboratory. Each pathology report was consistent in that the obstruction was newly formed fibrin clot without tissue attached. Furthermore, all of the observed clots were similar in appearance and varied in size only.

Coincident with our ongoing internal documentation, we regularly reported the events to the manufacturer, sent the affected cannulae to them for inspection, and held at least monthly conference calls. Our aim was to identify the cause, which we increasingly saw as a manufacturing issue and not related to patient factors or anticoagulation management. To note, we found no correlation of clotting events with activated clotting times, operating surgeon, original patient diagnosis, operation performed, or use of antifibrinolytics. The manufacturer eventually identified differences in the metal tip manufacturing process, which resulted in a less smooth metal surface and side port holes. We inquired about the FDA reporting requirement in February 2012 with the manufacturer stating that they comply with all mandatory reporting requirements to the FDA and that there was nothing else our institution needed to do in that regard. The manufacturer stated at

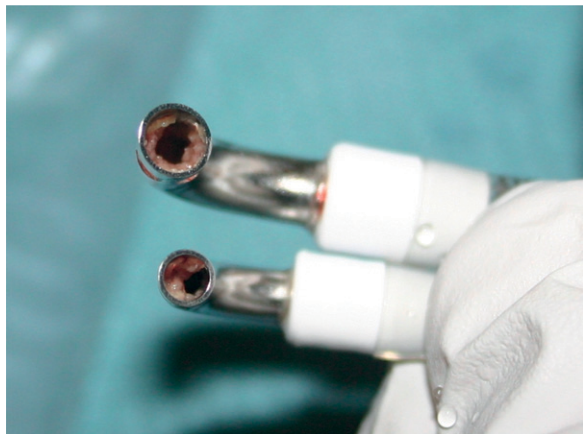


Figure 1. First observed venous cannulae clots.

that time and during the summer of 2012 that we were the only center in the world reporting the issue.

Throughout the spring and summer of 2012, the manufacturer identified the specification gaps that were coincident with their new metal tip supplier, qualified an improved production method to address the specification differences, which likely led to the luminal clots, and began production with the new method for some of the product line. We began receiving 12-, 14-, and 16-Fr angled metal-tipped cannulae produced under the new method in September 2012. We continue to inspect cannulae postbypass. We have had one incident of venous cannula clot requiring change-out on bypass since receiving the newly produced metal tips. This was with a 14-Fr cannula in December 2012. The incident was reported through MedSun and directly to the manufacturer. The manufacturer inspected that particular metal tip and found it did not meet their new specification requirements. Additional lot inspections by the manufacturer have been implemented to prevent such a recurrence. To note, the entire product line is reportedly using the new method of production and so lots produced in December 2012 and later will have the updated metal tips, according to the manufacturer. We continue to inspect all venous cannulae postbypass and recommend this practice.

DISCUSSION

Cannulae issues that affect venous return are a serious concern for patients undergoing cardiopulmonary bypass. We reported our institution's events internally through the NRE Reporting Program. This system effectively disseminated the information within the institution.

The FDA has two reporting systems for known or suspected medical device and drug issues. MedSun is an FDA reporting program for 350 member institutions and has a formal reporting system with trained staff at those institutions. MedSun reports are readily processed and clarified with established two-way communications between the FDA and member institutions.

MedWatch is the FDA reporting program open to all healthcare professionals and consumers and also allows for direct reporting. MedWatch reports generally take more time to be processed and clarified because it is an open system.

We were informed by the manufacturer early in our experience that they follow all FDA reporting guidelines with the strong inference that they reported the problem to the FDA. We found this not to be the case when months later, we requested the report directly from the manufacturer and the FDA. The FDA requires reports from manufacturers for devices that cause significant morbidity, mortality, or those that may jeopardize the patient and may require medical or surgical intervention to prevent

morbidity or mortality (4). The manufacturer did not believe the incidents we continued to report met the threshold for reporting. We reported our overall experience directly to the FDA once we learned that no manufacturer reports had been filed. We also filed a direct MedWatch report for the August 2012 incident, which required cannula change-out on bypass, because it required surgical intervention, one of the FDA's reporting threshold requirements. Subsequent cannulae issues will be reported through MedSun because Boston Children's Hospital is a member institution. Our December 2012 incident was reported through this system once our internal reporting network was established for the perfusion program.

Although MedWatch and MedSun have been the nation's best solution to date for disseminating real and potential medical safety issues, the system is still not well used nor understood in the perfusion community. Each reporting system has its own searchable database, which can be found on the FDA web site. Member institution MedSun reports can be searched using the MedSun database. Direct reports through the MedWatch program can be searched using the MAUDE (Manufacturer and User Facility Device Experience) database. Perhaps the most understood and useful tool for perfusionists is reading Perflist posts. Perflist is a moderated e-mail posting service (www.amsect.org/sections/perftopics/perflist/) run by The American Society of Extracorporeal Technology (AmSECT). This service is widely used within the perfu-

sion community and quickly gets the word out about important perfusion equipment and professional issues. However, this less formal system does not have mandatory reporting or the FDA–manufacturer relationship, which ensures proper handling of medical device issues. Regardless, perfusionists should understand their institution policies regarding internal and external reporting as well the current FDA systems. Prompt reporting improves the safety of our healthcare system and should be an obligation of healthcare professionals to the community.

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REFERENCES

1. Matte GS, Riley D, Lapierre RA, et al. The Children's Hospital Boston non-routine event reporting program. *J Extra Corpor Technol.* 2010;42:158–62.
2. Mora CT, ed. *Cardiopulmonary Bypass.* New York, NY: Springer-Verlag; 1995:262, 273, 320.
3. Larach DR. Anesthetic management during cardiopulmonary bypass. In: Hensley FA, Martin DE, eds. *A Practical Approach to Cardiac Anesthesia.* 2nd ed. Boston, MA: Little, Brown and Company; 1995:32–95.
4. U.S. Food and Drug Administration. Available at: www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm. Accessed June 23, 2011.