The Perfusion Business of Heater-Cooler Devices: Much ado about nothing?

Around the 1590s Shakespeare wrote a comedy Much Ado About Nothing. It is thought that the "nothing" is rumor and gossip. There has been a lot of information flying around PERFList and PERFMail about heater-coolers and patient infections. I assure you the heater-cooler issues are not "much to do about nothing." The current threat to the Perfusion Business is the epidemic of nontuberculous mycobacterial (NTM) infections occurring in the world of cardiac surgery now. Rough estimates of the incidence of NTM infection after cardiac surgery fall between 1:20,000 to 1:7,000 infections per cardiac procedures.

HCDs are in the headlines

Go to the US Food and Drug Administration Heater-Cooler Device website and read all about it – and I do mean ALL about it. The FDA website is all-inclusive on the issue.

There are two HCD articles in the most recent issue of JECT. One article is a report on the perfusion related issues coming out of the FDA panel written by the two perfusionists invited to contribute to the panel (1). The other JECT article is a classic reprint of what appears to be the first peer-reviewed journal article on the topic (2), My friend Kelly Hedlund CCP read the classic article and recalled an even earlier article in the 1993 Perfusion Life (AmSECT's news magazine in the 90's) (3).

Even the most recent ELSO Newsletter cites the FDA website and the warnings for NTM related infections (4,5). You can never get tired of ready about cleaning ECMO heaters. There are probably more case reports of water-borne pathogens causing infections in ECMO patients than in CPB patients – some of our readers may be aware of this literature and it should be reviewed for us - we just have not uncovered the literature.

Perfusionists need to be mindful of heater-coolers

How does the threat of NTM infections affect the business of Perfusion? One HCD manufacturer who has the market share in Europe and the US in particular has been impacted significantly. The balance of HCD vendors have also invested significant research, marketing talent and time to address NTM infections in their devices and to optimize their disinfection / cleaning instructions. You should be receiving updates from your HCD vendors regarding cleaning, disinfection and possible culturing of your HCDs.

Heater-Cooler Devices: A convenience and a threat

Do you remember wall-water delivery systems in the operating room? Do you remember turning a single mixing valve knob (like your shower) and dialing in the desired water temperature to set your water-venous blood temperature gradient? Do you remember being informed that your wall-water delivery system was dirty and you needed to consider stand-alone water delivery systems? If you are a student or have just graduated from perfusion school in the last five years, you probably cannot relate to these memories. If you are using ice in the operating room theater – go inspect the ice machine and ask when the last time it was cleaned or cultured for NTM! We purchased more than 10 heater-coolers to replace our wall water system – before we realized the impact that NTMs would have on our practice and perfusionist workflow.

Hospitals stopping cardiac surgery

Several US cardiac surgery facilities (Iowa, Pennsylvania) have stopped cardiac surgery while they rooted out the cause of NTM infections in their patients from the last five years. You and your facility need to have a plan in place to respond to your first identified NTM infection. It is best to sort out the action plan and ethical, political issues before you are faced with a real patient scenario. NTM infections can present three to five years after surgery with exposure.

Perfusionist work flow

Perfusion teams have reorganized their work flow to accommodate new recommendations from the FDA and updates to Instructions for Use for their HCDs. Cardiac surgery facilities and their infectious disease teams have examined their policies and practices to minimize the NTM threat, and to put systems in place to capture NTM infections when patients are affected. Large cardiac surgery centers have stopped surgery while they have cleaned up their HCDs and put policies and procedures in place to keep the HCDs clean.

It's only a matter of time

If they have not already, statistically speaking your cardiac surgical team and infectious disease team will identify a NTM infected patient in your population of CPB patients. Remember there are a myriad of other causes for NTM infections in cardiac surgical patients including their home environment and even the hotel they are visiting near your facility in the perioperative period. Help your infectious disease team keep an open mind and look for all potential sources for your patient's infection.

More HCD Reading

1. Stammers AH, Riley JB. The heater cooler as a source of infection from nontuberculous myocobacteria. J Extra Corpor Technol 2016;48:55-59.
2. Riley JB. JECT Classic Article: Heater-Cooler Devices as a Conceivable Source of Infection. J Extra Corpor Technol 2016;48:60-66.
3. Toigo J, Giraud S. What's growing in your cooler/heater? Cleaning and sanitization for temperature control systems. Perfusion Life 1993 10(10):8-9.
4. FDA issued Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices – Safety Communication, October 15, 2015.
5. FDA issued Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stöckert 3T Heater-Cooler System- Safety Communication, June 1, 2016.

Jeff Riley

Harrington Heart & Vascular Institute, University Hospitals Case Medical Center, Cleveland Ohio

Jeff Riley has relocated to Cleveland Ohio where he is chief perfusionist at Case University Hospital Medical Center working in the Harrington Heart & Vascular Institute.