Litigation Involving Contaminated Heater-Cooler Devices Used in Open-Heart Surgery

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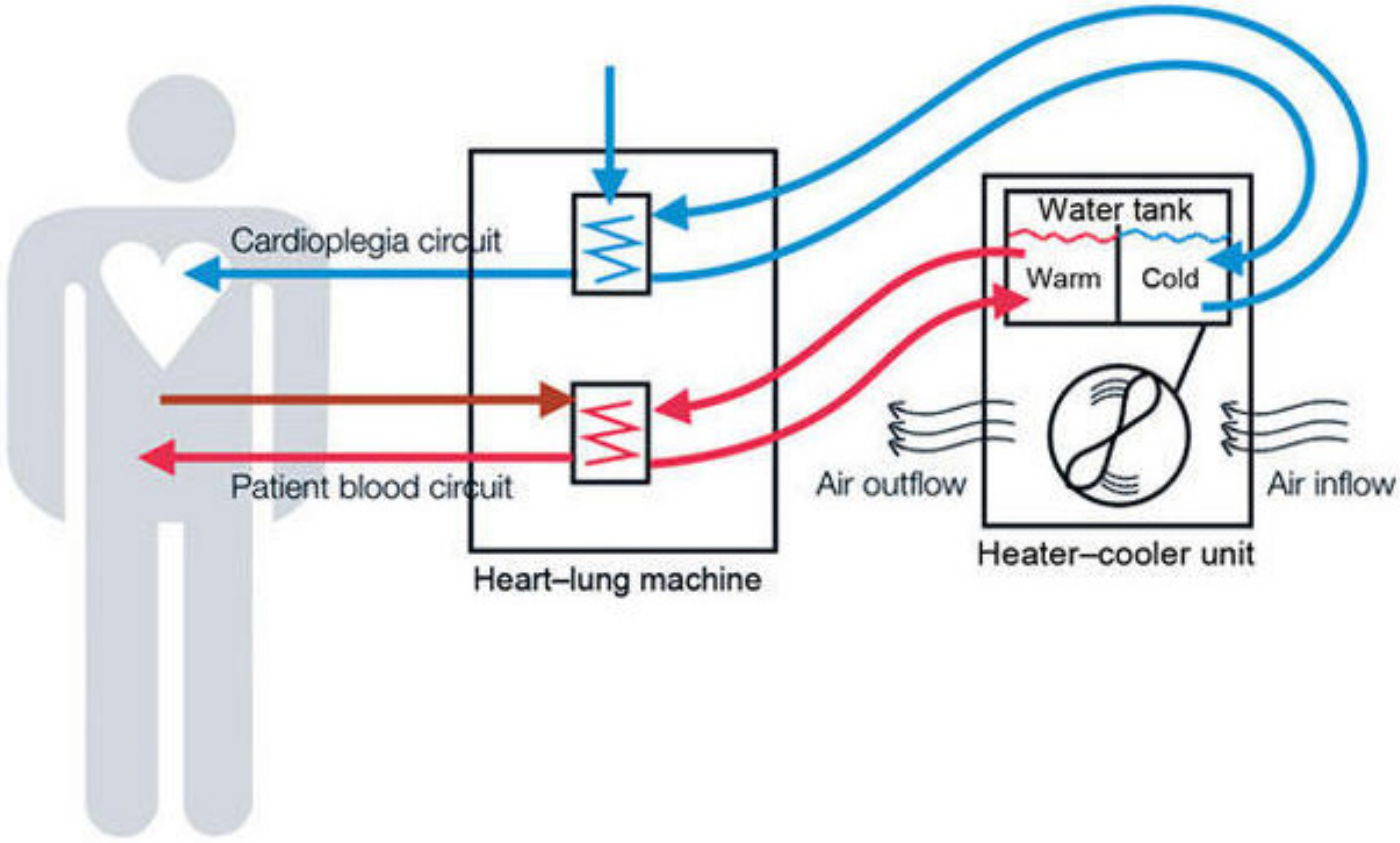
Non-tuberculin Mycobacterium (NTB) or Mycobacterium chimaera (M. chimaera) infections caused by heater-cooler devices used during open heart surgery are a rapidly growing area of product liability litigation. This article makes the legal nurse consultant aware of the background of this litigation to assist plaintiff and defense attorneys determine causation, liability, and damages.

INTRODUCTION

Imagine: you must have open-heart surgery. You probably research your illness, your doctor, the medical facility where you are undergoing the procedure and the procedure itself. You have it; you recover and think all is well. But several weeks to several years later, you do not feel well., You may just think that you have the flu, or perhaps it's something more: your incision opens. Time passes because your symptoms are vague; fever, pain, night sweats, joint pain, muscle pain and fatigue, persistent cough, weight loss, nausea and vomiting or redness, or heat or pus around the surgical incision. You are found to have Mycobacterium chimaera (M. chimaera), a non-tuberculin Mycobacterium (NTM). The source was the contaminated heater-cooler device used in your surgery.

THE HEATER-COOLER DEVICE

A heater-cooler device has tanks of temperature-controlled water used



Schematic of cardiopulmonary bypass circuit.

to regulate blood temperature during cardiopulmonary bypass. The CDC learned that Stockert 3T Heater-Coolers, made in Germany, "might have been contaminated during manufacturing which could put patients at risk for life-threatening infections" (Mundy 2017) by releasing contaminated aerosols into operating rooms. This is not the only heater-cooler system in use, but about 60% of the 250,000 heart bypass procedures performed each year in the US involve use 3T Heater-Cooler systems (Perkins 2016).

THE INFECTION

M. chimaera is a slow-growing bacterium commonly found in soil and water but not generally associated with infections. It can take from two weeks to four years for pulmonary and cardiovascular symptoms to appear; median time is 18 months after surgery (Antonation et al., 2017). Clinicians rarely screen for it, so diagnosis may be delayed. Roughly half of the people who contract it die.

This organism can cause:

- Prosthetic valve endocarditis
- Prosthetic vascular graft infection
- Paravalvular abscess
- Pseudo aneurysm
- Mycotic aneurysms
- Osteomyelitis
- Ocular mycotic emboli
- Immunologic manifestations
- Splenomegaly. (Antonation 2017)

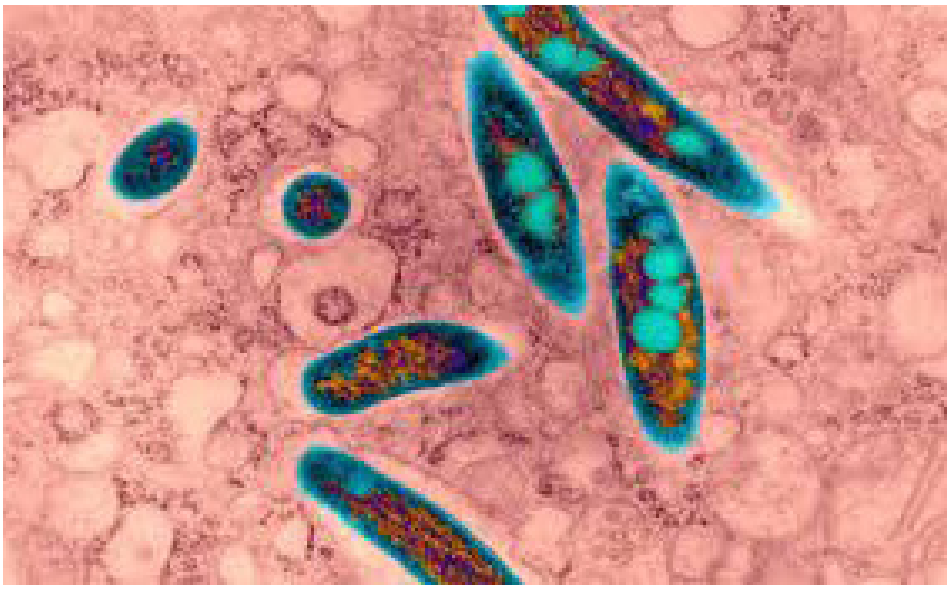
Blood and tissue cultures are used to confirm the diagnosis.

Treatment includes maximum-strength multiple antibiotics over months to years. Early diagnosis and treatment may lead to a successful recovery. However, there is a significant risk of death with late diagnosis and immunocompromise. Additional surgery may be necessary to remove a contaminated implant.

WARNINGS

Although The University Hospital of Zurich initially traced infections to this company with cases as far back as 2006, this information was not made public until March 2015. The European Society of Cardiology reported 10 open heart cases with M. chimaera infections at three European hospitals. Public Health England and Medicine and Health Care Products Regulatory Agency issued guidance to surgical centers and infection risk was identified (Mundy 2017).

The US Center for Disease Control and Prevention (CDC) issued a Health Alert Network Advisory warning of possible contamination in devices



Mycobacterium chimaera

manufactured before September 2014 (Perkins 2016).

The FDA first issued warnings about the heater-cooler infection risk in October 2015 after receiving at least 34 adverse event reports between 2010 and August 2015 (CDC 2015). They issued an updated Safety Communication on June 1, 2016 indicating that the Stockert 3T Heater-Cooler System used in cardiothoracic surgeries had been associated with M. chimaera infections, based on a European gene study linking them to the 3T. (FDA 2017)

The FDA recommended that medical facilities inform their patients of the risk of contracting the infection. They also recommended establishing a surveillance procedure of patients whose cardiopulmonary bypass used the 3T.

On October 13, 2016 another FDA Safety Communication was announced to prevent spread of NTM infections. It recommended (FDA 2017) that:

- accessories, tubing, and connectors be changed to prevent recontamination
- the heater-cooler exhaust be directed away from the patient into an exhaust vent
- use only sterile water to rinse and fill water tanks
- regular cleaning, disinfection, and maintenance schedules
- all 3T units that tested positive for the infection be removed from service

THE LITIGATION

Litigation alleging exposure to M. chimaera or M. abscessus is proceeding against the manufacturer, Liva Nova/ Sorin Company, in individual suits in Florida, Pennsylvania, Illinois, Washington D.C., South Carolina, South Dakota, Tennessee, Iowa, and North Carolina and a class action in Iowa. Genetic testing confirmed the source of infection is most likely the manufacturing plant.

The suits ask the court to declare that the heater-cooler units are defective and unsafe for their intended use. Some seek medical monitoring of patients who may be at risk for NTM. (Luhana 2017) In March 2017 the US Judicial Panel on Multidistrict Litigation heard arguments to transfer cases to one judge for coordinated discovery and pretrial proceedings, but manufacturers won opposition to this motion. (About Law 2017)

Because the number of these cases has tripled, on November 6, 2017, defendants moved to ask for consolidation of all federal cases involving 3T Systems and transfer for cases to the US District Court for the District of South Carolina. As of this writing the decision is pending.

Infections in Switzerland, Germany, the Netherlands, UK, Australia, New Zealand and Canada have prompted suits against LivaNova PLC, Sorin Group Deutschland GMBH, and Sorin Group USA Inc. for taking insufficient measures to prevent injuries, negligence, product liability, and violation of federal law. LivaNova has a remediation plan with a design modification to include internal sealing and adding a vacuum system to new and existing devices to reduce risk of aerosol dispersion into operating rooms. The company also made a global announcement for plans for a no-charge deep disinfection service. (BusinessWire March 1, 2017)

Many hospitals have ordered new machines, but there is a backlog of orders. Some have sent letters to patients who have had open heart surgery at their facility warning them of NTM symptoms; others have not. Potentially 250,000 patients in the US who undergo procedures using cardiopulmonary bypass per year could be affected. (Perkins 2016)

It can take from two weeks to four years for symptoms to appear. Diagnosis may be delayed. Roughly half of all the people who contract it die.

CONCLUSION

Watch this increasing litigation closely. Legal nurse consultants will be of value in these product liability cases by assisting in determining causation, liability, and damages for both plaintiff and defense attorneys.

REFERENCES

AboutLawSuits.com (2017). Com 3T heater-cooler infection lawsuits to proceed as individual claims: JPML April 18, 2017 Available at: https://www.aboutlawsuits.com/3t-heater-cooler-mdl-denied-125003/ Retrieved January 29, 2018

Antonation K, Patel S, et al. (2017) Interim laboratory testing guidelines for the detection of non-tuberculous Mycobacterium (NTM) infections in post-operative patients exposed to heater-cooler units, CCDR 2017 Jan 5; 43(1), 25-27

Business Wire (2017) LivaNova Pic-Product remediation plan related to 3T heater cooler device. March 1, 2017 Available at: file:///C:/Users/jbaro/Downloads/Releasec7d0f441-a6cb-4b9e-809a-ebfbd57c5a0f_2250486%20(1).pdf Retrieved January 29, 2018

Center for Disease Control and Prevention (CDC) (2015) Non-tuberculous Mycobacterium (NTM) infections and heater-cooler devices interim practical guidance: update October 27, 2015 Available at: https://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf Retrieved January 29, 2018

CDC (2016) Interim guide for the identification of possible cases of nontuberculous Mycobacterium infections associated with exposure to heater-cooler units. May 13, 2016 Available at: https://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf Retrieved January 29, 2018

FDA (2016) UPDATE: Mycobacterium chimaera infections associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T HeaterCooler System: FDA Safety Communication October 13, 2016. http://www.fda.gov/Medical/Devices/Safety/AlertsandNotices/UCM520191.htm Retrieved December 15, 2016

Federal Drug Administration (FDA) (2017) FDA's Ongoing Investigation of Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices (2017) Updated Dec 4, 2017 Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492590.htm Retrieved January 29, 2018

FDA (2017) Heater-cooler devices: information for patients (2017) Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492585.htm Retrieved January 29, 2018

Luhana R (2017) New class action lawsuit filed in Iowa over contaminated heater-cooler units The Legal Examiner, August 8, 2017. Available at: http://newyork.legalexaminer.com Retrieved August 9, 2017

Lyman M, Grigg C, et al. (2017) Invasive nontuberculous Mycobacterial infections among cardiothoracic surgical patients exposed to heater-cooler devices, Emerging Infectious Disease, (2017) May; 23(5) Center for Disease Control and Prevention https://wwwnc.cdc.gov/eid/article/23/5/16-1899_article Retrieved January 30, 2018

Mundy J. (2017) Stockert 3T Not the only heater-cooler unit associated with infection discovered years ago: May 2, 20017 Available at https://www.lawyersandsettlements.com/articles/Stockert-3T-Heater-Cooler-System/heart-surgery-infection-lawsuit-stockert-3t-8-22251.html January 29, 2018

Perkins K, Lawsin M (2016) Notes from the field: Mycobacterium chimaera contamination of heater-cooler devices used in cardiac surgery-United States MMWR October 14, 2016 65(40) 1117-1118 Available at https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w Retrieved January 29, 2018

Stobbe M (2016) Contaminated machines linked to heart surgery infections. The Washington Post October 13, 2016 Available at: http://www.modernhealthcare.com/article/20161013/NEWS/310139998 Retrieved January 29, 2018

Sun L (2016) More than half a million heart surgery patients at risk for deadly infection, The Washington Post October 13, 2016 Available at: https://www.washingtonpost.com/news/to-your-health/wp/2016/10/13/more-than-half-a-million-heart-surgery-patients-at-risk-of-a-dangerous-infection/ Retrieved January 29, 2018

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