



Heater–cooler units: contamination of crucial devices in cardiothoracic surgery

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SUMMARY

Background: Several cases of *Mycobacterium chimaera* infection have recently been reported in cardiosurgical patients. So-called heater–cooler units (HCUs) used in cardiosurgical procedures are suspected to be the reservoir for pathogen growth and dissemination.

Aim: To assess the contamination status of HCUs at our facility.

Methods: Air sampling for mycobacteria was conducted at different distances from the machines and in the area around the operating table. Air sampling was also conducted for non-fermenters as a surrogate parameter for water-associated pathogens.

Findings: *Mycobacterium chimaera* was detected in the water tanks of the HCUs. When the devices were operating, *M. chimaera* was also found in their exhaust air, as well as in the area around the operating table. Non-fermenters were identified at different distances from the running HCU and the area around the operating table. Cultures remained negative when the devices were switched off.

Conclusions: Exhaust air from HCUs may be a pathway of pathogen transmission to patients undergoing open chest heart surgery. Although, for technical reasons, relocation of HCUs is difficult to achieve, only strict separation of the HCU from the operating room appears to enhance patient safety. Using non-fermenters as a surrogate parameter may be considered a viable option for a timely risk assessment. The design of HCUs should be modified to keep susceptibility to contamination at a minimum.

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Introduction

Several cases of severe infection with *Mycobacterium chimaera*, e.g. endocarditis and prosthetic graft infection have recently been reported from Switzerland, The Netherlands, Germany and Great Britain.^{1–5} These infections occurred after a latency period of between a few months and

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several years in patients having previously undergone open chest heart surgery.^{1,3}

Following a detailed outbreak investigation conducted by University Hospital Zürich, so-called heater–cooler units (HCUs) manufactured by the Sorin Group (Milan, Italy) were identified as the probable source of pathogen contamination.^{3,6} HCUs are used during open chest heart surgery to regulate the temperature of the blood during extracorporeal circulation, and contain tanks filled with sterile filtered tap water as a temperature exchange medium. They are connected by tubing to the membrane oxygenator of the heart–lung machine and are therefore usually placed inside the operating room. Regarding the possible transmission path during surgery, direct leakage between HCU circuits and extracorporeal circulation does not appear probable. *Mycobacterium chimaera* was, however, identified in the machines' exhaust air, which is propelled into the operating room by the HCU cooling fan and then disseminated. This was therefore identified as a potential transmission pathway.³

In this context, the Swiss Federal Health Office (BAG: Bundesamt für Gesundheit) launched a public alert in July 2014. In Germany, the Federal Institute for Drugs and Medical Devices (BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte) adopted the theme, as did the European Centre for Disease Prevention and Control (ECDC), which communicated the problem at European level.^{6,7}

As several Sorin HCUs are in use at our facility, their contamination status with *M. chimaera* was assessed. To develop recommendations for greater patient safety we aimed to confirm dissemination of the pathogens in air. As the scope of the problem was previously unknown, a series of exploratory and systematic investigations was launched.

Methods

Setting

The University Heart Center Freiburg–Bad Krozingen is affiliated to University Hospital Freiburg, a tertiary care university hospital located in south-west Germany. The Center's Department of Cardiac and Vascular Surgery conducts about 4650 surgical procedures annually at two separate locations in Freiburg and nearby Bad Krozingen. The survey focused on five HCUs (A, B, C, D, E) located at University Hospital Freiburg. During the investigation, HCU C was replaced by HCU D.

Four of the HCUs were placed in operating rooms (HCUs A–D). An additional HCU (E) was occasionally used in intensive care units (ICUs) and otherwise placed in a storage room.

Maintenance of the HCUs took place in accordance with the manufacturer's instructions valid at the time. The HCUs were not available for investigation at all times because our study had to be co-ordinated with clinical routine. Depending on availability, HCUs and operating rooms were chosen for investigation. The maintenance status of the different HCUs varied and could not be determined.

Initial investigations conducted at our facility suggested that HCU water tanks harbour *M. chimaera* (data not presented here). Since aerosol formation was proposed as the possible transmission pathway, air samples were taken for analysis.

Air sampling for non-fermenters (August 2014)

To allow for a timely risk assessment, and due to the fact that *M. chimaera* is a very slow-growing organism, we used non-fermenters as a surrogate parameter for water-associated pathogens. Air sampling was conducted at different distances from HCU C when running. In addition, air was sampled around the operating table while HCU B was placed at its usual location inside the operating room (Figure 1: placement of the HCU inside the operating room). Air (200 L in 2 min) was collected by air sampler (MBASS30 Umweltanalytik Holbach GmbH, Wadern, Germany) and conducted over microbiological plates (blood agar; 25 cm²) for culturing. This was done when the HCUs were in use or switched off. All investigations were done while conventional operating room ventilation was running.

Contamination of tanks and circuits (January 2015)

For systematic investigation of the water tanks for *M. chimaera*, 1 L of water was taken from the two circuits (patient circuit, cardioplegia circuit) of each HCU.

Air sampling for mycobacteria (January 2015)

Air (200 L in 2 min) was collected by air sampler and conducted over selective microbiological plates (7H11 agar) for culturing. Additionally, a 7H11 plate was placed 1 m in front of

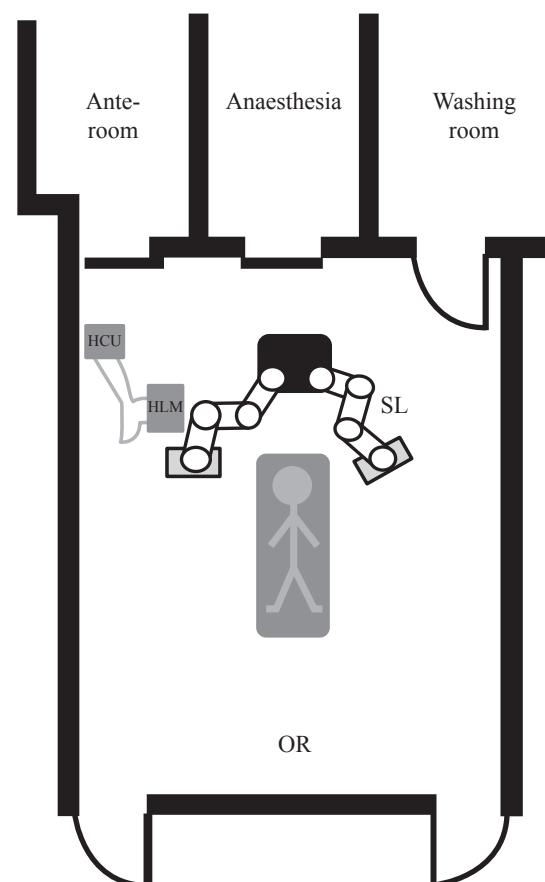


Figure 1. Placement of the heater–cooler unit (HCU) inside the operating room (OR). HLM, heart–lung machine; SL, surgical lights.

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