ORIGINAL ARTICLE

Mycobacterium chimaera in heater–cooler devices: an experience in a tertiary hospital in Spain

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Abstract

The aim of the study was to describe the *Mycobacterium chimaera* contamination in heater–cooler devices after the application of a protocol of cleaning and disinfection in a tertiary hospital. It was an observational study at the La Paz-Cantoblanco-Carlos III University Hospital, Madrid, Spain. Seven heater–cooler devices are used in our hospital: five 3T Sorin (LivaNova) and two Maquet. We followed the manufacturers' instructions for cleaning and disinfection of the different heater–cooler devices. Environmental testing was developed monthly from January 2017 to July 2019. Samples were obtained from both cardioplegia and patient circuits and before and after the disinfection process and were cultured in appropriate media for non-tuberculous mycobacteria and heterotrophic bacteria (coliforms and *Pseudomonas aeruginosa*). A total of 320 samples were taken. *Mycobacterium chimaera* grew in four water samples (1.25%) from three different heater–cooler devices, with two positive results occurring after disinfection. The heterotrophic bacteria *Delftia acidovorans* and *Stenotrophomonas maltophilia* were also found. There has not been a case of *M. chimaera* infection in patients after cardiac surgery in our hospital. In March 2019, we decided to move the heater–cooler device outside the operating room. *Mycobacterium chimaera* contamination is not always eradicated by disinfection processes. We believe that placing 3T heater–cooler devices outside the operating room is the best option in preventing *M. chimaera* infection during cardiac surgery.

Keywords: Aerosolization, cardiac surgery, disinfection, heater–cooler device, *Mycobacterium chimaera*
Original Submission: 27 July 2020; **Accepted:** 4 September 2020
Article published online: 7 September 2020

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Introduction

A global outbreak of invasive *Mycobacterium chimaera* infections became apparent since 2015 in patients following open-chest heart surgery. Investigation of the outbreak detected that specific heater–cooler devices (HCDs) used during cardiac surgery were the source of *M. chimaera*. HCDs are used in cardiac surgery during extracorporeal circulation to regulate the temperature of the blood and provide temperature-controlled water for cardioplegia [1]. The water in the circuit does not come into contact with the patient but the circuit is not airtight and cooling of the water is accomplished with a fan. The water used in the water circuit of each HCD allows optimal conditions for the multiplication of mycobacteria and for the formation of biofilms. Contaminated water in the reservoirs of the HCDs can generate bio-aerosols in the operating room, leading to airborne transmission through its ventilation fans into the air around the operating table followed by bacterial contamination of the open surgical site. This is the most likely transmission mechanism in the *M. chimaera* cases after open chest surgery [2].

The infections were associated with one type of heater–cooler, the 3T HCD (LivaNova, formerly produced by Stöckert, part of Sorin). These devices were likely to have been

https://doi.org/10.1016/j.nmni.2020.100757

contaminated with the bacteria at the manufacturing site in Germany up until September 2014.

In April 2015 the European Centre for Disease Prevention and Control published a protocol for case detection, laboratory diagnosis and environmental testing of *M. chimaera* [1].

The US Centers for Disease Control and Prevention and the US Food and Drug Administration recommended strict adherence to the cleaning, disinfection and maintenance instructions provided by the manufacturer of the device, as well as water sampling and monitoring [3,4]. But eradication of *M. chimaera* from contaminated HCDs is extremely difficult because the organism is resistant to disinfection because of biofilm formation.

In May 2017, the LivaNova company made structural changes to the 3T devices to eliminate the problem of aerosolization by the installation of the Vacuum and Sealing system.

In January 2017 our institution started an epidemiological surveillance programme of HCDs, evaluating their microbiological contamination.

Materials and methods

In this paper we describe the results of the application of a protocol of cleaning and disinfection of HCDs in a tertiary hospital. The study period started in January 2017 and ended in July 2019. HCD equipment used in our hospital during that period comprised a total of seven units, five 3T Sorin (LivaNova) HCDs and two Maquet HCDs, placed in operating rooms of adult cardiac surgery departments.

The protocol consists of cleaning and disinfection of the equipment (following the manufacturers' indications), environmental testing, measures to take when testing is positive, instructions for the elaboration of reports, task assignment among hospital units (Preventive Medicine department, Clinical Microbiology and Parasitology departments and Cardiac Surgery department) and case identification standards.

As detailed in the protocol, cleaning and disinfection of the Sorin (LivaNova) HCD includes the following: surfaces and water circuits disinfection (before first use, before device storage and during regular use), surfaces disinfections after every use, water replacement (adding hydrogen peroxide to the tanks) and overflow bottle disinfection every 7 days, water circuit disinfection every 14 days, tube replacement every year and annual cleaning and disinfection by the manufacturer.

Cleaning and disinfection of the Maquet HCD includes a daily check of water level and water circulation into the condenser, cleaning of internal circulation (using chlorate products) every week, cleaning by brushing the filter placed in the back and water replacement every month or every 100 hours of use and annual (or after 1000 hours of use) device revision by the manufacturer.

Environmental testing was developed monthly. Samples were obtained from both cardioplegia and patient circuits and before and after the disinfection process. Water samples (100 mL) from the drain valves on the back of the device were placed in two plates and cultured in appropriate media for non-tuberculous mycobacteria and heterotrophic bacteria (coliforms and *Pseudomonas aeruginosa*).

Negative testing implies undetectable levels of bacteria in 100 mL of water. If positive testing, the measures collected in the protocol are device withdrawal, revision of the cleaning and disinfection procedures, communication to the manufacturer and new environmental testing. Reports must be made every 6 months by routine, and urgently if positive environmental testing is recorded.

Results

A total of 320 samples were taken from seven different HCDs, 160 from the cardioplegia circuit and 160 from the patient circuit. In each circuit half of the samples were cultured in media for non-tuberculous mycobacteria and the other half in media for heterotrophic bacteria. The samples were taken twice, before and after disinfection process.

Mycobacterium chimaera grew in four water samples (1.25%) from three different devices. At the beginning of the surveillance period (January 2017) our hospital had two HCD 3T Sorin devices (numbered 1 and 2 in Table 1) and one Maquet HCD. The samples of the HCD 3T Sorin device number 1 tested positive for *M. chimaera* in the patient circuit after disinfection in December 2017 and number 2 also tested positive in the cardioplegia circuit before disinfection in February 2018. Both of them were replaced by two new Sorin devices (numbered 3 and 4). The HCD 3T Sorin number 3 device also tested positive for *M. chimaera* twice—in November 2018 in the patient circuit before disinfection and in March 2019 also in the patient circuit before and after disinfection—then it was also removed. The HCD 3T Sorin number 4 was a replacement loaned from the Sorin Group so it was returned to the manufacturer in October 2018.

Of the samples cultured for heterotrophic bacteria, in both the patient and cardioplegia circuits before disinfection three sample cultures for heterotrophic bacteria tested positive for *Delftia acidovorans* and one for *Stenotrophomonas maltophilia* and *Delftia acidovorans*. Following a disinfection process no bacteria were detected.

The Maquet device was broken in January 2018 and was not replaced by another one until May 2019.

The currently active HCDs in use are a Maquet HCD, acquired in May 2019, as well as a Sorin 3T HCD acquired in October 2018 (numbered 5 in Table 1).

TABLE 1. Presence of *Mycobacterium chimaera* in water samples

	Sample date			
HCD	**December 2017**	**February 2018**	**November 2018**	**March 2019**
Sorin 3T no. 1	Positive for *M. chimaera* after disinfection Removed January 2018			
Sorin 3T no. 2		Positive for *M. chimaera* before disinfection		
	Removed March 2018			
Sorin 3T no. 3			Positive for *M. chimaera* before disinfection	Positive for *M. chimaera* before and after disinfection
	Removed March 2019			
Sorin 3T no. 4	All samples negative Removed October 2018			
Sorin 3T no. 5	All samples negative Currently active device since October 2018			
Maquet no. 1	All samples negative Broken January 2018			
Maquet no. 2	All samples negative Currently active device since May 2019			

Abbreviation: HCD, heater–cooler device.

To the best of our knowledge, there has not yet been a case of *M. chimaera* infection in a patient after cardiac surgery in our hospital.

As a result of the presence of *M. chimaera* despite implementation of recommended procedures in March 2019, our medical centre decided to move the 3T HCDs outside the operating room by passing the tubes through holes in the wall (Figs. 1 and 2).

Discussion

Our results corroborate the presence of *M. chimaera* in Sorin HCDs despite the use of US Food and Drug Administration and manufacturer-recommended protocols. To date, all *M. chimaera* contaminations have been attributed to the 3T HCDs. We have not found growth of *M. chimaera* in the other HCD model we have at the hospital (Maquet). Independent genetic testing of microorganisms isolated from Sorin HCD from different countries suggests that the contamination of HCD may have occurred through contamination at the manufacturing site [5]. Investigations of Livanova devices revealed the presence of *M. chimaera* in the German factories in which these devices were assembled [6].

We have followed Livanova and Maquet recommendations for sampling and decontamination of both HCDs, but the decontamination procedures do not sufficiently inhibit the growth of microorganisms in Sorin HCDs. Several investigators have shown that *M. chimaera* is virtually ineradicable from HCDs once it has colonized the water circuit. Current HCD decontamination protocols have been found to be insufficient despite intensive disinfection efforts [7]. The water tanks contain a wide variety of microorganisms and extensive biofilms on a number of different components, which probably contribute to the survival of *M. chimaera* [8]. Once formed, biofilms are difficult to eliminate completely. Careful inspection, removal and replacement of all affected tubing, followed by a thorough disinfection may be needed to eradicate the biofilms [9].

Whenever an HCD yielded a positive result for *M. chimaera*, it was immediately removed and replaced by another one. All devices from which *M. chimaera* was isolated were sent to the manufacturer.

FIG. 1. 3T heater–cooler device outside the operating room.

FIG. 2. Tubes passing through hole in the wall, inside the operating room.

The 3T HCD number 3 yielded two positive tests, but the first result arrived 2 months later.

Despite the presence of *M. chimaera* in the water tanks, there have been no new cases of *M. chimaera* infections identified; however the diagnosis of cardiac *M. chimaera* infection can be difficult because initial symptoms may be non-specific, subtle and appear months to years after surgery [10]. *Mycobacterium chimaera* is a ubiquitous environmental organism that can cause disease in patients with underlying airway disease or individuals who are immunocompromised. When infection involves prosthetic devices, *M. chimaera* may disseminate to involve other organs like bone marrow, liver, lungs, urinary tract and retina [11,12]. The infection usually presents as prosthetic valve endocarditis, vascular graft infection or disseminated infection. Clinical manifestations of infection are diverse and symptoms may be non-specific. In some cases, extracardiac manifestations preceded cardiovascular disease [13].

At our hospital, species identification and susceptibility testing required submission to a reference laboratory. *Mycobacterium chimaera* grows slowly and cultures can take up to 8 weeks to turn positive, therefore, machines with positive water samples could be actively used in the operating room before the results of the cultures are known. Several authors do not recommend the sampling of water; cultures from the same HCD can alternate between positive and negative over time, suggesting that negative cultures do not indicate that the HCD is free of *M. chimaera* [14].

Due to the complexity of the situation in terms of decontamination of HCDs, culturing water samples and diagnosing *M. chimaera* infection, we decided to move the 3T HCD outside the operating room by passing the tubes through holes in the wall in March 2019.

We think that this simple change was the best option to prevent the exposure of patients to *M. chimaera* aerosolized from the HCDs during cardiac surgery.

Conclusions

Contamination of 3T HCDs by *M. chimaera* exists, and it is not always eradicated by disinfection processes. However, a protocol of cleaning and disinfection of the HCDs is mandatory because it allows standardization of the microbiological testing process and creates a framework for environmental surveillance. Additional measures such as externalization of devices out of the operating room may be useful. Although we have not detected clinical infections with *M. chimaera*, continued surveillance is a complex and long-term process. Additional efforts are needed to further evaluate new infections and how to best utilize potentially infected cooler devices.

Declaration of interest

None declared.

Funding sources

None.

Acknowledgements

The authors are grateful to Juan Ignacio Gómez Chaparro, the Head of Maintenance at our hospital, for his work in placing the heater–cooler outside the operating room.

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