

Classic Pages of the *Journal of Extracorporeal Technology*

Section Editor: Jeffrey B. Riley

Heater-Cooler Devices as a Conceivable Source of Infection

Weitekemper HH, Spilker A, Knobl HJ, Körfer R. The heater-cooler unit—A conceivable source of infection. *J ExtraCorp Technol.* 2002;34:276–80.

From the Heartcenter of North Rhine-Westphalia, Federal Republic of Germany and presented at the 40th International Conference of the American Society of Extra-Corporeal Technology, New Orleans, Louisiana, in March 2002.

2002 HEATER-COOLER INFECTION EARLY WARNING

Weitekemper et al. (1) concisely stated the 2002 issues surrounding the use of tap water in heater-cooler devices (the U.S. Food and Drug Administration [FDA] is using “HCDs”) in the operating room environment. They shared their method to handle the challenge of removing bacteria from the tap water in their heater-coolers and heat exchangers. This classic JECT article is profound reading within the context of nontuberculous *Mycobacterium* (NTM) epidemic we are experiencing today, worldwide with HCDs. Current estimates from case series publications suggest an approximate incidence rate of 4:10,000–1:1,000 cardiac surgical patients.

In retrospect, it is significant that JECT published the only article to provide a warning until about 2013 when *Mycobacterium chimera* reports with cardiac surgery started to appear (2). Our classic authors write on page 277:

“The infectious dose for an opportunistic pathogen is lower for immunocompromised subjects or those on antibiotic treatment. While connecting the HCU to oxygenator or blankets, it is impossible to avoid spilling water. This can contaminate the environment and place individuals at risk.”

In 2015, Achermann et al. raised the red flag when they reported the aerosolization of *M. chimera* from HCDs in the operating room environment (3). Manufacturers of HCDs have worked rapidly and effectively to study and update the instructions for cleaning and disinfecting heater-coolers. Perfusionists around the world are responding rapidly to update their practice and disinfection protocols. Because of work by the manufacturers, perfusionists, and the FDA, our current state is much improved from the

concerns expressed in our classic article on page 280 in 2002:

“Unfortunately, there are no guidelines about proper disinfection of HCU systems, neither from HCU manufacturers nor oxygenator producers. Inconsistent statements about the use of disinfectants on one hand and a possible failure of a heat exchanger with a high risk of infection on the other shows that this problem has yet to be addressed.”

HEATER-COOLERS AND THE FDA

Our 2002 JECT article is truly classic, considering the advent of recent warnings from the FDA and the U.S. Center for Disease Control (CDC) containing recommendations for maintaining and disinfecting HCDs. The FDA has dedicated a web site to education for HCDs and the results of the June 2–3, 2016 panel hearings regarding HCDs. The executive summary of the problem is mandatory reading (4).

AMSECT UNIVERSITY

AmSECT University (www.amsectu.org) has dedicated post-graduate courses to heater-coolers as potential sources of infection. The courses focus on the FDA warnings and the cleaning and disinfection protocols for the HCDs currently available.

MORE INFORMATION PENDING

Future issues of JECT, AmSECToday, and updated coursework at AmSECT University will focus on the

issues associated with HCD-related infections. Watch for presentations at national and local meetings on the topic of NTM and HCDs.

You and your team should be reviewing present HCD cleaning and disinfecting protocols to be informed by and consistent with FDA warnings and recommendations.

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The Heater–Cooler Unit—A Conceivable Source of Infection

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Abstract: Even drinking water is contaminated with pathogenic microorganisms. This does not necessarily pose a risk for healthy individuals, but it may result in serious consequences in people with impaired immune systems. This is particularly valid if drinking water is used for medical purposes. The heater–cooler unit (HCU) connected to heat exchangers or blankets by tubing, the connection is closed water circuit that contains microorganisms and algae. While connecting the tubing to the heat exchanger, spilling of water cannot be avoided. Microbiological examinations showed that germs and particles pollute the units. Exposure to the patient and the OR equipment has the potential to increase the risk of infection should the HCU water come in contact with the patient. As a result of the high incidence of particle and algae in the HCU, malfunction occurs. Sampling shows >1000/mL CFU (colony forming units) at 36°C and 55/mL CFU at 20°C on average. The specific findings include *Pseudomonas* and *Legionella*. Disinfecting HCU is very difficult. Often HCUs do not provide any technology to reduce bacterial or other con-

tamination. The instructions for use of oxygenators often exclude the use of disinfectants. Maintenance instructions for the HCU advocate the use of disinfectants that carry the risk of oxygenator damage and of heat exchanger leakage. The effect of chemical disinfectants and heat exchanger membranes have not been examined, they may impair heat exchanger permeability and function. As an alternative to chemical and thermal disinfection, we used the alternative method of filtration. Using a membrane filter element, we noticed a decreasing number of CFUs from 55 to sterile conditions at 20°C and from >1000 CFUs to 100 CFUs at 36°C (Figure 1). In addition, we noticed a removal of other particles and algae. In conclusion, we have demonstrated a technique that is simple to implement and effectively reduces the microbiological load of the water in the heater–cooler unit. **Keywords:** heater-cooler units, colony-forming-units, microorganism, disinfection, membrane filtration. *JECT*. 2002;34:276–280

Microorganisms can be found in drinking water, although they do not necessarily pose a risk for healthy people, even if the water is used for food and not for medical purposes. The German prescription for potable water does not allow use of drinking water containing pathogens.

During cardiac surgery using extracorporeal circulation, the patient's blood is cooled down or rewarmed by using the integrated heat exchanger of the oxygenator. The heat exchanger is connected by hoses and tubes to the heater–cooler unit (HCU), with the amount of water depending on the type of HCU used. In addition, the HCU is used with blankets to control peripheral body temperature; for example, in pediatric or in neurosurgical cases. The output of the HCU varies between 10–21 L/min depending on the way lines are connected. Because of its temporary use, the HCU system can be described as a stagnation system. We

cannot avoid contamination with microorganisms filling the system with drinking water. Drinking water often includes the following genera: *Pseudomonas*, *Acinetobacter*, *Moraxella*, *Aeromonas*, and xanthomas. Other bacteria that are also commonly found include *Legionella* and *Mycobacterium*. All these genera contain species that are opportunistic pathogens that may cause serious diseases. *Pseudomonas aeruginosa* is a major cause of hospital-acquired infection with a high mortality rate.

Pseudomonas causes infection of wounds as well as in urinary and respiratory tracts. *Legionella pneumophila* causes 4–20% of the cases of community-acquired pneumonia (1). *Legionella* strongly increase in the temperature range between 35–45°C and can still survive up to 45–55°C. They grow in symbiosis with other microorganisms and bacteria, such as amoebas in which they multiply similar to leukocytes or phagocytes (2). They die within minutes at 60–65°C and at 70°C they die within seconds.

Waterborne pathogens cause infections in health care facilities. Transmission occurs via contact, ingestion, aspiration, or aerosolization of potable water, or via the hands

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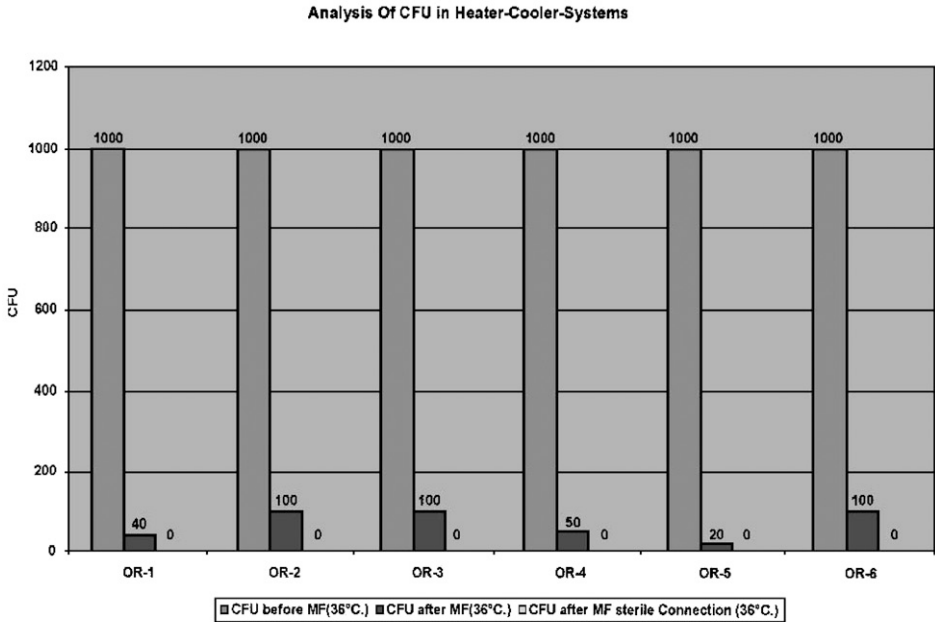


Figure 1. Colony forming unit analysis before and while using membrane filters and with sterile connection between filter and heat exchanger. CFU = colony forming unit

of health care workers (3). Many outbreaks of infection or pseudoinfection occur through lack of prevention measures and ignorance of the source and transmission of opportunistic pathogens (4). In the United States, an estimated 2.1 million nosocomial infections occur annually in acute care hospitals alone (5).

The infectious dose for an opportunistic pathogen is lower for immunocompromised subjects or those on antibiotic treatment. While connecting the HCU to oxygenator or blankets, it is impossible to avoid spilling water. This can contaminate the environment and place individuals at risk. Despite frequent change of water in the HCU, there still remains a biofilm covering the walls and tubes of the HCU. The culture medium for microorganisms is built up by sedimentation of lime and rust and other inorganic substances at the wall of the HCU and connecting tubes. The sensors of the HCU are affected by alga vegetation that leads to malfunction and expensive repair work. Flowing particles may also reduce the heat exchanger function, blocking the ribs. To determine what kind of contamination our HCU systems contained, we had to analyze and specify the germs.

In addition to frequent change of the containing water,

there are other procedures to disinfect HCU systems: chemically, thermally, ultraviolet (UV) radiation, and filtration. Different chemical agents are available to disinfect the water. Silver nitrate is most often used for touristic cases causes corrosion of aluminum and steel. Other chemical agents, such as chlorine, acetone, and methyl ethyl ketone are not recommended by HCU manufacturers because of their aggressive properties. When using noncorrosive agents, such as glutaraldehyde, it is imperative to ensure that no disinfectant remains in the system before use. Basically, there are no disinfectants to use for the HCU system recommended by any manufacturer, and interactions between different materials of the heat exchanger are unknown. Heating the HCU <90°C does not ensure that all bacteria or *Legionellae* have been eliminated (6). Frequent thermal disinfecting is advisable. UV irradiation eliminates only cells of flowing water; it does not influence the biofilm on the walls and *Legionellae* covered in amoeba. Thus, integrated UV light does not lead to sterile conditions in the HCU tank. Filters containing activated carbon or a cellulose acetate membrane are commonly used for filtration of potable water. Pore size ranged between 1–5 µm in membrane filters. For clinical use, we must be aware of retrograde contamination. Fre-

quent resterilization is necessary to maintain proper function of the filter unit. Therefore, we have investigated the ability of a pre-bypass filter to remove microbiological debris from the circulation volume of a heater-cooler.

MATERIALS AND METHODS

In our institution, we use the HCU 20 manufactured by Jostra (Jostra AG, Hirrlingen, Germany). The tank contains 33 L water. The temperature can be set between 3° to 41°C. The performance of the integrated pump is set to 10 L/min. Because of the distance of 5 m between the HCU and heart-lung machine (HLM), performance decreased down to 7.5 L/min. The HCU is set up in the washing room connected with hosepipes and remote wire beneath the floor to the HLM in the OR. The water of our six HCUs was analyzed according to International Organization of Standards 11731 (ISO11731). By direct analysis and membrane filtering the analyzing process was performed for each probe using buffered charcoal yeast extract agar medium and buffered charcoal yeast extract medium with selective supplements for culture medium.

The membrane filter we used later is a sterile double layered cellulose acetate membrane filter MaxiCaps (Sartorius AG, Göttingen, Germany) (Figure 2). Pore size of the integrated membrane was between 0.45 and 0.2 µm. The product is registered with the Food and Drug Administration under the Drug Master File No. 5967. The filter capsule was sterilized to the standards for "Sterilization of Medical Products" (7). This filter fulfills the USP demand for sterile water for injection. This filter is also used for industrial purposes when sterile water is needed. To determine the initial position of our HCU systems, we took samples of 500 mL water out of each system. After that, filter capsules were set in the tube system and de-aired (Figure 3). De-airing the capsule is necessary to keep continuous flow. Regular de-airing is necessary, because air will reduce the water flow giving indication that the filter

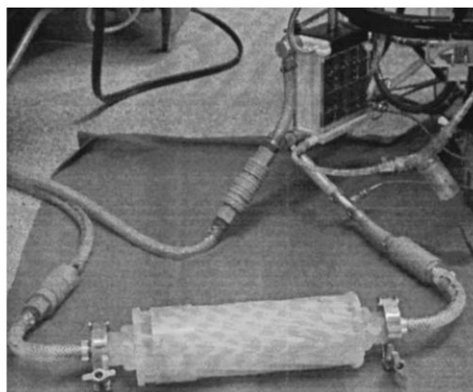


Figure 3. Filter connected with the heat exchanger.

may be exhausted. Samples were taken ahead of and behind the filter. To avoid recontamination, filters were sterilized by autoclave once a week. The flow drop was determined once a week by flowmeter (Koboldt, Hofheim, Germany). Filters were exchanged when the flow drop was less than 2 L/min.

RESULTS

The analysis of the initial sampling of six circuits showed: CFUs, mean = 55; SD = 109.8/mL under 20°C condition. More than 1000 CFUs were found under 36° conditions. *Legionella* and *Pseudomonas aeruginosa* were

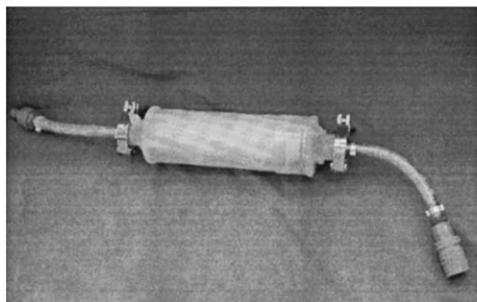


Figure 2. Membrane filter capsule with hitches.

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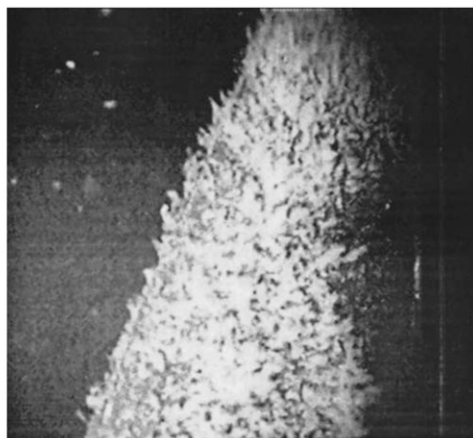


Figure 4. Vegetation inside the HCU.

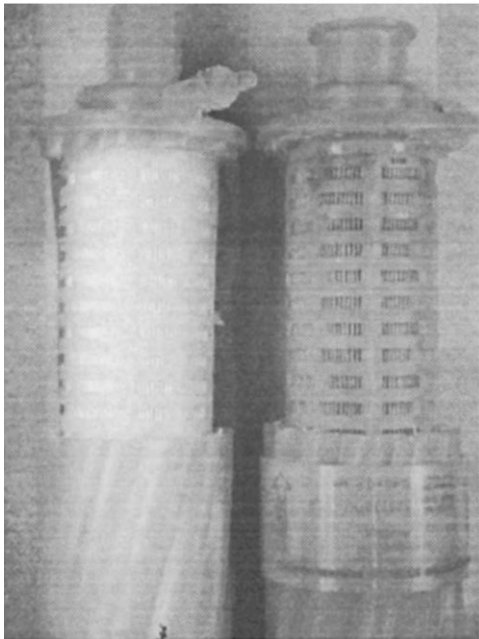


Figure 5. Filter before and after use (cleaning period).

found. A look into the inner tank of the HCU shows a mass of particles and vegetation at the wall (Figure 4). No *Coliforme* species was detected. These results do not correspond with hygienic guidelines for hospitals in Germany. The samples taken from behind the filter were different. CFUs decrease to sterile conditions by 20° and the mean 56.6/mL. CFUs were analyzed at 36°C. Recontamination occurred from behind the filter. To avoid recontamination, the tubes and pipes were rinsed thoroughly using a pulsation pump. Thus, we removed the soil from the tube walls, which contained a mass of *Pseudomonas* culture. Next, a sterile tube was positioned between the filter and heat exchanger and took samples every day for a week. Under all temperature conditions, all probes were sterile.

Determining the flow drop weekly demonstrated a decreased flow below 2 L/min in an exhausted used filter after ($N = 6$) 13.3 days (Figure 5). This first period using the membrane filter, was designated the “cleaning period.” In this period, particles and algae were removed from the HCU system by the membrane filter (Figure 6). Length of the filters increased up to ($N = 27$) mean = 25.3 days per filter. Examination of the tank after 50 days demonstrated clear water without particles or vegetation (Figure 7).

DISCUSSION

Because of the continuous discussion about patient safety and the avoidance of possible nosocomial infec-

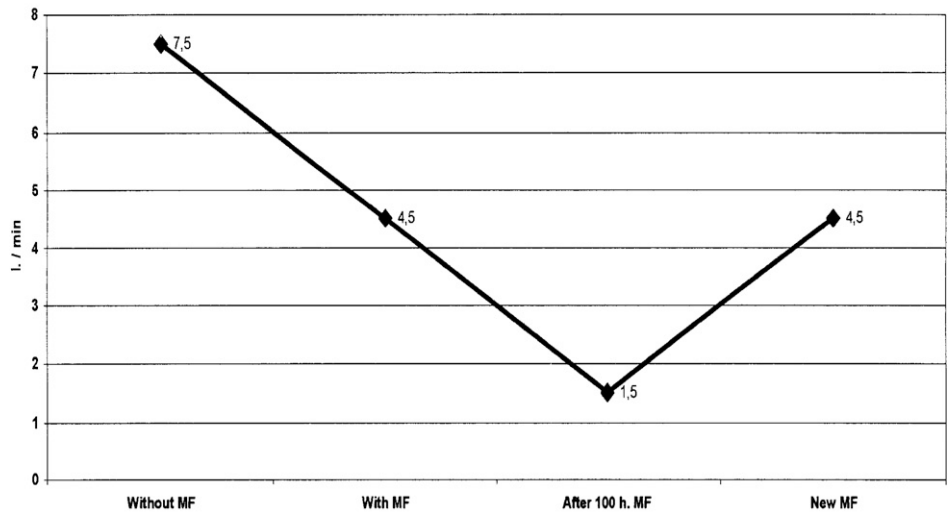


Figure 6. Flow drop of the membrane filter unit.

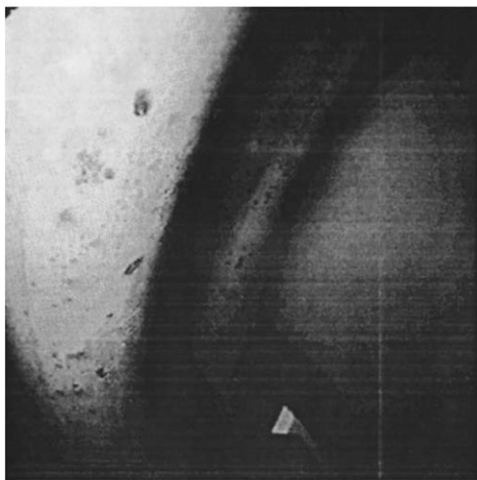


Figure 7. Inside the HCU after using membrane filters.

tions. Unfortunately, there are no guidelines about proper disinfection of HCU systems, neither from HCU manufacturers nor oxygenator producers. Inconsistent statements about the use of disinfectants on one hand and a possible failure of heat exchanger (8) with a high risk of infection on the other shows that this problem has yet to be addressed.

Thermal disinfectant of the HCU does not lead to absolutely germ-free conditions, and this process excludes

the tubes and hosepipes, resulting in recontamination of the circuit. A combination of thermal disinfectant and membrane filtration is imaginable. A basic disinfection with exchange of contaminated tubes of HCU system should be carried out, and frequent use of membrane-filters to avoid retrograde contamination (9) should be the usual practice. Our experiences with membrane filters during consistent application, considering manufacturer information concerning retrograde contamination, showed an efficient alternative for reducing germs and particles. Consequently, the risk of infection can be lowered. Additional elimination of particles and algae now leads to long-term, trouble-free use of the HCU.

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