J Extra Corpor Technol. 2019;51:73–7
The Journal of ExtraCorporeal Technology

Improving Decreased Heater–Cooler Efficiency as a Result of Heater–Cooler Infection Control Strategy

Adam K. Blakey, MPS, CCP;* David W. Holt, MA, CCT†

**Virginia Commonwealth University Health System, Richmond, Virginia; and †University of Nebraska Medical Center, Clinical Perfusion Education, Omaha, Nebraska*

Abstract: Heater–cooler units (HCUs) play a vital role in temperature management during cardiopulmonary bypass. In recent years, HCUs have been shown to play a significant role in the propagation of bacteria causing patient infection and significant harm. As a result, various institutions across the world have begun moving the HCU either far away or outside of the operative theater entirely. The purpose of this study was to examine the effect that the increased length of HCU water lines have on the ability of the device to heat and cool. We hypothesized that the increase in water line distance leads to a decrease in HCU efficiency and that insulating the water lines would blunt the effect of this increase in distance. Five water line conditions were compared under two cooling and two warming ranges. Short water lines, long water lines, and long water lines with foam, rubber, or tape insulation were compared. Cooling from an arterial line temperature of 26.7–19.7°C showed no difference between conditions with the exception that every long line condition takes significantly longer to cool than short water lines. Cooling from 35.6 to 28.6°C revealed that all insulations reduce the cooling time compared with long water lines without insulation, but only foam insulation reduces to the level of the short water lines. During warming conditions, all insulations reduced the warming time compared with long uninsulated water lines, but none were comparable with short water lines. Increased water line length leads to a decrease in HCU efficiency. Insulation is effective at increasing efficiency of long water lines, but only at warmer temperatures and not to the level of short water lines. Only foam-insulated long water lines were able to match the efficiency of short water lines, but only across a single temperature range. **Keywords:** cardiopulmonary bypass (CPB), CPB equipment, infection, hypothermia, wound infection, heater–cooler. *J Extra Corpor Technol. 2019;51:73–7*

Heater–cooler units (HCUs) are crucial devices responsible for regulating a patient's body temperature during cardiopulmonary bypass. HCUs control temperature by heating or cooling water and circulating that water via water lines to a disposable heat exchanger located on the cardiopulmonary bypass machine. HCUs typically consist of at least two circuits, a patient circuit responsible for maintaining patient body temperature and a cardioplegia circuit, which is responsible for cooling a solution that is delivered directly to the heart. Because of the presence of a water reservoir in these devices, they have long been postulated to be a potential source of infection (1). In 2015, a deadly outbreak of *Mycobacterium chimaera* was attributed to HCU use during cardiopulmonary bypass (2). The transmission pathway for these bacteria was confirmed to be aerosolization via the exhaust fan of the HCU, which dispersed bacteria into the operating theater air. Since this discovery, multiple cases of *M. chimaera* infections have been attributed to HCUs, causing significant patient harm and even death (3–7). Because of the risk of aerosolization, the current recommendation is to direct the HCU exhaust away from the operative field into the operating room exhaust, with some institutions removing the HCU from the operating room entirely (8–12). Increased distance of the HCU to the heat exchanger raises concern about the thermal efficiency of these devices while maintaining patient temperature. The purpose of this study was to determine if increased water line tubing length leads to a decrease in thermal efficiency and if insulation can be effectively used to blunt the decreased efficiency.

Received for publication December 17, 2018; accepted February 1, 2019.
Address correspondence to: Adam K. Blakey, MPS, CCP, Perfusionist, Virginia Commonwealth University Health System, 1250 East Marshall Street, Richmond, VA 23219. E-mail: ablakey86@gmail.com
The senior author has stated that the authors have reported no material, financial, or other relationship with any health-care–related business or other entity whose products or services are discussed in this paper.

Article available at https://ject.edpsciences.org or https://doi.org/10.1051/ject/201951073

MATERIALS AND METHODS

Circuitry

Five water line conditions were compared under two cooling and two warming ranges. Seven-foot short water lines, 17-foot long water lines, and long water lines with polyethylene foam (Frost King, Mahwah, NJ), rubber (Frost King), or rubber tape (Frost King) insulation were compared. A continuous circuit consisting of a mock patient and a testing portion was constructed using uncoated polyvinyl chloride tubing (LivaNova, London, UK) and used for all cooling and warming tests (Figure 1). Both the test and patient portions consisted of a venous hard-shell reservoir with an oxygenator/heat exchanger (Medtronic, Minneapolis, MN). The entire circuit was primed with 3 L of normal saline (Baxter, Deerfield, IL). The saline was pumped at 5 liters per minute (LPM) from the test reservoir through the test oxygenator to the inlet of the patient oxygenator using a centrifugal pump (Maquet, Wayne, NJ). From the outlet of the patient oxygenator, saline continued into the inlet of the patient hard-shell reservoir where it eventually drained into the inlet of the test hard-shell reservoir. The patient heat inertia was simulated by circulating a 10-L water reservoir at four LPM into the patient heat exchanger via a centrifugal pump (Maquet). Temperature was monitored at the arterial outlet of the test circuit using a myocardial temperature probe (Smith's Medical ASD, St. Paul, MN) and a vital signs monitor (Welch Allyn, Skaneateles Falls, NY). The HCU being tested (LivaNova) was connected to the test heat exchanger via water lines according to which water line condition was being tested. Only the patient circuit of the HCU was used. Water flow through the water lines was also measured in both short and long conditions using a flow probe (Transonic, Ithaca, NY). The temperature in the room where the experiment took place remained constant at 21°C.

Cooling Test

Two cooling ranges were tested under all five tubing conditions. The first cooling range tested was to measure the time it takes the arterial line temperature to decrease 7°C from baseline when the heater–cooler is cooling from 38 to 28°C. The second cooling range tested was to measure the time it takes the arterial line temperature to decrease 7°C from baseline when the heater–cooler is cooling from 28 to 18°C. Baseline arterial line temperature was established by allowing the starting temperature to reach a steady state for 5 minutes. The time was measured starting from the time the water bath temperature was decreased to the goal temperature until the arterial line temperature reached 7°C below baseline. Each tubing condition was tested three times.

Warming Test

Two warming ranges were tested under all five tubing conditions. The first warming range tested was to measure the time it takes the arterial line temperature to increase 7°C from baseline when the heater–cooler is warming from 28 to 38°C. The second warming range tested was to measure the time it takes the arterial line temperature to increase 7°C from baseline when the heater–cooler is warming from 18 to 28°C. Baseline arterial line temperature was determined as stated previously.

Statistical Analysis

Multiple comparisons were performed using one-way analysis of variance. Specifically, the variables of length/insulation condition and start temperature for the testing range, as well as the interaction between these two variables, were tested in separate models for warming and cooling. Model-adjusted means were calculated and post hoc pairwise comparisons were adjusted using Tukey's method. All analyses were performed using SAS software

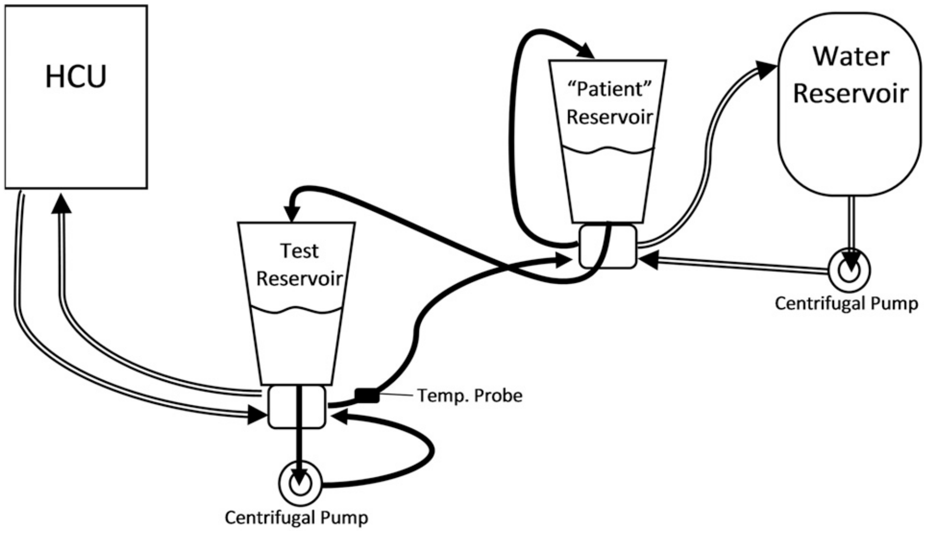

Figure 1. Schematic drawing of test circuitry.

version 9.4 (SAS Institute Inc., Cary, NC). Results were considered significant at $p < .05$.

RESULTS

Cooling Test

The flow of water through the water lines is the same between all tubing types at 13 LPM. Baseline arterial line temperatures for testing the ranges of 38–28 and 28–18°C were 35.6 and 26.7°C, respectively. The temperature-adjusted times can be found in Tables 1 and 2. Table 3 compares the cooling times for each water line condition between the two groups. In the cooling experiment with a baseline of 26.7°C, there are no significant differences among any of the conditions, with the exception that every long water line condition takes longer to cool than the short water lines, regardless of insulation ($p < .0001$) (Table 4). In the cooling experiment with a baseline of 35.6°C, all insulation and the short water lines cooled faster than uninsulated long water lines ($p < .0001$) (Table 5). Along with cooling faster than the long uninsulated water lines, foam-insulated long water lines also cooled faster than tape insulation ($p < .0001$) but was no different than short water lines ($p = .9435$) or rubber-insulated long water lines ($p = .2834$). In addition to long uninsulated water lines, rubber-insulated long water lines cooled faster than tape ($p = .0002$). Short water lines cooled faster than rubber-insulated long water lines ($p = .0245$) and tape insulation ($<.0001$), as well as long uninsulated water lines. When comparing the water line conditions and the time to cool between the two groups, there were two differences. The foam-insulated long water lines cooled faster from a water bath temperature of 38 to 28°C than from 28 to 18°C ($p = .0218$) (Table 3). The other difference found was that the long uninsulated water lines cooled faster from 28 to 18°C than from 38 to 28°C ($p < .0001$). Every other water line condition cooled at the same rate no matter the starting temperature.

Warming Test

The flow of water through the water lines is the same between all tubing conditions at 13 LPM. A significant difference between starting temperature groups was not found, so the results shown encompass both warming groups combined. The baseline arterial line temperatures for testing the condition of 28–38 and 18–28°C were 28.6 and 19.7°C, respectively (Table 6).

After adjusting for temperature, there were no significant differences between any of the insulation types and the time it took to warm (Table 7). Foam, rubber, tape, and short water lines all took a significantly shorter time to warm than long uninsulated water lines. Short water lines also warmed faster than any insulation condition.

Table 1. Temperature-adjusted mean times when cooling from 28 to 18°.

Water Bath Temperature 28 → 18		
Condition	Arterial Line Temperature	Time (s)
Foam	Cool 26.7 → 19.7	295
Rubber	Cool 26.7 → 19.7	303
Tape	Cool 26.7 → 19.7	310
Short	Cool 26.7 → 19.7	255
Long	Cool 26.7 → 19.7	303

Table 2. Temperature-adjusted mean times when cooling from 38 to 28°.

Water Bath Temperature 38 → 28		
Condition	Arterial Line Temperature	Time (s)
Foam	Cool 35.6 → 28.6	272
Rubber	Cool 35.6 → 28.6	287
Tape	Cool 35.6 → 28.6	323
Short	Cool 35.6 → 28.6	264
Long	Cool 35.6 → 28.6	392

DISCUSSION

Mycobacterium chimaera is a slow-growing bacterium belonging to the *Mycobacterium avium complex* first described in 2004 that until recently had been known primarily as a culprit for pulmonary disease in the elderly (13). *Mycobacterium chimaera* is typically found in environmental sources such as water and soil and survives by forming biofilms on the inside of water pipes and tubing, including hospital water systems (14–16). The HCU at the center of the *M. chimaera* outbreak is the LivaNova 3T (3–7). An HCU uses pumps to move water throughout the device. The 3T is unique in its design in that as the water is pumped through the device, bacteria in the water become aerosolized and pushed into the environment via an exhaust fan located inside the HCU (10–12,17). The aerosolized bacteria then move throughout the environment freely unless a barrier is installed.

The *M. chimaera* outbreak in 2015 was attributed to a point-source contamination during the production process at the 3T manufacturing site, which has since been

Table 3. Pairwise comparison of different cooling ranges.

Water Bath 28 → 18			Water Bath 38 → 28		
Condition	Time (s)	vs.	Condition	Time (s)	p Value*
Foam	295	vs.	Foam	272	**.0218**
Rubber	303	vs.	Rubber	287	.2594
Tape	310	vs.	Tape	323	.4895
Short	255	vs.	Short	264	.891
Long	303	vs.	Long	392	**<.0001**

*Tukey adjusted.
Bold values represent significant results.

Table 4. Comparison of insulation and water line lengths with cooling times when cooling from 28 to 18°.

Water Bath Temperature 28 → 18				
Arterial Line Temp. 26.7 → 19.7			Difference (s)	*p* Value*
Foam (295)	vs.	Rubber (303)	8	.9435
Foam (295)	vs.	Tape (310)	15	.3088
Short (264)	vs.	Foam (295)	**31**	**<.0001**
Foam (295)	vs.	Long (303)	8	.9109
Rubber (303)	vs.	Tape (310)	7	.9563
Short (264)	vs.	Rubber (303)	**39**	**<.0001**
Rubber (303)	vs.	Long (303)	0	1
Short (263)	vs.	Tape (310)	**47**	**<.0001**
Tape (310)	vs.	Long (303)	7	.9756
Short (264)	vs.	Long (303)	**39**	**<.0001**

*Tukey Adjusted.
Bold values represent significant results.

mitigated through a change in production procedures (18). The potential contamination during the production process was present on all 3T HCUs before September 2014, at which point, a change in process was implemented. Since September 2014, the manufacturer has offered sterile loaner HCUs and deep-cleaning programs to mitigate the infection risk. Although the risk of point-source contamination may be lower for HCUs purchased after September 2014, the United States Food and Drug Administration reported in a recent safety communication that there are reports of *M. chimaera* contamination present in HCUs manufactured after 2014 (8). Because of the design flaw and the reliance on strict cleaning duties assigned to the programs that buy the HCU, many institutions have taken steps to isolate the HCU from the operating room environment by moving the heater–cooler to a location far away from the operative field with its own exhaust system (2,9,17).

We hypothesized that the increased distance from the HCU to the cardiopulmonary bypass machine would lead to a significant reduction in the ability of the HCU to warm and cool. We also hypothesized that using insulation materials readily available at various hardware stores could reduce the decreased efficiency. For all cooling and warming conditions, we found that the short water lines cooled and warmed faster than the long water lines without insulation. Only one insulated long water line condition was as efficient as short water lines and that was foam insulation during cooling from a water bath temperature of 38 to 28°C (p = .9435). All other water line temperature conditions did not heat or cool as efficiently as the short water lines. Interestingly, none of the insulation types were able to decrease the cooling time under the water bath range 28 to 18°C compared with long uninsulated water lines, whereas all were effective at reducing the time to cool from 38 to 28°C. The difference does not appear to be that the insulation was less effective at 28–18°C, more so than the increase in circulating water volume required for long water lines exceeds the thermal capacity of the HCU when cooling from 38 to 28°C compared with 28–18°C (Table 3). The temperature in the room where the experiment was conducted remained constant at 21°C. So, in theory, the time it takes the uninsulated water lines to cool should be quicker at a warmer water line temperature given the larger gradient between water temperatures inside the lines vs. environmental temperature, but this did not occur and requires further investigation. When looking at the difference between cooling times for foam insulation, this could be partially explained by the variance in insulating capabilities seen at different temperatures for polyethylene foam (19).

Table 5. Comparison of insulation and water line lengths with cooling times when cooling from 38 to 28°.

Water Bath Temperature 38 → 28				
Arterial Line Temp. 35.6 → 28.6			Difference (s)	*p* Value*
Foam (272)	vs.	Rubber (287)	15	.2834
Foam (272)	vs.	Tape (323)	**51**	**<.0001**
Foam (272)	vs.	Short (264)	8	.9435
Foam (272)	vs.	Long (392)	**120**	**<.0001**
Rubber (287)	vs.	Tape (323)	**36**	**.0002**
Short (264)	vs.	Rubber (287)	**23**	**.0245**
Rubber (287)	vs.	Long (392)	**105**	**<.0001**
Short (264)	vs.	Tape (323)	**59**	**<.0001**
Tape (323)	vs.	Long (392)	**69**	**<.0001**
Short (264)	vs.	Long (392)	**128**	**<.0001**

*Tukey Adjusted.
Bold values represent significant results.

Table 6. Temperature-adjusted mean times when warming.

Warming		
Condition	Arterial Line Temperature	Time (s)
Foam	Warm 19.7 → 26.7/28.6 → 35.6	521
Rubber	Warm 19.7 → 26.7/28.6 → 35.6	538
Tape	Warm 19.7 → 26.7/28.6 → 35.6	532
Short	Warm 19.7 → 26.7/28.6 → 35.6	431
Long	Warm 19.7 → 26.7/28.6 → 35.6	597

Table 7. Comparison of insulation and water line lengths during warming.

Warming				
Arterial Line Temp. 19.7 → 26.7/28.6 → 35.6			Difference (s)	*p* Value*
Foam (521)	vs.	Rubber (538)	17	.8557
Foam (521)	vs.	Tape (532)	11	.9651
Foam (521)	vs.	Long (597)	**76**	**.0017**
Short (431)	vs.	Foam (521)	**90**	**.0003**
Tape (532)	vs.	Rubber (538)	6	.9968
Rubber (538)	vs.	Long (597)	**59**	**.0189**
Short (431)	vs.	Rubber (538)	**107**	**<.0001**
Short (431)	vs.	Tape (532)	**101**	**<.0001**
Tape (532)	vs.	Long (597)	**65**	**.0085**
Short (431)	vs.	Long (597)	**166**	**<.0001**

*Tukey Adjusted.
Bold values represent significant results.

During the warming experiment, the insulations were able to improve the warming time compared with long uninsulated water lines. Although not statistically compared, it should be noted that the HCU appears to cool much faster than it can warm, perhaps because of the compressor-based cooling technology for the HCU.

It should be noted that while we did not test for condensation amounts, we observed a decrease in the amount of condensation that formed on the insulated water lines compared with the uninsulated water lines during cooling conditions. It is not uncommon during clinical conditions for condensation to form on the water lines, particularly during procedures in which hypothermia is used. It is plausible that the condensation formed on the water lines could act as a conduit for bacteria to enter the operating room (OR) when the HCU is placed outside the OR.

CONCLUSION

In this study, we showed that longer water lines were less effective at cooling and warming than were shorter water lines. We also exhibited that readily available insulation could be used to help decrease the time of long water lines to warm and cool but not eliminate the inefficiency at all temperature ranges. As institutions look to improve patient infection risk by relocating the HCU far away from the cardiopulmonary bypass machine, cardiac teams should be aware that HCU inefficiency may be present that may cause delayed warming or cooling times. The authors caution applying the results of this study directly to patient care, as this experiment was conducted strictly under laboratory conditions. Further studies should include ergonomic implications of having the HCU with very long water lines so far away from the operative field and the infection risk that water line condensation may pose as a conduit for bacteria to enter the OR.

ACKNOWLEDGMENT

We thank Ms. Kaeli Samson, MA, MPH, for her statistical expertise in the design of this study.

REFERENCES

1. Weitkemper HH, Spilker A, Knobl HJ, et al. The heater-cooler unit–a conceivable source of infection. J Extra Corpor Technol. 2002;34:276–80.
2. Sax H, Bloemberg G, Hasse B, et al. Prolonged outbreak of *Mycobacterium chimaera* infection after open-chest heart surgery. Clin Infect Dis. 2015;61:67–75.
3. Balsam LB, Louie E, Hill, F, et al. *Mycobacterium chimaera* left ventricular assist device infections. J Card Surg. 2017;32:402–4.
4. Chand M, Lamagni T, Kranzer K, et al. Insidious risk of severe *Mycobacterium chimaera* infection in cardiac surgery patients. Clin Infect Dis. 2017;64:335–42.
5. Hamad R, Noly PE, Perrault LP, et al. *Mycobacterium chimaera* infection after cardiac surgery: First Canadian outbreak. Ann Thorac Surg. 2017;104:e43–5.
6. Kohler P, Kuster SP, Bloemberg G, et al. Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated *Mycobacterium chimaera* infections subsequent to open heart surgery. Eur Heart J. 2015;36:2745–53.
7. Scriven JE, Scobie A, Verlander NQ, et al. *Mycobacterium chimaera* infection following cardiac surgery in the United Kingdom: Clinical features and outcome of the first 30 cases. Clin Microbiol Infect. 2018; 24:1164–70.
8. US Food and Drug Administration. Update: Availability of Deep-Cleaning Service of Certain LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T Heater-Cooler Systems in the US: FDA Safety Communication. 2018. Available at: https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm610394.htm. Accessed June 12, 2018 [cited 2018 Jul].
9. Barker TA, Dandekar U, Fraser N, et al. Minimising the risk of *Mycobacterium chimaera* infection during cardiopulmonary bypass by the removal of heater-cooler units from the operating room. Perfusion. 2017;33:264–9.
10. Sommerstein R, Ruegg C, Kohler P, et al. Transmission of *Mycobacterium chimaera* from heater-cooler units during cardiac surgery despite an ultraclean air ventilation system. Emerg Infect Dis. 2016;22: 1008–13.
11. Stammers AH, Riley JB. The heater-cooler as a source of infection from nontuberculous mycobacteria. J Extra Corpor Technol. 2016;48: 55–9.
12. Gotting T, Klassen S, Jonas D, et al. Heater-cooler units: Contamination of crucial devices in cardiothoracic surgery. J Hosp Infect. 2016; 93:223–8.
13. Tortoli E, Rindi L, Garcia MJ, et al. Proposal to elevate the genetic variant MAC-A, included in the *Mycobacterium avium complex*, to species rank as *Mycobacterium chimaera* sp. nov. Int J Syst Evol Microbiol. 2004;54:1277–85.
14. Wallace RJ Jr, Iakhiaeva E, Williams MD, et al. Absence of *Mycobacterium intracellulare* and presence of *Mycobacterium chimaera* in household water and biofilm samples of patients in the United States with *Mycobacterium avium complex* respiratory disease. J Clin Microbiol. 2013;51:1747–52.
15. Walker J, Moore G, Collins S, et al. Microbiological problems and biofilms associated with *Mycobacterium chimaera* in heater-cooler units used for cardiopulmonary bypass. J Hosp Infect. 2017;96:209–20.
16. Kanamori H, Weber DJ, Rutala WA. Healthcare outbreaks associated with a water reservoir and infection prevention strategies. Clin Infect Dis. 2016;62:1423–35.
17. Kuehl R, Banderet F, Egli A, et al. Different types of heater-cooler units and their risk of transmission of *Mycobacterium chimaera* during open-heart surgery: Clues from device design. Infect Control Hosp Epidemiol. 2018;39:834–40.
18. Haller S, Holler C, Jacobshagen A, et al. Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: Results of an outbreak investigation in Germany, April 2015 to February 2016. Euro Surveill. 2016;28:21. doi: 10.2807/1560-7917.ES.2016.21.17.30215.
19. Abdou AA, Budaiwi IM. Comparison of thermal conductivity measurements of building insulation materials under various operating temperatures. J Buil Phys. 2005;29:171–84.