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RAPID COMMUNICATION

Efficacy of Disinfection Procedure in Air-Tight ECMOLIFE HC Heater–Cooler Unit for ECMO

Ignazio Condello[1] · Bellesia Letizia[2] · Carlo Alberto Tassi[2] · Caterina Fanelli[2] · Luca Sicignano[2] · Alessandra Pedarzini[2] · Raffaele Russo[1] · Giampaolo Buriani[3] · Giuseppe Speziale[1]

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Abstract

Water-borne opportunistic pathogens are responsible for a range of infections in immunocompromised and vulnerable patients, especially in healthcare facilities. Since 2013, over 100 cases of Mycobacterium chimaera prosthetic valve endocarditis and disseminated disease were notified in Europe and the USA, linked to contaminated heater–cooler units used during cardiac surgery. There is the potential for non-tuberculous mycobacteria bacteria to grow in the water tank in the heater–cooler unit. The purpose of this study is to clinically prove that ECMOLIFE HC heater–cooler ordinary disinfection procedure is effective in the prevention of Mycobacterium Chimaera contamination. ECMOLIFE HC heater–cooler was used on seven Extracorporeal Membrane Oxygenation (ECMO) procedures with mean duration of 154 ± 18 (hours). Seven water samples have been collected pre and post disinfection procedure. As disinfection procedure the ordinary was followed according to ECMOLIFE HC User Manual. Each sample was subjected to laboratory test for research by means of Real-Time PCR system of DNA M. Chimaera strain (extraction and quantification). During the clinical practice on seven ECMO procedures involving the use of ECMOLIFE HC, no Mycobacterium chimaera contamination was found in pre- and post-disinfection samples. The test can be considered pass as during normal clinical practice the ECMOLIFE HC resulted not contaminated by Mycobacterium Chimaera. Molecular analysis of all sampled solutions showed no detection of Mycobacterium Chimaera. According to ECMOLIFE HC User Manual, the disinfection method is proved to effectively disinfect ECMOLIFE HC.

Keywords Disinfection · Mycobacterium chimaera · ECMOLIFE HC · Heater–cooler

Introduction

Heater–cooler units play a crucial role in maintaining optimal temperatures during extracorporeal procedures, directly impacting patient safety. Effective disinfection serves as a frontline defense against potential infections that could compromise the well-being of individuals undergoing medical interventions [1]. Adhering to stringent disinfection protocols aligns with regulatory standards and guidelines. This not only ensures compliance with industry regulations but also underscores the commitment to upholding the highest standards of healthcare, fostering trust among both patients and healthcare professionals. Heater–cooler devices are susceptible to biofilm formation, creating a breeding ground for harmful microorganisms [2]. Thorough disinfection protocols are instrumental in preventing biofilm buildup, mitigating the risk of bacterial contamination and subsequent infections in patients. Infections resulting from inadequate heater–cooler disinfection can lead to extended hospital stays, additional medical treatments, and increased healthcare costs. By prioritizing effective disinfection, healthcare institutions can mitigate financial burdens associated with treating preventable infections. Controlling the spread of infections is not confined to individual patients but extends to the broader community [3]. Heater–cooler disinfection contributes significantly to public health by curbing the transmission of infectious agents, thereby minimizing the potential for healthcare-associated outbreaks [4]. Proper disinfection practices not only safeguard patients but also

✉ Ignazio Condello
ignicondello@hotmail.it

[1] Department of Cardiac Surgery, Anthea Hospital, GVM Care & Research, Via Camillo Rosalba 35/37, 70124 Bari, Italy

[2] Eurosets S.r.l., Medolla, MO, Italy

[3] WhiteLab S.r.l., Zola Predosa, BO, Italy

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contribute to the longevity and reliability of heater–cooler equipment. Regular maintenance and disinfection can enhance the lifespan of these devices, optimizing their performance and reducing the need for premature replacements [5]. Disseminating knowledge about the importance of heater–cooler disinfection is crucial among healthcare professionals. This article aims to serve as an educational resource, fostering awareness and understanding of the integral role played by disinfection in maintaining the highest standards of patient care. These points collectively underscore the multifaceted importance of heater–cooler disinfection in extracorporeal technology, emphasizing its far-reaching implications for patient safety, regulatory adherence, and overall healthcare efficacy. This article delves into the critical significance of maintaining rigorous hygiene protocol in ECMOLIFE HC heater–cooler on clinical practice during 7 Extracorporeal Membrane Oxygenation (ECMO) procedures, emphasizing the pivotal role played in safeguarding patient well-being during medical procedures [6].

Background

Water-borne opportunistic pathogens are responsible for a range of infections in immunocompromised and vulnerable patients, especially in healthcare facilities. Infections caused by rapidly growing non-tuberculous mycobacteria NTM have been reported following cardiac bypass surgery, peritoneal dialysis, and middle ear cleaning [2]. The first report of M. chimaera infections following cardiac surgery was published in 2013 [3]. A follow-up investigation by Sax et al. described a total of six M. chimaera prosthetic valve endocarditis or vascular graft infections and an epidemiological link to heater–cooler units (HCUs) used during surgery [4]. Since then, additional reports of M. chimaera infections associated with the use of HCUs have emerged reflecting the global use of these devices [5]. Microbial contamination of HCUs is widespread and is not specific to particular manufacturers or models. Such contamination implies a systemic failure of the decontamination regimen resulting in the formation of biofilms. The environmental conditions and usage of the HCU favors the growth of a wide range of micro-organisms [7]. Since 2013, over 100 cases of M. chimaera prosthetic valve endocarditis and disseminated disease were notified in Europe and the USA, linked to contaminated heater–cooler units (HCUs) used during cardiac surgery. Van Ingen et al. conducted a molecular epidemiological investigation to establish the source of these patients' disease [8]. Sax et al. hypothesized that contaminated water leaking from the circulation tubing or connectors may reach the turbulent airflow produced by fans in the lower body of the HCU [4]. Gotting et al. also attributed the aerosolization of water droplets to the operating fans; specifically, a fan located in the upper rear part of the HCU [9]. As reported in the guidelines developed by the European Association for Cardio-Thoracic Surgery (EACTS) Council, the Board of Directors of the European Association of Cardiothoracic Anaesthesiology (EACTA), and the Quality and Outcomes Committee of the European Board of cardiovascular Perfusion (EBCP), recommended preventive measures include the placement of HCUs outside of operating rooms, adherence to manufacturers' decontamination procedures, local monitoring, and international cooperation [10]:

- Validated decontamination and maintenance procedures for HCUs are recommended.
- It is recommended that HCUs be placed outside operating rooms to prevent the contaminated air from entering the operative field.

HCUs units used in ECMO, featuring air-tight design, have been investigated for evaluation of the presence of Mycobacterium in cultures from water and air samples, by Thomas et al. [11]. In this study, 3 HCUs were in use for patients undergoing veno-venous ECMO for 7–15 days for severe respiratory failure, in cardiothoracic critical care unit (CTCCU). Sampling from water and air were made to evaluate presence of Mycobacterium. Thomas et al. concluded that Mycobacteria spp. were detected in 2 of 3 ECMO water samples. However, unlike previous studies on HCUs used for cardiothoracic bypass, no aerosolization into the environment was demonstrated.

Same results were obtained by another study from Trudzinski et al. [12], where the potential exposure of patients subjected to veno-venous ECMO treatment to water-borne pathogens such as M. chimaera were investigated. Although M. chimaera was detected in nine examined water samples (half of all examined water samples), the analysis of nine room air samples from the pneumological ICU did not detect any atypical mycobacteria.

Both studies above confirms that the HCUs intended for use in ICU (ECMO) are air-tight and closed system in contrast to the HCUs used in cardiothoracic surgery and they have precluded the release of aerosol in the environment.

Based on these clinical evidence, Eurosets selected a HCU having a safe design in terms of air tightness and closed system.

In addition, Eurosets S.r.l. established validated use method and disinfection procedures for the ECMOLIFE HC heater–cooler unit, in particular

- Use of sterile water when filling the heater–cooler tank,

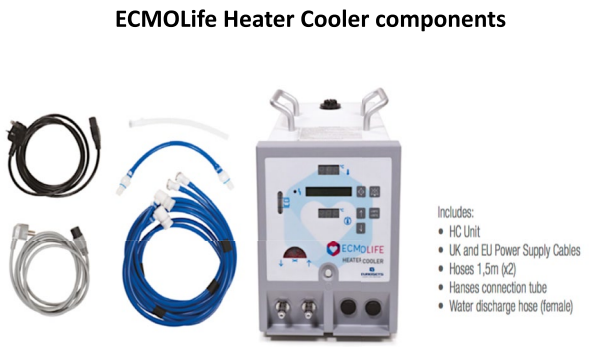

Fig. 1 ECMOLIFE HC heater–cooler components

Fig. 2 ECMOLIFE HC heater–cooler on ECMOLIFE console

- Ordinary (intermediate level) disinfection procedure of water circuit,
- Cleaning and disinfection procedure for the external surfaces,
- Periodical microbiological monitoring of water,
- Extraordinary (high level) disinfection procedure, in case Nontuberculous Mycobacteria (NTM) are found.

All these directions are clearly reported in ECMOLIFE HC User Manual.

Materials and Methods

ECMOLIFE Heater–Cooler Features

The ECMOLIFE HC heater–cooler is a system designed to facilitate patient thermo-regulation during ECMO. This innovative device is part of the ECMOLIFE portfolio and is capable of warming/cooling the patient in the range of 15–39 °C, making it suitable to respond to different clinical needs (Figs. 1 and 2). The ECMOLIFE HC heater–cooler benefits from employing a fully "closed" water circulatory system (ECMOLIFE HC water tank is air tight). "In this type of closed heater cooler, air-borne transmission of Mycobacterium chimaera is prevented. Nevertheless, Mycobacterium Chimaera ingrowth in the water tank shall be minimized by implementation of effective disinfection procedure, recommended by Manufacturer in the User Manual."

Disinfection Procedure

Disinfection procedure shall be performed in the hospital area dedicated to devices decontamination.

The disinfection protocol was defined and validated by Eurosets S.r.l., Medolla (MO), Italy.

For the disinfection of water circuit the operator shall proceed according to ECMOLIFE HC User Manual, following ordinary disinfection procedure.

The ordinary disinfection process for ECMOLIFE HC involves the following steps:

1. Emptying the unit.
2. Preparation of a 2% Chloramine-T solution.
3. Disinfection of external parts and accessories with spray disinfectant.
4. Filling the unit with Chloramine-T solution.
5. Running the ECMOLIFE HC for approximately 20 min.
6. Emptying and rinsing the unit to remove any chemical residues.

This process ensures proper disinfection of the ECMOLIFE HC after each use or at least every 7 days.

In case of atypical microbial contamination presence, extraordinary disinfection shall be performed in accordance with ECMOLIFE HC User Manual.

The extraordinary disinfection process for ECMOLIFE HC involves the following steps:

1. Emptying the unit.
2. Preparation of a 5% Chloramine-T solution.
3. Disinfection of external parts and accessories with spray disinfectant.
4. Filling the unit with Chloramine-T solution.
5. Running the ECMOLIFE HC for approximately 90 min.
6. Allowing Chloramine-T to work for 24 h in the water system.
7. Running the ECMOLIFE HC for 5 min.
8. Emptying and rinsing the unit to remove any chemical residues.

This process is necessary when atypical microbial contamination, such as Mycobacteria, is present, ensuring thorough disinfection of the ECMOLIFE HC.

After disinfection of water circuit, the operator shall proceed with cleaning and disinfection of device external surfaces according to ECMOLIFE HC User Manual.

External Cleaning and Disinfection process for ECMOLIFE HC involves the following steps:

1. Clean all accessible surfaces with the cleaning solution, focusing on critical areas.
2. Rinse if necessary and then hand dry.
3. Disinfect all surfaces using the recommended disinfecting solution, ensuring dryness before use.

Once disinfection process has been accomplished, the heater–cooler can be used for the ECMO procedure.

The unit shall be filled with water with hardness ≤ 14°dH (2.5-mmol/l CaCO3) and must be sterile or filtered with a sterile filter with pore size ≤ 0.22 µm.

Study Population and Laboratory Tests

ECMOLIFE HC was used on seven Extracorporeal Membrane Oxygenation (ECMO) procedures with mean duration of 154 ± 18 (hours). The temperature management setting in ECMOLIFE HC in the seven ECMO procedures was 36.5 (0.8 ± 0.2) °C.

Seven samples have been collected in the period from 10/06/2023 to 13/11/2023.

After collection each sample was conserved in refrigerated environment and shipped to WhiteLab S.r.l. Laboratory with a dedicated shipping kit (polystyrene heat-preserving container with blue ice) in order to avoid any bacterial deterioration or growing. Also, in WhiteLab S.r.l. Laboratory the samples were stored in a controlled refrigerated environment (2–8 °C) until processing.

Each sample consists of two sterile bags that contain 1) water collected before disinfection process (1L sterile bags) and 2) water collected after disinfection process (1L sterile bags). For the disinfection protocol, ordinary disinfection procedure, according to ECMOLIFE HC User Manual, was used.

Samples (pre- and post-disinfection) were subjected to molecular analysis for the detection of Mycobacterium Chimaera. In particular, DNA from water samples were extracted, purified, and concentrated with commercial kit. A 79-bp fragment of the SR1 region identified as highly specific for Mycobacterium Chimaera was amplified [13]; [14] in order to detect the presence or absence of the microbial target. In the amplification procedure was also performed a quantification with a reference Mycobacterium Chimaera stand for microbial quantification if detected.

Ethical Considerations and Approvals

Given the post-market nature of the study and its lack of direct patient involvement in the collection of clinical data, as well as the absence of additional risks associated, neither ethical committee approval nor ministerial authorization was required.

Results

During the clinical practice on seven ECMO procedures involving the use of the ECMOLIFE HC, no Mycobacterium chimaera contamination was found in pre-disinfection and post-disinfection samples.

Discussion

Addressing challenges in disinfecting heater–cooler devices for Mycobacterium chimaera is crucial. These devices often have intricate components and complex designs, making thorough disinfection challenging [7, 13]. Factors such as accessibility to certain areas, material compatibility, and the persistence of biofilms can hinder the complete eradication of the bacteria. Moreover, the prolonged disinfection process may impact device availability, potentially affecting timely medical procedures. Identifying and mitigating these challenges is essential for ensuring the efficacy of the disinfection procedures and preventing the risk of Mycobacterium chimaera transmission in healthcare settings [8]. Strict adherence to disinfection protocols by healthcare professionals is critical for effective prevention of Mycobacterium chimaera contamination. Inadequate disinfection directly impacts patient safety, leading to potential infections and associated complications. Our study aimed to evaluate the efficacy of a disinfection protocol implemented for the ECMOLIFE HC heater–cooler system in preventing infections among seven patients [9]. The absence of reported infections post-sanitization is a notable outcome, signaling the potential effectiveness of the applied measures. The background context emphasized the inherent risks associated with heater–cooler devices, particularly in contributing to nosocomial infections. The necessity for stringent disinfection protocols was underscored by previous incidents, setting the stage for our investigation. The implemented disinfection protocol was characterized by its meticulous nature, incorporating novel steps to ensure a comprehensive sanitization process [15]. This

approach aimed to address the unique challenges posed by the ECMOLIFE HC heater–cooler system, aligning with the broader objective of minimizing infection risks [10]. The observed absence of infections among the seven patients following the sanitization protocol is a positive outcome, highlighting the potential success of our approach. Considering the historical association between heater–cooler systems and nosocomial infections, these results suggest a promising step toward improving patient safety. Comparisons with previous studies reinforced the significance of our findings [11]. The effectiveness of our protocol in preventing infections adds to the evolving body of knowledge surrounding heater–cooler device sanitization. This aligns with a broader trend in healthcare settings emphasizing the importance of robust disinfection measures to mitigate infection risks. Acknowledging the limitations of our study, such as the small sample size, is crucial for a balanced interpretation of the results. While the outcomes are promising, further research with a larger and more diverse patient population is warranted to strengthen the generalizability and reliability of our findings. The practical implications of our study are substantial. Implementing a comprehensive disinfection protocol for the ECMOLIFE HC heater–cooler system could significantly contribute to patient safety in healthcare settings [12]. This study provides a foundation for future research, encouraging exploration into potential refinements of existing protocols and assessing the sustainability of infection prevention measures over time [16]. In conclusion, our study suggests that a meticulous disinfection protocol for the ECMOLIFE HC heater–cooler system has the potential to prevent infections in a limited patient cohort. These findings contribute to the ongoing efforts to enhance the safety of medical equipment and improve patient outcomes in healthcare environments.

Conclusion

During clinical practice, the ECMOLIFE HC resulted Mycobacterium Chimaera contamination free. Molecular analysis of all sampled solutions showed no detection of Mycobacterium Chimaera. The disinfection method of ECMOLIFE HC User Manual is effective.

Author Contributions IC analyzed the data and wrote the original draft; LB and CT supported in the research and develop; LS and AP revised the paper; RR and GB supported in data analysis; and GS supervised the research. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

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Data Availability The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest Ignazio Condello is Consultant for Eurosets SRL, Medolla, Italy. Some of the authors of this article are employees of Eurosets S.r.l., the company that manufactures the medical device described in this study. Therefore, it is important to note that the financial and professional interests of the authors may be influenced by the effectiveness and promotion of the described device. This could potentially affect the objectivity of the research and conclusions presented in this article. However, we are committed to conducting and reporting the results accurately and impartially, in line with the best scientific practices. We encourage readers to consider this conflict of interest when evaluating the information provided herein.

Ethical Approval This study was conducted according to the guidelines of the Declaration of Helsinki. The GVM Care & Research review board approved the study (internal protocol; decision 2 September 2022).

Informed Consent Informed consent was obtained from all subjects involved in the study.

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