White Paper

Mitigation of Airborne Cardiac Heater-Cooler Emissions using the HEPA-Ultraviolet Air Recirculation System (HUAIRS): A Laboratory Analysis

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ABSTRACT:

Introduction: Nearly a century of literature supports the relationship between airborne pathogen levels and healthcare-associated infection. Recently, surgical infections have been reported as a result of aerosolized nontuberculous mycobacteria (NTM) exhausted from contaminated heater-cooler units (HCUs) during cardiac surgery in multiple countries. There is currently no reliable risk mitigation strategy available for cardiac operating rooms, other than replacing the expensive HCU. This study was designed to evaluate the applicability of a new technology HEPA/Ultraviolet Air Recirculation System (HUAIRS) for use in conjunction with Stockert 3T HCU to reduce microbial aerosol emissions from the ambient air.

Materials and Methods: Laboratory air testing was performed in a modified ASHRAE 52.2 test chamber. The HUAIRS device and Stockert 3T Heater-Cooler System (3T) were positioned inside the chamber and air samples were collected under different modes of operation. The TSI laser particle counter was utilized to detect and quantify airborne emissions.

Results: Deployment of the HUAIRS device in conjunction with 3T HCU resulted in over 79% reduction in 3T HCU-generated particle emissions in a test chamber air, and 100% when the 3T HCU was exhausting directly into the HUAIRS air intake.

Conclusion: The HUAIRS system represents a potential solution for the mitigation of bioaerosol emissions in order to eliminate SSI risk due to HCU in cardiac ORs. The transmission of infection from aerosolized NTM suggests that airborne bacteria in the OR may warrant greater attention in the context of a comprehensive SSI prevention, particularly in light of recent innovation in OR air quality technology.

INTRODUCTION

Nearly a century of peer reviewed literature supports the relationship between airborne pathogen levels and healthcare associated infection (HAI). While historically most of the emphasis has been on respiratory infection such as TB and influenza, there is a growing body of evidence in support of contaminated air as a primary route of infection for non-respiratory HAIs.[1,2,3,4,5] As early as 1971, Brachman estimated that airborne transmission was responsible for 10%–20% of all endemic hospital-associated infections.[6] Over three decades ago, Lidwell and colleagues showed direct correlations between airborne bacterial counts, bacteria isolated from the surgical wounds and

prosthetic joint sepsis rates.[7,8] More recently, in a study of 53 ICU rooms in a 1500-bed teaching hospital, Munoz-Price and colleagues found a clear association between the colonization status of patients and colonization of room air with A. baumannii.9 The investigators deemed the findings alarming and concluded that an environmental infection prevention and control approach that focuses on surface decontamination will likely be unsuccessful in preventing *A. baumannii* transmission.

Studies have documented airborne transmission of a number of important healthcare-associated pathogens such as Staphylococcus aureus (including methicillin-resistant strains) [10], *A. baumannii*. [11,9] Mycobacterium tuberculosis [12,13], Pseudomonas aeruginosa[14], and *Legionella pneumophila*[15]. Environmental carriers of viable bacterial cells include dust, skin scales, fabric fibers and respiratory or mechanically-generated aerosols. Air contamination in the operating room (OR) including smoke plume, and bacteria laden airborne particles, poses substantial risks to both surgical patients and staff.[16,17,18,19,20,21,22,23] There is a growing body of evidence which correlates airborne bacteria to HAI and SSI in particular. [1,3,4,7,8,24-30]

In recent years, significant emphasis has been placed on elucidating the role of environmental sources in the spread of HAI.[31-35]However, the emphasis and investment in environmental decontamination strategies has focused primarily on hard surfaces. Air quality has received comparatively little attention.

Aerosolized pathogens present a unique array of challenges including measurement, which until recently has been both labor intensive and costly. Because air quality has not been subject to routine infection surveillance, the risk is also not well understood. As a result, air as a route of transmission of HAI has not been prioritized by healthcare providers or health quality standards-setting organizations. Unlike many countries in Europe, which place limitations on airborne colony forming units (CFUs) based on unit-related risk, there are currently no standards or guidelines in the US that make similar recommendations.

In 2016, the most compelling epidemiological evidence of airborne transmission, to date, surfaced with the outbreak of nontuberculous mycobacteria (NTM). NTM are slow growing, difficult to detect and difficult to treat. The first patients were identified in Europe where investigators concluded there was evidence of airborne transmission of *M. chimaera* originating from contaminated heater-cooler unit water tanks used during open heart surgery.[36-38] Subsequently in the US, at least 28 NTM cases have been identified with infections reported in Pennsylvania, Iowa and Michigan. Approximately 60 percent of cases used the Stockert 3T Heater-Cooler System implicated in the outbreaks[39]. Additionally, there have been reported outbreaks associated with other HCU manufacturers and other micro-organisms with the CDC reporting more than 100,000 cardiac surgery patients have been notified of potential exposure.[41]

A primary responsibility of the Infection Prevention and Control and the Healthcare Epidemiology community is to maintain a patient safety approach that vigilantly monitors patient outcomes with the purpose of identifying emerging or previously unrecognized risks. At present, there is currently

no reliable strategy for mitigating the risk presented by contaminated heater-cooler units (HCUs) although a number of steps have been taken by institutions in an attempt to limit exposure. Options such as ventilating the exhaust away from the surgical field or outside of the operating room, rigorous maintenance and routine air and water sampling are sub-optimal at best in protecting the patient from risk of transmission. FDA has recommended replacing the units[39]. However, at the time of this writing HCUs were both costly and in short supply. There is no guarantee that new units won't become colonized with NTMs and cause future outbreaks. To this end, there is need to evaluate new technologies and the ability to remove airborne microorganisms and particulates from the active operative environment.

This study was designed to evaluate the applicability of a new technology HEPA/Ultraviolet Air Recirculation System (HUAIRS) for use in conjunction with Stockert 3T HCU to reduce microbial aerosol emissions from the ambient air.

MATERIALS AND METHODS

The HUAIRS device (AEROBIOTIX, Dayton, OH) is a novel in-room air disinfection/recirculation unit. It utilizes a hybrid of biological and physical systems to remove circulating particles, smoke plume as well as inactivating bacteria, fungi and viruses in operating room air. The technology uses a reactor system which provides simultaneous physical filtration and ultraviolet (UV) irradiation of high-volume air flow (12.7 m^3/min). The reactor system utilizes germicidal C-band ultraviolet light (UV-C) focused on a reaction chamber containing clear cylindrical silicate crystals. The silicate crystals function as a solid media filter designed to slow down and trap passing airborne microorganisms ensuring complete inactivation of viable microorganisms by increasing the UV-C light exposure duration[5] (Figure 1). The HUAIRS ultraviolet chamber is completely enclosed and shielded within the device to avoid UV-C light penetration into the room environment.

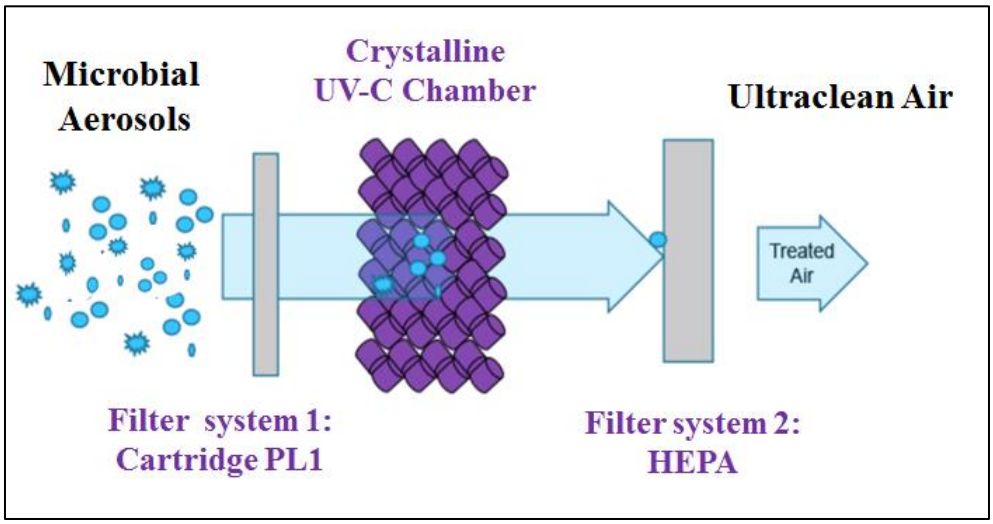

Figure 1. Mechanism of ultraviolet activation in HUAIRS system

The Stockert 3T Heater-Cooler System (3T), manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH) was utilized for testing the efficacy of the HUAIRS device. The heater cooler unit (HCU) reservoir was filled with distilled water in the absence of hydrogen peroxide or other additives. The 3T HCU was powered ON with internal fan actuated. External lines were not connected, all valves were closed.

Figure 2. Test Setup with HUAIRS (left) and Steckert 3T (right)

Air testing was performed in a modified ASHRAE 52.2 test chamber (10 m^3). The HUAIRS device and 3T HCU were placed inside the chamber (Figure 2). A TSI (Minneapolis, MN) laser particle counter was utilized to detect and quantify airborne emissions. Multiple air samplings were conducted at the 3T HCU exhaust duct, the HUAIRS exhaust duct, the HUAIRS intake, and the test chamber. The 5 micrometer (µm) size particles were evaluated as a surrogate measure for an infectious bioaerosol. Studies have shown that on average 30% of circulating air particles are bacteria laden.[3,38]

RESULTS

The deployment of 3T HCU generated significant levels of bioaerosol-sized particle emissions at its exhaust vent, with an average of 34,000 particles per m^3 (Figure 3). There were no detectable (ND) emissions from the HUAIRS device, even when the 3T HCU was exhausting directly into the unit as shown in Figure 2. The levels of air contamination in the test chamber with the 3T HCU functioning alone were 26,000 particles per m^3 (Figure 3). Particle emissions into the test chamber air were reduced to 5300 particles per m^3 after only 15 minutes, translating to a 79.6% improvement in airborne particulate content (Student's t-test $p=0.006$) (Table 1).

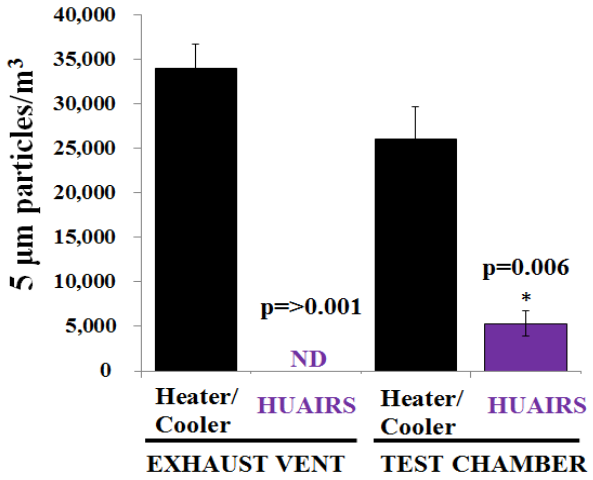

Table 1: Reduction in HCU contamination at HUAIRS exhaust vent and ambient test chamber.

CONCLUSION

HUAIRS technology warrants additional study as a potential means of mitigating the risk of airborne transmission from the Stockert 3T HCUs still in use. Further study may also shed additional light on the opportunity to reduce overall levels of airborne contamination and the impact on SSI at large.

DISCUSSION

While the relative contribution of air to HAI is subject to debate, the heater-cooler outbreaks which involved a unique organism traceable to contaminated OR air, brings greater focus to a broader, as yet unresolved patient safety issue.[28] Ongoing efforts to eliminate preventable SSI, and HAI more broadly, would benefit from future study of the impact of air quality on pathogen transmission and the role that HUAIRS and other technologies can play in mitigating this risk.

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