Novel Negative Pressure Helmet Reduces Aerosolized Particles in a Simulated Prehospital Setting

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Abstract

Background/Objective: The coronavirus disease 2019 (COVID-19) pandemic has created challenges in maintaining the safety of prehospital providers caring for patients. Reports have shown increased rates of Emergency Medical Services (EMS) provider infection with COVID-19 after patient care exposure, especially while utilizing aerosol-generating procedures (AGPs). Given the increased risk and rising call volumes for AGP-necessitating complaints, development of novel devices for the protection of EMS clinicians is of great importance.

Drawn from the concept of the powered air purifying respirator (PAPR), the AerosolVE helmet creates a personal negative pressure space to contain aerosolized infectious particles produced by patients, making the cabin of an EMS vehicle safer for providers. The helmet was developed initially for use in hospitals and could be of significant use in the prehospital setting. The objective of this study was to determine the efficacy and safety of the helmet in mitigating simulated infectious particle spread in varied EMS transport platforms during AGP utilization.

Methods: Fifteen healthy volunteers were enrolled and distributed amongst three EMS vehicles: a ground ambulance, a medical helicopter, and a medical jet. Sodium chloride particles were used to simulate infectious particles, and particle counts were obtained in numerous locations close to the helmet and around the patient compartment. Counts near the helmet were compared to ambient air with and without use of AGPs (non-rebreather mask [NRB], continuous positive airway pressure mask [CPAP], and high-flow nasal cannula [HFNC]).

Results: Without the helmet fan on, the particle generator alone and with all AGPs produced particle counts inside the helmet significantly higher than ambient particle counts. With the fan on, there was no significant difference in particle counts around the helmet compared to baseline ambient particle counts. Particle counts at the filter exit averaged less than one despite markedly higher particle counts inside the helmet.

Conflicts of interest/funding: Kevin Ward has intellectual property regarding the AerosolVE Helmet through the University of Michigan which has been licensed to Inspire Rx LLC. Kevin Ward, Ben Bassin, and Nathan Haas have equity in Inspire Rx LLC. Ben Bassin is the Chief Medical Officer for Inspire Rx LLC. The remaining authors have no competing interests.

Keywords: aerosol; COVID-19; helmet; mitigation; prehospital

Abbreviations:
AGP: aerosol-generating procedure
COVID-19: coronavirus disease 2019
CPAP: continuous positive airway pressure
EMS: Emergency Medical Services
HEPA: high efficiency particulate air filter

HFNC: high-flow nasal cannula
HHFNC: heated high-flow nasal cannula
HVAC: heat, ventilation, air conditioning
NRB: non-rebreather mask
O2: oxygen
PAPR: powered air purifying respirator
PPE: personal protective equipment

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Conclusion: Given the risk to EMS providers by communicable respiratory diseases, development of devices to improve safety while still enabling use of respiratory therapies is of paramount importance. The AerosolVE helmet demonstrated efficacy in creating a negative pressure environment and provided significant filtration of simulated respiratory droplets, thus making the confined space of transport vehicles potentially safer for EMS personnel.


Introduction
The coronavirus disease 2019 (COVID-19) pandemic has created challenges in maintaining the safety of Emergency Medical Services (EMS) providers while also allowing the provision of maximally aggressive respiratory therapies for patient care. Many patients transported by EMS require respiratory therapies, including nebulized medications, continuous positive airway pressure (CPAP) non-invasive ventilation, or heated high-flow nasal cannula oxygen therapy (HHFNC). These treatments are considered aerosol-generating procedures (AGPs) and thus have the potential to increase spread of infectious viral agents, such as COVID-19.1,2

Use of such therapies places EMS providers at particular risk given the small physical confines of an ambulance or helicopter and lack of ventilation systems designed to mitigate aerosolization of infectious agents. Consequently, many EMS agencies have limited the use of these AGPs despite the potential patient benefit.

Prior data indicate EMS providers can be actively infected during transport of COVID-19 patients. At the start of the pandemic in New York City (New York USA), there was a significant increase in 9-1-1 calls for respiratory complaints, cardiovascular complaints, and cardiopulmonary arrest. There was also an increase in high-acuity life-threatening calls resulting in increased exposure of EMS staff to aerosolizing procedures and augmented risk of contracting COVID-19.3 Data from King County, Washington (USA) demonstrated that 16.3% (182 of 1,115) of encounters for COVID-19 had one or more aerosolizing procedures performed by EMS. Incidence of COVID-19 in EMS personnel during that period was 0.57 infections/10,000 person-days.4 Out of 274 EMS encounters with COVID-19 confirmed patients, there were 151 person-exposures among 129 EMS providers, resulting in 981 quarantine days with a 0.4% positive test rate.5 Additionally, early in the pandemic testing of 3,326 first responders in Arizona (USA), 1.5% tested positive for COVID-19.6

Heinzinger, et al found that 67% of medical personnel who assisted COVID-19-infected patients undergoing nebulization developed infection themselves. The authors noted that since the virus has spread within the hospital environment, it should be assumed that chances of getting infected are significantly higher in the limited space of an ambulance.7 The increasing exposure to respiratory complaints in the EMS field necessitates updated personal protective equipment (PPE) to minimize prehospital exposures, especially during AGPs. The risk of COVID-19 infection and/or mandatory quarantine following a significant exposure can be mitigated by improving prehospital PPE.

During the COVID-19 pandemic, the University of Michigan Department of Emergency Medicine (Ann Arbor, Michigan USA), Michigan Center for Integrative Research in Critical Care (M-CIRCC; Ann Arbor, Michigan USA), and the College of Engineering (Ann Arbor, Michigan USA) collaborated with a local manufacturing company to develop a device capable of mitigating these risks. The device (AerosolVE Helmet; Inspire Rx LLC; Ann Arbor, Michigan USA) consists of a helmet equipped with an air purifying filter, based on the common powered air purifying respirator (PAPR), but is uniquely re-engineered to reverse air flow. This design allows room air to be pulled into the helmet which is then passed through a high efficiency particulate air (HEPA) filter before being released back into the ambient environment (Figure 1). This creates a negative pressure environment within the helmet, thus infectious particles produced and aerosolized by the patient and/or any AGP are contained within the helmet and filtered before release into ambient air. The device is designed to be able to accommodate use of HHFNC, CPAP/BiPAP, and nebulized aerosol therapies. The secured face shield can be opened for emergency access to the patient’s face. The lower portion (bib) of the helmet is loosely fitted to allow large volumes of room air to be pulled through the helmet and to allow provider and patient access to the patient’s face by the patient or provider without having to open the face shield. The HEPA filter is integral to the motor (fan) and is designed to pull air through the helmet at 220 liters/minute. When compared to current recommendations for hospital negative pressure rooms of at least 12 air exchanges per hour,8 the helmet produces 840 air exchanges per hour, or 70-times more air exchanges than current hospital room recommendations. The helmet, shroud, and hose are designed to be disposable. The motor and filter are designed to be reusable with filter life of 12 months or until the filter alarm activates. An alarm exists to detect when flow decreases to 170 liters/minute.

The helmet and a similar negative pressure tent were initially developed for use in hospitals. Previous publications have demonstrated their efficacy in reducing air particle counts, likely improving the safety of providers caring for patients with communicable respiratory illnesses.9–12

The prehospital transport environment varies significantly from a hospital room, and environments between transport vehicle platforms (ie, jet versus helicopter versus ground ambulance) are also not equivocal. Thus, testing the device in each different transport platform is integral to ensure efficacy and safety.

The objective of this study was to test the effects of the negative pressure helmet device on air particle counts in healthy volunteers undergoing a variety of AGPs in simulated prehospital settings. It is hypothesized the AerosolVE helmet would prevent increases in air particle counts in the ambient cabin air.

Methods
This was an open-label study of the efficacy of the AerosolVE helmet and filtration system. Fifteen healthy volunteers were enrolled, twelve men and three women, and were distributed amongst three transport platforms: a Learjet 75 configured for medical transport, a Eurocopter EC155 medical helicopter, and a Ford E450 modular ambulance. While not a requirement, all volunteers had been fully vaccinated for COVID-19 prior to participation. Each participant was screened for signs and symptoms of COVID-19 or other respiratory illness prior to enrollment. Sodium chloride particles, generated by a TSI 8026 particle generator (TSI Inc; Shoreview, Minnesota USA), were emitted near the subjects’ mouths to
Figure 1. AerosolVE Helmet.
Note: The AerosolVE helmet is a negative pressure device modeled after a PAPR. The clear face shield (A) allows for good visibility and can be opened by the red tab (B) for immediate access to the patient’s face. The filter and motor (E) can be held or worn by a belt. Abbreviation: PAPR, powered air purifying respirator.

Figure 2. EMS Transport Platforms.
include the size of the COVID-19 virus (0.1 μm) which would cause small shifts in particle counts at that location (eg, participants breathing in particles resulting in a momentary reduction in counts inside the helmet). Primary outcome was the difference in ambient particle counts and counts close to the helmet compared to counts inside the helmet with the filter motor on.

### Results

ANOVA was used to compare the primary outcome (particle count inside helmet with filter on) to particle count in the ambient air and particle count near the helmet. The particle generator alone and all AGPs produced particle counts. With the helmet fan on, particle counts near the helmet significantly higher than ambient particle counts. Without the use of the O2 delivery device, there was no significant difference in ambient particle counts. The participant had to briefly remove the helmet for each change of O2 delivery device. At each testing location, ten particle counts were obtained and the mean recorded. This was to account for respiratory variation and other environmental factors that may cause small shifts in particle counts at that location (eg, participants breathing in particles resulting in a momentary reduction in counts inside the helmet).

### Statistical Analysis

Data are presented as mean (standard deviation). One way ANOVA was used to compare the primary outcome (particle count inside helmet with filter on) to particle count in the ambient air and the environment close to the helmet. Statistical significance was considered as α=0.05. All data were analyzed using PRISM 9 (GraphPad Software; San Diego, California USA).

### Results

Table 1 and Figure 3 present the mean air particle counts with and without the use of each O2 delivery device. Without the helmet fan on, the particle generator alone and all AGPs produced particle counts inside the helmet significantly higher than ambient particle counts. With the helmet fan on, particle counts near the helmet showed no significant elevation compared to baseline ambient particle counts during the use of the particle generator alone or with use of any of the AGPs. Additionally, particle counts were significantly lower in the helmet while the motor was on compared to when the motor was off for each O2 delivery device. Table 2 demonstrates that particle counts taken at the fan exit (post-HEPA filter) were reduced to nearly zero compared to counts inside the helmet. Interestingly, with the face shield up (which could be necessary for emergent access), there was no significant difference in

### Abbreviations


### Table 1. Mean (SD) Particle Counts for Each Transport Platform and AGP

<table>
<thead>
<tr>
<th>Transport Platform</th>
<th>Ambient</th>
<th>Close to Helmet</th>
<th>Inside Helmet Motor On</th>
<th>Inside Helmet Motor Off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>4057 (3581)</td>
<td>4063 (2961)</td>
<td>5529 (2805)</td>
<td>–</td>
</tr>
<tr>
<td>NRB</td>
<td>4058 (3671)</td>
<td>3222 (2726)</td>
<td>4485 (3999)</td>
<td>115369 (2974)</td>
</tr>
<tr>
<td>CPAP</td>
<td>3567 (2846)</td>
<td>3616 (3204)</td>
<td>5554 (5820)</td>
<td>75862 (22350)</td>
</tr>
<tr>
<td>HFNC</td>
<td>3755 (3057)</td>
<td>3636 (3387)</td>
<td>4653 (2113)</td>
<td>85270 (30332)</td>
</tr>
<tr>
<td><strong>Helicopter</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6548 (4313)</td>
<td>6495 (3985)</td>
<td>11258 (12483)</td>
<td>–</td>
</tr>
<tr>
<td>NRB</td>
<td>5419 (3101)</td>
<td>4579 (2220)</td>
<td>17880 (23266)</td>
<td>142670 (20558)</td>
</tr>
<tr>
<td>CPAP</td>
<td>5939 (3338)</td>
<td>6072 (2786)</td>
<td>13138 (13424)</td>
<td>101466 (41164)</td>
</tr>
<tr>
<td>HFNC</td>
<td>5666 (3087)</td>
<td>5736 (2798)</td>
<td>18247 (16798)</td>
<td>164699 (16970)</td>
</tr>
<tr>
<td><strong>Jet</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1522 (1312)</td>
<td>1726 (1009)</td>
<td>25118 (20242)</td>
<td>–</td>
</tr>
<tr>
<td>NRB</td>
<td>1452 (968)</td>
<td>1927 (921)</td>
<td>23346 (26248)</td>
<td>144469 (25178)</td>
</tr>
<tr>
<td>CPAP</td>
<td>1535 (852)</td>
<td>1679 (693)</td>
<td>5666 (8599)</td>
<td>117833 (42340)</td>
</tr>
<tr>
<td>HFNC</td>
<td>1517 (824)</td>
<td>1976 (1200)</td>
<td>9931 (10969)</td>
<td>117494 (40309)</td>
</tr>
</tbody>
</table>

Note: Mean (standard deviation) particle counts for each transport platform and each AGP tested around the cabin, close to the helmet, inside the helmet with the motor on and off.

Abbreviations: AGP, aerosol-generating procedure; NRB, non-rebreather mask; CPAP, continuous positive airway pressure; HFNC, high-flow nasal cannula.

Dens denotes significant difference between “Inside Helmet Motor off” and “Ambient” (P<.0001).

b Denotes significant difference between “Inside Helmet Motor off” and “Close to Helmet” (P<.0001).

c Denotes significant difference between “Inside Helmet Motor off” and “Inside Helmet Motor on” (P<.0001).
counts was observed in most settings, indicating that the powerful
the face shield open, no significant change in ambient particle
indicating excellent filtration efficiency. Additionally, even with
table counts at the filter exit with an average of 0.75 particles
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to the patient attendant(s). Interestingly, a gradual decline in the
released into the patient compartment and thus may reduce risks
to the patient in the absence of the helmet device. The particle count in the helmet during the AGP without
the ambient particle counts near the helmet nor in the cabin. This
The results of this analysis demonstrated no significant increase in
compartment. These results show this device not only filters air but
also effectively contains simulated infectious particles, preventing
disbursement and potentially reducing risk to providers during
AGPs.

The testing protocol specifically excluded the use of a nebulizer,
a common respiratory care device used in the treatment of respira-
tory distress in the prehospital setting. Previous testing had shown
similar generation of aerosolized particles from the particle gener-
ator and the nebulizer. The authors chose to use only the generator
for simplicity. They also chose not to test participants in various
transport positions. Given the dynamics of the AerosolVE device
(i.e., pulling environmental air into the helmet), any increase in gaps
under the shroud would allow more air flow and would likely
improve the air exchange; thus, various positions would be unlikely
to have a significant negative impact on results. Lastly, the authors
elected not to modulate the air flow (i.e., heat, ventilation, air con-
ditioning [HVAC]) in the patient compartment of the ambulance
as they wanted to specifically test the device in a “worst-case sce-
ario” (no air exchange present). Any HVAC use would only serve
to improve the ambient air quality. In addition, for the helicopter
and jet, the authors would not have been able to test the device with
HVAC running as this requires the aircraft to be running. The
baseline ambient particle counts, as a result from dust or exhaust,
were too high to measure any difference generated by the particle
generator.

Despite the protracted nature of the current COVID-19 pan-
demic, there are no negative pressure or containment technologies
approved for prehospital patient transport use. While a number of
negative pressure/isolation “tents” have gained Emergency Use
Authorization (EUA) for use within hospitals, none to the authors’
knowledge are approved for prehospital use. Furthermore, some of
these rely on regular hospital wall suction to produce a negative
pressure within the tent. The efficacy of this level of negative pres-
sure and flow to reduce AGP increases in ambient particle counts
back to baseline has not been reported.

Due to the risk of contamination, many EMS systems have
reduced their transport of patients with known or highly suspected
COVID-19 infections or modified protocols to reduce risk to pro-
viders (e.g., using supraglottic airways rather than oral endotracheal
intubation, metered-dose inhalers rather than nebulizer treat-
ment). While the ability was tested of the AerosolVE Helmet to
reduce AGP particle counts to baseline, the device can likely
Figure 3. Mean Particle Counts by Platform and AGP.
Note: Mean particle counts by EMS transport platform and by AGP. Scale differs by platform.
Abbreviations: AGP, aerosol-generating procedure; EMS, Emergency Medical Services; NRB, non-rebreather mask; CPAP, con-
tinuous positive airway pressure; HFNC, high-flow nasal cannula.

Table 2. Mean Particle Counts at Filter Exit
Note: Mean particle counts (95% confidence interval) at the filter exit
to the patient compartment with the filter motor and the particle gen-
erator on.
Abbreviations: O2, oxygen; NRB, non-rebreather mask; CPAP, con-
tinuous positive airway pressure; HFNC, high-flow nasal cannula.

<table>
<thead>
<tr>
<th>O2 Device</th>
<th>Ambulance</th>
<th>Helicopter</th>
<th>Jet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.6 (0.41, 0.87)</td>
<td>0.8 (0.46, 1.1)</td>
<td>0.8 (0.42, 1.14)</td>
</tr>
<tr>
<td>NRB</td>
<td>0.6 (0.31, 0.89)</td>
<td>0.7 (0.35, 0.77)</td>
<td>1.4 (-0.54, 3.3)</td>
</tr>
<tr>
<td>CPAP</td>
<td>0.6 (0.28, 1)</td>
<td>0.7 (0.54, 0.9)</td>
<td>0.9 (0.47, 1.25)</td>
</tr>
<tr>
<td>HFNC</td>
<td>0.6 (0.19, 1.05)</td>
<td>0.8 (0.44, 1.16)</td>
<td>0.6 (0.48, 0.72)</td>
</tr>
</tbody>
</table>
provide benefit during transport of any patient with unknown COVID-19 status, regardless of symptoms, as a means to reduce EMS provider exposure and allow for maximal patient therapy. It could also allow transport of multiple infected patients without increasing the risks of infection to EMS providers.

Similar challenges exist in the transport of military patients with COVID-19 as have been described in the civilian EMS sector, and the likelihood of a multiple-patient transport environment is higher in the military sector. Negative pressure transport conbes have been designed to transport multiple infected individuals. Use of devices like the helmet described in this report may offer additional options.

Limitations
This study was conducted on healthy volunteers who were breth-
ing normally (not coughing) with simulated infectious droplets dis-
persed within the helmet. As this study was to determine efficacy of the device’s ability to prevent increases in cabin particle counts and particle counts near the subject in the EMS transport environment, it utilized a small convenience sample of volunteers rather than a large population. Given the efficiency of the device in its ability to filter particles, it is unlikely that additional test participants would have made a significant difference in the results obtained. Future studies will be required examining the device and particle counts with real patients being transported and undergoing AGPs.

As mentioned above, testing was not possible in the helicopter or jet with HVAC cabin air modulation due to high levels of environmental particles with the aircraft running. It is believed this creates a “worst-case scenario” in that no cabin air is exchanged, however, it is difficult to say with certainty how HVAC would have impacted results.

There were no reported or observed safety events during the use of the AerosolVE helmet. Although the study originally intended to deliver CPAP pressure at 10cm of water and HFNC flow at 60L/minute, due to participant discomfort, these were reduced to 5cm of water and 30L/minute, respectively.

Conclusion
Given the risk posed to prehospital medical providers by communicable respiratory diseases, development of novel devices to improve safety for these caretakers while still enabling use of respiratory therapies is of paramount importance. This holds true not only in the setting of a pandemic, but also during traditional “respiratory virus season” when a healthy workforce is critical to the function of the prehospital system. The AerosolVE Helmet demonstrated efficacy in creating a negative pressure environment around simulated patients and provided significant filtration of simulated respiratory droplets, thus making the confined space of various EMS transport vehicle types potentially safer for EMS personnel.

References