Research Article: Clinical Case Study

The prehospital use of a novel portable negative-pressure scavenger during nebulizer administration in status asthmaticus: a case study

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Abstract:

Introduction: The COVID -19 pandemic has generated significant concern for the transmission of the SARS-CoV-2 virus to health-care personnel conducting aerosol generating procedures. Nebulizer use is one of many aerosol generating procedures that carry a high risk of exposing health-care personnel to airborne infectious particles from patients under investigation for COVID-19. For this reason, the use of nebulizer treatments in routine emergency care for asthma, copd, and other conditions, has been discouraged by regulatory bodies, and in some cases, curtailed or eliminated altogether by many pre-hospital and hospital organizations. These restrictions can delay life-saving treatments, and impose more costly and invasive treatment options.

Background: The SARS-CoV-2 virus that is responsible for COVID-19 is highly infectious and pathogenic with limited prophylactic or therapeutic countermeasures available. COVID-19 can be contracted via the aerosol route, a feature it shares with other dangerous biowarfare diseases such as TB, Tularemia, The Plague, and others. COVID-19 has caused 3.5 million deaths thus far worldwide. The very first HCW to become infected in the United States conducted nebulizer treatments on the very first index patient in the US. Significant concern has arisen for the occupational and nosocomial transmission of the virus to healthcare workers (HCW) conducting aerosol generating procedures (AGP's). Nebulizers can aerosolize the virus and other microbes and increase risk of infection to HCW's over 10 fold. Current recommendations for performing AGP's, such as nebulizers, include the use of a negative pressure environment coupled with HEPA or ULPA filtration.

Case Report: This report details the successful use of a novel portable negative-pressure scavenger featuring ultra-low particulate air filtration. The scavenger device enabled pre-hospital Paramedics, who were previously restricted, the use of a nebulizer treatment in a patient with Status Asthmaticus.

Discussion: The use of an ULPA filtered, novel portable negative-pressure scavenger device may enable Pre-hospital and emergency department personnel to reduce their exposure to exhaled aerosolized infectious particulate. Such devices may offer an additional layer of protection in addition to personal protective equipment. The use of a portable negative pressure "room" may enable earlier intervention of obstructive airway conditions, such as asthma or COPD, thus reducing morbidities associated with delayed or more invasive intervention, such as

intubation. A filtered scavenging device has further reaching implications in the use with other aerosol generating procedures such as positive pressure non-invasive ventilation, Bag Valve Mask ventilation, and endotracheal intubation.

Keywords: Portable, Negative pressure, Nebulizer, Aerosol Generating Procedure

Introduction: As Healthcare Workers (HCW) go about taking care of sick patients, they are exposed to multiple dangerous infectious diseases on a continual basis. One study estimated that 75% of all HCW are exposed to an infectious disease on a weekly basis {1}. Despite the use of personal protective equipment and safety procedures the HCW has a disproportionate risk of becoming sick. Healthcare workers account for 1 in 7 coronavirus cases globally, despite only representing less than 3% of the population {2}. Front-line HCW have 3 times the risk of COVID-19 infection when compared to the general community and 7 times more likely to have severe COVID-19 {3,4}. In addition, a HCW that becomes infected can then trigger a super-spreader event. Such was the case when a Chinese physician was identified as the source of the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak in Hong Kong and several other countries {5}. Some activities that HCW's engage in while caring for patients carry a much higher risk of the transmission of infectious diseases. One such high-risk activity that is performed routinely by front-line HCW's is that of Aerosol Generating Procedures (AGP's).

Background: The SARS- CoV-2 virus that is responsible for COVID-19 is a high risk pathogen if inhaled or comes in contact with mucous membranes. It is highly infectious and pathogenic with limited prophylactic or therapeutic countermeasures available. The Centers for Disease Control and Prevention (CDC) has classified the SARS- Co-2 virus as a Biosafety level 3 pathogen (BSL-3). BSL-3 precautions are appropriate for work involving microbes which can cause serious and potentially lethal disease via the inhalation route {6}. In order to work with BSL-3 pathogens, a negative pressure environment and HEPA filtration is required. Examples of BSL-3 agents that have also been researched and developed as biowarfare agents include, *Francisella Tularensis* (Tularemia), *Mycobacterium Tuberculosis* (TB), *Yersinia Pestis* (the Plague), *Venezuelan and Eastern Equine encephalitis virus,* and more {7}. Other examples of BSL-3 microbes are SARS-CoV-2's cousins, MERS and SARS-Cov-1, both of which caused their own respective pandemics. Tuberculosis continues to kill over a million people per year {8}. The Plague, caused by *Yersinia Pestis*, has caused an estimated 50 million deaths worldwide {9}. Thus far, SARS-CoV-2 has caused 3.5 million deaths as of May 29, 2021 {10}. These pathogens all have one thing in common - they are all transmitted via the aerosol route.

The COVID -19 pandemic has generated significant concern for the occupational and nosocomial transmission of the SARS CoV-2 virus to health-care personnel conducting aerosol generating procedures. A study published in 2012 highlighted the risk of transmission of SARS to HCW's who performed AGP's {11}. Such procedures include nebulizer use, endotracheal intubation, positive pressure mask ventilation, and non-invasive positive pressure ventilation, among others {12}. Aerosol generating procedures produce both large droplet (>5um) and smaller aerosols (<5um). Droplets fall to the ground or onto surfaces within close proximity of the patient (1-2m), while smaller aerosols can remain suspended in the air for longer periods

and can travel further (7-8m) from the patient {13,14}. Viable SARS CoV-2 virus has been detected in aerosols for 3 hours and on surfaces for 72 hours {15,16}. In addition to aerosols, contact with inanimate objects has led to infection amongst HCW's {17,18}. The doffing of personal protective equipment (PPE) can lead to the widespread transfer of contaminants to the skin and clothing of HCW's leading to self-contamination, making the current CDC PPE removal sequence inadequate in protecting the HCW from nosocomial infections {19}.

Nebulizers use compressed air or oxygen forced through a reservoir to aerosolize medications. This aerosolized medication is then inhaled deeply into the patient's lungs. They are used for a variety of respiratory conditions where the small airways and terminal alveoli are the target sites of the medication. Such common conditions where nebulizers are used include asthma, chronic obstructive pulmonary disease, and airway inflammation. Common medications utilized in the nebulizer include albuterol sulfate, ipratropium bromide, epinephrine, and steroids. These are common procedures that are done several times a day in every emergency department or hospital in the world. More than 99.3% of of nebulized drug particles are < 2um in diameter and create a particle plume that is 400 times greater than the mean background level. Particles of this size are therefore small enough to enter the lower respiratory tract {20}. Inhaled particles < 5um are most likely to cause infection in the lower respiratory tract {21}. Airborne particles < 5um convey the highest coronavirus RNA titres {22}. Nebulizers and other AGP's convey a significant risk of transmission of disease to the HCP {23-26}. Until recently it was believed that endotracheal intubation carried the highest risk of infection transmission of all AGP's ,at a nearly 700% increase. In a recent meta-analysis, nebulizers yielded a 1000% increase in infection risk to HCW's. (OR 10.03; 95% CI, 1.98-50.69; p= 0.005) {26}. The very first confirmed COVID-19 case in the United States resulted in the exposure of 121 HCW's who were not wearing full PPE. The CDC concluded in a review of that index patient, that being present during nebulizer treatments was more common among HCW who developed COVID-19 (67%) than those who did not (9%) (p=0.04) {25}. While the substitution of a Multiple Dose Inhaler (MDI) in place of nebulizers has been suggested as a strategy, the MDI is much more costly on a unit dose basis, has been in short supply, does not contain some of the necessary medications, and its use is limited or inappropriate for some of the most critical patients {27-31}.

Current recommendations for performing an AGP include the use of negative-pressure isolation rooms capable of 12 air changes per hour {32}. There are 2 ventilation strategies. One is the use of negative pressure rooms. Negative pressure rooms are ideal in the hospital setting but are often not available for many patients, including those in the prehospital phase of care. The second ventilation strategy is local exhaust ventilation close to the source. Capture at the point of generation is the most efficient means of capture of aerosols and reduce exposure during simulated AGP's {20,33}. The strategy of using a negative pressure vacuum scavenger equipped with a HEPA or ULPA filter has been proposed as a simple and viable solution to ameliorate or eliminate altogether the risk of virus dispersion from the therapies {29,34-36}.

Case Report: A 62 year old female with a history of asthma from out of town had left her nebulizer at home when leaving for vacation. She has been using her Albuterol metered-dose

inhaler several times throughout the day. While attending a theater event, she began having significant difficulty breathing and collapsed. While it is not clear if the patient suffered full cardiac arrest or Respiratory Arrest, nonetheless bystanders initiated CPR for less than 2 minutes. Paramedics were dispatched and found the patient to have a pulse but having extreme difficulty breathing “guppy breathing” and was not able to talk. Her Lung sounds were diminished and she was moving little air. Pulse oximetry read 63%.

Paramedics were able to sit the patient upright and begin a nebulized albuterol treatment utilizing the *SafER Respiratory Shield.* A novel portable negative pressure scavenging device that uses a clear, polycarbonate mask clipped in front of and onto a generic aerosol acorn nebulizer mask. The scavenging device shield is attached to a portable vacuum source, utilizing 22mm respiratory tubing, that filters the exhaled air and cloud plume from around the aerosol nebulizer mask via Ultra Low Particulate Air {ULPA} filtration. The Emergency Medical Service (EMS) had only recently taken delivery of the scavenger system and until then, discouraged and limited the use of nebulizers and other Aerosol Generating Procedures {AGP’s} after the COVID-19 virus presented a high risk of pathogen exposure to the EMS personnel.

The patient began to improve her work of breathing while on scene and during the nebulizer treatment. The patient was transported to the emergency department on a non-rebreather mask where she arrived sitting up on the stretcher, able to talk, and a 93% oxygen saturation. She was given 125mg of Methylprednisolone IV. A portable chest X-Ray and ECG was unremarkable. Per hospital policy, a rapid COVID test was performed prior to the administration of additional nebulizer treatments out of the same exposure concerns. The COVID test was negative. She then underwent an Albuterol Sulfate 3 mg/Ipratropium Bromide 0.5mg {Duoneb} nebulizer treatment and was observed for about 3 hours in the emergency department where she continued to improve. She was diagnosed with Status Asthmaticus and then discharged home for outpatient follow up with a prescription of 50mg Prednisone for 5 days.

Discussion: This case is an example of the conundrums that EMS and hospital emergency personnel are faced with daily in regards to their measured response of adequately safeguarding themselves, their co-workers, and their equipment from exposure to, and contamination from, aerosolized pathogens versus performing AGP’s early in the course of the disease. The decision to perform AGP’s, such as nebulizers, is often done without the benefit of knowing whether a patient has COVID-19 or some other airborne disease. The knowledge that asymptomatic COVID-19 patients can still shed virus, has led to the recommendation that every patient is assumed to be potentially infectious during this pandemic {37}. With intubated COVID-19 patients carrying a 76% mortality rate, having a safe opportunity to perform the AGP early may prevent the delay of acutely necessary care, thus preventing the escalation to more invasive options {33,38}

There have been many attempts at mitigating this exposure using homemade or commercial passive barrier shields, such as plexiglass boxes, tents, and drapes. Evidence suggested from experimental testing of these devices have shown concern for worsening the exposure to healthcare personnel,{36,39,40}, anesthesia articles, fda} leading the FDA to withdraw its Emergency Use Authorization of such devices unless they incorporated negative pressure {41}. Turer, et al study showed that various negative pressure sources, attached to

these barriers, contained test smoke and aerosol surrogate to standards required for certification of Class 1 biosafety cabinets used in laboratories {36}. In addition to added exposure risk, the FDA cautioned that many such makeshift devices can lengthen procedures such as intubation, decrease 1st pass success of procedures, potentially resulting in dangerous hypoxia or airway failure. In addition, some of the rigid boxes resulted in damage to PPE worn by the proceduralist {39, 40}.

This knowledge has led to the experimentation and development of simple systems that combine a patient “Hood” or “Shield”, connected to a portable HEPA filter via negative pressure suction. These systems have been shown to ameliorate or eliminate altogether the risk of virus dispersion from these therapies {20,29,33-35}. One such system is the SafER scavenging system, it brings the “negative pressure room” to the patient. It uses a built-for-purpose vacuum generator and has a superior filtration level when compared to HEPA filters, filtering particles down to 0.1 microns. It is ergonomically designed to fit common standard respiratory circuIts. It does not wall the patient off with full upper body enclosures, and allows immediate access to and visualization of the patient. It does not pose a risk of damaging or interfering with other PPE worn by personnel. It has additional implications in potentially reducing airborne exposure to healthcare personnel during a variety of AGP’s such as non-invasive ventilation, Bag valve mask ventilation, endotracheal intubation, bronchoscopy and other endoscopic procedures. Furthermore, it may enable earlier and less invasive intervention during acute respiratory distress and airway conditions.

The efficacy of these scavenger systems has led to the call for urgent research in order to minimize risk of Healthcare Worker infection and the nosocomial spread of disease {13}. The potential benefits of these scavenger systems doesn’t end with COVID-19, but has the high likelihood of translating to the mitigation of other dangerous aerosol and droplet pathogens such as Influenza, Tuberculosis, SARS, MERS, Enteroviruses, and more. As more emphasis is placed on prevention of the occupational or nosocomial exposures, these systems are likely to become the standard of care in delivering AGP’s such as nebulizer treatments, regardless of the infective status of the patient.

In this case, the ability to administer a nebulizer treatment relatively early in this patient’s disease course, undoubtedly contributed to a positive outcome while protecting the treating prehospital personnel. The SafER Respiratory Shield and its portable ULPA filtered vacuum source is a viable solution for containing and filtering the aerosol plume produced during nebulization while potentially adding an additional layer of PPE protection for healthcare personnel.

Disclosures: The author is the Chief Medical Officer and a shareholder of SafER Medical Products LLC.

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