Original Research

Containment of Procedure-Associated Aerosols and Droplets by a Novel, Handheld Barrier Shield, Coupled with a Portable Negative Pressure Filtration Device during Simulated Endotracheal Intubation

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Abstract:

Background: High risk diseases such as the MERS and SARS Coronaviruses and Tuberculosis can be transmitted to healthcare workers by aerosols or surface fomites generated during airway and respiratory procedures, such as endotracheal intubation. Standard personal protective equipment worn by healthcare providers may fall short of adequate protection. Endotracheal intubation has been linked to serious risk of these diseases to the healthcare worker.
Aim: To evaluate the ability of a handheld, portable, negative pressure shield (*SafER Endoshield*) to capture emitted aerosol and droplets in a simulated endotracheal intubation procedure.
Methods: Video documentation is used to evaluate the system under two scenarios. First, an airway training manikin was connected to an artificial smoke source to simulate an exhaled particle plume. The ability of the vacuum source to continuously evacuate the smoke plume from beneath the shield was observed and recorded. Second, the manikin was equipped to simulate a cough during the intubation procedure. Fluorescent artificial sputum was expelled from the manikin and observed and recorded under ultraviolet light to determine the barriers effectiveness of containing the droplets.
Results: The smoke plume is consistently contained by the shield and evacuated by the negative pressure vacuum. The fluorescent spatter is fully contained by the handheld, intubation barrier shield as recorded under ultraviolet light.
Summary: The *SafER Endoshield* and its ULPA filtered, negative pressure system is a portable, handheld, FDA compliant barrier device to be used during endotracheal intubation. The system may provide an additional layer of protection against droplets, spatter, and aerosol plume for healthcare personnel performing the intubation procedure near the head of the patient. The systems efficacy when performing other endoscopic procedures such as bronchoscopy and upper GI endoscopy should be evaluated.

Background:
Emerging high-risk diseases are those that have both a high likelihood of infection if an aerosol is inhaled or comes in contact with mucous membranes and a high case-fatality rate. These are viruses and bacteria, such as the MERS and SARS coronaviruses and multi-drug resistant Tuberculosis (TB), that are highly infectious and pathogenic, and for which limited prophylactic or therapeutic countermeasures are available {1}. There is significant evidence supporting the aerosol transmission of SARS and stronger evidence for TB {2,3,4,5}. Aerosols generated by breathing, coughing, or during certain medical procedures can produce large droplets (>20um) which fall directly to the floor or nearby surfaces, medium-sized particles (5-20um) that either fall more slowly, or remain suspended temporarily by air currents, evaporating to become droplet nuclei aerosols, or small particles (<5um) that can remain suspended in the air for hours. Particles less than 10um are more likely to be inhaled and cause infection in the lower respiratory tract {6}. Studies have shown the SARS-CoV-2 virus can survive in aerosols for greater than 3 hours {7,8,9}. The suspension of these small particles can cause infection over greater distances and increase the duration of infection risk following the generation of the respiratory aerosol. The amount and concentration of viral particles dispersed is directly correlated with the patient's severity of infection {10}. Patients requiring respiratory procedures are likely those who are the sickest and thus emitting a larger infective dose. The amount of infectious inoculum dose that might be acquired by the healthcare personnel in attendance is likely to contribute to their own severity of illness {11}.

Corona Viruses such as MERS-CoV and SARS-CoV-1 and CoV-2 have a significant association of nosocomial transmission with Aerosol Generating Procedures (AGP's), such as endotracheal intubation {12,13,14}. Aerosol Generating Procedures may create opportunities for aerosol transmission of small droplets inhaled into the lower respiratory tract and large droplets that can splash into the eyes, mouth, or upper respiratory tract {1}. Surface contamination of equipment, clothing, and fixtures also represents a significant risk of viral transmission for healthcare workers, as the virus can remain viable on surfaces for days {8,15}. Healthcare workers (HCW) are at risk of self-contamination by improperly doffing or donning Personal Protective Equipment (PPE). One study found widespread viral transfer to skin and clothing of healthcare workers from contaminated PPE, even when used correctly {16}. The infection of healthcare workers despite wearing full PPE raises questions over the efficacy of PPE.

The prevention of transmission to healthcare workers is paramount for public safety. Since the beginning of the Covid 19 pandemic, serious concerns have been raised over the exposure of healthcare personnel to infectious airborne particles produced during aerosol-generating procedures, such as endotracheal intubation. As many as 8% of hospitalized SARS-CoV-2 patients may require intubation {17}. Endotracheal intubation has been identified as one of riskiest procedures based on data from the MERS-CoV, SARS-CoV-1, and SARS-CoV-2 outbreaks where healthcare personnel participating in such procedures became ill. The procedure poses an absolute risk increase to the HCW of 10-15% {12,17,18}. Two different metanalysis have estimated the odds ratio of transmission of the MERS-CoV, SARS-CoV-1, and SARS-CoV-2, from patients to healthcare workers performing tracheal intubation at 6.6 -6.7 {12,19}. A more recent prospective study indicated that of healthcare workers participating in tracheal

intubation on suspected or confirmed Covid-19 patients, nearly 11% of those healthcare personnel became symptomatic or contracted Covid-19 within 14 days of performing the procedure {20}. The risk associated with TB infection appears to occur in clinical settings as a result of procedures that produce large quantities of aerosol, such as bronchoscopy or intubation {21}. William Firth Wells, of Harvard University, published his book *Airborne Contagion and Air Hygiene* in 1955. Wells described a method for quantifying the relative infectiousness of airborne agents. His concept of quantum of infection describes both the amount of infectious agent in a room and the infectivity of that agent. Whereas a Quanta is defined as the number of infectious droplet nuclei required to infect {22}. The quanta production rate of an average TB patient is 1.25 quanta/hour. The estimated quanta of an intubation-related outbreak that occurred in a hospital emergency department was nearly 31,000 quanta/hour. This is 5.5 times higher than any other procedure reported as a result of a nosocomial outbreak {21}. This means that the infectious dose generated during the intubation of a patient was enough to potentially infect 31,000 people per hour.

Aim:

To access the efficiency of a proprietary handheld, Ultra Low Particulate Air filtering, negative pressure barrier shield used during endotracheal intubation that produces local exhaust ventilation and filtration at the source by capturing the aerosol dispersion of simulated aerosol plume (smoke) and the containment of droplets and spatter (fluorescent artificial nasopharyngeal secretions) during a simulated cough.

Methods:

A novel hand-held, protective barrier device, that incorporates ULPA filtration with negative pressure used when performing endotracheal intubation (*SafER Endoshield and the SafER Portable Negative Pressure System*) is tested and filmed to access and document its ability to capture droplets and particles during simulated exhalation and cough.

An adult airway training manikin (unbranded) was modified by making a 1 cm opening at the anterior gastroesophageal junction using #15 scalpel. A 60 cm length of 10mm OD/7.5mm ID, clear vinyl tubing was inserted into the opening and advanced into the manikin mouth in a retrograde fashion. A 7.5mm/15mm endotracheal tube adapter was inserted into the distal end of the tubing. In the proximal end, a brass 5/16" x ¼" barb x Mip adapter is inserted. A spray tip is made by drilling three 5/64" holes into a ¼" brass Fip cap in a triangular pattern. The cap is then hand tightened onto the barb adapter. The vinyl tube is adjusted so that the proximal end of the assembly is positioned at the level of the manikin teeth.

The *Endoshield* assembly is fastened 5cm above the manikin face using a custom-made jig. A standard metal laryngoscope handle is placed thru the center laryngoscope opening. The 22mm suction hose is attached to the *Endoshield* and the SafER negative pressure vacuum unit and the unit is turned on generating 240 lpm of constant suction.

The manikin was placed on a table, in a 1152 cubic foot room, at a simulated bed height of 76cm. A flat black photographer's screen was placed in the background and the manikin was

backlit with led lighting. An apple iPad Air 2 camera (Apple, Cupertino, CA) is used to record video from the most optimal viewing angles.

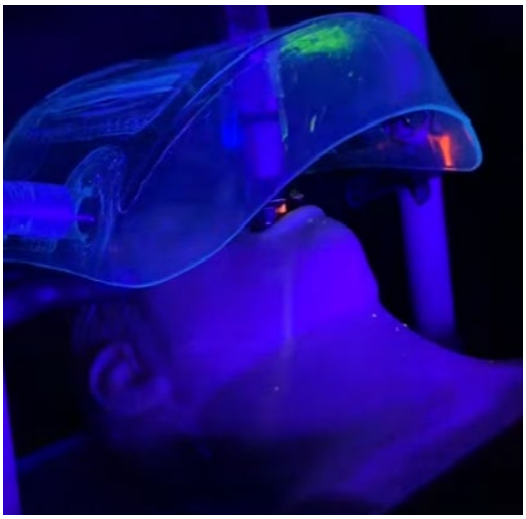
The trial is made up of two parts: First, a glycerol smoke "fog" generator is attached to the distal end of the vinyl tubing and continuous smoke is forced out through the mouth opening of the manikin in order to simulate an exhaled aerosol plume. The smoke generator is periodically boosted, sending a larger bolus of smoke thru the mouth in order to simulate coughing or sneezing or heavy breathing.

In the second part, fluorescent dye mixed with artificial sputum is used to simulate coughed droplets using an ultraviolet light source for visual enhancement. A test solution using 5 parts of artificial nasopharyngeal fluid (Biochemazone, Edmonton, Alberta) and 1 part of liquid Uranine concentrate (Cole-Parmer, Vernon Hills, Illinois) is mixed. One ml of the test solution is injecting into the vinyl tube in the posterior pharyngeal portion of the manikin. Using an adult-sized bag-valve resuscitator (unbranded), with a projected stroke volume of 1,000 ml, is attached to the distal end of the tubing. The resuscitator bag was rapidly squeezed several times by the investigator expelling the test solution. Video was recorded in slow-motion mode. This process was repeated 3 times using an additional 1 ml of test solution. Between each trial set, the *Endoshield* was cleaned with soap and water and dried.

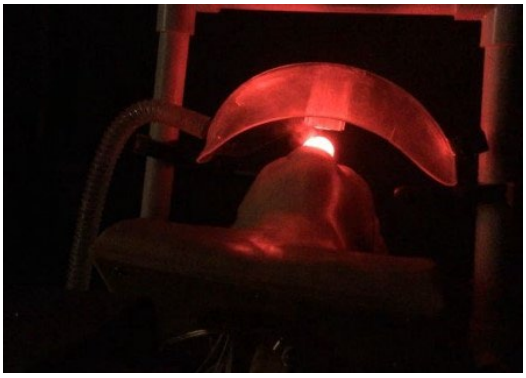
Results:

The capture of both smoke and fluorescent droplet spatter by the *SafER Endoshield* and negative pressure vacuum is observed real-time, and video footage is reviewed by the investigator. In the first phase, smoke is observed to be consistently drawn into the vacuum tubing and away from manikin face. No smoke is observed to escape outside of the *Endoshield* domain. In the second phase, fluorescent spatter is contained within the underside of the *Endoshield* barrier. Some spatter is observed to settle on the manikin face and neck beneath the shield. There is no spatter observed to escape the shield domain.

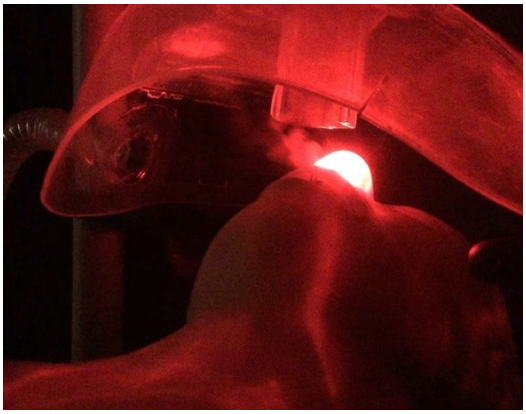
Endoshield Smoke White



Endoshield Simulated Cough Fluorescein



Endoshield Smoke Red



Endoshield Smoke Red – Close Up

Discussion:
Michael Klompas, MD, MPH, et al, in the 2021 JAMA Surgery manuscript *What is an Aerosol-Generating Procedure?* described four factors explaining the transmission risk during medical procedures. 1). Air forced over moist respiratory mucosa. 2). Degree of symptom and disease severity. 3). Distance – proximity to source. 4). Duration of exposure. "These factors explain the intubation paradox, the fact that controlled intubations generate negligible amounts of aerosols but performing the procedure has been associated with substantial risk for healthcare worker infections. Intubating a patient with viral respiratory failure forces the operator to be very close to the respiratory tract of a highly symptomatic patient, while forcing gas over the respiratory mucosa during preoxygenation or preintubation respiratory support. Higher level respiratory protection may be necessary under these conditions" {23}.

It is with little surprise that the COVID-19 pandemic has generated a great deal of concern and renewed discussion surrounding mitigating infectious exposure risk to HCW's performing Aerosol Generating Procedures. While the reduction of infection transmission can be brought about using personal protective equipment (PPE), it may not provide adequate protection from exposure to personnel performing endotracheal intubation in emergency department settings {24}. While the emphasis has been on wearing PPE, the elimination of pathogens from room air is a superior intervention according to the CDC {25}. The Centers for Disease Control have recommended that aerosol-generating procedures ideally be performed in an airborne isolation room i.e., a negative pressure room or using a local exhaust device {26,27}. The rooms are designed to prevent those airborne contaminates from escaping the room and entering adjacent hallways or work areas. Unfortunately, these rooms offer little to no protection of the personnel occupying the room and can create a false sense of security amongst the healthcare worker {28}. Isolation rooms are limited in numbers in hospitals and are usually quickly inundated with the sick during an outbreak. Maintaining proper negative pressure in isolation rooms is difficult due to leaks, windows, utilities, and design {29}. One study found 52 out of 115 "negative pressure" rooms were found to have positive airflow to the corridors {30}.

Early in the pandemic, numerous materials and devices were reimagined and fabricated in an effort to mitigate this exposure, including plastic drapes, tents, plexiglass boxes, and others. Many of these devices did not incorporate any sort of negative pressure vacuum or suction to remove and/or filter the infected patients expired air. The devices simply contained the contaminated air and when the device was removed, the HCW's were subject to the release of a large plume of aerosolized infectious particles. Even worse, the devices often redirected the contaminated air from under the box or drape into the face of the endoscopist standing above the patient {31}. Several studies published raised concern with this paradoxical phenomenon, prompting the United States FDA to withdraw emergency use authorization for such devices, unless they incorporated negative pressure suction {32,33,34}. Several attempts were made to modify these barriers enclosures using shop vacs with HEPA filtration or hospital wall suction. None of these devices have proved effective and practicable. The shop vacs were too loud, were bulky and lacked the portability needed in the prehospital and air ambulance arena. Industrial or shop vacuums are powerful and trade their air-handling ability for column lift, usually measured in inches of water. Moreover, very few of these types of vacuums have easily

replaceable HEPA filtration. Some of the barrier devices have relied on hospital wall suction as the negative pressure source. However, hospital wall suction is designed to move fluids rather than air. The standard diameter of the pipeline connecting to the wall suction outlets is ½", thus limiting the air flow capacity to around 100 liters per minute.

The tested shield, coupled with the vacuum source, produces a negative pressure environment or a local exhaust ventilation (LEV) by capturing contaminates or fumes directly at their source, thereby reducing aerosol removal time in the room to zero. The portable LEV device affords an opportunity to perform AGP's in rooms with low air exchange rates. This can expand the availability of suitable environments to include ambulances, aircraft, non-hospital environments or anywhere where an AGP might take place. The device also can be used within the isolation rooms in order to offer an additional layer of security to the HCW.

The design of the SafER portable vacuum utilized state-of-the-art computational fluid dynamic modeling to determine the optimal air-flow specifications. The vacuum delivers 260 liters per minute of negative pressure airflow at a low open pressure of 0.757 PSI. The system creates 140 air exchanges per minute, or 8,400 per hour, and utilizes Ultra Low Particulate Air Filtration (ULPA). This is juxtaposed against the typical hospital negative pressure rooms that have air exchange rates of about 12 per hour and take 35 minutes to clear 99.9% of the room. The typical standard hospital room has about 6 air exchanges per hour and can take 69 minutes to clear 99.9% of particles from the room {28}. The noise level of the system is less than 60 dB, which is the level of a normal conversation. The unit utilizes disposable ULPA filtration, which is 99.999% effective at removing submicron particulate matter of 0.12-micron diameter or larger. The diameter of the SARS CoV-2 virus is approximately 0.125 microns.

Summary:

The *SafER Endoshield* and its ULPA filtered, portable negative pressure vacuum tics off all the boxes of an effective, user friendly, FDA compliant barrier device for use during endotracheal intubation. The shield adds an additional layer of protection against droplets and spatter for the endoscopist and other personnel positioned over and near the head of the patient. The Shield is not an enclosure placed over the patient, but rather attaches to standard direct and video laryngoscope handles. This design preserves the normal mechanics and ergonomics used in standard endotracheal intubation technique. The video diary demonstrates the shield's ability to block large droplets and spatter during a simulated cough. Using smoke to simulate small aerosol particles being exhaled by the patient, the footage shows the companion vacuum's ability to suction smoke plumes away from the manikin mouth and thus preventing those aerosols and droplets from reaching the attending healthcare personnel at the bedside, and in turn reducing those professionals' exposure to potentially infectious inhaled particles. A separate study should be undertaken to quantify particle reduction and to evaluate the first-pass success rate of intubation and time required to complete the procedure using the novel negative-pressure barrier. The shield should also be evaluated for its role when performing other aerosol-generating procedures such as bronchoscopy, nasopharyngoscopy, and upper GI endoscopy.

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