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Use of a negative pressure procedural tent in the Emergency Department during the COVID-19 pandemic



Clinicians in Emergency Departments (EDs) face unprecedented and unparalleled risks during the COVID-19 pandemic [1]. Many healthcare systems continue to face challenges posed by ED overcrowding and boarding of critically ill patients due to limited inpatient capacity [2]. Aerosol generating procedures (AGPs), including non-invasive ventilation (NIV), oxygen delivery via high flow nasal cannula (HFNC), nebulized medication therapy, and endotracheal intubation, are frequently performed in EDs in patients with respiratory distress and respiratory failure. AGPs must be performed in the ED on COVID positive patients or patients with unknown COVID status due to the emergent and unplanned nature of the patient's arrival and need for resuscitative therapies. AGPs have been associated with higher rates of viral transmission to healthcare workers [3], and allocating appropriate and timely personal protective equipment (PPE) and negative pressure rooms is required to mitigate this risk. During the COVID-19 pandemic, PPE shortages exist and negative pressure rooms may be unavailable at the time an emergent AGP is required in the ED.

To help mitigate these risks, efforts have been undertaken to rapidly develop devices and extensions of traditional PPE to better protect healthcare workers. Many of these innovations have had significant limitations, including limited scope and clinical applicability (ie, "intubation boxes" suited only for endotracheal intubation), mechanical limitations (heavy, inflexible, non-disposable with risk of patient to patient transmission), risks of damaging PPE, and limited adjustability preventing wide use for differing procedures and proceduralists. In one simulation, passive enclosures failed to contain aerosols, whereas the addition of a vacuum and air filtration contributed to reduced aerosol transmission [4]. Protective barrier enclosures *without* negative pressure have appeared ineffective in decreasing healthcare worker exposure, and instead appear to possibly contribute to increased healthcare worker exposure to airborne particles, resulting in the United States Food & Drug Administration revoking an Emergency Use Authorization that had previously supported their use [5].

Initial pre-clinical testing and clinical use of a negative pressure procedural tent that mitigates the aforementioned device limitations (Fig. 1) has been previously described, demonstrating the ability to keep particle counts ($0.01 \mu\text{m}$ to $>1 \mu\text{m}$) at ambient levels during AGPs [6]. The negative pressure procedural tent was developed collaboratively across disciplines (medicine and engineering) at the University of Michigan in collaboration with industry. It was designed to allow healthcare workers separation and protection from aerosols and respiratory droplets while supporting a wide range of procedures including AGPs. Room air is pulled through the tent by a fan with air exiting the tent through a HEPA filter prior to release into the room, generating up to 600 air exchanges per hour. In contrast, only 12 air exchanges per hour are required by negative pressure rooms [7]. The canopy is

collapsible, and openings can be created at any location to facilitate procedures such as intubation and medication administration. Even with these openings, room air particle counts are not increased during AGPs [6]. The vacuum motor and plastic manifold base can be cleaned and reused, while the clear plastic canopy and ducting are single patient use and disposable. We now report on expanded clinical uses of the same device on adult ED patients.

The negative pressure procedural tent has been used at our institution on 20 consented adult ED patients under an institutional Innovative Care Protocol while seeking Emergency Use Authorization from the United States Food and Drug Administration. Of these 20 patients, the mean age was 64.9 years (range 29–96 years), nine were female, eight were COVID positive, and 12 were COVID unknown (persons under investigation) at the time of tent use. AGPs performed inside the negative pressure procedural tent included endotracheal intubations with 100% first pass success, delivery of oxygen via non-rebreather mask, NIV, HFNC, and nebulized treatments (Fig. 2). Additional interventions performed with patients inside tents included bedside ultrasound, ultrasound-guided peripheral IV insertion, blood draws, medication administration, electrocardiograms, and portable chest radiography. The tents were well tolerated by patients and received positive feedback from healthcare workers across job disciplines including physicians, nurses, respiratory therapists, radiology technicians and patient care technicians. No serious adverse events were observed, and one patient experienced mild claustrophobia that quickly resolved. The ambient noise generated by the vacuum motor was minimal and without consequence. Patients inside tents easily communicated with family members via phone and healthcare workers, and healthcare workers' communication with each other was not impaired. A detailed goals of care conversation was carried out between a patient inside a tent on NIV and a physician, demonstrating the absence of interference in patient assessment and communication.



Fig. 1. Negative pressure procedural tent with attached vacuum motor.

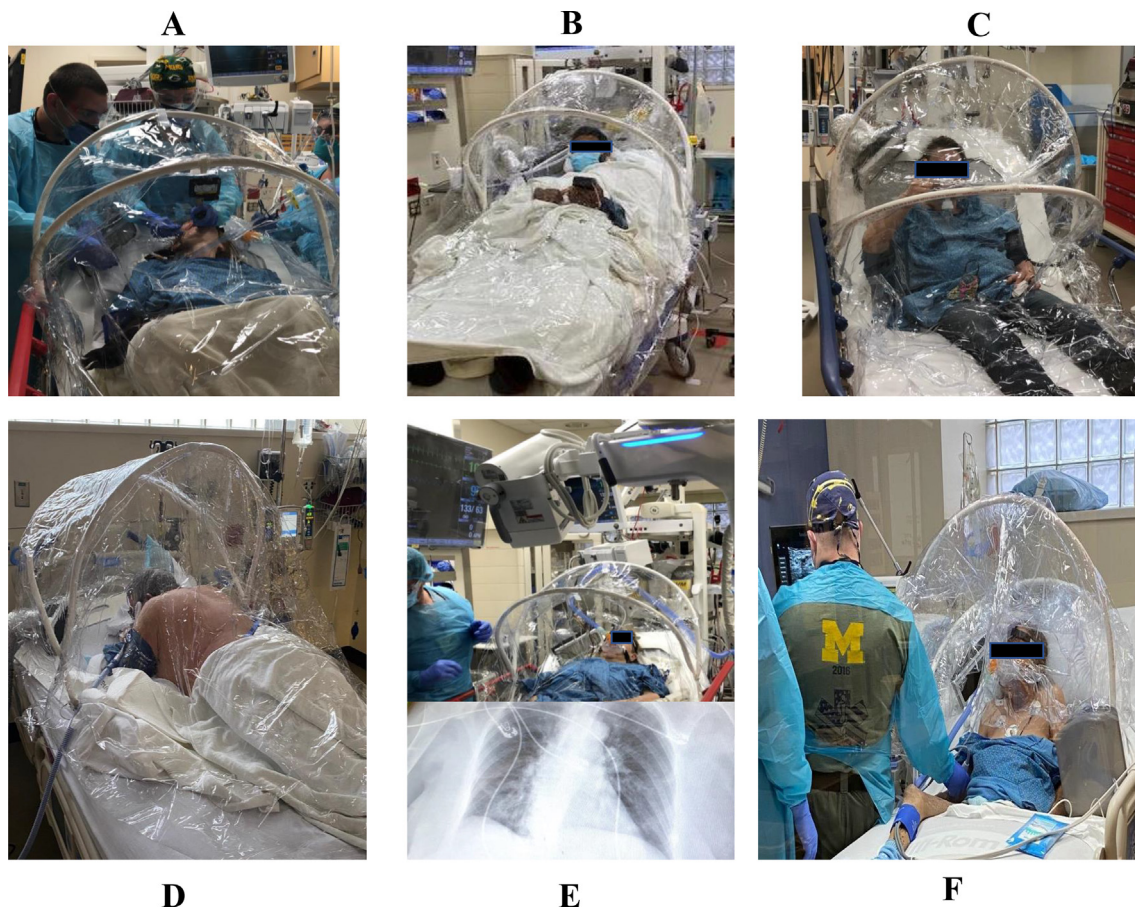


Fig. 2. Emergency Department uses of a negative pressure procedural tent. A) endotracheal intubation; B) heated high flow nasal cannula; C) nebulized treatments; D) awake prone while on heated high flow nasal cannula; E) non-invasive ventilation and portable chest radiograph taken with tent in place; F) non-invasive ventilation and ultrasound-guided peripheral IV insertion.

Use of a portable negative pressure procedural enclosure has potential to benefit patients, healthcare workers, and institutions, including those in lower resourced environments. It may allow for more liberal use of AGPs including NIV and HFNC obviating the need for mechanical ventilation in select patients, and may potentially facilitate earlier weaning from mechanical ventilation via tracheostomy [8]. It may reduce viral transmission from patient to healthcare workers, though further research is required. The inexpensive materials may help institutions, including those in resource-poor environments, create more negative pressure environments in a cost-effective manner, since building new negative pressure rooms and re-fitting existing rooms into negative pressure rooms have substantial associated costs.

Use of the portable negative pressure tent has proven successful and effective in a cohort of adult ED patients, with no serious adverse events observed. Such devices are needed during the current pandemic and beyond to protect healthcare workers and provide creative, effective solutions to the challenges facing many ED clinicians.

Declaration of Competing Interest

Drs. Haas, Bassin, and Ward have intellectual property regarding the tent device submitted through the University of Michigan and FlexSys Inc. Drs. Haas, Bassin, and Ward also report equity in the company InspireRx which is manufacturing the device. The device is currently undergoing EUA review by the FDA.

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Nathan L. Haas

Department of Emergency Medicine, University of Michigan, Ann Arbor, MI,
USA
Division of Critical Care, Department of Emergency Medicine, University of
Michigan, Ann Arbor, MI, USA
Michigan Center for Integrative Research in Critical Care, Ann Arbor, MI,
USA

*Corresponding author at: Michigan Medicine, Department of
Emergency Medicine, Taubman Center B1354, 1500 E Medical Center
Dr., SPC 5303, Ann Arbor, MI 48109-5305, USA.
E-mail address: haasn@med.umich.edu

Benjamin S. Bassin

Department of Emergency Medicine, University of Michigan, Ann Arbor, MI,
USA
Division of Critical Care, Department of Emergency Medicine, University of
Michigan, Ann Arbor, MI, USA
Michigan Center for Integrative Research in Critical Care, Ann Arbor, MI,
USA

Henrique A. Puls

Department of Emergency Medicine, University of Michigan, Ann Arbor, MI,
USA
Michigan Center for Integrative Research in Critical Care, Ann Arbor, MI,
USA

Kevin R. Ward

Department of Emergency Medicine, University of Michigan, Ann Arbor, MI,
USA
Michigan Center for Integrative Research in Critical Care, Ann Arbor, MI,
USA
Department of Biomedical Engineering, University of Michigan, Ann Arbor,
MI, USA

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