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Portable negative pressure environment to protect staff during aerosol-generating procedures in patients with COVID-19

James Nilson,[1,2] Nikolay Bugaev,[2,3] Pavan Sekhar,[1,2] Haracio Hojman,[2,3] Luis Gonzalez-Ciccarelli,[1] Sadeq A Quraishi[1,2]

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[1]Anesthesiology and Perioperative Medicine, Tufts Medical Center, Boston, Massachusetts, USA
[2]Tufts University School of Medicine, Boston, Massachusetts, USA
[3]Surgery, Tufts Medical Center, Boston, Massachusetts, USA

Correspondence to
Dr Sadeq A Quraishi; squraishi@tuftsmedicalcenter.org

ABSTRACT

Patients with COVID-19 often need therapeutic interventions that are considered high aerosol-generating procedures. These are either being performed by healthcare providers with potentially inadequate personal protective equipment or the procedures are being delayed until patients clear their viral load. Both scenarios are suboptimal. We present a simple, cost-effective method of creating a portable negative pressure environment using equipment that is found in most hospitals to better protect healthcare providers and to facilitate more timely care for patients with COVID-19.

Mechanical ventilation is critical for managing patients with severe COVID-19 disease. Insertion and removal of an endotracheal tube are essential components of care but are considered high aerosol-generating procedures.[1] Optimal personal protective equipment for healthcare providers involved with intubations and extubations are unknown. To enhance safety, several devices have been manufactured to contain aerosolised secretions but they are either awkward to use, relatively costly or are limited in their clinical use.[2] Other high aerosol-generating procedures related to mechanically ventilated patients, such as bronchoscopy and tracheostomy, remain controversial with most professional societies arguing against them until patients clear their viral load.[3 4] Such delays in care may complicate the management of patients with COVID-19, who typically require a prolonged course of mechanical ventilation. Indeed, airway mucus plugging, high sedation requirements, secondary infections and respiratory muscle weakness are all frequently observed in these patients.[5] Therefore, our goal was to develop an easy-to-assemble, low-cost and versatile device to enhance healthcare provider safety and to provide more timely management of patients with COVID-19.

The Splash Bivy design is based on the bivouac sack (or bivy sack), which is commonly used by camping enthusiasts. The first version of our minimalist, single-occupancy protective sack was highly versatile and was used successfully for intubations, extubations and patient transport (figure 1). The concept was to have a very adaptable system with either all disposable components or so that the majority of components could be sterilised. We also wanted to develop a system that could be used on a variety of clinical care surfaces such as operating room tables, hospital beds and transport stretchers. At the core of the design (figure 2) is a 1.5 cm diameter by 183 cm long medical grade cross-linked polyethylene tubing (Zeus, Orangeburg, SC). The tubing forms an arch over the head of the patient and is anchored at either end with a set of Clark sockets (Mid Central Medical, Oldsmar, FL) for the operating room table or a pair of 5 cm spring clamps (Bessey Tools, Lithia Springs, GA) with custom holes drilled into the clamp to receive the tubing for all other attachment surfaces. We used a clear plastic, 71 cm×56 cm×137 cm, equipment bag (Tri-Anim, Dublin, OH) to create a hood over the tubing arch.

To safely allow for non-invasive ventilation, or procedures such as bronchoscopy or tracheostomy, we sought to develop a method of providing a negative pressure environment within the Splash Bivy using equipment already available in most hospitals (online supplemental video 1). We therefore used a commercially manufactured surgical waste management suction device (Stryker, Kalamazoo, MI) with an in-line high-efficiency particulate air filter and validated the ability to create a negative pressure environment using a smoke evacuation model (online supplemental video 2). To attach the smoke

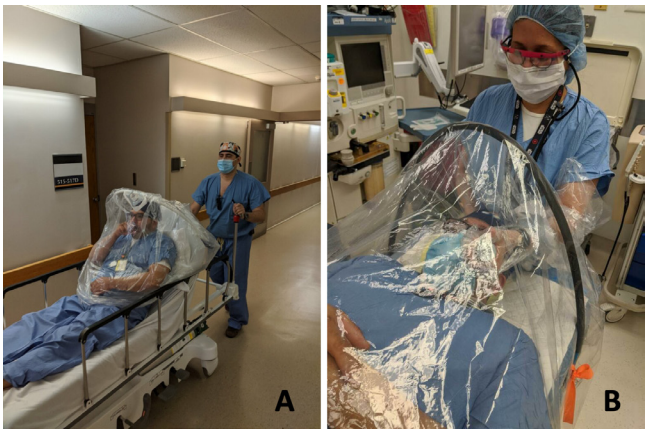

Figure 1 Original use of the Splash Bivy. (A) Simulated patient to demonstrate how patients with COVID-19 are being safely transported throughout the hospital; and (B) simulated patient to demonstrate how patients with COVID-19 are being safely positioned for laryngoscopy and endotracheal intubation. All individuals have consented to being photographed and consented for the material to be published in a public forum.

exhaust to the Splash Bivy, a piece of heavy construction paper and large adhesive tape strips (3M, St. Paul, MN) were used to fix the hose to the polyethylene arch. The purpose of the construction paper was to create a cone around the end of the suction tubing to prevent the plastic drape from getting sucked into the hose

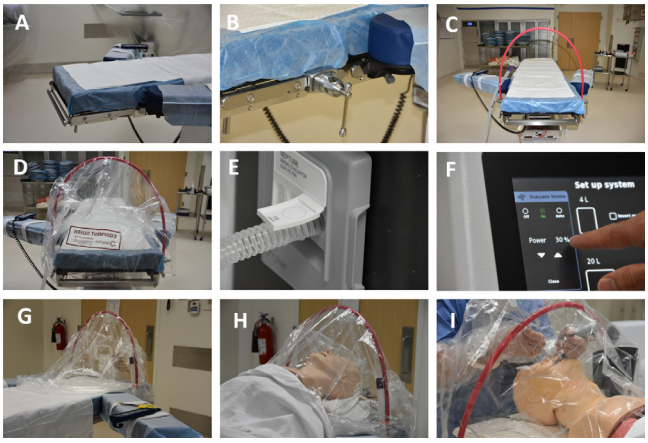

Figure 2 Basic set-up for the Splash Bivy. (A) A standard operating room table is used in this example. (B) Standard Clark sockets are mounted on the side rails of the operating room bed. (C) The polyethylene tubing forms an arch over the head of the bed and the distal end of the smoke exhaust tubing is attached to the arch. (D) A clear equipment cover is draped over the arch. (E) The proximal end of the smoke exhaust tubing is connected to the port on the surgical waste management system. (F) The flow rate is set on the smoke exhaust system. (G) Note that the clear equipment cover edges are not tucked in—it is left loose to allow air flow under the drape. (H) Demonstration of complete set-up with a mannequin. (I) Demonstration of direct laryngoscopy for endotracheal intubation on a mannequin.

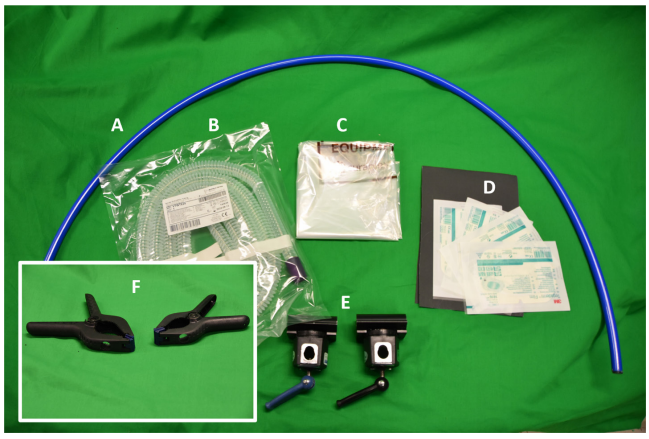

Figure 3 Components of the Splash Bivy. (A) Polyethylene tubing (1.5 cm×183 cm). (B) Smoke exhaust tubing: 22 mm×3 m. (C) Clear equipment cover: 71 cm×56 cm×137 cm. (D) Heavy construction paper: 13 cm×25 cm and 10 cm adhesive tape strips. (E) Clark sockets. (F) Alternative spring clamps.

(figure 3). According to manufacturing specifications, using a corrugated 22 mm diameter by 3 m long smoke evacuation tubing (Buffalo Filter, Utica, NY) through the smoke exhaust port on the surgical waste management system at 100% power generates approximately 1 m^3/min of air flow. The Splash Bivy design assumes roughly one-fourth of the volume of a sphere ($V=4/3\times r^3$), and therefore, a 183 cm polyethylene tubing on a 0.8 m bed produces a radius of approximately 0.4 m and an approximate volume of 0.08 m^3. As such, even at low smoke exhaust power settings, total air exchange would occur several times a minute. For example, at 30% power and using a commercially available meter (Medtronic, Minneapolis, MN), we achieved an air flow rate of 0.24 m^3/min. This would result in three complete air volume exchanges per minute under the Splash Bivy hood.

In early April 2020, after running through simulations to optimise work flow, we used the Splash Bivy to smoothly perform the first open tracheostomy of a patient with COVID-19 in Boston, Massachusetts (online supplemental video 3). At 2 weeks after the procedure, all involved providers remained free of any symptoms to suggest COVID-19 infection. To date, the full Splash Bivy system has been used to provide surgical site negative pressure environments in an additional 10 patients with COVID-19, with several more upcoming cases. Even without the negative pressure environment, the Splash Bivy is incredibly cost-effective and simple to assemble on a variety of patient care beds, which allows it to be used in many clinical scenarios. In conjunction with continuous negative pressure, using a commercially available surgical suction device, the Splash Bivy may facilitate more controversial (eg, non-invasive ventilation) or complex procedures (eg, bronchoscopy, tracheostomy, laparoscopic procedures) in patients with COVID-19.

The COVID-19 pandemic has pressed many institutions to adapt to stresses and limitation in supply chains.

Our approach to creating the Splash Bivy was to find a solution to a problem, such as contain potential contagions during aerosolising procedures, using materials readily available at our institution and would require the least amount of manufacturing time. This allowed the system to be quickly approved and produced in sufficient numbers to be available for use by providers during the peak of the pandemic.

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Contributors JN, PS and SAQ were responsible for conception and design of the work. JN, PS, LG-C, NB and HH were responsible for data collection. JN, LG-C and SAQ were responsible for data analysis and interpretation. JN and SAQ drafted the manuscript. NB, HH, LG-C and PS provided critical revision of the manuscript. All authors provided final approval of the version to be published.

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