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Novel Tracheostomy and Percutaneous Endoscopic Gastrostomy Technique for COVID-19 Patients in a Nonnegative Pressure Environment

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The 2020 SARS-CoV-2 pandemic has created unprecedented utilization of critical care resources across the globe. Respiratory failure associated with SARS-CoV-2 infection is thought to be secondary to diffuse alveolar damage and proteinaceous exudate leading to acute lung injury.[1] Timely performance of tracheostomy has many benefits, including increased liberalization from the ventilator, decreased intensive care unit (ICU) length of stay, and improved patient comfort.[2] COVID-19 patients, however, presents with unique challenges with regard to evaluating the appropriateness for performing this procedure from both the patients' and health care provider (HCP) safety perspective.

A tracheostomy is an aerosol generating procedure and, as such, increases the risk of viral transmission to operating room personnel. A gold standard safety protocol has yet to be established for tracheostomy and PEG tube placement in COVID-19 patients. Utilizing a multidisciplinary approach between surgical, critical care, and anesthesiology departments, we sought to design a safe, low-cost technique for tracheostomy and PEG placement in a nonnegative pressure room that minimizes exposure to involved HCPs. The aim of this study is to describe our operative protocol, report early patient outcomes, and describe the safety of the technique to the hospital staff.

Institutional review board (IRB) exemption was obtained from Tufts Medical Center IRB. Procedures were performed by 4 trauma surgeons at a single academic medical center. The procedures were first performed in the operating room during the development of this technique. This was then transitioned to the bedside in COVID-19-designated ICU rooms in order to minimize the risk of the disease transmission during patient transport. Twenty-four (92%) procedures were performed in nonnegative pressure rooms. Proper personal protective equipment was worn throughout the entire of the case: protective gown, gloves, N-95 mask, eye protection, and hair protection.

The creation of a localized negative pressure surgical environment was designed as an extension of the existing "splash bivy" setup created by 2 of the authors (JN and PS) in the anesthesiology department for COVID-19 intubations and extubations. Three cross-linked polyethylene (PEX) arches were attached to the bed using two-inch spring clamps. A plastic, nonsterile, sheet was then placed over the first arch to create a tent at the head of the bed (Figure 1A). A smoke evacuator connected to an ultralow penetration air filter was placed under this tent for removal of any aerosolized particles.

Sterile drapes were then placed over the patient to create a continuous field to include the tracheostomy and PEG sites (Figure 1B). A second smoke evacuator was secured just caudal to the operative field. A sterile plastic isolation barrier (Halyard Health, Alpharetta, Georgia) was then placed over the arches and secured with clamps. Wound protector ports and plastic adherent drapes (Ioban, 3M, St. Paul, Minnesota) were utilized to create arm holes for the operating surgeons (Figure 1C). Surgeons then placed arms through these access points to perform the open tracheostomy (Figures 1D and 1E). The simplicity of this setup allowed for adaptability of access points per surgeon preference (Figure 1F). Following tracheostomy placement, additional access points could be made in the "splash bivy" overlying the abdomen for PEG placement (Bard Guidewire PEG System, C.R. Bard, Salt Lake City, Utah).

This localized negative pressure environment was not hermetically sealed in order to prevent complete collapse of the chamber. At 100% flow rate, air flow through the smoke evacuator was approximately 934 liters per minute.

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Figure 1. Surgical setup utilizing "splash bivy" technique. (A) Three PEX arches attached to bed using spring clamps and nonsterile plastic sheet placed over the first arch toward the head of the patient. (B) Tracheostomy site prepped/draped and smoke evacuator (red arrow) connected to a ultra-low particulate air filter. Sterile plastic sheet placed over all 3 arches. (C) Ioban used to create surgeon access points. (D) Operating surgeon and assistant entering operative field through access points. (E) Tracheostomy performed under "splash bivy" with a smoke evacuator (red arrow) secured just caudal to operative field. (F) Optional access created by covering a longitudinal opening in the "splash bivy" with partially overlapping 3M™ Steri-Drape™ 1000 Towel Drapes. Note: PEX, polyethylene.

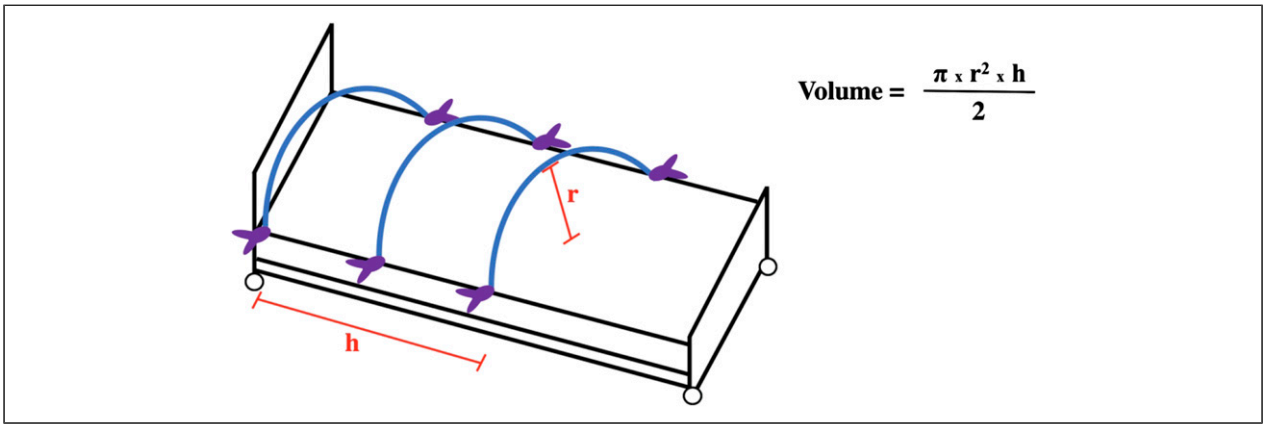

Figure 2. Total surgical volume underneath "splash bivy." Approximation of total surgical volume within a localized negative pressure environment (r, radius and h, height).

ICU beds at our institution are 83 cm wide with a covered bivy length of 167 cm. This formed an approximated total surgical field volume of 467 liters (Figure 2). Thus, the entire volume of air was exchanged approximately twice per minute.

The PEX tubing can be purchased at any local hardware store for less than $2 per 5' section. The spring clamps are available at various online hardware stores and averaged $7 per clamp. The smoke evacuation hoses were purchased in units of 24 for $222.79 ($9.28 each). The sterile drapes were purchased in units of 24 for $151.44 ($6.31 each). The average cost of all materials required to perform this technique totaled $30.87, excluding the reusable equipment.

From March to June 2020, 134 patients with confirmed COVID-19 infection required invasive mechanical ventilation at our institution. Twenty-six patients underwent open tracheostomy with our technique. Twenty-three of these patients also underwent simultaneous PEG tube placement. Within our cohort population, the median age was 61.5 (range 29-84) years . Thirteen patients (76.5%) were male. The average time from intubation to tracheostomy was 22 (SD ± 7.95) days. Seventeen (65%) cases were performed at the bedside and 9 (35%) cases were performed in the operating room. The mean operative time was 47 (SD ± 15) minutes. There was no significant difference in operative time when comparing bedside vs. operating room cases (49 vs. 46 minutes, P = .6361). Twenty-four (92%) cases were performed in nonnegative pressure rooms. The described technique was successful in 26 (100%) of patients.

To date, 25 (96%) patients had their tracheostomies downsized, 9 (35%) patients have been decannulated, and 18 (69%) patients have been discharged from the hospital. Three (12%) patients died as a result of COVID-19-related complications but not surgical complications. Two patients required return to the operating room for tracheostomy revision. Both these patients have been successfully weaned to tracheostomy collar and discharged to rehabilitation facilities.

This study is the first to our knowledge to report early outcomes in COVID-19 patients who underwent both tracheostomy and PEG tube placement in nonnegative pressure procedure rooms. The creation of a localized negative pressure environment allowed our system to be adaptable to any hospital bed. No HCPs involved in the procedures have developed symptoms or tested positive for COVID-19. This new technique has potential applications worldwide where resources such as negative pressure rooms are more limited.

Similar case series have demonstrated little to no HCP transmission. Angel et al[3] describe a novel percutaneous tracheostomy technique which was performed in 98 patients with promising early outcomes. Chao et al[4] report early outcomes from 53 tracheostomies, utilizing both percutaneous and open techniques. Our study is unique that the majority of our procedures were performed in nonnegative pressure rooms due to institutional design. Despite these constraints, our results did not show any increase in disease transmission to HCPs.

Our study is not without limitations. Though this study is one of the first studies to describe preliminary outcomes after tracheostomy and PEG in COVID-19 patients, it is limited by a small sample size. While no HCPs developed symptoms for COVID-19, not all personnel received a confirmatory negative test. As per our hospital's institutional policy, testing was deemed unnecessary if providers had no symptoms. Last, the true quantifiable viral load and aerosol generation during these procedures are unknown.

In summary, we describe a novel technique of performing open tracheostomy and PEG placement in COVID-19 patients that does not require a negative pressure procedure room and can be performed at any bedside. The available data showed that this technique is safe for both the patients and providers involved. This technique is low cost and can be easily adaptable to any medical center.

Declaration of Conflicting Interests

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