Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Rapid implementation of COVID-19 tracheostomy simulation training to increase surgeon safety and confidence

Phillip S. LoSavio, Michael Eggerstedt*, Bobby A. Tajudeen, Peter Papagiannopoulos, Peter C. Revenaugh, Pete S. Batra, Inna Husain

Department of Otorhinolaryngology – Head and Neck Surgery, Rush University Medical Center, Chicago, IL 60612, United States of America

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ABSTRACT

Objective: To determine if rapid implementation of simulation training for anticipated COVID-19 tracheostomy procedures can increase physician confidence regarding procedure competency and use of enhanced personal protective equipment (PPE).

Methods: A brief simulation training exercise was designed in conjunction with the development of a COVID-19 Tracheostomy Protocol. The simulation training focused primarily on provider safety, pre and post-surgical steps and the proper use of enhanced PPE. Simulation training was performed in the simulation lab at the institution over 2 days. Pre and post self-evaluations were measured using standardized clinical competency questionnaires on a 5-point Likert Scale ranging from "No knowledge, unable to perform" up to "Highly knowledgeable and confident, independent."

Results: Physicians self-reported a significant increase in knowledge and competency immediately after completing the training exercise. Resident physicians increased from a mean score of 3.00 to 4.67, *p*-value 0.0041, mean increase 1.67 (CI 95% 0.81 to 2.52). Attending physicians increased from a mean score of 2.89 to 4.67, *p*-value 0.0002, mean increase 1.78 (CI 95% 1.14 to 2.42). Overall, all participants increased from a mean score of 3.06 to 4.71, *p*-value 0.0001, mean increase 1.65 (CI 95% 1.24 to 2.05).

Discussion: Implementation of this simulation training at our institution resulted in a significant increase in physician confidence regarding the safe performance of tracheostomy surgery in COVID-19 patients.

Implications for practice: Adoption of standardized COVID-19 tracheostomy simulation training at centers treating COVID-19 patients may result in improved physician safety and enhanced confidence in anticipation of performing these procedures in real-life scenarios.

1. Introduction

COVID-19, the disease caused by the novel coronavirus (SARS-CoV2) was declared a global pandemic in March 2020 with nearly 2 million infections worldwide by April 14th, 2020. The highly contagious virus is transmitted via respiratory droplets. Critical illness develops from progression of pneumonia into acute respiratory distress syndrome (ARDS) and, thus, the need for prolonged mechanical ventilation associated with the disease. As the pandemic continues, the number of tracheostomies needed will surge in order to facilitate long-term ventilation or vent weaning. As of April 14th, our institution had 58 COVID-19 confirmed ventilated patients and 6 Persons of Interest (PUI) being ventilated. This reality prompted the need to proactively prepare for the anticipated surge in tracheostomy surgery for this patient population.

Health care workers (HCWs) are particularly at risk for nosocomial transmission of the disease due to close and continued patient exposure. However, certain procedures, such as endotracheal intubation and tracheostomy can further increase risk of transmission due to viral aerosolization. These aerosolized particles can remain airborne for up to 3 h and longer on surfaces increasing the viral transmission potential [1]. In prior coronavirus outbreaks, infectious aerosols arising from airway procedures have been implicated as key etiologic factors in spread of disease among HCWs [2].

Proper personal protective equipment (PPE) has been shown to reduce transmission of infection to HCWs during the SARS epidemic [3]. The WHO has recommended PPE to include mask, eye protection, gown, and gloves. For aerosol generating procedures, N95 respirator or

* Corresponding author at: Department of Otorhinolaryngology – Head and Neck Surgery, Rush University Medical Center, 1611 W. Harrison St., Suite 550 Orthopedic Building, Chicago, IL 60612, United States of America.
E-mail address: michael_eggerstedt@rush.edu (M. Eggerstedt).

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RUSH

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COVID-19 Tracheostomy Protocol - FINAL
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Background – Due to the COVID-19 Pandemic, a dedicated Tracheostomy protocol is being implemented for the purposes of a standardized care pathway, maintenance of infection control, provider safety, and optimization of patient care outcomes.

Protocol Development – Coordination and development of the protocol done after consultation with representatives from Otolaryngology, General Surgery, Critical Care, Anesthesia, Infection Control, OR Nursing, and Respiratory Therapy. Additional literature review of SARS experience conducted by team. Unpublished data from Wuhan hospitals reviewed.

Indications for Surgery – Currently there is no available evidence to support early or aggressive tracheostomy for COVID-19 patients. In fact, early anecdotal evidence from China demonstrates a very low rate of tracheostomy overall in COVID patients Concerns about the procedure center around intraoperative and postoperative infection control, care provider safety, post-hospital care setting availability (LTAC), patient safety related to prone positioning, and ultimate effect on mortality outcomes. Therefore, initial protocols will focus on limited consideration of tracheostomy after careful individual patient consideration.

- Mechanical ventilation >14-21d
- FiO2 <50%
- PEEP <8-10
- PIP < 30
- Not requiring high-dose vasoactive agent, and/or more than 1 vasopressor
- Absence of uncontrolled dysrhythmia
- Absence of severe acidosis
- INR < 1.5
- Platelets > 100k
- No anatomic contraindications
- Availability of recommended PPE equipment
- COVID-19 PCR testing that is negative x 2 before surgery. If testing positive, conference between surgical and medical team will discuss risks and benefits of surgery taking into account all medical, safety and infection control factors.

Setting/Technique

- Initial technique consideration will be to perform Percutaneous Tracheostomy.
- If contraindicated medically or due to other limitations, will perform Open Technique.
- Bedside technique vs. Operating Room after consideration of medical status including COVID testing status.

Fig. 1. Rush University Medical Center COVID-19 tracheostomy protocol.

equivalent should be worn. Given accounts of health care workers acquiring SARS despite wearing N95 respirators, some clinicians recommend use of powered air purifying respirators (PAPRs) [4]. During an acute infectious disease outbreak, access to appropriate PPE can be challenging due to supply-chain and availability issues. However, even with access to appropriate PPE, proper donning and doffing technique is critical in reducing potential provider exposures. There is evidence that there is substantial risk of self-contamination when doffing PPE and therefore training on the specific steps of wearing and removing PPE is crucial to mitigate HCW exposure and infection [5]. With the SARS epidemic, training programs and the use of PPE were associated with decreased risk of transmission to HCWs [3].

COVID-19 is a highly transmissible disease and risk of exposure is increased with aerosol generating procedures such as tracheostomy. Provider protection is afforded through appropriate PPE utilization, however training and user familiarity is key to proper use. Simulation training can be used to increase physician confidence and preparedness for anticipated COVID-19 tracheostomy procedures as well as use of enhanced personal protective equipment (PPE).

2. Methods

The study was considered exempt by the IRB given there was no involvement of patients or protected health information. After the development of an institution approved COVID-19 tracheostomy protocol (Fig. 1), a core group of faculty members and one resident worked over the course of approximately 5 days to develop a simulation program to teach faculty and residents the surgical protocol and the proper use of enhanced PPE for the procedure, specifically focusing on the use of CAPR devices (Controlled Air Purifying Respirator) – MAXAIR ® Systems (Irvine, CA) in conjunction with sterile gowning technique. (Figs. 2 and 3).

All faculty and residents were given the new tracheostomy protocol to review in advance. Two otolaryngology operating room nurses

Fig. 2. CAPR® devices with charging stand allocated for dedicated use by the Otolaryngology Service.

Fig. 3. CAPR® device in use during simulation training exercise.

participated in the exercise as well. The session began by explaining the purpose of the training. All participants were given a standardized clinical competency questionnaire to complete prior to the start of the exercise and after completion. It is based on a 5-point Likert scale asking the participant to rate their confidence in performing a tracheostomy safely on a COVID-19 patient in a real-life scenario. The scale ranged from 1 – (No knowledge, Unable to Perform) up to 5 – (Highly knowledgeable and confident, independent). (Fig. 4).

The training was performed on two separate days in the same week with two of the authors serving as instructors. After reviewing the steps of the protocol with the group, next there was a demonstration of the use of the PPE equipment while the instructor read a standardized script. (Fig. 5) Participants then were allowed time to use the equipment and ask questions about the protocol and procedures. The exercise lasted one-hour total on each day. A video was created reviewing the steps of proper donning and doffing and made available publicly for review and use by individual physicians in the future (https://www.youtube.com/watch?v=bQip1UAsDw8).

Results were tabulated and summarized. Statistical analysis was conducted using a paired Student *t*-test based on category (resident, attending) and for all the participants as an aggregate.

3. Results

Overall, 9 attendings, 6 residents and 2 operating room nurses participated in the training exercise. Participation was voluntary based on anticipated involvement in tracheostomy surgery or other types of upper aerodigestive procedures requiring the use of these PPE protocols. Results are summarized in Table 1 and Fig. 6. Improvement in confidence scores was statistically significant for both resident and attending physicians. Statistical tests were not performed for the nursing group given small sample size. Overall, the entire group demonstrated an even greater significant effect. Resident physicians increased from a mean score of 3.00 to 4.67, *p*-value 0.0041, mean increase 1.67 (CI 95% 0.81 to 2.52). Attending physicians increased from a mean score of 2.89 to 4.67, p-value 0.0002, mean increase 1.78 (CI 95% 1.14 to 2.42). Overall, all participants increased from a mean score of 3.06 to 4.71, p-value 0.0001, mean increase 1.65 (CI 95% 1.24 to 2.05). Participants reported the session to be very helpful and increased their comfort level in surgically treating COVID-19 patients.

4. Discussion

Since its emergence, and as of the date of this writing, the COVID-19 pandemic has afflicted nearly 2 million people worldwide and caused over 120,000 deaths [6]. The United States has recently emerged as the epicenter for this disease, suffering from the largest number of confirmed cases and deaths. A significant number of infected patients progress to require ventilatory support or extracorporeal membrane oxygenation (ECMO), with reports from China quoting a rate of (9.8%–15.2%) [7]. Though early tracheostomy is to be avoided due to infectivity concerns, late tracheostomy may be indicated in a subset of these patients to facilitate ventilator weaning or discharge to long-term care facilities especially if Intensive Care Units (ICU) become overwhelmed. Airway procedures such as intubation and tracheostomy pose a unique risk to HCWs, who have been disproportionately affected by both the SARS virus in 2003, as well as the novel COVID-19 [8–10]. Given the patient surge both observed and expected within our medical center, it was determined that rapid implementation of a COVID-19 specific mobile tracheostomy team was indicated to provide adequate care and mitigate risk to healthcare workers.

Previous experience with the SARS outbreak in 2003 led anesthesiologists and otolaryngologists to develop tracheostomy protocols that

COVID-19 Tracheostomy PPE Self-Assessment

Please rate your confidence with performing a tracheostomy safely on a Covid-19 patient in a real-life scenario by selecting the appropriate response (*circle choice*):

1 – No knowledge, unable to perform

2 – Some knowledge but need a lot of guidance

3 – Basic knowledge but guidance still needed

4 – Reasonably confident, some guidance needed

5 – Highly knowledgeable and confident, independent

Fig. 4. Clinical competency questionnaire self-reporting tool.

Enhanced Personal Protective Equipment for COVID-19 Tracheostomy Surgery

Instruction Script:

1. Start with putting on shoe covers, standard scrubs, and a head cover.
2. Next you should place your respiratory protective gear. Currently at Rush, for COVID-19 tracheostomy, we are recommending the use of a powered air respirator device. If not available, an N95 respirator should be used.
3. Next we will go through the steps for proper placement of the CAPR device. Note, this is done prior to sterile gowning. This is different than non-sterile procedures.
4. First, attach the belt to your waistline. The battery goes on your right side with the battery port facing backward.
5. Plug the battery cable into the battery until you hear a click.
6. Initially the unit should show 5 LED's from left to right. One yellow, three green, and one red. After a few seconds the lights should ideally show 3 green LED's.
    a. 3 green lights means 75-100% charge
    b. 2 green lights means 50-75% charge
    c. 1 green light means 25-50% charge
    d. 1 red light means 0-25% charge
    e. 1 yellow light means there is an issue with the Filter or Air Flow

    If at any time you see 1 yellow or red light doff the system as soon as possible. Surgical procedures do not typically allow for a pause in care, therefore, it is recommended that 3 green lights be available before starting the procedure.
7. Next, don the CAPR helmet.
    a. Loosen the headband adjustment knob. This will ensure the head circumference is large as possible.
    b. Next attach the disposable lens cuff. Most people can use a medium to large size. A small to medium size is available.
    c. Attach the lens cuff to the 3 mounting points on the helmet. Next remove the protective film from the lens cuff.
    d. Next don the helmet. Then locate the cuff and pull it around your face and around your chin. Run your fingers around the cuff to ensure slight tension. In the correct position, the head strap should be about a half inch above your eyebrows and you should be able to see the LED indicators in your peripheral vision. Tighten the headband to ensure a proper fit. Lastly move the cable behind your back and not under your arm.
8. Next, proceed to perform a standard scrubbing technique using either a standard alcohol based solution or traditional scrub.
9. First don a pair of gloves that will go under your gown.
10. Next place your surgical gown either yourself or with the help of an assistant.
11. Next place a second set of surgical gloves as standard over the gown wrists.
12. Lastly do a check of your gear with a buddy:
    a. Check that the gown is not torn, gloves intact.
    b. Check that the helmet has 3 green LED's and tucked well under the chin
    c. Check that the shield is fixed to the 3 attachment points.

Fig. 5. Protocol script for simulation training – donning and doffing enhanced PPE.

Table 1
Mean clinical competency questionnaire score pre and post intervention.

	Pre-simulation training	Post-Simulation Training	p-Value	N
Residents	3.00	4.67	0.0041	6
Attendings	2.89	4.67	0.0002	9
Nurses	4.00	5.00	n/a	2
Overall	3.06	4.71	0.0001	17

Results of pre and post simulation training questionnaire scores. Overall results were statistically significant showing improvement in confidence levels among resident and attending surgeons.

take into account the infectivity of virus-infected patients. Early tracheostomy was uniformly recommended against during the SARS outbreak, due to significant infectivity during the early acute period, high mortality in patients who were mechanically ventilated, and lack of data regarding tracheostomy-facilitated weaning efficacy [11]. In general, open tracheostomy was preferred over percutaneous means, due to concern for aerosolization with bronchoscopy, multiple disconnections from ventilator circuit, multiple dilations entering the airway, and high positive end-expiratory pressure (PEEP) requirements [11–13]. Personal protective equipment (PPE) recommendations range from N95 masking and face shields, to CAPR units with complete body coverage and postoperative showering [11,12,14,15]. Most authors from this era recommend PAPR/CAPR units for high-risk aerosol generating procedures (AGPs) such as tracheostomy, in conjunction with gloves, surgical gown, and shoe covers. Preparatory and protocol-related recommendations included consolidation of necessary materials into a sterile pack or cart, recruitment of most experienced surgeons to perform efficient tracheostomy, frequent and thorough simulation, and preoperative communication – as intraoperative communication can be impaired by PPE [11,14]. Intraoperative techniques to minimize aerosolization include complete paralysis throughout the case, ventilator cessation prior to entering the airway, avoidance of diathermy once airway is incised, and restriction to in-line suctioning only [11,14]. Finally, during the SARS outbreak, most tracheostomy procedures were performed in a negative-pressure ICU setting, rather than in the operating room. This minimized patient transport and unnecessary disconnections from the ventilator circuit [11].

Lessons learned from the SARS outbreak have been appropriately extrapolated in dealing with the current COVID-19 pandemic. Less emphasis has been placed on ICU bedside tracheostomy, with some groups advocating for the operating room being the primary location for tracheostomy, and others leaving this decision to individual hospitals [10]. Operative indications remain similar to that of SARS patients, though a stronger push toward delayed tracheostomy, frequently past 14 days, is evident in initial reports. Indications for timing of the procedure have been postulated as patients with greater than 14 days since onset, high likelihood of recovery, and ventilator weaning as the primary goal [8]. Percutaneous tracheostomy is a consideration in patients with suitable anatomy, if bronchoscopy and multiple ventilator disconnections can be avoided [8,16]. Technical advances since the SARS outbreak include maintenance of lower respiratory isolation by pushing the endotracheal tube lower and re-inflating the cuff prior to incision of the trachea [10,16]. This, in-conjunction with cessation of ventilation and mild cuff hyperinflation further minimizes risk of aerosolization upon entering the trachea. Postoperatively, the tracheostomy cuff is kept inflated, with delayed first tracheostomy tube change and early application of a humidity and moisture exchange (HME) system following liberation from the ventilator [8].

With regard to choice of PPE system when performing tracheostomy, most authors have recommended the use of powered air purifiers. In-vitro assigned protection factor testing demonstrates superiority of PAPR/CAPR systems at filtering particulate matter, however it has not yet been elucidated whether this translates to a clinically-relevant reduction in risk to providers [17]. Manufacturers of the CAPR system offer additional equipment including hoods and shrouds, capable of covering the head, neck, and trunk of proceduralists. Drawbacks to the powered systems include impairment of communication, concern for sterility of the surgical field, fogging of face shields, limited use of headlights, and frequent head collisions with the uninitiated [8]. Whatever system is chosen at a given institution, the importance of simulation and practice cannot be overstated in overcoming such impairments prior to surgery in a COVID-19 infected patient.

At our own institution, we assembled, developed, and implemented a mobile tracheostomy team over the course of a 4-day period. This accelerated timeline was realized in response to an observed surge in critically ill COVID-19 patients admitted to our institution, as well as to develop a framework for other institutions to employ similarly rapid implementation. In addition, previous authors during the SARS epidemic have demonstrated that graduated rollout of operating room PPE

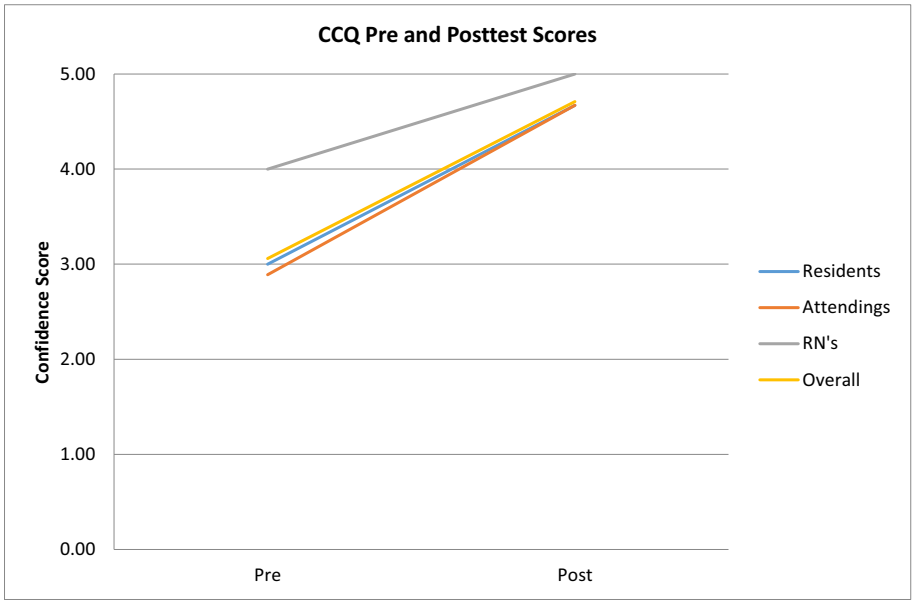

Fig. 6. Clinical competency questionnaire results pre and post training.

for high-risk procedures was associated with continued infection of healthcare workers until the time of complete implementation [12]. Based upon the findings and recommendations of previous authors, we developed the following timeline. Day 1 saw the realization of a tracheostomy workgroup, which included representatives from otolaryngology, critical care, anesthesiology, and operating room nursing. This group met regularly during days 1 and 2 to develop indications, setting, protocols, and both electronic and physical ICU tracheostomy bundles. Days 3 and 4 facilitated training and simulation for all parties, overseen by surgeon super-users, infection control practitioners, and occupational health and safety representatives.

Experienced airway surgeons were paired with senior resident surgeons to balance efficiency of procedure with maintenance of redundant experienced parties. Pre- and post-training surveys demonstrated significant improvements in comfort with the donning/doffing and tracheostomy protocols, underscoring the importance of simulation and rehearsal when planning such implementations. Previous authors have used similar models to assess otolaryngologist comfort pre/post simulation, and found that otolaryngologists are more likely to accurately predict their pre-intervention knowledge than are primary care providers [18,19]. In addition, decay in knowledge and comfort appears to occur more slowly in otolaryngology providers, when topics are within their field of practice. Despite this, frequent simulation and reassessment is critical in maintaining proper technique and vigilance.

5. Conclusions

COVID-19 presents a unique set of challenges and concerns regarding high-risk upper airway procedures, most notably tracheostomy in critically ill patients. Rapidly implemented simulation training was demonstrated to successfully increase confidence levels among resident and attending surgeons. This protocol can serve as a blueprint for any medical center being faced with the scenario of potentially having to perform tracheostomy in COVID-19 patients.

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Declaration of competing interest

None.

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Rush University Medical Center Simulation Laboratory.

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