



Implementation of a Tracheostomy Protocol During the COVID-19 Pandemic

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Abstract: The coronavirus SARS-CoV-2 (COVID-19) pandemic has offered a unique set of challenges to the medical community often requiring prolonged treatment algorithms. The illness, afflicting more than 7.3 million people worldwide with estimates of 5-20% requiring critical care, has become a burden on the healthcare community. These critically ill patients who acquire the severe form of the disease routinely require prolonged invasive mechanical ventilation. The questions then arise, “when and for whom does tracheostomy become indicated,” and “how to safely perform a tracheostomy in this patient population.” With consideration to aerosolization of the virus, we have derived and instituted a protocol at a community institution with aims of reducing provider risk while safely performing a tracheostomy. An open tracheostomy was performed at bedside, within a negative pressure intensive care unit (ICU) setting, utilizing a closed-circuit technique as described in this text. A total of 17 tracheostomies were performed employing the described technique. Minimal complications were noted throughout the study and no adverse oxygenation events were observed with an average total apneic time of 106 seconds. An acceptable mortality rate of 23% was observed given the lethal nature of this disease in ventilated, critically ill patients. No nosocomial transmission of the virus was documented for all team members. This protocol can be used to determine efficacy and safely execute a tracheostomy in COVID-19 patients. As information about COVID-19 continues to unfold, protocols for high risk procedures will need to fluidly evolve.

Keywords: COVID-19, Tracheostomy, Protocol, Indication

1. Introduction

At present, the COVID-19 pandemic has a confirmed 7.38 million cases and 415,000 deaths worldwide with an estimated 53,000 of cases requiring critical care [1]. In early studies approximately 9.8-15.2% of infected individuals have been found to require invasive mechanical ventilation [2]. Healthcare systems around the world have responded by increasing their critical care capacity and have therefore accumulated an abundance of chronically endotracheal intubated patients. Traditional ICU care offers a tracheostomy around intubation day 7-10 to provide a stable surgical airway, good pulmonary hygiene, shorter ICU/hospital stays and overall comfort to these patients [3]. With this influx of endotracheally intubated patients, with a highly transmissible pathogen, one must question the timing,

efficacy, and proper execution of tracheostomy.

The novel coronavirus outbreak, shares a common route of infection due to airborne and fine droplet transmission via human-human contact and eventual entry via mucosal membranes and conjunctiva with the Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) outbreaks [4, 5]. Therefore, we sought out to implement similar protocols as during these epidemics. In the previous SARS/MERS outbreaks, there is very little literature regarding tracheostomy, mostly consisting of small case report studies and surgical protocol recommendations. Procedures such as endotracheal intubation, bronchoscopy, and tracheostomy are considered high risk procedures for providers due to their propensity for aerosolization of viruses. These studies recommend utilization of additional personal protective equipment and performance of an open

tracheostomy in a negative pressure, ICU, bedside setting to reduce high viral load aerosolization. No long-term studies were undertaken to evaluate the efficacy and safety of those procedures however no immediate adverse events were identified and no healthcare workers contracted the virus postoperatively [6, 7, 8, 9]. Seemingly, the low rates of tracheostomies performed in the aforementioned diseases are likely secondary to the potential of high provider risk and the determination of overall futility of surgical intervention.

With the onset of COVID-19 there have been many recommended protocols offered within the literature to safely perform high risk procedures with a corresponding absence of literature demonstrating implementation and execution of these techniques [10-13]. As our institution is located within the greater New York area we have been heavily burdened by this pandemic and may be among the first in the United States to undertake high risk procedures such as tracheostomy. We attempted to balance the risks involved to the healthcare workers while also addressing the ethical dilemma of which patient would be deemed acceptable for tracheostomy. We propose a thorough preoperative checklist that was formulated in a multidisciplinary manner to establish those who were believed to have optimal long-term viability. In similar fashion, we established a surgical protocol in performing a tracheostomy, while minimizing the aerosolization time period limiting the nosocomial transmission of this harrowing disease.

2. Methods

A multidisciplinary team of specialists was assembled in order to procure a safe tracheostomy protocol that would limit nosocomial transmission of COVID-19. The steps taken in creating this protocol are with the design of maintaining a closed circuit to reduce exposure to aerosolized virus. Tracheostomies were limited to 3 per day in order to minimize fatigue and instance of breach of protocol. The preoperative evaluation, indications, equipment needed, necessary personnel and protocol are outlined below.

2.1. Indications

Patients approved by our team for tracheostomy had to meet our indication criteria for tracheostomy (Table 1). Patients must be diagnosed COVID-19 positive via endotracheal nasal swab sent for Polymerase chain reaction (PCR) analysis and be endotracheally intubated for a minimum of 21 days. Ventilator settings must not exceed a fraction of inhaled oxygen (FiO_2) of 40% and a positive end expiratory pressure (PEEP) greater than 8mmHg. A complete neurological exam was performed by a neurosurgeon to evaluate reasonable cognitive function. Acute phase reactants such as C-reactive Protein, Erythrocyte sedimentation rate and Procalcitonin levels must be observed to downtrend. Lastly, patients chosen to undergo tracheostomy revealed a promising prognosis and ideally minimal co-morbidities.

2.2. Equipment

A standardized checklist of necessary equipment was devised and made readily available by the operating room staff (Table 2). A negative pressure ICU bed setting was used in order to perform all tracheostomies. Standard, full, disposable personal protective equipment (PPE) consisting of N95 mask, eye protection (face shield or goggles), sterile operating room (OR) gowns and gloves, shoe covers and scrub caps were utilized. A standard open tracheostomy tray and Bovie electrocautery was brought from the OR to the ICU. Cuffed tracheostomy tubes ranging in size from 7-8 Shiley with extended length tracheostomy (XLT) options were available. A portable headlight and shoulder roll were vital in obtaining optimal visualization of tracheal dissection. A viral filter compatible with ventilator tubing was placed prior to ventilation after the procedure was completed. Numerous hemostatic agents were readily made available at bedside.

2.3. Personnel

A dedicated tracheostomy team of specialists was chosen who were preoperatively briefed on the details of the procedure. This team included the following personnel (Table 3): attending anesthesiologist, attending general/thoracic surgeon, chief surgical resident first assistant, surgical scrub nurse, a circulating registered nurse (RN) and respiratory therapist. All procedures were performed by 2 senior Attending Surgeons with the same chief resident. The above individuals donned the appropriate PPE and were the only individuals allowed within the converted ICU operating room. A second circulating RN was on standby outside of the ICU operating room, in order to allocate unforeseen supplies in a fastidious manner.

2.4. Procedure

The dedicated tracheostomy team would conduct a preoperative brief of the procedure and don all necessary PPE prior to entering the negative pressure ICU room. A surgical time out was performed, confirming all personnel and equipment was available. The patient was placed on FiO_2 of 100% and paralytic anesthesia administered. A shoulder roll was used for adequate exposure of the surgical field. The patient was prepped and draped in sterile fashion. Skin incision was made and trachea exposed via dissection with bovie electrocautery which was used at 40 Watts and decreased to 20 Watts once trachea visualized. Once the trachea was satisfactorily dissected, the anesthesia team was queued to turn off/hold the ventilator, deflate the endotracheal cuff and advance the endotracheal tube (ETT) approximately 2cm. The cuff was then re-inflated and the ventilator turned back. The time frame spent off the ventilator above was deemed apneic period 1 (AP1).

The patient was pre-oxygenated for approximately 30 seconds, thereafter the anesthesiologist would queue the surgical team to proceed. A tracheal hook was used to stabilize the trachea at the cricoid cartilage. The ventilator was then

turned off/held, the patient was allowed to exhale and the endotracheal tube was clamped. The tracheostomy was then created and dilated. The endotracheal tube was withdrawn by the anesthesiologist under direct visualization of the surgical team. The trachea was then intubated with an appropriate sized tracheostomy tube. The tracheostomy cuff was over-inflated and tracheostomy connected to the ventilator with a viral filter.

Ventilation was then resumed. End tidal Carbon dioxide and adequate tidal volume administration were used to confirm positioning of the Tracheostomy. The second time frame spent off the ventilator above was deemed apneic period 2 (AP2). The skin incision was closed and the tracheostomy flange was secured with 2-0 silk sutures. The above tracheostomy protocol is summarized in Table 4.

Table 1. Indications for Tracheostomy.

1	COVID 19 +
2	Endotracheal intubation for > 21 days
3	Minimal Vent Settings: FiO ₂ % < 40%, PEEP < 8mmHg
4	Preoperative stable Neurologic Examination (Neurology/NeuroSurgical Specialist)
5	Promising prognosis with minimal Co-morbidities

Table 2. Equipment Utilized for Tracheostomy.

1	Negative pressure ICU room.
2	Standard Open Tracheostomy tray/ Head & Neck Sterile drapes.
3	Bovie electrocautery
4	Cuffed Tracheostomy tube ranging in size 7-8 shiley XLT.
5	Portable Headlight/Shoulder roll.
6	Viral filter.
7	Surgical hemostatic agents
8	Standard Full PPE (N95 mask, gown, gloves, face shield/goggles, shoe covers).

Table 3. Personnel for Tracheostomy.

1	Attending Anesthesiologist.
2	Senior Attending General/Thoracic Surgeon.
3	Chief Surgical Resident First Assistant.
4	Surgical Scrub RN.
5	Circulating RN x 2.
6	Respiratory Therapist.

Table 4. Tracheostomy Protocol.

1	Preoperative briefing of Tracheostomy protocol by all team members.
2	PPE administration, Sterile gowning, enter negative pressure ICU room.
3	Surgical time out performed. Patient positioning, shoulder roll placed.
4	Patient Pre-oxygenated with 100% FiO ₂ .
5	Paralytic anesthesia administration.
6	Skin incision, trachea exposed.
7	Ventilator turned off/held.
8	ETT cuff deflated, advanced 2cm and ETT cuff re-inflated.
9	Ventilator turned on, given 100% FiO ₂ for 30 seconds.
10	Ventilator turned off, patient allowed to exhale.
11	ETT clamped.
12	Tracheostomy.
13	ETT visualized by the surgical team and withdrawn by anesthesia.
14	Tracheostomy intubation once distal tip of ETT visualized, cuff over-inflated.
15	Viral filter attached to trach and connected to Ventilator.
16	Vent turned back on, end tidal CO ₂ used to confirm placement, ETT removed.
17	Skin incision closed and tracheostomy secured.

3. Results

A total of 17 Tracheostomies were performed at our community hospital who fulfilled our indication criteria (Table 5). The average age was 62 years old, average body mass index (BMI) was 30 and 15 of our 17 patients were male. The most common comorbidities present in our patient population were as follows: 64% had hypertension (HTN), 47% had hyperlipidemia (HLD) and 35% had type 2 diabetes

mellitus (DM2). Secondary to COVID-19 patient's high incidence of thrombotic events, 59% of our patients were actively on therapeutic anticoagulation regimens at time of tracheostomy. Patients had an average endotracheal intubation preoperative time period of 24 (17-35) days. The average duration of tracheostomy which was measured from skin incision until all team members exited the ICU room was 19 (13-31) minutes. The average AP1 was 26 (14-61) seconds and AP2 was 79 (40-166) seconds with the total apneic period time averaging 106 (67-153) seconds which

did not yield any adverse oxygenation events.

There were minimal complications noted within our study within a mean follow up time of 21 days. These included a minor complication of oozing from the tracheostomy site which required suture ligation and two major complications; tracheostomy revision for displacement on postoperative day 7 (POD) and a left sided pneumothorax which required a chest tube insertion on POD 1. At the time of completion of

this manuscript four patients were decannulated, one patient was downsized, tolerating capping trials and eight patients had been discharged to rehabilitation centers. Four patients died as a result of cardiopulmonary effects of COVID-19, unrelated to the tracheostomy procedure, yielding a mortality rate of 23%. No healthcare workers involved with tracheostomy procedure displayed symptoms or documented newly diagnosed COVID-19 positive status.

Table 5. Tracheostomy Patient Data.

Patient	Age	Gender	BMI	Comorbidities	Preop vent setting
1	57	M	31	HTN, DM2	AC 30 500 40% 5
2	63	M	32	HLD, GERD	AC 30 450 40% 5
3	55	M	26	HTN, DM2, HLD, CKD3	AC 14 460 30% 5
4	58	F	28	HLD, DM2, HTN	AC 16 480 40% 5
5	41	M	24	None	AC 34 400 40% 5
6	57	M	31	HTN, HLD	AC 32 490 40% 6
7	62	M	37	Anemia, Gout, GERD, HLD, HTN, OSA, TIA	AC 18 500 30% 5
8	80	M	24	HTN, CAD, BPH, CKD3, Depression, HLD, Afib	AC 25 500 40% 5
9	75	M	37	HTN, DM2, hypothyroid	AC 18 450 35% 5
10	78	F	36	HTN	AC 20 450 40% 6
11	62	M	34	OSA	AC 20 500 40% 8
12	72	M	24	BPH	AC 30 450 40% 5
13	58	M	27	HTN, HLD, CAD	AC 18 420 40% 5
14	69	M	33	HTN, DM2	AC 34 450 40% 5
15	54	M	27	Asthma, Fibromyalgia	AC 26 360 40% 8
16	47	M	39	None	AC 34 450 40% 5
17	60	M	27	DM2, HTN, HLD	AC 36 450 40% 5

Table 5. Continued.

Patient	Preop Days intubated	AP1 (sec)	AP2 (sec)	Total Apneic period (sec)	Duration (Min)	Tracheostomy Complications
1	21	40	44	84	25	None
2	22	27	40	67	21	Minimal bleeding
3	23	31	122	153	15	LPTHX POD 1 Trach CT placed
4	21	50	51	101	12	None
5	23	18	72	90	31	Revision for dislodged Trach POD7
6	30	15	94	109	19	None
7	23	41	60	101	13.00	None
8	20	37	49	86	18	None
9	22	61	44	105	23	None
10	17	15	80	95	14	None
11	35	23	165	188	18	None
12	31	16	67	83	18	None
13	18	14	86	100	18	None
14	21	19	106	125	13	None
15	21	19	75	94	13	None
16	33	15	127	142	25	None
17	29	15	75	90	15	None

Ingredients of a Successful Tracheostomy in COVID-19 Patient Population

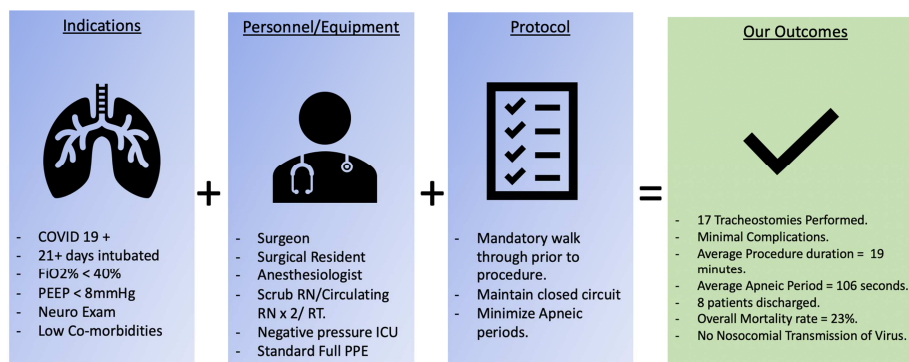


Figure 1. Visual Abstract.

4. Discussion

The COVID-19 pandemic presents unique difficulties when considering performing a tracheostomy for such patients for a variety of reasons. First, the prognosis of this novel disease is not yet fully understood but preliminary mortality rates for those requiring critical care have been estimated as high as 70-80%. This in general is noticeably greater than patients who are critically ill with non-COVID pneumonia. Thus, there is a heightened risk of performing a futile procedure. Second, the duration of detectable viral load and correlation with transmission rates during aerosol generating procedures is not yet specifically known. Therefore, there is an increased risk of infection to the healthcare workers performing a potentially futile procedure. Finally, there is no evidence to support a standardized approach for tracheostomy insertion in terms of minimizing risk of healthcare personnel exposure to airborne droplets. It is not surprising that there remains little literature documenting implementation of high-risk procedures in highly contagious upper airway diseases.

Post-intubation laryngo-tracheal stenosis is a well-known risk of prolonged endotracheal intubation. There is a challenge involved in balancing this complication with the ethical issue of if a tracheostomy should be performed on these patients at all. If so, how to perform the procedure minimizing the risk to healthcare workers providing care is of critical importance. We attempt to mitigate these variables, vetted in a multidisciplinary approach, with a stringent protocol applied to the surgical end.

In our recent history we have not been confronted with a pandemic that COVID-19 has surmounted. Therefore, we must curate innovative strategies to respond to this novel entity. With our proposed tracheostomy protocol, efforts to maintain a closed system and thus limit aerosolized virus to the provider was at utmost importance. The endotracheal tube was advanced prior to tracheotomy in order to decrease incidence of injuring the balloon cuff in the circumstance of tracheostomy failure and need for resumption of a closed system endotracheal airway. We found that a tracheostomy was not more difficult and performed in a timely fashion (averaging 18 minutes in duration) with an experienced provider performing the procedure despite a suboptimal setting and patient positioning. We sought out to calculate and limit apnea periods in this specific patient population as they are hypothesized to have less pulmonary reserve due to their severe COVID-19 pneumonia. The total apneic period during tracheostomy within our study of 106 seconds on average did not yield any observed hypoxic events. We observed a low incidence of postoperative bleeding events even with 59% of our patient population being restarted on therapeutic anticoagulation on POD 1 for thrombotic COVID-19 sequela. The relatively low postoperative mortality rate compared to the overall mortality rate of intubated COVID-19 patients indicated that our

preoperative indications may reliably be used to determine candidacy for Tracheostomy in COVID-19 patients. Furthermore, tracheostomy may offer a benefit for these patients as conventional bronchoscopy and lavage should be avoided, allowing for better suctioning and viral pneumonia clearance. At the time of publication, no nosocomial transmission of virus has been observed in any providers participating in the study confirming the safety of the proposed protocol.

5. Conclusion

Surgical airways and tracheostomy care, normally considered routine, carries significant risk of COVID-19 exposure to healthcare providers and the community. This preliminary study indicates that promising outcomes can be achieved with tracheostomy in the COVID-19 patient population. A key feature of our proposed protocol is that it can readily be implemented with the resource's community hospitals have readily available.

The COVID-19 pandemic presented the surgical community with novel quandaries. We recommend a multidisciplinary approach to tracheostomy, which can be performed in this high-risk population if strict indications, equipment, personnel and protocol recommendations are followed. No nosocomial transmission was observed while minimizing apneic periods and overall mortality with this protocol. A larger study of COVID-19 tracheostomy patients with extended follow up is indicated to confirm the long-term efficacy of our proposed protocol. As this pandemic continues to evolve, the healthcare community will continue to be challenged with problematic scenarios. As evidence-based guidelines and recommendations evolve, practices and procedures will need to be continually re-evaluated to ensure safety and appropriateness in high-risk populations.

Abbreviations

AC	Assist Control
AP1	Apneic period 1
AP2	Apneic period 2
CAD	Coronary Artery Disease
CKD3	Chronic Kidney Disease Stage 3
COVID-19	Coronavirus disease 2019
DM2	Diabetes Mellitus 2
FiO ₂	Fraction of inhaled of inhaled oxygen
GERD	Gastroesophageal reflux disease
HLD	Hyperlipidemia
HTN	Hypertension
ICU	Intensive care unit
MERS	Middle East Respiratory Syndrome
OR	Operating room
OSA	Obstructive sleep apnea
PCR	Polymerase chain reaction
PEEP	Positive end expiratory pressure

POD	Postoperative day
PPE	Personal Protective Equipment
RN	Registered Nurse
SARS	Severe Acute Respiratory Syndrome
TIA	Transient Ischemic attack
XLT	Extended Length Tracheostomy

Conflict of Interest

All the authors do not have any possible conflicts of interest.

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Informed Consent

Full detailed written consent was obtained from patient's healthcare proxy for Tracheostomy to be performed with the proposed protocol as well as permission to collect data perioperatively. The protocol was reviewed and approved by a multi-disciplinary team at Huntington Hospital, NY.

Author Contributions

B. T. is guarantor and has full responsibility over the manuscript. B. T., M. S. and V. A. S. searched literature and wrote the manuscript. B. T., V. A. S., R. Z., R. K. and D. G. contributed substantially to the study design, development of protocol, data analysis and interpretation and reviewed the manuscript. B. T., V. A. S. and D. G. were responsible for performing all procedures described within this manuscript.

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