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Protocols and outcomes

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Abstract

Purpose: Approximately 3-15% of COVID-19 patients will require prolonged mechanical ventilation thereby requiring consideration for tracheotomy. Guidelines for tracheotomy in this cohort of patients are therefore required with assessed outcomes of tracheotomies.

Patients and methods: A retrospective chart review was performed of COVID-19 patients undergoing tracheotomy. Inclusion criteria were the performance of a tracheotomy in COVID-19 positive patients between March 11 and December 31, 2020. Exclusion criteria were lack of consent, extubation prior to the performance of a tracheotomy, death prior to the performance of the tracheotomy; and COVID-19 patients undergoing tracheotomy who tested negative twice after medical treatment. The primary predictor variable was the performance of a tracheotomy in COVID-19 positive patients and the primary outcome variable was the time to cessation of mechanical ventilation with the institution of supplemental oxygen via trach mask.

Results: Seventeen tracheotomies were performed between 4-25 days following intubation (mean=17 days). Seven patients died between 4-6 days (mean=8.7 days) following tracheotomy and 10 living patients realized cessation of mechanical ventilation from 4 hours to 61 days following tracheotomy (mean=19.3 days). These patients underwent tracheotomy between 4-22 days following intubation (mean=14 days). The 7 patients who died following tracheotomy underwent the procedure between 7-25 days following intubation (mean=18.2 days). Seven patients underwent tracheotomy on or after 20 days of intubation and 3 survived (43%). Ten patients underwent tracheotomy before 20 days of intubation and 7 patients survived (70%). Significant differences between the mortality groups were detected for age (p=0.006), and for P/F ratio at time of consult (p=0.047) and the time of tracheotomy (p=0.03).

Conclusion: Tracheotomies are safely performed in COVID-19 patients with a standardized protocol. The timing of tracheotomy in COVID-19 patients is based on ventilator parameters, P/F ratio, patient prognosis, patient advanced directives, and family wishes.

The coronavirus disease (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), originated in Wuhan, Hubei Province, China in December 2019 and has since spread worldwide. The World Health Organization declared SARS-Co-V-2 a pandemic on March 11, 2020 due to the increasing number of worldwide cases[1]. Huang et al[2] first reported 41 patients with novel coronavirus-infected pneumonia in January 2020 and 27 of the patients had exposure to the Huanan Seafood Wholesale Market. These patients demonstrated radiographic evidence of pneumonia, with 98% of patients showing bilateral multiple lobular and subsegmental areas of consolidation (figure 1). Fever was noted in 98%, a non-productive cough in 76%, shortness of breath in 55%, and fatigue in 44% of patients in this cohort. This notwithstanding, COVID-19 exhibits diverse clinical presentations. A report of 44,672 COVID-19 patients from China demonstrated 81% of patients with mild symptoms, 14% of patients with severe symptoms, and 5% of patients with critical symptoms including respiratory failure, septic shock, and multi-system organ failure[3, 4]. Approximately 25% of all COVID-19 positive patients have medical comorbidities and it has been estimated that 60-90% of hospitalized COVID-19 positive patients have medical comorbidities[4]. These diagnoses in hospitalized patients include hypertension, cardiovascular disease, diabetes, chronic kidney disease, chronic pulmonary disease, cancer, and chronic liver disease[5-7].

Approximately 17-35% of hospitalized COVID-19 patients are admitted to an intensive care unit, primarily due to hypoxemic respiratory failure[4]. Greater than 75% of hospitalized COVID-19 patients require the administration of supplemental oxygen and 3-15% of COVID-19 patients will require mechanical ventilation[1, 8]. An early report indicated that death was common in patients who were mechanically ventilated. In a study of 52 critically ill COVID-19 patients, thirty (81%) of 37 mechanically ventilated patients were dead by 28 days[9.] Moreover, there were no intubated patients who

were extubated and alive at the end of the study. Another study reported on 191 hospitalized COVID-19 patients of which 137 were alive and 54 were dead. Thirty-two patients (17%) were mechanically ventilated, of which 31 patients died and 1 patient survived[10]. It becomes clear, therefore, that the prognosis of mechanically ventilated COVID-19 patients is poor and some patients require long periods of ventilator support. Tracheotomy might be beneficial to these patients, particularly those who otherwise have a favorable prognosis. The surgical intervention of tracheotomy might also be indicated since COVID-19 has become the leading cause of death in the United States[11, 12]. Since tracheotomy is 1 of the final efforts to be offered to mechanically ventilated intensive unit care patients in general, consideration should certainly be given to performing tracheotomies in COVID-19 patients who are similarly experiencing prolonged periods of mechanical ventilation. In doing so, however, the health care team must be protected from transmission of the disease, the concern for which has produced anxiety in these individuals[13]. The purpose of this study was to outline protocols and safety measures taken to protect all members of the health care team while determining the outcomes of COVID-19 patients undergoing tracheotomy, particularly regarding cessation of mechanical ventilation with transitioning to supplemental oxygen in these patients.

Patients and methods

A retrospective chart review was conducted of all patients undergoing tracheotomy by a single surgeon (ERC) of the Department of Oral and Maxillofacial Surgery at the University of Tennessee Medical Center from the beginning of the pandemic, March 11, 2020 through December 31, 2020. University of Tennessee Institutional Review Board (IRB) review and approval was obtained to conduct the study (IRB #4712). Study patients were those who were consulted for tracheotomy by the surgeon from t3 intensive care units in the hospital, including the Cardiovascular Intensive Care Unit (CVICU), the Medical Intensive Care Unit (MICU), and the Neuro Intensive Care Unit (NCC) where COVID-19 patients were primarily admitted. Consults were placed by intensivists when their efforts to successfully provide ventilator wean and extubation of patients failed to come to fruition, thereby necessitating

tracheotomy for continued mechanical ventilation and ventilator weaning. The threshold and timing for consultation varied in terms of the patient's length of time intubated. This threshold was arbitrary among the critical care physicians primarily caring for these patients, and was therefore very individualized. Inclusion criteria for the study were patients who tested positive for COVID-19 at least once during their hospital admission and who underwent tracheotomy. Exclusion criteria were patients who were not tested for COVID-19, patients who were negative by 2 tests prior to the tracheotomy procedure, and patients who underwent tracheotomy before the designation of the pandemic on March 11, 2020 or after December 31, 2020. The primary predictor variable of the study was a mechanically ventilated COVID-19 positive patient who underwent a tracheotomy. The primary outcome variable of the study was the time to cessation of mechanical ventilation with the institution of supplemental oxygen via trach mask following tracheotomy.

Preoperative COVID workup

All patients admitted to the University of Tennessee Medical Center since the designation of the pandemic on March 11, 2020 undergo COVID-19 nasopharyngeal swab sampling, including those patients directly admitted to an intensive care unit. The SARS-Co-V-2 assay manufactured by Intergy Laboratories (Knoxville, Tennessee) was utilized in the assessment of patients at the University of Tennessee Medical Center beginning on March 19, 2020. The Xpert Xpress SARS-Co-V-2 test (Cepheid; Sunnyvale, California) was utilized beginning in mid-April 2020, and the Panther Fusion SARS-C0-V-2 assay (Hologic, Inc.; Marlborough, Massachusetts) was used effective June 29, 2020, and continued to be used at the time of the completion of this study. While all patients underwent testing upon admission, non-uniform testing occurred thereafter. Some patients underwent repeat testing following a positive test result in preparation for tracheotomy, while some patients did not undergo repeat testing. All COVID-19 patients underwent chest imaging with plain films and CT scans without intravenous contrast. All symptomatic patients underwent CT angiograms of the chest to rule out pulmonary emboli.

Preoperative medical workup

All patients were medically assessed preoperatively by the critical care team, the oral and maxillofacial surgery team, and the anesthesia team in terms of the ideal time to perform the tracheotomy following consultation. While strict ventilator parameters [maximum rate in breaths per minute, maximum positive end-expiratory pressure (PEEP), and maximum fraction of inspired oxygen ($Fi0_2$)] varied in terms of suitability for the tracheotomy procedure, the 3 teams agreed on a $Pa0_2/Fi0_2$ (P/F) of 100 or greater as an absolute standard to proceed.

Operating room protocol and support staff

All tracheotomy procedures were performed in an operating room with an anteroom located immediately adjacent to the operating room. The anteroom contained an inside door permitting entrance directly to the operating room and an exit door to the main hallway. Entrance to and exit from the operating room to the hallway can occur through the anteroom or directly through the operating room. Team members entered and exited the operating room, however through the anteroom rather than the front door to the operating room proper. In this manner, any potentially aerosolized virus in the operating room would be better contained within the operating room, rather than disseminating to the main hallway outside the operating room where other OR personnel not involved in the case might otherwise be exposed to aerosolized virus. Stated differently, the front door to the operating room was not opened during the procedure, but only permitted entrance and exit of the patient before and following the procedure. A 17-minute delay occurred by hospital protocol following all COVID-19 tracheotomy procedures before opening the front door to the operating room and transporting the patient back to the ICU. Additionally, the door from the anteroom to the operating and the door from the anteroom to the main hallway were never simultaneously opened. This protocol prevented aerosolized virus present in the operating from disseminating to the main hallway outside the operating room through the anteroom. The

anteroom contained the scrub sinks and represented the area where doffing of the surgical team's personal protective equipment (PPE) occurred following the procedure.

All tracheotomy procedures were rehearsed with the 2 circulator nurses and 1 surgical technologist familiar with the team's standardized routine. Due to the short nature of the procedure, as well as the intention to limit team member exposure to the patient, this staff was not replaced during the procedure. One circulator nurse was physically present in the OR during the procedure and the other circulator nurse was present in the anteroom for retrieval of additional supplies that might be required of the surgical team during the tracheotomy procedure.

Enhanced PPE was donned by all members of the support staff, surgical team, and anesthesia team. Enhanced PPE included an N95 mask, eye goggles or surgical loupes, a face/neck shield, surgical gown, and double gloves.

Surgical technique

All tracheotomies were performed in the operating room under full sterile conditions, and all tracheotomies were open. A supramanubrial approach was uniformly executed and a standard dissection was performed of deep layers, identical to our approach for non-COVID patients[14]. Use of the electrocautery was minimized during the dissection. Use of the suction was similarly minimized during the procedure. The trachea was entered with an I incision and no suctioning of the airway occurred. An 8-Shiley® (Medtronic, Minneapolis, MN), cuffed and non-fenestrated tracheostomy tube was placed when this tube was perceived to be of acceptable length, while a proximal XLT Shiley® tracheostomy tube (13.3 mm outer diameter) was placed when extra length was required. A Bivona® (Smiths Medical, Dublin, OH) tracheostomy tube was requested preoperatively for severely obese patients when the proximal XLT tracheostomy tube was anticipated to be of insufficient length (figure 2). The exchange of the endotracheal tube for the tracheostomy tube occurred as quickly as possible. Members of the surgical team secured the anesthetic circuitry to the tracheostomy tube and hyperinflated the tracheostomy tube

cuff. The tracheostomy tube was secured to the neck skin with 4 point 2-0 silk sutures and a reinforcing VELCRO® strap around the neck.

Anesthestic technique

All patients were administered long-acting neuromuscular blockade in the intensive care unit to avoid coughing during transport to the operating room and during the procedure. General anesthesia was administered through the existing endotracheal tube. Full and effective endotracheal cuff pressure was ensured prior to prepping the patient's skin. The heat and moisture exchanger (HME) was maintained on the endotracheal tube during the entirety of the case. The patient was maintained on 100% oxygen for most of the surgical procedure. Cessation of ventilation by the anesthesia team occurred upon request by the surgeon before the trachea was incised. Ventilation resumed immediately following hyperinflation of the tracheostomy tube cuff and verification of maintenance of cuff pressure. The HME was maintained on the circuitry connected to the tracheostomy tube. The patient was transported back to the ICU on 100% oxygen. The tracheostomy tube cuff pressure was converted from hyperinflation to conventional inflation thereafter.

Doffing (removal) of PPE

Following completion of the surgical procedure, members of the surgical team, including the surgical technologist individually and sequentially entered the anteroom for doffing of PPE. A dedicated team member, present in the anteroom during the surgical procedure, assisted individual team members with incremental removal of PPE with wiping of gloves and hands with a virucidal wipe (Sani-Cloth AF3 germicidal disposable wipe; PDI, Woodcliff Lake, New Jersey), before and after each step. The first step was removal of the outer set of gloves. The virucidal wiping of the outer set of gloves took place before their removal. Thereafter, a virucidal wiping of the inner set of gloves occurred. The face/neck shield was removed followed by virucidal wiping of the inner set of gloves. The gown was then removed followed by virucidal wiping of the inner set of gloves that were then removed. Bare hands were cleaned by

virucidal wiping followed by removal of surgical loupes that were then placed in the loupe box. The team member then washed hands at the scrub sink and the door from the anteroom to the hallway was opened for the team member. This sequence was identically repeated for each team member until all members were doffed and exited the anteroom. All team members then changed their scrubs and exited the operating room complex. Team members were encouraged to shower if blood or other body fluids touched their skin.

Statistical analysis

Descriptive and frequency statistics were performed to describe the sample's demographic and clinical characteristics. Statistical assumptions for continuous variables (normality and homogeneity of variance) were assessed before comparing the mortality groups (0 = lived versus 1 = died). There was a limited sample size for purposes of between-subjects analyses, and while non-parametric statistics could have been performed, the researchers chose to use parametric statistics to increase statistical power, as well as the precision of the statistical inferences. An adjustment was mace to the degrees of freedom when homogeneity of variance was violated so that parametric analyses could still be applied. Independent samples *t*-tests were performed to compare the mortality groups on age, BMI, P/F ratio at time of consultation, time to performance of tracheotomy after intubation, P/F ratio at time of tracheotomy, and time to consultation following intubation. Means and standard deviations were reported and interpreted for the *t*-test analyses. Statistical significance was assumed at an alpha value of 0.05 and the statistical analyses were conducted using SPSS Version 26 (Armonk, NY: IBM Corp.).

Results

The retrospective chart review of all patients consulted for the tracheotomy procedure by the primary surgeon (ERC) between March 11, 2020 and December 31, 2020 identified 76 patients. Fifty-six COVID-19 negative patients (53 underwent tracheotomy), and 20 COVID-19 patients were identified. Of the 20 COVID-19 positive patients, 17 underwent the tracheotomy procedure and comprise the focus of

this retrospective study (table 1). Of the 3 COVID-19 patients who did not undergo the tracheotomy procedure, 1 patient (patient 2) was successfully extubated the day prior to the intended procedure, and 2 patients (patient 3 and 5) died before the tracheotomy procedure could be performed (table 2). Of the 17 COVID-19 patients undergoing the tracheotomy procedure, there were 13 males and 4 females. The age range was 30 to 75 years with a mean of 58 years. The patients' body mass index (BMI) ranged from 10.8 to 70.4 with a mean of 34.5. Eight patients were obese, with 5 patients satisfying a diagnosis of obesity (BMI > 30, < 40) and 3 patients satisfying a diagnosis of severe obesity (BMI > 40). Other pre-existing medical comorbidity was noted in all patients, with 14 patients diagnosed with hypertension, 8 patients diagnosed with type 2 diabetes, and 6 patients diagnosed with hyperlipidemia. Obstructive sleep apnea syndrome was pre-existing in 3 patients, chronic kidney disease was pre-existing in 3 patients, and coronary heart disease and cerebrovascular disease were pre-existing in 1 patient each. The time from intubation to tracheotomy consult ranged from 1 day to 22 days with a mean of 13.5 days. Preoperative medical treatment for the COVID-19 diagnoses in these 17 patients included remdesivir in 14 patients, convalescent plasma in 10 patients, dexamethasone in 10 patients, and extracorporeal membrane oxygenation (ECMO) in 1 patient.

The P/F ratio was available at the time of consult and at the time of tracheotomy in 14 of 17 COVID-19 patients undergoing tracheotomy (table 3). Of these 14 patients, the P/F was uniformly greater than 100 at the time of tracheotomy, and ranged from 101 to 341, with a range of 180. Only 1 study patient (patient 7) demonstrated a P/F greater than 300 at the time of consult and the time of tracheotomy. The tracheotomies were performed with a range of 4 days to 25 days following intubation, with a mean of 17 days. Estimated blood loss associated with the tracheotomy procedures ranged from 5-20 mL with a mean of 10 mL. There was no intraoperative morbidity or mortality associated with the procedures. Conventional 8-Shiley tracheostomy tubes were placed in 6 patients, proximal XLT tracheostomy tubes were placed in 10 patients, and a Bivona tracheostomy tube was placed in 1 patient. No tracheostomy

tube dislodgements occurred postoperatively and no instances of clinically concerning bleeding were noted from the surgical sites postoperatively.

Seven patients died between 4 and 16 days (mean = 8.7 days) following tracheotomy and died due to cessation of ventilator support (terminal wean) based on collective decisions made between our palliative care team, the medical center's biomedical ethicist, and family members. The 7 patients who died underwent their tracheotomy procedures between 7 and 25 days following intubation (mean = 18.2 days). Ten patients realized cessation of mechanical ventilation from 4 hours to 61 days, with a mean of 19.3 days. These 10 patients underwent their tracheotomy procedures between 4 and 22 days following intubation (mean = 14 days). Five patients realized successful ventilator weaning at our medical center while 5 patients were transferred to a long-term acute care facility and realized their successful ventilator weaning at that facility. All 10 patients who successfully weaned off mechanical ventilation are alive at the end of the study period. Three of these patients have been successfully decannulated. Of the 7 patients who underwent tracheotomy on or after 20 days of intubation (figure 3), 3 were alive at the end of the study period and 4 patients were dead. Of the 10 patients who underwent tracheotomy before 20 days of intubation (figure 3), 7 patients were alive at the end of the study period and 3 patients were dead.

The statistical assumptions of normality and homogeneity of variance were met for the between-subjects comparisons of age, time to performance of tracheotomy after intubation, and time to consultation following intubation. Adjustments were made to the degrees of freedom for BMI, P/F ratio at time of consult, and P/F ratio at time of tracheotomy. Based on an independent samples t-test, it was found that participants that died were significantly older (mean [M] = 65.86, standard deviation [SD] = 6.01), versus those who survived (M = 52.70, SD = 9.55), $p = 0.006$. Individuals that died also had significantly lower P/F ratios at the time of consult, $p = 0.047$, and at the time of tracheotomy, $p = 0.03$. There were no significant differences between the mortality groups for BMI, $p = 0.19$; time to performance of tracheotomy after intubation, $p = 0.44$; and time to consultation following intubation, $p = 0.64$. The means and standard deviations for the independent samples t-tests are presented in Table 4.

Discussion

From March 13, 2020 through December 31, 2020, the University of Tennessee Medical Center in Knoxville tested 22,487 patients for COVID-19. Of these tested patients, 15,951 were negative (71%) and 6,536 (29%) were positive. During this same inclusive period, 151 COVID-19 positive patients (2.3%) required mechanical ventilation and 77 of these 151 patients (51%) died. The decision to perform a tracheotomy, the timing therein, and the protocols for the tracheotomy procedure represent very contentious issues in the care of the COVID-19 patient. At the core of this debate includes the perceived benefit of early vs. late tracheotomy, assumptions regarding the chronology of transmission of the virus, and justifiable concerns related to infectious risk to surgeons performing the tracheotomy procedure, members of the anesthesia team, and other personnel in the operating room during the procedure[15]. Numerous consensus and anecdotal guidelines recommended delaying tracheotomy, or avoiding the procedure entirely, to minimize the risk of transmission of the infection to team members caring for the patient [8, 15-19]. Specifically, avoiding early tracheotomy in this patient cohort was advised with the assumption that peak infectivity of the virus occurred at 7-10 days following the onset of symptoms such that performing the tracheotomy at that time would produce maximal risk to surgeons performing these procedures[20].

The P/F ratio, as utilized in our study cohort, has been previously described to designate the severity of acute respiratory distress syndrome (ARDS)[21] as well as a prognostic index in COVID-19 patients[22]. In 2012, Ranieri et al[23] published findings of the European Society of Intensive Care Medicine that convened a panel of international experts to discuss the definition of ARDS. The resulting Berlin definition of ARDS was established to predict the prognosis of ARDS and categorized ARDS as: mild (P/F between 200 and 300), moderate (P/F between 100 and 199), and severe (P/F less than 100). These categories were validated in 4188 ARDS patients that demonstrated an in-hospital mortality of 45% for severe ARDS, 32% for moderate ARDS, and 27% for mild ARDS. Delaying tracheotomy until the P/F was greater than 100 in our patient cohort was performed to further assess the short-term prognosis of

these patients and to select those COVID-19 patients whose prognosis might be better, thereby justifying the performance of the tracheotomy procedure in these patients.

Heyd et al[17] reviewed the COVID-19 tracheotomy guidelines of 13 society or organizations including 5 from otolaryngology-head and neck surgery, 6 from anesthesiology, and 1 from pulmonary/critical care. All guidelines recommended postponing elective tracheotomy in these patients. Seven guidelines suggested only including essential team members such as 1 surgeon and 1 anesthesia team member. It was suggested that trainees not be present for the tracheotomy procedure. Delaying the tracheotomy procedure until the COVID patient had cleared the virus should be performed, if possible. To this end, Heyd et al[17] recommended operating these patients only when negative testing existed, as might occur with 2 negative tests that are obtained 48 hours apart.

Discussion of COVID-19 in general, and pontification of tracheotomy procedures for these patients in particular, frequently result in conversations about aerosol-generating circumstances and interventions. Aerosols are defined as very small respiratory particles that can remain suspended in ambient air for long periods of time, can migrate greater than 6 feet beyond the patient, and can penetrate conventional surgical masks[24]. Klompas et al[24] reviewed the World Health Organization's classification of endotracheal intubation, sputum induction, tracheotomy, cardiopulmonary resuscitation, and noninvasive positive pressure ventilation as unequivocal aerosol-generating procedures. These procedures are so designated because they represent greater risk for health care team members in terms of transmission of disease. Klompas et al[24] provide explanation of 4 factors that encourage infectious disease during medical and surgical procedures. The first factor is forced air as occurs in sustained ventilation during a tracheotomy procedure when the tube exchange is occurring. The second factor is patient symptomatology and disease severity. Symptomatic patients likely have a larger magnitude of virus than asymptomatic patients, and are therefore more likely to transmit disease to members of the health care team, particularly when procedures are performed. The third factor is distance, specifically related to the feature of respiratory emissions to become diluted in the surrounding air. Finally, the fourth

factor is duration. Longer exposures to infected intuitively translate to higher incidences of transmissions of disease to health care team members. These 4 factors of aerosol-generating procedures must be carefully considered when planning and performing tracheotomy procedures in COVID-19 positive patients. In the protocol that we observed in our cohort of COVID-19 patients undergoing tracheotomy, the intentional period of apnea observed during entrance into the trachea and placement of the tracheotomy tube, as well as avoiding suctioning of the trachea during the procedure, decreased aerosolization associated with the procedure and decreased team member safety.

Chao et al[16] reported on their determination as to whether a subset of mechanically ventilated COVID-19 patients existed for whom tracheotomy was indicated while also taking the risk of transmission to team members into account and the patient's prognosis. Their recommendations included considering tracheotomy in patients with a good prognosis and without significant medical comorbidity who had been intubated longer than 21 days. Further, they recommended against routine tracheotomy prior to 21 days in COVID-19 patients solely for ventilator dependence due to the high risk of infectious disease transmission to team members and the perceived poor prognosis of these patients requiring mechanical ventilation. Finally, the authors recommended that all patients should undergo COVID testing when they are being considered for tracheotomy, regardless of the presence or absence of COVID related symptoms.

Sommer et al[8] indicated that elective tracheotomy should not be planned in a COVID-19 patient who is intubated until the patient is noted to be cleared of the virus and until isolation procedures are no longer in place. They indicated that the standard of care should involve extended endotracheal intubation of patients for the entire period of mechanical ventilation in these patients. Further, these authors recommended open tracheotomy performed in the operating room in the COVID-19 negative patient. Under these circumstances, the operating room personnel should be kept to a minimum, and the surgical team should wear N95 masks and full facial and neck protection due to the possibility of false-negative COVID-19 tests. The patient should be paralyzed during the procedure to prevent coughing that would

otherwise result in aerosolization of virus when entering the trachea. The heat and moisture exchanger (HME) should be connected directly to the tracheotomy tube to reduce aerosolization of the virus in the event of disconnection of the anesthetic circuitry. Finally, the authors recommended avoiding or minimizing suctioning the airway after entrance into the trachea and before the tracheostomy tube is inserted.

Skoog et al[25] provided recommendations for tracheotomy during the COVID-19 pandemic in order the minimize transmission to members of the health care team. They indicated that tracheotomy can be delayed greater than 14 days in patients experiencing prolonged intubation. When performed in COVID-19 patients, the tracheotomy procedure should be performed in the intensive care unit to avoid transport of the patient in the hospital. The authors recommended neuromuscular blockade to avoid coughing and aerosolization, ventilation with inflation of the endotracheal cuff, ceasing ventilation before surgical entering the trachea, avoiding the use of suction once the trachea is entered, and the uniform use of personal protective equipment by team members to include and N95 mask, face shield, double gloves, powered air purifying respirator (PAPR) and/or Association for the Advancement of Medical Instrumentation (AAMI) level 4 suit. All of these transmission precautions were observed in the care of our patients with the exception of the PAPR and AAMI level 4 suit.

Stubington et al[26] prospectively reported the results of 12 COVID-19 patients undergoing a tracheotomy procedure in March-April, 2020. Their recommendations for patient selection included those who were at least 14 days post-nasopharyngeal swab positive test result, FiO2 less than or equal to 40% for at least 24 hours prior to the procedure, supine patients, 2 unsuccessful trials of withholding sedation, and the patient's tolerance of clamping the tube for 1 minute in the intensive care unit. Their patient outcomes were more favorable when the FiO2 was 50% or less and the PEEP was 8 or less in the first 48 hours following the tracheotomy procedure than patients whose ventilator settings exceeded these values.

Yeung et al[27] reported on 1257 COVID-19 positive patients who were admitted to King's College Hospital in London, England from March 10 – May 18, 2020. One hundred seventy-six of these patients were admitted to the intensive care unit and required mechanical ventilation. Of these 176 patients, 72 underwent tracheotomy. Forty-four patients underwent open tracheotomy while 28 patients underwent percutaneous tracheotomy. The tracheotomy procedures took place at a median of 17 days following intubation with a median FiO2 of 40% and a median PEEP of 8.5. The objective to wean sedation and mechanical ventilation was successful in 79 and 61% of patients, respectively. Twenty-one percent of patients were weaned from mechanical ventilation in 7 days or less, and 44.4% of patients were weaned from mechanical ventilation at 14 days or less. The authors concluded that the outcomes of open tracheotomy were comparable to those of percutaneous tracheotomy, and open tracheotomy did not pose an increased risk of COVID-19 transmission to team members.

Tornari et al[28] performed an observational cohort study of 312 patients admitted to the intensive unit of their hospital from March 1, 2020 – May 10, 2020. Two hundred sixty-six patients were intubated and 78 patients underwent tracheotomy with a median of 16 days following endotracheal intubation. Four patients died before sedation weaning as a result of their COVID-19 and 5 additional patients did not meet inclusion criteria for the study. The outcomes of 69 patients undergoing tracheotomy were therefore able to be analyzed. Fifty-nine patients (85.5%) experienced cessation of sedation following tracheotomy with a mean of 4 days. Cessation of mechanical ventilation occurred in 46 patients (66.6%) with a mean of 12 days following tracheotomy. Decannulation occurred in 35 patients (50.7%) with a mean of 16 days following tracheotomy. The authors did not assess cessation of mechanical ventilation as a function of timing of the tracheotomy procedure, but they indicated that decannulation was delayed in patients with higher FiO2 (> 40%) and higher pre-tracheotomy peak cough flow.

Aviles-Juardo et al[29] prospectively studied 50 consecutive COVID-19 patients who were admitted to an intensive care unit and who required open bedside tracheotomy between March 16, 2020 and April 10, 2020. The median length of time of endotracheal intubation was 9 days prior to tracheotomy. Thirty-

two patients underwent early tracheotomy, not temporally defined by the authors and 18 patients underwent late tracheotomy, also not temporally defined by the authors. The success of weaning mechanical ventilation following tracheotomy was greater in the early tracheotomy group compared to the late tracheotomy group, but the difference was not statistically significant. There was less overall time of mechanical ventilation in the early tracheotomy group compared to the late tracheotomy group, and the reduction was accomplished with the reduction of the pre-tracheotomy time of mechanical ventilation. The authors concluded that open tracheotomy performed bedside in the intensive care unit with a standardized approach is safe for patients and surgeons. They indicated that early tracheotomy might be associated with reduced intensive care unit beds during the COVID-19 pandemic.

Tay et al[30] made recommendations for tracheotomy during the COVID-19 pandemic by drawing on experiences from the SARS epidemic of 2003 when tracheotomy was the most common surgical procedure performed. They indicated that percutaneous tracheotomy involves excessive manipulation of the airway including bronchoscopy and sequential dilations during entrance in the trachea. Increased aerosolization occurs compared to open tracheotomy such that open tracheotomies were performed during the 2003 SARS epidemic and might be favored during the COVID-19 pandemic. The authors emphasized that the principles of team planning and the protection of team members are paramount. Further, they indicated that as the COVID-19 pandemic escalates, so will the requirement for tracheotomies in this patient cohort with prolonged mechanical ventilation. While these authors recommended open tracheotomy as the preferred method in the management of COVID-19 patients, other authors discussed the acceptable safety profiles of percutaneous tracheotomy in these patients[31, 32].

Kwak et al[15] performed a retrospective chart review of 148 patients with confirmed COVID-19 who required mechanical ventilation from March 1 to May 7, 2020, and who required a tracheotomy. For the patients (n = 52 patients) undergoing early tracheotomy, the mean time from intubation to tracheotomy was 5.58 days, and the time to discontinuation of mechanical ventilation was 26.5 days following intubation. For the late tracheotomy group (n = 96 patients), the mean time from intubation to

tracheotomy was 15.83 days., and the time to discontinuation of mechanical ventilation was 31 days following intubation. At the conclusion of the study, 108 patients (73%) had experienced discontinuation of ventilator support, 94 patients (64%) had been decannulated, 107 (72%) had been discharged from the hospital, and 30 patients (20%) had died.

Breik et al[33] reported the outcomes of the first 100 COVID-19 patients who underwent tracheotomy by a dedicated airway team at the Queen Elizabeth Hospital in Birmingham, England from March 9 to April 21, 2020. One hundred sixty-four COVID-19 patients were identified during this time, 100 of whom underwent tracheotomy. The time from intubation to the tracheotomy procedure ranged from 5 to 29 days with a mean of 13.9 days. Twenty-five patients underwent tracheotomy in the operating room and 75 patients underwent percutaneous tracheotomy in the intensive care unit. Nine patients underwent tracheotomy before 10 days of endotracheal intubation, 55 patients underwent tracheotomy between 10 and 14 days, and 36 patients underwent tracheotomy after 14 days of endotracheal intubation. The 3-day survival for the 100 patients undergoing tracheotomy was 68.3% (112/164). The 30-day survival was statistically higher for patients undergoing tracheotomy (85/100) compared to the patients who did not (27/64). The improved survival was independent of the patient's baseline prognosis. The authors indicated that tracheotomy is recommended to their COVID-19 patients when they are intubated longer than 10 days. Benefits therein included the ability to safely wean sedation, the performance of more effective pulmonary toilet, and improved patient comfort. They concluded that the performance of a tracheotomy in COVID-19 positive patients was consistent with patient safety and reasonable to perform when the patient was physiologically suitable to undergo this procedure rather than waiting for a defined period to transpire following intubation. Schultz et al[34] supported the 10-day recommendation for tracheotomy in mechanically ventilated COVID-19 patients based on their review of the literature.

Finally, increased team member safety during the performance of tracheotomies in COVID-19 patients is at least theoretically possible when these patients have been treated pharmacologically. As noted in our cohort, 3 agents, remdesivir, convalescent plasma, and dexamethasone, have been

recommended for use in these patients[35, 36]. Remdesivir, a monophosphate prodrug that is metabolized to a biologically active C-adenosine nucleoside triphosphate analogue, was originally discovered during an antimicrobial assessment of drugs against RNA viruses including Coronaviridae and Flaviviridae[36]. The initial clinical use of remdesivir was in the setting of Ebola, but its use in COVID-19 is at least theoretically indicated based on case report data[31]. Unanswered questions exist regarding the transmissibility of remdesivir treated COVID-19 patients to health care workers during tracheotomy procedures. Shen et al[36] treated 5critically ill COVID-19 patients with convalescent plasma. The viral load of these patients declined within days of treatment, and the clinical and radiographic parameters of these patients improved as noted by improved P/F, decreased temperature, and improved chest imaging. Due to a decreased viral load of COVID-19 patients treated with convalescent plasma, one could surmise that their viral transmissibility would decrease to team members involved in tracheotomy procedures. The use of corticosteroids such as dexamethasone in the management of COVID-19 patients is based on the ability to decrease the host inflammatory lung response that promotes acute lung injury and ARDS. This treatment is of questionable benefit due to the possibility of delayed clearance of the virus and the increased potential for secondary bacterial infection of the lungs[35]. The use of corticosteroids remains controversial in the management of COVID-19 patients, and no ability exists to predict the potential increased safety of team members participating in tracheotomy procedures in these patients.

The limitations of this study include the low number of patients and the inability to determine team member safety related to the procedure. In terms of team member safety, it is not possible to trace transmission of disease to team members from specific contacts, including patients who underwent tracheotomy in this study. While 4 residents participating in the care of these patients became COVID-19 positive at variable times following the tracheotomy procedures, the primary surgeon repeatedly tested negative for COVID-19 and was vaccinated in January 2021. Contact tracing for the positive residents could therefore not definitively establish transmission from a patient in this study, or another COVID-19 patient, unrelated to this study, for whom the residents cared during the study period. Finally, the sample

size for the present study was relatively small (n = 17) and larger studies might be able yield more precise and accurate effects associated with tracheotomies in COVID-19 patients. Causal inferences cannot be made from the current study due to the lack of randomization. Future researchers may want to use the effect sizes generated from our study to power larger retrospective studies to permit further investigation regarding the association of tracheotomies and COVID-19 survival, especially as it relates to clinical parameters such as BMI and comorbid disease history. We anticipate larger numbers of tracheotomies in COVID-19 patients in the future with the ability to ascertain durable benefit to these patients who experience prolonged intubation. Moreover, we plan to perform a follow-up study of the 10 surviving tracheotomy patients in this study to determine any future adverse sequelae of their disease such as pulmonary fibrosis and cognitive dysfunction.

Conclusion

Tracheotomies performed in COVID-19 patients are safe and medically beneficial procedures for patients when performed with a standardized protocol such as that discussed in this study. The exact timing of this surgical procedure remains speculative in the international literature however, we recommend guidelines identical to those of non-COVID-19 patients in which intentions to reduce the incidence of laryngeal stenosis and subglottic stenosis, and limiting medical resources such as ventilators and sedative agents are important. To this end, early consultation might be beneficial to patients, with the exact timing of tracheotomy in COVID-19 patients being based on their ventilator parameters, P/F result, perceived patient prognosis, the existence of patient advanced directives, and family wishes. Not uncommonly, medical center ethics committees are very useful to this end and should be utilized in the decision-making process. Finally, we recommend the inclusion of trainees in the performance of tracheotomies in COVID-19 patients as part of standardized teams and protocols to properly prepare these residents and fellows for their future practices.

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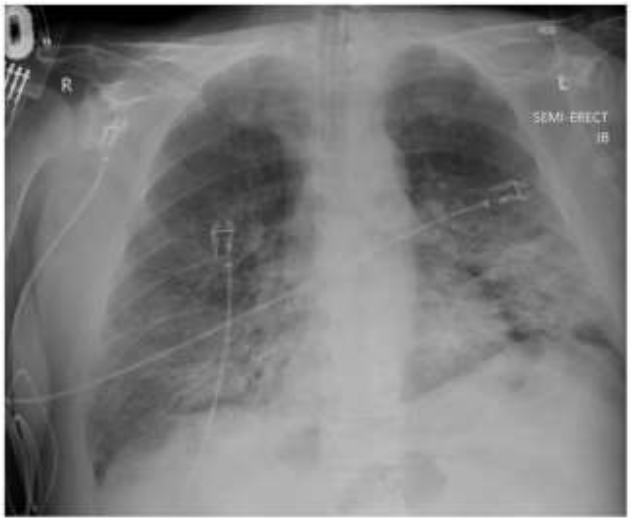

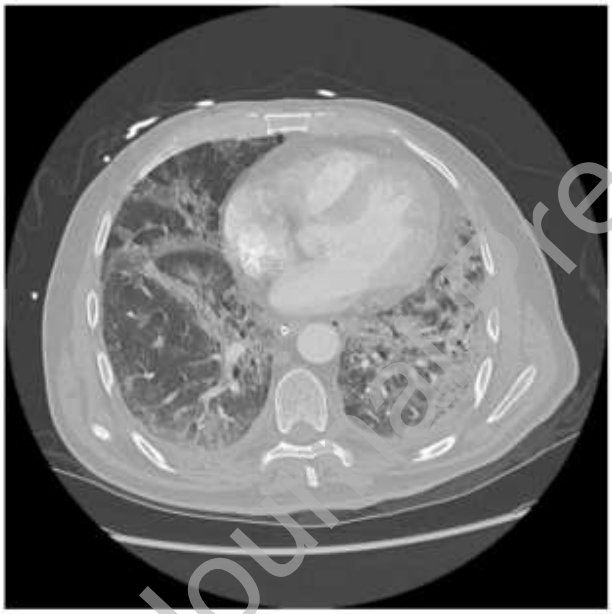

Figure 1: Plain chest film (figure 1a) of patient #9 and CT chest imaging (figure 1b) of patient # 8. Radiographic signs of pneumonia exist in these patients, consistent with COVID-19 pneumonia. In addition to the patients' symptoms on presentation, as well as their high ventilator parameters and low P/F, the radiographic findings of these patients should alert the intensive care unit team of the likely need for tracheotomy in the future, particularly as prolonged intubation occurs. Proactive planning should occur accordingly.

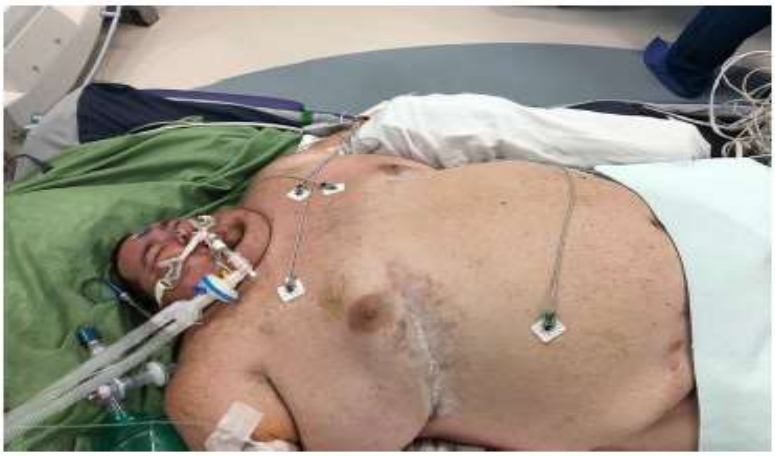

Figure 2: Patient #6 (BMI 70.4) in preparation for tracheotomy in the operating room. Preoperative physical examination suggested the need for a Bivona® tracheostomy tube as it was anticipated that the neck girth exceeded the ability to properly cannulate the tracheotomy with a Shiley® XLT tracheotomy tube. This judgement required ensuring that the operating room supply chain of 2 such Bivona® tracheotomy tubes available for the case on the day prior to the surgery.

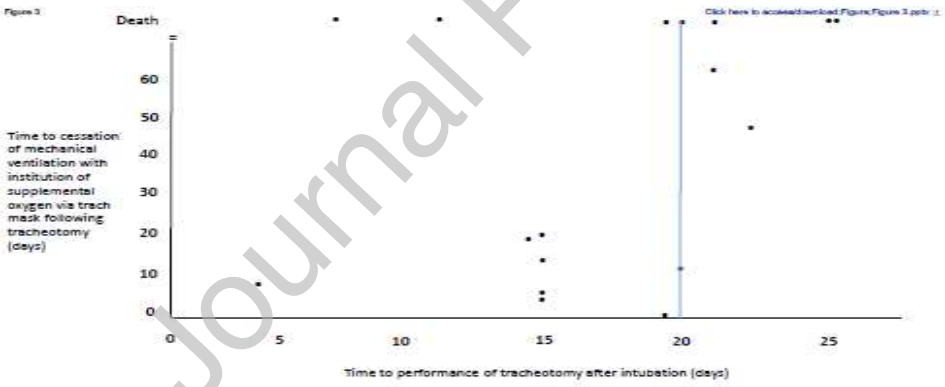

Figure 3: Time to cessation of mechanical ventilation with institution of supplemental oxygen via trach mask as a function of time to performance of tracheotomy after intubation in 17 COVID-19 patients. When the tracheotomy was performed prior to 20 days (blue line) following intubation, 7/10 patients (70%) survived, while when the tracheotomy was performed at 20 days or longer following intubation, 3/7 patients (43%) survived.

Patient	Age/Gender	BMI	Medical Comorbidity	Time of consultation following intubation	Medical treatment for COVID-19 positivity
1	54/M	32.5	Glaucoma Cataracts Obesity	14 days	Remdesivir Convalescent plasma
4	54/M	25.8	HTN Type 2 DM CKD Hyperlipidemia	1 day	None
6	30/M	70.4	HTN Type 2 DM OSAS Severe obesity	11 days	Remdesivir Convalsecent plasma
7	48/M	24.7	HTN APKD CVD	18 days	None
8	55/M	10.8	HTN COPD Hyperlipidemia CKD CHD	17 days	Remdesivir Convalescent plasma
9	63/M	34.2	HTN OSAS	19 days	Remdesivir Convalescent

			Type 2 DM GERD Obesity		plasma
10	52/M	32.7	HTN Hyperlipidemia PVD Obesity	13 days	Remdesivir Convalescent plasma
11	55/F	65.4	HTN Hyperlipidemia OSAS Type 2 DM COPD Gout Severe obesity	19 days	Remdesivir Convalescent plasma Dexamethasone
12	67/F	36.6	HTN Type 2 DM Hypothyroidism Asthma Fibromyalgia IBD Obesity	22 days	Remdesivir Convalescent plasma Dexamethasone
13	65/M	28.7	HTN Type 2 DM Chronic inflammatory demyelinating	13 days	Remdesivir Convalescent plasma Dexamethasone

			polyneuropathy Hypothyroidism		
14	59/M	28.6	HTN	15 days	Remdesivir Convalescent plasma Dexamethasone
15	67/M	29	Nephrolithiasis	17 days	Remdesivir Convalescent plasma Dexamethasone
16	68/M	28.9	HTN Hyperlipidemia Type 2 DM CKD Multiple sclerosis	5 days	Dexamethasone
17	66/F	36	HTN GERD Obesity	12 days	Remdesivir Dexamethasone ECMO
18	61/F	45.7	HTN Type 2 DM Severe obesity	13 days	Remdesivir Dexamethasone
19	75/M	26	HTN Hyperlipidemia GERD	8 days	Remdesivir Dexamethasone
20	49/M	29.3	CHD	13 days	Remdesivir

					Dexamethasone

Table 1: COVID-19 patients undergoing tracheotomy

HTN = hypertension, DM = diabetes mellitus, CKD = chronic kidney disease, OSAS = obstructive sleep apnea syndrome, APKD = adult polycystic kidney disease; HD = coronary heart disease, GERD = gastroesophageal reflux disease, PVD = peripheral vascular disease, COPD = chronic obstructive pulmonary disease, IBD = inflammatory bowel disease.

\Patient	Age/Gender	BMI	Medical Comorbidity	P/F at consult	Outcome (reason for not performing tracheotomy)
2	66/F	31.4	Type 2 DM Breast cancer Osteoarthritis Hypothyroidism Obesity	199	Extubated 12 days after intubation
3	77/M	100.1	HTN Bladder cancer Hypothyroidism CHD Severe obesity	230	Died 6 days after intubation
5	50/M	33.8	HTN Type 2 DM Hyperlipidemia Obesity	70	Died 24 days after intubation

Table 2 – COVID-19 patients consulted who did not undergo tracheotomy

HTN = hypertension, DM = diabetes mellitus, CHD = coronary heart disease.

Patient	P/F at time of consult	Time to performance of tracheotomy after intubation	P/F at time of tracheotomy	Time to cessation of mechanical ventilation with institution of supplemental oxygen via trach mask	Outcomes
1	195	15 days	195	6 days	Decannulated Alive
4	Not available	4 days	Not available	8 days	Decannulated Alive
6	111	15 days	215	21 days	Alive
7	341	19 days	341	4 hours	Decannulated Alive
8	Not available	21 days	Not available	Never	Patient died 16 days postop
9	Not available	20 days	Not available	Never	Patient died 12 days postop
10	81	21 days	134	61 days	Alive
11	267	20 days	267	12 days	Alive
12	118	25 days	147	Never	Patient died 4 days postop
13	255	14 days	150	20 days	Alive
14	125	22 days	140	48 days	Alive
15	111	19 days	129	Never	Patient died 4 days postop

16	157	7 days	160	Never	Patient died 12 days postop
17	120	25 days	154	Never	Patient died 6 days postop
18	160	15 days	142	13 days	Alive
19	95	11 days	101	Never	Patient died 7 days postop
20	158	15 days	242	4 days	Alive

Table 3: Outcomes of COVID-19 patients undergoing tracheotomy

P/F = PaO_2/FiO_2.

Variable	Survived	Died	*p*-value
Age	52.70 (9.55)	65.86 (6.01)	0.006*
BMI	38.38 (16.64)	28.79 (8.89)	0.19
P/F ratio at time of consult	188.11 (84.57)	120.20 (22.80)	0.047*
Time to performance of tracheotomy after intubation	16.00 (5.14)	18.29 (6.85)	0.44
P/F ratio at time of tracheotomy	202.89 (70.82)	138.20 (23.83)	0.03*
Time to consultation following intubation	13.00 (4.88)	14.29 (6.16)	0.64

Note: * $p < 0.05$, statistically significant

Table 4 – Means and standard deviations for the independent samples t-tests

BMI = body mass index, P/F = PaO_2/FiO_2.