

Tracheostomy guidelines developed at a large academic medical center during the COVID-19 pandemic

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Abstract

Background: During the SARS-CoV-2 pandemic, tracheostomy may be required for COVID-19 patients requiring long term ventilation in addition to other conditions such as airway compromise from head and neck cancer. As an aerosol generating procedure, tracheostomy increases healthcare worker exposure to COVID-19 infection. Performing surgical tracheostomy and tracheostomy care requires a strategy that mitigates these risks and maintains the quality of patient care.

Methods: A multidisciplinary review of institutional tracheostomy guidelines and clinical pathways. Modifications to support clinical-decision making in the context of COVID-19 were derived by consensus and available evidence.

Results: Modified guidelines for all phases of tracheostomy care at an academic tertiary care center in the setting of COVID-19 are presented.

Discussion: During the various phases of the COVID-19 pandemic, clinicians must carefully consider the indications, procedural precautions, and post-operative care for tracheostomies. We present guidelines to mitigate risk to healthcare workers while preserving the quality of care.

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Introduction

The novel coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is impacting hospital care globally at multiple levels. Otolaryngologists and other surgeons

will be called to assess and manage airways during this time period. Since the primary morbidity associated with COVID-19 is acute respiratory distress syndrome (ARDS), tracheostomy for patients requiring prolonged ventilation has emerged as an important element of care. The impact of COVID-19 on hospital resources includes heightened need for intensive care unit (ICU) capacity and ability to provide ventilatory support. Performance of tracheostomy has traditionally played an important role in ventilatory weaning, and its role in COVID-19 is now a primary focus.

Transmission of the SARS-CoV-2 virus is primarily thought to occur through aerosolization or contact with contaminated surfaces.¹ As an aerosol generating procedure (AGP), tracheostomy is associated with high droplet and particle generation, placing healthcare providers at increased risk for transmission of respiratory viral infections.² The predominant response during this pandemic has been to increase the level of personal protective equipment (PPE) to airborne-level precaution during tracheostomy. While effective PPE is of critical importance, additional consideration and modification of routine tracheostomy guidelines is prudent. Clinical decision-making regarding indications and timing should be considered in the context of resource utilization, risk to health care providers and patient benefit.

Methods

At the University of California, San Francisco (UCSF) Medical Center, an ad hoc work group consisting of stakeholders in the departments of Otolaryngology -Head and Neck Surgery (OHNS), Infectious Diseases, Critical Care Medicine and Anesthesiology, was developed to analyze the impact of COVID-19 at various levels of clinical care and administration. Several COVID-19 related factors were considered, including availability of viral testing, critical care capacity, availability of PPE, and risk to healthcare providers. All phases of routine tracheostomy care were considered in the review and modification of existing tracheostomy guidelines and clinical pathways. The concurrent goals of these modifications were to (1) mitigate risk to the health care providers while (2) preserving the risk-benefit profile for patients. Published reports from countries with previous COVID-19 pandemic experience and the published literature from the 2003 severe acute respiratory syndrome (SARS) pandemic were reviewed and augmented by individual expertise in order to develop working guidelines for management of tracheostomy at UCSF.

Results

The following are COVID-19 related tracheostomy guidelines developed at the UCSF Medical Center.

Personal Protective Equipment

PPE is regarded as the primary mechanism by which to reduce transmission of the SARS-CoV-2 virus to healthcare workers. Barrier protection with gowns, gloves, face shields and surgical masks may be augmented with respiratory filtration systems, including N95 masks and powered air-purifying respirator (PAPR) systems. At the UCSF Medical Center, we created a paradigm to delineate PPE for AGPs, which carry a higher risk for healthcare providers. Because of the potential for asymptomatic SARS-CoV-2 infection, we recommend the same level of precautions and PPE in COVID-19 positive and asymptomatic patients undergoing aerosol generating procedures.

The perioperative PPE guidelines developed at UCSF are outlined in Table 2. All team members involved in tracheostomy (anesthesia, surgery, nursing) don contact and airborne precaution-level PPE, including gown, double gloves, and either N95 respirator and face shield or PAPR hood. To conserve PPE, N95 masks may be reused in the setting of asymptomatic or COVID-negative patients. For known COVID-19 positive patients or person under investigation (PUI), N95 masks should be single-use.

Donning and doffing of PPE must be appropriately carried out. Fit testing protocols for respirators and education for providers on proper PPE use are necessary. Proper doffing of PPE is particularly critical, as this is the most likely time for inadvertent self-contamination. A PPE “champion” observer may be utilized to monitor providers during doffing of PPE to ensure adherence to proper protocol.

Viral Load reduction

Viral reduction is managed with a time-based strategy until effective antiviral treatment becomes available. Maintaining endotracheal intubation for an average of 21 days prior to tracheotomy is undertaken to limit viral shedding.

Preoperative Testing

At the time of this writing, preoperative testing in asymptomatic patients is not routinely performed due to lack of testing availability, though remains an active area of protocol development.

Indications and timing for tracheostomy in the COVID-19 positive or person under investigation (PUI) patient

The decision to proceed with tracheostomy should involve a multidisciplinary discussion and should be supported by multiple OHNS team members. Notably, survival is reported to be extremely poor (<20%) in patients with COVID-19 requiring mechanical ventilation, which argues against early tracheostomy.³⁻⁵ When the determination is made to perform tracheostomy, a delay in timing from 14 days post-intubation to 21 days post-intubation should be considered to allow for sufficient decline in viral load. In the event of a surge with need for ventilator rationing, reconsideration of timing may need to occur. Ventilator parameters to qualify for safe tracheostomy placement include positive end expiratory pressure (PEEP) < 12 and fraction of inspired oxygen (FiO₂) < 0.60.

Technical considerations during tracheostomy

Technical considerations for performance of tracheostomy are summarized in Table 1. For COVID-19 positive or PUI patients, tracheostomy procedures will preferentially be performed in the ICU to allow for a negative pressure environment and to minimize potential contamination of additional patient care areas. The number of providers in the procedure should be kept to a minimum. Tracheostomy may be performed either as an open or percutaneous procedure, depending on patient factors and surgeon preference. Coughing during the procedure can aerosolize droplets and special modifications are employed to reduce the risk. During the time of tracheal incision and endotracheal tube exchange, a systemic paralytic agent should be administered to minimize coughing and aerosolized topical anesthetic should be avoided. Meticulous hemostatic technique should be employed prior to tracheal incision to limit the need for additional tissue manipulation after the tracheal window is created.

Close communication between surgical and anesthesia teams is necessary. Ventilation should be held prior to creation of the tracheal window and while the endotracheal tube (ETT) cuff is deflated. Application of suction to the surgical wound may be used to create a local negative pressure environment during exchange of the ETT for the tracheostomy tube. Importantly, the suction circuit should include a high-efficiency particulate arrestance (HEPA) filter to capture aerosolized viral particles and avoid aerosolizing them into the operating theater. After placement of the tracheostomy tube, closed circuit ventilation with in-line HEPA filtration should be maintained and only in-line suction should be performed.

Tracheostomy Maintenance

Tracheostomy care should be performed with droplet-level precautions (gloves, gown, mask/eye protection) at a minimum. Tracheostomy in COVID-19 positive patients should utilize closed-circuit suction, heat and moisture exchanger (HME) if not ventilated, and in-line HEPA filtration if ventilated. Cuff inflation is preferred in patients with known COVID-19 disease until viral shedding has subsided. The frequency of tracheostomy changes should be reduced to every 1-3 months for all patients, except for down-sizing and cuff related issues that are determined to be clinically urgent. Tracheostomy changes should be avoided in COVID-19 positive patients until viral clearance has been achieved to minimize unnecessary healthcare worker exposure.

Discussion

The COVID-19 pandemic has presented healthcare systems with the unprecedented task of managing large volumes of patients with critical respiratory illness. Tracheostomy has emerged as a downstream component

of care with heightened risk of viral transmission to healthcare providers and requires careful consideration in this context. Our multi-specialty work group was created during the early spread of COVID-19 cases in the United States and we evaluated and modified our current institutional tracheostomy guidelines in preparation for a surge of COVID-19 positive patients with the potential to overwhelm our healthcare system. These guidelines were created with the intent of preserving quality of patient care and reducing clinician exposure in order to maintain a capable healthcare workforce. Factors relevant to our review included optimal timing of tracheostomy, duration of viral shedding in patients with COVID-19, risk to procedural teams from aerosol generation during tracheostomy, ICU capacity, and availability of PPE. A summary of risk mitigation strategies is presented in Table 2.

There is limited evidence available during this evolving stage of the COVID-19 pandemic. As such, modifications to our existing protocols were made by consensus and were based upon published reports from countries with earlier COVID-19 experience and data available from the 2003 SARS epidemic. The policies that were developed at UCSF are aligned with the position statement on tracheostomy recently published by the Airway and Swallowing Committee of the American Academy of Otolaryngology-Head & Neck Surgery (AAO-HNS).⁶

Tracheostomy and the SARS epidemic

Experience with tracheostomy during the 2003 SARS epidemic offers a framework for management strategy during the COVID-19 pandemic. In the context of the current pandemic, Tay et al. conducted a literature review of tracheostomies performed during the SARS epidemic and concluded the following: (1) proper PPE (N95 mask, surgical cap, gown, goggles, and gloves) is of utmost importance; (2) surgical tracheostomy is preferably performed in a negative pressure ICU room by experienced providers with meticulous planning and seamless communication; (3) aerosol generation should be minimized through patient paralysis, ventilation hold during creation of tracheal window, and utilization of HEPA-filtered suction systems. This group identified no cases of SARS transmission to the surgical team in 23 tracheostomies.⁷ Others have reported on PPE for tracheostomy during the SARS epidemic, drawing similar conclusions that use of N95 masks, face shields, fluid resistant gowns, and gloves (contact and airborne precautions) provides effective protection against transmission to providers during tracheostomy.^{8,9} N95 masks filter 99.5% of particles larger than 0.75 μ m, providing excellent protection against airborne particles with a mask that is appropriately fitted.¹⁰

Role of Preoperative Testing and Duration of Viral Shedding

COVID-19 testing is accomplished via detection of SARS-CoV-2 in a nasopharyngeal specimen or bronchoalveolar lavage (BAL) using reverse transcriptase-polymerase chain reaction (RT-PCR).¹¹ The role of preoperative testing in ascertaining the COVID-19 status of asymptomatic individuals has emerged as a point of discussion, as the prevalence of asymptomatic SARS-CoV-2 infection is unknown but assumed to be meaningful given high rates of community transmission.^{12,13}

At the time of this writing, due in large part to the relative lack of available testing supplies, there is not a standard protocol for preoperative testing of asymptomatic patients planned for tracheostomy or other AGPs. Patients who do not have respiratory symptoms suggestive of COVID-19 have an unknown risk of being asymptomatic carriers of disease. If resource availability permits, preoperative testing prior to surgical intervention is preferred, as a positive test would alert the healthcare team to the increased risk, and surgery may be deferred to maximize safety if clinically appropriate.

Importantly, for patient with some conditions, including head and neck cancer, airway compromise may be imminent and necessitate urgent treatment with tracheostomy.¹⁴ Acute airway compromise, or inability to intubate, as can occur in patients with head and neck cancer, could necessitate an awake tracheotomy. In this scenario, the patient is breathing orally and potentially seeding the room with aerosolized viral particles. All precautions with appropriate PPE should be taken by the surgical team in cases where potential airway manipulation is anticipated. Currently, specialized hoods to cover the patient and prevent aerosolization have been proposed but are not widely available.¹⁵

Preoperative testing is significant in determining the appropriate timing of tracheostomy for patients with COVID-19 infection. For patients with known disease, testing is a reasonable surrogate for viral clearance. BAL is the most sensitive means of testing and is recommended in intubated patients.¹¹ These tests will be important in enacting de-isolation protocols, whereby hospitalized patients with recent infection may be removed from an isolation environment. One such proposed de-isolation protocol calls for two consecutive negative PCR tests 24 hours apart.¹⁶ Due to constraints on the availability of testing and the turnaround time for results, preoperative testing may not be universally feasible.

In the absence of a standard preoperative testing protocol, we have proposed not pursuing early tracheotomy, but rather delaying for COVID-19 positive patients in order to reduce exposure to higher viral loads, which are expected to peak in the first few days of symptom onset.¹⁶ The duration of viral shedding is estimated to be between 20-24 days from symptom onset, based on laboratory testing of nasopharyngeal swabs. The longest observed duration of shedding reported in one study was 37 days.^{5,16} Importantly, viral loads in asymptomatic and symptomatic patients are believed to be similar¹³, highlighting the need for proper PPE and surgical protocols in all cases of tracheostomy. The optimal timing of tracheostomy for asymptomatic patients without ARDS is not clear. At UCSF, we have elected to maintain standard timing of 10-14 days post-intubation for this group.

The clinical course of the COVID-19 infected patient is well described by Zhou et al. who found the median time from illness onset to dyspnea was 13 days and dyspnea to invasive mechanical ventilation was 10 days.⁵ In pre-pandemic conditions, we typically aim to perform tracheostomy for patients requiring prolonged mechanical ventilation by 10-14 days post-intubation. In the current pandemic, we propose when resources are available, that an additional week of mechanical ventilation be permitted to reduce viral load and thereby limit risk to healthcare personnel.

Indications for Tracheostomy

The benefits of tracheostomy are well-established. These include facilitated ability to wean sedation and mitigation of sedation-associated delirium, improved patient comfort, and facilitation of weaning to spontaneous ventilation. The optimal timing of tracheostomy varies by clinical context; outside of the current pandemic, it is generally recommended to be performed within 2 weeks post-intubation. Prolonged intubation is associated with post-intubation laryngotracheal stenosis, but in systematic reviews, early tracheostomy (typically < 10 days) has not been shown to reduce risk of this complication.^{17,18}

The role of tracheostomy during the COVID-19 pandemic remains to be determined. Poor patient outcomes and resource scarcity may well have a dramatic influence on the total number of tracheostomies performed. In published studies from the Chinese experience, survival of COVID-19 after mechanical ventilation is low (< 20%) and Zhou et al. determined that the time from illness onset to death in non-survivors of COVID-19 was just 18.5 days.³⁻⁵ If this trend holds as the pandemic progresses, the obvious implication is that early tracheostomy may be a futile endeavor for most patients, and late tracheostomy is not likely to assist in ventilatory weaning.

Potential Alterations in Event of a Surge in Cases

The COVID-19 pandemic presents a rapidly shifting landscape of clinical care. Of primary concern within the United States at the time of this writing is the relative scarcity of mechanical ventilators to support critically ill patients. This resource scarcity could lead to a push to perform tracheostomies, though whether this would allow for a more expeditious ventilator weaning process is unclear. Continued close collaboration with our Critical Care and Ethics colleagues will be imperative to navigate this scenario should it arise. It is important to acknowledge that conditions other than COVID-19 will still need to be addressed during this time period and may require tracheostomy. The need for mechanical ventilation in patients with other conditions should be considered when developing and applying COVID-19 guidelines.

Conclusions

During the COVID-19 pandemic, standard pathways and guidelines for tracheostomy and tracheostomy care

should be carefully reconsidered. Additional measures should be taken to protect healthcare providers who are at increased risk of infection. Special care must be taken in the selection of patients for tracheostomy with consideration of delayed timing for patients with COVID-19. While the landscape of care is rapidly shifting, the above guidelines are intended to support safe and effective clinical decision making during this challenging time.

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Tables

Table 1: Technical and logistic considerations regarding tracheostomy

COVID-19 Status	Recommendations	Other Considerations
Positive/PUI or Unknown	Location: ICU preferred, negative pressure room PPE: N95 mask or PAPR, head covering, eye protection, gown and two pairs of gloves	Limit number of providers in the room during the procedure Use of paralysis recommended to prevent coughing Clear and constant communication with anesthesia during the tracheostomy, holding ventilation when the ETT cuff is deflated and when the trachea is opened Avoid use of laryngotracheal topical anesthesia (aerosolizing)
Negative (one test 48-72 hours prior) or Asymptomatic	Location: OR or ICU, negative pressure room PPE: N95 mask or PAPR, head covering, eye protection, gown and two pairs of gloves	

COVID-19 – coronavirus disease 2019; PUI – person under investigation; ICU – intensive care unit; PAPR – powered air-purifying respiratory; OR – operating room, ETT – endotracheal tube

Table 2: Summary of mitigation strategies at various phases of tracheostomy care.

Phase of Care	Considerations and Mitigation Strategies
Preoperative	Decrease in viral shedding: Testing available – De-isolation after two negative PCR tests in 24 hours Testing unavailable – Consider delaying tracheostomy until 21 days post-intubation
Perioperative	Location: ICU preferable- minimizes transport Negative pressure room Surgical Team: Minimize number of staff members during the procedure Use of appropriate PPE (airborne and contact precautions) Technical Considerations: Patient paralysis to prevent coughing Holding ventilation during tracheotomy until cuff inflated and circuit reconnected
Postoperative	Droplet precautions during tracheostomy care Use of closed, inline suctioning Closed circuit with HEPA filter if on mechanical ventilatory support HME when off ventilatory support Delaying the first tracheostomy change to one month or after de-isolation occurs for COVID-19 positive patients

PCR – polymerase chain reaction; ICU – intensive care unit; PPE – personal protective equipment; HEPA –

high efficiency particulate arrestance; HME – heat and moisture exchange; COVID-19 – coronavirus disease 2019