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Abstract

Objective. The coronavirus disease 2019 (COVID-19) pandemic has led to a global surge in critically ill patients requiring invasive mechanical ventilation, some of whom may benefit from tracheostomy. Decisions on if, when, and how to perform tracheostomy in patients with COVID-19 have major implications for patients, clinicians, and hospitals. We investigated the tracheostomy protocols and practices that institutions around the world have put into place in response to the COVID-19 pandemic.

Data Sources. Protocols for tracheostomy in patients with severe acute respiratory syndrome coronavirus 2 infection from individual institutions (n = 59) were obtained from the United States and 25 other countries, including data from several low- and middle-income countries, 23 published or society-endorsed protocols, and 36 institutional protocols.

Review Methods. The comparative document analysis involved cross-sectional review of institutional protocols and practices. Data sources were analyzed for timing of tracheostomy, contraindications, preoperative testing, personal protective equipment (PPE), surgical technique, and postoperative management.

Conclusions. Timing of tracheostomy varied from 3 to >21 days, with over 90% of protocols recommending 14 days of intubation prior to tracheostomy. Most protocols advocate delaying tracheostomy until COVID-19 testing was negative. All protocols involved use of N95 or higher PPE. Both open and percutaneous techniques were reported. Timing of tracheostomy changes ranged from 5 to >30 days postoperatively, sometimes contingent on negative COVID-19 test results.

Implications for Practice. Wide variation exists in tracheostomy protocols, reflecting geographical variation, different resource constraints, and limited data to drive evidence-based care standards. Findings presented herein may provide reference points and a framework for evolving care standards.

Keywords

tracheostomy, tracheotomy, COVID-19, SARS-CoV-2, novel coronavirus, intensive care, intensive care unit, ventilator, weaning, aerosol generating procedure, AGP, patient safety, quality improvement, health care workers, ethics, pandemic, timing, infectivity

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The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus and the resulting coronavirus disease 2019 (COVID-19) pandemic have swept across the globe despite international efforts to contain and mitigate spread.¹ An estimated 5% rate of infected patients requiring intensive care unit (ICU) support^{2,3} has translated into high numbers of patients receiving prolonged periods of mechanical ventilation; some are potential candidates for tracheostomy. However, tracheostomy and the continuing care are considered aerosol-generating procedures (AGPs), placing health care workers at risk for infection.

Concerns about the viral transmission during and after tracheostomy and high mortality among patients requiring mechanical ventilation have challenged preexisting practice standards that primarily focused on critical care parameters, resource stewardship, and patients and family preferences. Practices around preoperative COVID-19 testing, timing of tracheostomy, proper personal protective equipment (PPE), and postoperative care to minimize potential viral transmission have relied heavily on anecdotal experience. The lack of evidence surrounding this rapidly evolving airborne pandemic has led to considerable uncertainty and variability on if, when, and how to safely perform tracheostomy for patients with COVID-19.⁴⁻⁶

In the face of uncertainty, institutions around the world have developed individual protocols and guidelines for many aspects of medical care during the COVID-19 pandemic, including tracheostomy. These guidelines are primarily based on local expertise and resources, as well as guidance from professional organizations and extrapolations from similar diseases. The objectives of this study were to explore the range of tracheostomy practices in the United States and globally for patients with COVID-19. We compared and contrasted worldwide COVID-19 protocols and interpreted these findings in the context of currently available evidence.

Methods

This was a comparative document analysis.^{7,8} We identified protocols for tracheostomy in patients infected with SARS-CoV-2 through literature review, committee collaboration, and accessing a global network of experts. The project was led by the Patient Safety and Quality Improvement Committee (PSQI) and supported by the Outcomes Research and Evidence Based Medicine (OREBM) Committees of the American Academy of Otolaryngology–Head and Neck Surgery. We searched the PubMed/MEDLINE database for relevant publications using the search terms *tracheostomy*, *tracheotomy*, *coronavirus*, *COVID-19*, and *SARS-CoV-2*. These searches were supplemented by reference review and accessing existing global networks established through

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collaborations with otolaryngologists and other specialists through international conferences, guideline/consensus workgroups, research collaborations, and quality improvement collaboratives (eg, Global Tracheostomy Collaborative). Non-published protocols were collected between May 6 and July 22, 2020. We identified 59 protocols, 23 previously published in the literature or presented as society consensus protocols. Institutional review board approval was not required for this study as the documents and published guidelines contained no individual patient information.

After identifying tracheostomy protocols for patients infected with SARS-CoV-2, we used a consensus-based iterative approach to prioritize topics for inclusion through conference calls, phone calls, emails, and videoconferencing. The core work group discussed extraction parameters for data analysis and/or inclusion. We limited the review to protocols designed to manage patients who were known to be COVID-19 positive. The analysis included both quantitative and qualitative data. A primary reviewer extracted the predetermined data from each protocol into a Microsoft Excel data matrix. A secondary reviewer assessed the data matrix for accuracy, and a third reviewer adjudicated disagreements. For qualitative analysis, 2 people participated in review of relevant quotes and themes. For countries where published documents were incomplete, notably in some low- and middle-income countries (LMICs), we accepted expert opinion to a structured set of inquiry questions regarding tracheostomy care. Data were identified as expert opinion, institutional/professional group guideline or protocol, or peer-reviewed publication. We categorized data by country and for the United States by geographic region. These data were synthesized into a final review. A list of the protocols is provided in the supplementary materials (in the online version of the article), and published protocols are noted in the references.

Results

Overview

We identified 59 protocols developed for tracheostomy in patients infected with SARS-CoV-2. Of these, 23 were previously published and 36 were protocols for institutions or countries. Thirty-four protocols were provided from international locations, with 25 from the United States (**Table 1**).

Timing of Tracheostomy

Recommendations on timing for performing tracheostomy in patients with known COVID-19 varied widely. Many sources lacked a clear recommendation for timing. Commentary in some sources recommended never performing a tracheostomy if it can be avoided, whereas other sources advocated treating ventilator-dependent patients with COVID-19 similarly to all other critically ill ventilated patients. When a timeframe for tracheostomy was stated, the timing ranged from 3–4 days to 21–28 days. Four protocols favored times less than 14 days, and 18 provided no statement about timing or a brief narrative comment such as “delay until active infection has passed,” “wait until absolutely necessary,” “individualize the treatment plan,” or “controversial.” Among protocols that defined

a time ($n = 43$), 91% recommended a minimum of 14 days of mechanical ventilation prior to consideration of tracheostomy.

Contraindication to Tracheostomy

The majority of the protocols addressed some relative contraindications for performing tracheostomy in patients with COVID-19. In 29 protocols, no statement was made about contraindication to tracheostomy. Of 32 that referred to contraindications, 14 specifically listed unstable respiratory or cardiac status (43.7%), 7 listed a positive COVID-19 (SARS-CoV-2) test, and 6 specifically stated “poor prognosis,” “no clinical improvement,” or “unfit for surgery.” The majority of protocols, including most that listed no specific contraindications to tracheostomy, emphasized the need for input from and discussion between the clinicians responsible for care of these COVID-19 patients, including nursing, intensive care teams, infectious disease specialists, and surgeons. The role of allied health professionals (eg, respiratory therapists and speech language pathologists) and the importance of learning about the goals and wishes of the family were also stressed in several protocols.

Preoperative COVID-19 Testing

Recommendations varied widely about preoperative COVID-19 testing, with some protocols recommending delaying tracheostomy until COVID-19 testing is negative, often with the initial test performed at 2 weeks of intubation and then, if positive, an additional retest at 1 week. Of 32 protocols that addressed testing, 25 (78%) recommended repeat testing prior to surgery, while 7 protocols would not repeat a COVID-19 test before surgery. The remaining 30 protocols make no statement about testing before tracheostomy. When testing was recommended, the source of the clinical material was variable, with some recommending nasopharyngeal swabs and other recommending tracheal aspirates. However, of the 9 protocols that specifically stated the testing type, there was 100% consensus for polymerase chain reaction (PCR) based.

Approach and Location

Of 45 protocols that addressed tracheostomy technique, recommendations were nearly evenly split. Twelve (27%) favored a traditional, open tracheostomy while 15 (33%) recommended percutaneous tracheostomy. Eighteen protocols (40%) discuss using either. However, there was uniformity (where stated) that the approach should be based on the experience and preference of the surgeon or proceduralist.

Of the 54 protocols that discussion location, 48 (89%) stated preference for a negative-pressure room or, if not available, a room with a portable high-efficiency particulate air (HEPA) filter unit for tracheostomy. Forty-two (78%) protocols internationally favored a negative-pressure intensive care unit (ICU) room for bedside tracheostomy. Four protocols (7%) preferred the procedure be performed in a traditional or negative-pressure operating room, and 8 (15%) listed either approach as viable options. Several of protocols

Table 1. Summary of Preoperative, Intraoperative, and Postoperative Tracheostomy Protocols.^a

Institution/publication	Country	Timing, d	Testing	Technique	Location	PPE	Postoperative	First tube change, d
Hospital Italiano de Buenos Aires	Argentina	21	Yes	Percutaneous	Bedside, negative pressure	N95	Inline suction	Minimize
The Alfred ICU, Melbourne	Australia			Percutaneous	Bedside	PAPR		
Catholic University Rio de Janeiro	Brazil	4-21	Unclear	Either	Bedside, negative pressure		Inline suction	No longer infectious
Sommer et al ²⁷	Canada	Late	Yes	Open	Either, negative pressure	PAPR	HME connected to tracheostomy	
Tongji Medical College, Huazhong University of Science and Technology, Wuhan	China	7		Percutaneous	Bedside	PAPR	Inline suction	
Tongji Medical College, Huazhong University of Science and Technology, Wuhan	China	14	If possible	Percutaneous	Bedside, negative pressure			>30
Fundación Valle del Lili	Columbia		Yes	Percutaneous	Bedside	N95		
Ministerio de Salud Público del Ecuador	Ecuador	14-21	If possible	Percutaneous	Bedside, negative pressure	PAPR	Inline suction	COVID-19 negative
Cairo University	Egypt	14	Yes	Open	OR			5
Oulu University Hospital	Finland	7-14	Unclear	Percutaneous	Bedside, negative pressure	FFP3	Usual	12-21
Schultz et al ²⁸	France	Early	Yes	Percutaneous	Bedside	N99 preferred; if not available N95	PPE with N95, HME connected to tracheostomy	
University Hospital Augsburg	Germany	Late		Open	Either, negative pressure	FFP3	Inline suction, HME connected to tracheostomy	Late
Chinese University	Hong Kong	14-21	×2		Negative pressure		PPE with N95	>30
Prince of Wales Hospital	Hong Kong	10-14	×2	Open	Negative pressure	N95, PAPR if still positive	Inline suction; HME	
Perenyi et al ²⁹	Hungary translated		If possible	Either	Negative pressure	FFP3		7-10
Tata Memorial Centre	India		Open	Open	OR	N95		7-10
Pichi et al ³⁰	Italy		Open	Open	Either, negative pressure	N99 preferred; if not available N95	PPE with N95; inline suction	7

(continued)

Table 1. (continued)

Institution/publication	Country	Timing, d	Testing	Technique	Location	PPE	Postoperative	First tube change, d
University of Modena & Reggio	Italy			Open	Bedside, negative pressure	N99 preferred; if not available N95 FFP3		
University of Naples	Italy			Either				
University of Perugia	Italy	14		Open	OR, negative pressure	N99 preferred; if not available N95	Inline suction	10
Sheba Medical Center	Israel	3-4	Yes	Open	Bedside	N95	Inline suction	Avoid
Nagoya University	Japan	17		Open	Bedside, negative pressure	N95 or PAPR		
Seoul National University	South Korea							
University of Amsterdam & Dutch Society of IC	Netherlands	>14	No	Percutaneous	Bedside	N95	HME connected to tracheostomy	Never
Auckland University	New Zealand	14	No	Open	Either, negative pressure	N95 or PAPR	PPE with N95; HME connected to tracheostomy	COVID-19 negative
Seguro Social de Salud del Perú	Peru			Percutaneous	Negative pressure	N95		
National University Hospital	Singapore	>14	Yes	Open	Bedside, negative pressure	PAPR	PPE including N95	>90
University of Capetown	South Africa	>14	If possible	Either	Negative pressure	N95	Inline suctioning; HME	>14
Villalonga Vadel et al ³¹	Spain			Either	Either, negative pressure	FFP2 or FFP3		
Villalonga Vadel et al ³¹	Spain	10-14	No	Percutaneous	Bedside		Inline suction	>7
Harrison et al ³²	United Kingdom	Infection passed		Open		FFP3	HME	
Guy's and St Thomas NHS London	United Kingdom	14	Unclear	Either	Either, negative pressure	FFP3, consider PAPR		
McGrath et al ³³	United Kingdom	>10		Either	Either, negative pressure	N95 or FFP3 or PAPR	Inline suction; HME	Avoid
North Manchester General Hospital	United Kingdom			Open	OR, negative pressure	FFP3		
Beth Israel Deaconess	United States	14-21	Consider	Either	Bedside, negative pressure	N95 or PAPR	Inline suction, viral filter when off ventilator	COVID-19 negative
Harvard	United States	>14		Either	Negative pressure	N95 or PAPR		
Henry Ford	United States		Yes	Percutaneous	Bedside	N95 or PAPR	Inline suction	Avoid
Johns Hopkins University	United States	10-14		Either	Either	N95 or PAPR	Closed inline suction	>30 d
Lamb et al ³¹	United States	Individualize	No	Either		N95 or PAPR		Minimize

(continued)

Table 1. (continued)

Institution/publication	Country	Timing, d	Testing	Technique	Location	PPE	Postoperative	First tube change, d
Loyola University	United States	21	No	Open	Bedside, negative pressure Bronchoscopy suite, negative pressure	N95	Inline suction; HME/viral filter when off ventilator Inline suction; viral filter connected to tracheostomy HME	
University of Michigan	United States	Late	Yes, ×2	Either	Bedside, negative pressure			
Michetti et al ³⁴	United States		Yes	Either	Negative pressure	N95 and PAPR		
Miles et al ³⁵	United States	>21	No	Either	Bedside, negative pressure	N95 or PAPR	Inline suctioning; HME/viral filter	Avoid
Mt Sinai, New York	United States	>14		Either	Bedside, negative pressure			
Parker et al ³⁶	United States	14-21	Yes			N95	Inline suction, HME when off ventilator	COVID-19 negative
Portland VAMC	United States	Late		Open	Bedside	PAPR		
Rutgers University	United States	10-14	If possible	Open	Bedside, negative pressure	N95 or PAPR	Inline suction; HME/viral filter when off ventilator	COVID-19 negative
Stanford University	United States		If possible	Either	Bedside, negative pressure	N95		COVID-19 negative ×2
Temple University	United States	>14		Open	OR	N95 or PAPR	PPE with N95; HME/viral filter when off ventilator	Avoid
Thomas Jefferson	United States	>14	No	Percutaneous	Bedside negative pressure	PAPR preferred; if not available, N95	Inline suction; HME	
University of Alabama–Birmingham	United States	>14	Yes, ×2	Either	Bedside, negative pressure	N95	PPE with N95, inline suction	COVID-19 negative
UCLA	United States	>14	Yes	Percutaneous	Bedside	PAPR or N99	PPE with N95; inline suction and viral filter	COVID-19 negative
UCSF	United States	>21	Yes	Either	Bedside, negative pressure	N95 or PAPR	Inline suction, viral filter on ventilator; HME when off ventilator	COVID-19 negative
University of Chicago	United States	Controversial		Open	Bedside, negative pressure	PAPR preferred; if not available, N95		
University of Pennsylvania	United States	>21	Yes	Open	Either, negative pressure	PAPR preferred; if not available, N95	PPE with N95; closed inline suction; HME/viral filter	No longer infectious

(continued)

Table 1. (continued)

Institution/publication	Country	Timing, d	Testing	Technique	Location	PPE	Postoperative	First tube change, d
University of Pittsburgh	United States	14-21	Yes	Open	Bedside negative pressure	N95 or PAPR	Suction, HME	COVID-19 negative
University Texas–Houston	United States	21-28	Yes, ×2	Open	Either, negative pressure	PAPR preferred; if not available, N95	Inline suction; HME/viral filter when off ventilator	COVID-19 negative
Wayne State University	United States	> 14	Yes	Either	Either, negative pressure	PAPR preferred; if not available, N95	HME when off ventilator	
University of Illinois–Chicago	United States	> 21	Yes, ×2	Percutaneous	Bedside negative pressure	PAPR	Inline suction	

^aProtocols that do not mention this component of care are left blank.

Abbreviations: HME, heat moisture exchanger; NHS, National Health Service; OHNS, otolaryngology–head and neck surgery; OR, operating room; PAPR, powered air-purifying respirator; PPE, personal protective equipment; VAMC, Veterans Affairs.

recommended a bedside location due to the concern for viral spread during transport.

Personnel

While it was difficult to subcategorize protocol recommendations for personnel, almost every protocol discussed minimizing the number to only essential personnel. Approximately one-half the protocols (31/59) specifically recommended using the minimal number of staff members. Those that provided narrative comments universally suggested the most experienced personnel perform the procedure. The need for excellent communication was emphasized in many sources.

PPE

All protocols addressed the need for appropriate PPE, and most provided at least some specifics. Every protocol referred to using at least N95-level respiratory filtration; 29 (29/59; 49%) specifically stated powered air-purifying respirator (PAPR) as a preferred option when available with N95 required if PAPR is not available. Some protocols recommended FFP3 or N99 respirators if available but acknowledged that FFP2 or N95 respirators were acceptable. Some sources suggested wearing a mask over the respirator, primarily to protect the respirator from gross contamination to allow for reuse and/or reprocessing. All the protocols that addressed PPE specifically noted the need for a mask over a respirator and recommended some level of eye protection should be used.

The protocols that addressed eye protection ranged in specific description from goggles, full face shields, “surgical hoodies,” and Stryker Flyte T4 hoods. Most sources recommended gowns, with a handful of sources recommending a waterproof base-layer gowns. Of those references that addressed gloves, most recommended double gloves (23/41; 56%), while 18 protocols (44%) listed the need for gloves without specifically mentioning double gloves. Of sources that referenced hats and shoe covers, all favored the use of this type of PPE, and there were no protocols that stated these should not be used.

Tracheostomy Technique

Most sources discussed specifics of technique, although 32% (19 of 59 protocols) did not address operative technique or intraoperative considerations. Of protocols that addressed operative technique, 36 protocols (36/43, 84%) advised full paralysis during the procedure. At least 1 protocol specifically advised against transtracheal injection of local anesthetic to avoid the potential for coughing. Three sources suggested glycopyrrolate to decrease secretions, and 4 specifically mentioned deep, inline, closed suctioning immediately prior to the procedure. Several sources specifically recommended preoxygenation with 100% O₂ for times ranging from 3 minutes to the entire procedure. One protocol advised decreasing to an FiO₂ of 0.21 just prior to entering the trachea.

The majority of protocols advised apnea prior to entry into the trachea (44/59; 75%), and some specifically

mentioned ventilation only when the cuff of the endotracheal tube (ETT) or tracheostomy tube is inflated. A few protocols specifically recommended clamping the ETT, while one protocol discouraged this procedure due to the possibility of damaging the ETT. Particularly in protocols that discussed open tracheostomy ($n = 30$), 67% recommended advancing the ETT under apnea prior to beginning the procedure.

In percutaneous tracheostomy, wider variability existed in the recommended ETT management, with occasional statements of tube advancement, and 1 protocol described a procedure in which the ETT is replaced with a smaller ETT and the bronchoscope is passed alongside the ETT instead of through it. Several protocols specifically addressed maintaining apneic conditions for the entire time from needle puncture, through dilation, with resumption of ventilation only after the tracheostomy tube is in place and the cuff is inflated. Some protocols also recommended the use of disposable bronchoscopes while a few recommended either no bronchoscope or the use of ultrasound for guidance.

Of the 20 protocols that addressed cautery use, 16 (80%) recommended to avoid or minimize cautery due to the potential for further generation of aerosol. Four protocols (20%) approved use of cautery, with 3 of these specifically identifying the use of a smoke evacuator.

With regards to suctioning, almost half (29/59) of the protocols made specific recommendations. Twenty-four (83%) recommended avoiding or limiting suctioning. Five protocols stated the need for closed suction systems or a HEPA filter on the suction circuit. A small number identified the use of a clear drape with suction to create a localized negative-pressure site over the surgical site. Twenty-seven (46%) specifically recommended a cuffed, nonfenestrated tube while the remainder did not address the type of tube. One source recommended placing the largest size possible.

Postoperative Management

The majority of sources provided some specific guidance about posttracheostomy care. When PPE for postoperative care was discussed, all protocols recommended the use of N95 respirators. Forty-one (70%) of 59 protocols specifically discussed the use of suction for tracheostomy care, and all of these protocols advised an inline, closed suction system. Many protocols recommended heat moisture exchangers (HMEs) to be placed on the tracheostomy tube of patients when off the ventilator, while others recommended HMEs plus a mask, or a viral filter when on or off the ventilator.

Of those protocols that specifically addressed tracheostomy tube change ($n = 35$), 11 (31%) recommended waiting until the patient was COVID-19 negative. Another one-third (12/35; 34%) recommended either avoiding or delaying tracheostomy tube changes, while the remaining one-third (12/35; 34%) recommended tube changes ranging from 5 days to >3 months.

Multidisciplinary Teams and Communication

Many protocols stressed the importance of using a multidisciplinary team for making decisions around tracheostomy.

Additionally, there were several specific recommendations for preprocedure rehearsals, strong team dynamics, and communication, including closed-loop communication, and post-procedure debriefings. Several sources emphasized that the protocol was a guideline and that individual cases should be discussed. Finally, some protocols recommended managing cases in groups due to the complexity of the setup and to only perform tracheostomy on COVID-19 patients during usual, daytime hours.

Discussion

This comparative analysis of global COVID-19 tracheostomy protocols provides insight into how the global community has approached high-stakes decisions amid a paucity of scientific data. The high level of consensus around safety standards such as using PPE (using N95 masks, gowns, and eye protection), apneic approach during tracheostomy, and inline suction as part of the care for patients with tracheostomy reflects international solidarity around ensuring the safety of health care workers. In contrast, far greater variation is evident where there is a tension between the interests of individual patients or groups of patients and those of the health care workers at risk for infection. For example, the potential benefits of tracheostomy for patients include freeing up scarce ventilators amid a surge (through swifter weaning), reducing risk of chronic laryngeal or tracheal injury, improving pulmonary hygiene, allowing earlier communication, expediting rehabilitation, and mitigating cumulative effects of sedation, muscle atrophy, and postintensive care syndrome. Few, if any, benefits are likely to accrue to COVID-19 patients from waiting several weeks on the ventilator prior to tracheostomy.

Timing of Tracheostomy

Prior to COVID-19, a meta-analysis of 8 randomized trials comparing the timing of tracheostomy in critically ill patients demonstrated that early tracheostomy (<10 days after intubation) had lower mortality (relative risk [RR], 0.83; 95% CI, 0.70-0.98) and greater rates of ICU discharge by day 28 (RR, 1.29; 95% CI, 1.08-1.55).⁹ Supported by this evidence, it is common practice in many centers for non-COVID-19 patients to undergo tracheostomy 7 to 10 days after intubation. In the case of critically ill patients with COVID-19, our results show that recommendations for timing vary considerably, primarily based on the country. Some countries (Israel, Spain, Brazil, Netherlands) are proactive about performing tracheostomy early, in some cases within days of intubation. Other protocols—most notably those from the United States—have suggested waiting for longer periods, uncommonly beyond 21 days. Some institutions have since modified standards during the pandemic, usually moving toward more conventional (earlier) timing for tracheostomy.^{10,11}

Why have parts of the United States favored late tracheostomy, sometimes deferring the procedure beyond 21 days on mechanical ventilation? One likely driver of this approach was perceived futility of tracheostomy in this

patient population. This perception of grim prognosis likely arose from early, small reports that found a 52% to 86% mortality rate among COVID-19 patients receiving mechanical ventilation.¹²⁻¹⁴ However, since those early reports, more robust studies in the United States and Italy have reported mortality rates of 24% to 26% in COVID-19 patients who require mechanical ventilation.^{15,16} While still high, these rates are more in line with mortality rates seen for the population of non-COVID-19, critically ill, ventilated patients. There is a growing realization that the pathophysiology and prognosis of COVID-19 acute respiratory distress syndrome (ARDS) are not remarkably different from other forms of ARDS and that patients are likely well served by time-proven standards of care. Similar uncertainty is reflected in protocols for suctioning; the frequency of suctioning was recommended in 1 protocol to be “frequent” and in another to be limited to “as needed,” reflecting the competing priorities of prevention of tube occlusion vs avoidance of viral spread.

Conservative recommendations on the timing of tracheostomy in COVID-19 patients may also reflect information on the duration of viral shedding after infection. The highest viral load typically occurs at the time of symptom onset,¹⁷ with a mean duration of respiratory viral shedding (as measured by viral RNA) of 18 to 20 days (interquartile range varied from 17-24 days to 14-30 days).^{13,18} Patients with more severe disease have higher viral loads,^{18,19} and specimens from the lower airways may be positive for longer than specimens from the upper airways.²⁰ A challenge in interpreting these varying studies is understanding the difference between viral RNA, which may persist for extended times, vs the shedding of live, infective virus. Live virus can be consistently isolated in the first week of symptoms by viral cell culture but declines during the second week, more rapidly than viral RNA levels.²¹ The variability in protocols on use of preoperative COVID-19 testing likely reflects this scientific uncertainty.

Technique Considerations and Tracheostomy Tube Changes

Our review of tracheostomy protocols for COVID-19 patients found near consensus on use of paralytics during the procedure, minimizing suction, apnea prior to entering the airway, and use of nonfenestrated cuffed tracheostomy tubes. In regard to PPE, all protocols recommended at minimum an N95 respirator during tracheostomy, with variable recommendations for use of a PAPR as a preferred option when available. There was greater consensus supporting universal eye protection, gown, gloves, and hair covering. Reflecting differences in local expertise, we observed significant variability surrounding tracheostomy technique (open vs percutaneous). Many parameters, such as timing of the tracheostomy, do not directly relate to resource availability. This may explain why analysis did not uncover major differences, and some guidelines may be more aspiration than reflective of practice, particularly with respect to PPE or testing.

Uncertainty about the potential duration of infectivity was reflected in the variability observed in recommendations

on the time for first tracheostomy tube change. These recommendations varied from advising the first tracheostomy tube change at 5 days postoperatively to recommending tube changes no sooner than 30 days postoperatively. Some protocols recommended delaying tube change until after COVID-19 testing is negative, which would often imply the primary team that placed the tracheostomy would not be available to perform the first tracheostomy change, particularly for patients at long-term ventilation facilities.

Limitations

There are several limitations to consider. While we were able to use a systematic, reproducible approach for identification of protocols from the literature, the reliance on international societies and networks, particularly for international data, led to a bias toward larger centers with an international reputation. We relied on AAO-HNS PSQI, Medical Devices and Drugs, and OREBM committee members as the principal source of US-based protocols with an attempt to represent the different geographic areas of the United States. We acknowledge inherent biases of the authors who often served roles in development of some of the guidelines that were reviewed. All authors of this article had their institutional protocols included. While the data extraction from protocols is reproducible, there were protocols for which there was no information given for certain parameters, limiting conclusions about that parameter. As with any protocol or guideline, actual practices may differ significantly. Sometimes protocols do not translate into changes in practice and, conversely, that sometimes protocols do not keep up with changes in practice.

We preferentially sought out international representation wherever possible from individuals with defined leadership roles, but due to structural factors such as more fragmented institutional governance, lack of resources, and publication bias, there was a notable underrepresentation of low- and middle-income countries. The bias of erratic sampling where a single institution or even country is unlikely reflective of the entire region was evident as our review included only a single protocol from India and only a single protocol from Africa. This approach left large regions under- or unexamined, with data collection that was not always proportionate to either population or landmass.

This study was not a solicited, standardized survey study where respondents could choose from a limited number of options, which would allow for a more accurate description of “consensus” on certain subjects. Instead, this article provides a high-level review of institutional protocols and practices already in place at institutions worldwide, which introduces variability in data extraction. Nonetheless, this document is arguably the most diversified effort to date in collection of such data, reflecting a wide range of countries, continents, cultures, and languages.

Variation in Practices

These data summarize a multitude of responses to COVID-19 with varying resource constraints. Creating a new protocol

for a high-risk procedure in a novel disease is best accomplished with the input of an expert team across multiple disciplines. No one member of the health care team will be cognizant of the concerns, expertise, worries, and ideas of all other members. It is also important to remember that a new protocol, especially in a situation such as COVID-19, is a fluid document. As more information is gained about the disease, modifications may be required, and changes to guidelines may be necessary to better reflect the current situation. Flexibility is important not only for protocols but also for optimal patient care, as there will inevitably be situations that require deviation from an established protocol. If these variations occur frequently, it may be a sign that the protocol needs to be modified or that increased education and communication are necessary.

Finally, whereas standardization of approaches within institutions is likely to improve outcomes, the optimal approach for one institution or region may differ from that of another, based on experience, infrastructure, and capacity relative to case volume, particularly in the setting of a surge during future waves. We foresee 2 avenues of future study focused on the safety of clinicians and benefit to patients.²² First, health care worker-centered studies are needed to examine risk of COVID-19 transmission and optimal prevention strategies. Second, patient-centered studies in the COVID-19 population are needed to examine the impact of early vs late tracheostomy on important outcomes and to understand and mitigate disparities, particularly related to overall care delivery and availability of PPE globally. It will be critical for future studies to track data in tracheostomy care, as is done for example in the Global Tracheostomy Collaborative.²³⁻²⁵ These data are already starting to emerge. For example, a national cohort study from Spain recently published their experience with 1890 COVID-19 tracheostomies.²⁶ They found that 1 month after tracheostomy, 52% were weaned from mechanical ventilation, 35% still required mechanical ventilation, and 24% died.

Conclusion

We compared tracheostomy protocols developed for COVID-19 and found substantial variability and several common themes. While these data cannot determine a single best approach or define “best practices,” they do provide perspective on how institutions around the world have responded to this crisis. Time will tell to what extent these protocols achieve the goal of providing the best care for patients while protecting the health care workers caring for them.

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