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Review

Systematic review of international guidelines for tracheostomy in COVID-19 patients

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ABSTRACT

At this moment, the world lives under the SARS-CoV-2 outbreak pandemic. As Otolaryngologists - Head & Neck Surgeons, we need to perform and participate in examinations and procedures within the head and neck region and airway that carry a particularly high risk of exposure and infection because of aerosol and droplet contamination. One of those surgical procedures in demand at this moment is tracheostomy due the increasing ICU admissions. This review of international guidelines for tracheostomy in COVID-19 infected patients, aims to summarize in a systematic way the available recommendations: indications, timing, technique and safety measures for tracheostomy, from all over the world.

Introduction

Since the first described cases of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were identified in the Hubei region of China in December 2019, Coronavirus has been spreading rapidly across countries [1].

On March 11th 2020, the World Health Organization (WHO) finally declared the SARS-CoV-2 a pandemic due to the increasing number of cases around the world [2]. This has resulted in high rates of emergency visits, hospitalizations and intensive care unit (ICU) admissions [3]. By April 10th 2020, a total of 1,521,252 patients had tested positive for the new SARS-CoV-2 coronavirus worldwide and 92,798 (6.1%) cases were fatal [4]. Nonetheless, reported mortality can vary across countries due

to differences in proportions of elderly patients, prevalence of comorbidities, available resources and criteria for testing the population [5].

Despite increasing information on the incidence of the disease, clinical characteristics of critically ill patients diagnosed with COVID-19 are still limited. According to the Johns Hopkins Dashboard the infection predominantly affects people aged 30–79 years-old (87%). Almost 81% are asymptomatic or experience mild symptoms, whereas 15% of patients suffer severe symptoms requiring hospitalization, and 3–15% of those hospitalized will reportedly require respiratory support in an intensive care unit (ICU) setting with mechanical ventilation or extracorporeal membrane oxygenation (ECMO) [6–8].

Otolaryngologists - Head & Neck Surgeons need to perform and

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Table 1
Worldwide guideline comparison. OR (Operating Room), COVID-19 (Coronavirus disease 2019), ICU (Intensive Care Unit), PPE (Personal Protective Equipment), NE (Not specified), PAPP (Powered air-purifying respirator).

Country/Society	Last update	Indications and COVID-19 status.	General precautions (PPE)	Technique	Team	Operative Setting	Type of dissection	Post-tracheostomy care	Other
The Australian and New Zealand Intensive Care Society (Australia & New Zealand) [13]	March 16, 2020	Clinical Decision Making COVID-19 Test required.	Optimal PPE	NE	NE	NE	NE	NE	ICU guideline, not specific for tracheostomy.
The South African Society of Otorhinolaryngology-Head & Neck Surgery. (South Africa) [28]	March 19, 2020	COVID-19 testing to be performed in all patients prior to elective tracheostomy. In COVID-19 positive patients ENT & ICU consultant need to discuss appropriateness of tracheostomy.	Full PPE. FFP3 mask. Eye/Face Protection. Full Face Shield/Visor.	NE	Most Skilled Surgeon. Minimal Staff.	NE	NE	Cuffed non-fenestrated tracheostomy should be used to avoid aerosolizing the virus. HME filter. Avoid changing the tracheostomy tube until COVID-19 has passed.	No
ENT-UK (UK) [22]	March 19, 2020	Semi-elective procedure. Consider whether the patient is relatively stable and will tolerate lying flat with periods of brief apnea.	Full PPE	Open or percutaneous according to local factors, competencies, and experience	Essential personnel.	Negative pressure theatre or isolation room.		Use only closed suction circuits. First tube changes in confirmed negative COVID-19 test Cuff to remain inflated and check for leaks First tube changes in confirmed negative COVID-19 test Create a COVID airway team.	
NTSP – UK (National Tracheostomy Safety Project) (UK) [20]	March 20, 2020	Tracheostomy should ideally be undertaken when the patient is COVID-19 negative. For patients at high risk of a failed extubation, a tracheostomy can be considered.	Full PPE	NE	Minimal Staff	ICU or isolated room with negative pressure.	NE	Cuffed tracheostomy. Decannulation when patient is confirmed COVID-19 negative and is to be moved to a COVID-19 negative ward. Laryngectomy patients' needs to wear a Stomal HME filter. Hands-Free valves minimize touching the stoma.	

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Table 1 (continued)

Country/Society	Last update	Indications and COVID-19 status.	General precautions (PPE)	Technique	Team	Operative Setting	Type of dissection	Post-tracheostomy care	Other
Canadian Society of Otolaryngology - Head and Neck Surgery (Canada) [14]	March 22, 2020	Strongly recommendation against tracheotomy in COVID-19 patients who are still infectious. This should only be considered if the endotracheal tube ventilation is insufficient	Full aerosol PPE. N95 mask. Complete neuromuscular paralysis.	Open tracheostomy	NE	ICU or OR With negative pressure.	NE	NE	Initial advancement of the endotracheal tube could be performed to make the cuff distal to the tracheotomy incision (to prevent airflow through the surgical tracheotomy). Awake tracheotomy and cricothyroidotomy are to be considered very high risk for viral plume spread and should be avoided
Società Italiana di Otorinolaringologia e Chirurgia Cervico-Faciale (Italy) [26]	March 25, 2020	PCR Test is Required for elective tracheostomy. In Emergency tracheostomy, every patient Needs to be Manage the patient as presumed COVID-19 positive Semi-Elective procedure.	Non-fenestrated, cuffed tracheostomy tube with balloon inflated. HME filter. Full PPF FFP3 or FFP2 mask. Face Shield or helmet. Double glove.	Open tracheostomy	Team COVID	OR	Try to avoid diathermy.	First tube changes 7-10 day after tracheostomy.	Cuffed and non-fenestrated cannulas must be used until the patient is confirmed COVID-19 negative.
Henry Ford Health System (USA) [17]	March 25, 2020	In case of emergent or urgent tracheostomy, proceed. In case of elective. Staff physician discussion. Decision confirmed by two intensivists. COVID-19 negative test is necessary to consider a patient candidate for elective tracheostomy. In high risk patients two-documented negative COVID-19 test being performed 48-72 h after first test. ICU patients: multidisciplinary decision.	Closed circuit aspiration N95 mask (or PAPR if available) Face shield Head covering. Moisture barrier gown, and gloves. Proper removal of PPE will be followed.	When possible and appropriate, percutaneous tracheostomy at bedside is preferable to Open tracheostomy in the OR to minimize aerosolization, transport and resource utilization.	Minimal Staff	OR	NE	No tracheostomy tube exchange unless clinically indicated Cuff to remain inflated and check for leaks Make every effort not to disconnect the circuit Only closed in line suctioning should be used	As a rule, COVID-19 positive cases will NOT undergo tracheostomy unless there is a life-threatening situation that the tracheostomy has the potential to improve, such as upper airway obstruction with inability to intubate.
			In patients with unknown COVID19	Consider either open tracheostomy or	Minimal Staff	ICU or airborne	NE	HME filters and closed suctioning if	Decannulation: Should be done as soon as medically (continued on next page)

Table 1 (continued)

Country/Society	Last update	Indications and COVID-19 status.	General precautions (PPE)	Technique	Team	Operative Setting	Type of dissection	Post-tracheostomy care	Other
The Michigan Critical Care Collaborative Network (USA) [18]	March 25, 2020	Elective: Prolonged mechanical ventilation, major head and neck cancer/reconstructive cases to bypass potential airway obstruction. If previously COVID-19 positive and considering elective tracheostomy, recommend 2 negative COVID-19 tests separated by 24 h and resolution of fever and improvement of symptoms prior to proceeding to tracheostomy.	status, COVID19-positive or pending, all health care providers performing emergent tracheostomy should wear COVID19 PPE.	percutaneous tracheostomy at the discretion of the faculty performing the procedure		isolation rooms with negative pressure. Negative pressure rooms with HEPA filter. Avoid Neutral rooms.		available.	safe and immediately place occlusive dressing. In laryngectomy patients HME filter should be placed immediately and kept at all times regardless of COVID19 status given many carriers are asymptomatic.
American College of surgeons (USA) [16]	March 27, 2020	NE	Wash hands frequently and maintain safe social distancing. PPE. N95 mask. Smoke evacuator when electrocautery is used Remove clothes worn from home and keep in garment bag Wear scrub clothes after arrival at hospital	This guideline follows Considerations for tracheostomy from the ENT-UK guideline.	Establish a minimum number of personal for each task.	NE	NE	NE	Guide for optimum surgeon protection and not specific for tracheostomy.
University of California San Francisco (USA) [19]	March 28, 2020	The optimal timing of tracheostomy in patients with COVID-19 is unknown. The decision for tracheostomy will be made on a case-by-case basis. In most circumstances, patients should have two negative COVID-19 PCR tests prior to surgery.	Full PPE	NE	NE	NE	NE	NE	Hospital guideline, not specific for tracheostomy.

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Table 1 (continued)

Country/Society	Last update	Indications and COVID-19 status.	General precautions (PPE)	Technique	Team	Operative Setting	Type of dissection	Post-tracheostomy care	Other
Spanish Society of Maxillofacial - Head & Neck Surgery. (Spain) [24]	March 28, 2020	NE	Full PPE. N95 (FFP2 - FFP3) masks. Facial Shield and goggles. NE	Percutaneous tracheostomy	Minimal and most experienced staff	ICU	Minimize use of diathermy.	NE	No
American Academy of Otolaryngology – Head & Neck Surgery (USA) [15]	April 2, 2020	Decision-making in tracheotomy should take into consideration the surgical and ICU team's discretion as well as institutional policy. Avoid tracheotomy in COVID-19 positive or suspected patients during periods of respiratory instability or heightened ventilator dependence. Tracheotomy can be considered in patients with stable pulmonary status. Tracheostomy should not take place sooner than 2–3 weeks from intubation and, preferably, with negative COVID-19 testing.	NE	NE	Minimal Staff	NE	Rely on cold instrumentation and avoid monopolar electrocautery. Choose cuffed, non-fenestrated tracheostomy tube. Maintain cuff appropriately inflated post-operatively and attempt to avoid cuff leaks. Avoid circuit disconnections and suction via closed circuit. HME with viral filter Delay routine post-operative tracheotomy tube changes until COVID-19 testing is negative.	Advance ETT and cuff safely below the intended tracheotomy site and hold respirations while incising trachea.	
Spanish Society of Otorhinolaryngology – Head & Neck Surgery (Spain) [23]	April 3, 2020	NE	Full PPE. N95, FFP2 or FFP3 mask. Double glove. Face Shield and goggles.	Open or percutaneous according to each hospital protocol.	Minimal Staff required	OR or ICU with negative pressure	Try to avoid the use of diathermy.	First tube change should be deferred for up to 14–21 days. HME filters are recommended. Maintain Cuff always inflated.	No

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Table 1 (continued)

Country/Society	Last update	Indications and COVID-19 status.	General precautions (PPE)	Technique	Team	Operative Setting	Type of dissection	Post-tracheostomy care	Other
British Laryngological Association (UK) [21]	April 3, 2020	Unlikely to be indicated after < 14 days of ventilation	Full PPE. FFP3 mask and visor.	Consider Powered Hoods (PAPR).	Consultant surgeon Skilled Assistant Scrub nurse	OR or ICU with negative pressure	Minimize use of diathermy during dissection	Check cuff pressure. First tube change should be deferred for up to 4 weeks.	Consider reducing theatre temperature for staff comfort wearing PPE.
		Consider trial of extubation – i.e. high threshold to perform tracheostomy							
		The patient should be apyrexial with falling inflammatory markers (a surgical procedure undertaken during viremia risks precipitating a clinical deterioration)			Consultant anesthetist				
		Two Negative viral swabs (48 hrs apart) preferred, but it is accepted this may not always be possible.							
		Hemodynamically stable with minimal pressor requirement							
French Society of Otorhinolaryngology - Head & Neck Surgery. (France) [25]	April 9, 2020	Multidisciplinary medical decision made by the anesthesiologist in charge of the patient, in discussion with the ENT surgeon.	Full PPE. N95 (FFP2 – FFP3) masks. Headlight covered by a head cap. An impermeable protective apron or an overcoat that must be worn under the surgical gown as it is not sterile Full PPE N95 Mask	Percutaneous tracheostomy. Open tracheostomy can be recommended in the event of anatomical contraindications, failure of percutaneous technique or exhaustion of percutaneous kits.	NE ICU	ICU	Minimize use of diathermy.	NE	Suture the cannula particularly if a prone position of the patient is planned. Tracheostomy under local anesthesia is not recommended.
Division of ENT Surgery - University Of Cape Town (South Africa) [27]	April 2020	Multidisciplinary medical decision in case of reduced number of ICU beds.		NE	Minimal Staff	NE	NE	NE	No
		Tracheostomy only once patients is COVID-19 Negative test.							
Singapore General Hospital (Singapore) [29]	April 6, 2020	ICU-ENT Protocol for COVID-19 positive patients.	Full PPE N95 Mask Eye protection, Cap, PARR	Open tracheostomy. Percutaneous in selected cases.	Experienced surgeons. Minimal Staff.	Isolated OR specific for COVID-19 positive patient. ICU in selected patients.	NE	NE	Anesthesiology will be focused on reducing aerosolization during procedure.
		Tracheostomy is performed when the pulmonary function of ventilated patients not show improvement beyond 7 days.							

Table 2
Tracheostomy care guidelines. HME (Humidity-Moisture Exchange), HEPA (High Efficiency Particulate Air), NE (Not specified).

Country	Last Update	COVID-19 Status	Airway protection for patients	Tracheal tube changes by healthcare workers	Voice Prosthesis changes	Other
Spanish Society of Otorhinolaryngology – Head & Neck Surgery. (Spain) [30]	March 26, 2020	COVID-19 Negative	HME filter, surgical mask over the tracheal stoma when is indicated or HEPA filter.	Basic PPE (Gloves, Goggles, Surgical mask or FFP2, gown)	Basic PPE	No
French Society of Otorhinolaryngology - Head & Neck Surgery. (France) [25]	April 9, 2020	COVID-19 Suspected or Positive. Any patient should be considered as potentially infected	HME filter or HEPA filter. NE	Full PPE. Apron or surgical gown. Forehead protection to protect skin exposure. Gloves. Goggles. FFP2 – N95 Mask.	Full PPE NE	Aspiration on close suction system. If the patient is ventilated on the tracheostomy cannula, ask the anesthesiologist to sedate the patient and perform a neuromuscular block to reduce any risk of coughing during the change of the cannula.

participate in examinations and procedures within the head and neck region and airway that carry a particularly high risk of exposure and infection because of droplet contamination [9]. Moreover, we need to highlight the role of aerosolization as an additional means of spread during high-risk procedures, in particular tracheostomy. Tracheostomy is currently in demand due increasing ICU admission with the increased need for ventilatory support secondary to respiratory distress syndrome. In this respect, it is therefore of paramount importance to establish tracheostomy guidelines that focus equally on both patient’s and health care team’s well-being during the COVID-19 pandemic that minimize risk of viral exposure.

As an initiative of the “*Young Otolaryngologist Group of the International Federation of Otolaryngologic Societies*” (YO-IFOS), this review aims to summarize in a systematic way the available recommendations for tracheostomy in COVID-19 infected patients.

Methods

The systematic review was performed in accordance with PRISMA guidelines [10]. This review involved a systematic search of the electronic databases MEDLINE/PUBMED, Google Scholar, the Chinese SinoMed (<http://www.sinomed.ac.cn/zh/>), Ovid Medline, Scielo, Embase, Scopus, and the Database of Abstracts of Reviews of Effects. In addition, Otolaryngology-Head and Neck Surgery (OHNS) societies and institutions across the world were contacted (Table 1). Guidelines and recommendations from January 2020 to April 2020 were included. No language restriction was applied to the search strategy. Search terms (medical subject headings or keywords) included: “tracheotomy”, “tracheostomy,” “SARS CoV-2”, “COVID-19”, “guidelines/practice guidelines/clinical guidelines,” “consensus,” “ENT,” and “Head & Neck surgery.” Titles and abstracts were screened by two investigators (C.M.C.E and T.A) to discard irrelevant publications. All searches were completed in April 13, 2020.

Guidelines Credibility, as measured by whether the guidelines were developed, cited by subsequent guidelines or by other publications regarding tracheostomy in COVID-19 patients was assessed. A recent version of each clinical guideline was included and analyzed.

Inclusion criteria for the systematic review were based on the population, intervention, comparison, and outcomes according to (PICO) framework [11].

Population

Inclusion criteria consisted of clinical guidelines comprehensively reporting on severe COVID-19 patients’ treatment strategies, and consider recommendations for severe patients requiring hospitalization and/or ventilatory support.

Intervention and comparison

Intervention and comparison parameters were defined according to guideline statements related to COVID-19 status, indication, measures of protection, type of tracheostomy technique, diathermy or not, surgical setting, post-tracheostomy care.

Outcome

The primary outcome was to describe a set of recommendations to improve tracheostomy safety. Included common questions related to: indications, COVID-19 status, patients’ comorbidities, standard personal protective equipment (PPE), operative room setting, methods of dissection, type of tracheostomy and post-tracheostomy care.

To assess the methodological quality of guidelines included The AGREE II (Appraisal of Guidelines for Research and Evaluation II) validated instrument was used [12]. The quality assessment of all included clinical practice guidelines was performed by four appraisers

Table 3
Guideline assessment according to the AGREE-II Instrument.

Guideline organization or society	Scope and Purpose	Stakeholder Involvement	Rigor of development	Clarity and Presentation	Applicability	Editorial Independence	Mean domain scores (%)	Agreement between appraisers (Kappa 95% CI)
The Australian and New Zealand Intensive Care Society (Australia & New Zealand) [13]	66.6	63.8	57	61.1	69.4	75	65.4	0.63 (0.59 to 0.68)
The South African Society of Otorhinolaryngology- Head & Neck Surgery. (South Africa) [28]	94.6	72.2	55	83.3	80.5	83	78.1	0.77 (0.63 to 0.87)
ENT-UK (UK) [22]	100	70.5	59.5	88.8	91.6	83	82.2	0.92 (0.72 to 0.97)
NTSP – UK (National Tracheostomy Safety Project) (UK) [20]	94.6	76.5	55	83.3	86.1	70.8	77.7	0.84 (0.77 to 0.90)
Canadian Society of Otolaryngology - Head and Neck Surgery (Canada) [14]	100	65	57	86.1	88.8	87.5	77	0.81 (0.69 to 0.89)
Società Italiana di Otorinolaringologia e Chirurgia Cervico-Faciale (Italy) [26]	100	62.2	52.3	83.3	82.1	75	75.8	0.73 (0.54 to 0.97)
Henry Ford Health System (USA) [17]	94.6	72.2	52.4	83.3	86.1	70.8	76	0.77 (0.58 to 0.91)
The Michigan Critical Care Collaborative Network (USA) [18]	94.6	66.6	55	80.5	83.3	70.8	75.1	0.75 (0.54 to 0.83)
American College of surgeons (USA) [16]	66.6	69.4	50	61.1	77	75	66.5	0.84 (0.67 to 0.93)
University of California San Francisco (USA) [19]	94.6	72.2	51.4	77	83.3	70.8	74.8	0.92 (0.73 to 0.99)
Spanish Society of Maxillofacial - Head & Neck Surgery. (Spain) [24]	94.6	72.2	52.4	83.3	86.1	83	78.6	0.47 (0.39 to 0.56)
American Academy of Otolaryngology – Head & Neck Surgery (USA) [15]	100	74.5	57	86.1	88.8	83	81.5	0.86 (0.71 to 0.96)
Spanish Society of Otorhinolaryngology – Head & Neck Surgery (Spain) [23]	100	72.2	52.4	86.1	88.8	81	80	0.71 (0.65 to 0.84)
British Laryngological Association (UK) [21]	100	78.5	59.5	88.8	91.6	83	83.5	0.81 (0.71 to 0.89)
French Society of Otorhinolaryngology - Head & Neck Surgery. (France) [25]	100	72.5	52.4	83.3	86.1	87.5	80.3	0.79 (0.71 to 0.93)
Division of ENT Surgery - University Of Cape Town (South Africa) [27]	94.6	72.2	55	83.3	83.3	87.5	79.3.6	0.78 (0.69 to 0.84)
Singapore General Hospital (Singapore) [29]	100	72.2	52.4	86.1	86.1	87.5	80.7	0.87 (0.72 to 0.96)

independently (C.C.E, J.A.S, J.A.G.G & T.A). We defined this as 50% or higher as acceptable. To measure interobserver agreement across the ordinal categories of the AGREE-II ratings, a weighted kappa was calculated using SPSS V.21.0. The degrees of agreement were graded as minor (≤ 0.20), fair (0.21–0.40), moderate (0.41–0.60), substantial (0.61–0.80) and almost perfect (≥ 0.81).

Results

17 guidelines that were published between March 16th and April 9th about tracheostomy in COVID-19 patients were identified for analysis, including 1 guideline from Oceania (Australian and New Zealand) [13], 6 from North America (1 from Canada and 5 from USA) [14–19], 3 from the United Kingdom [20–22], 4 from Europe (2 Spanish, 1 French and 1 Italian) [23–26], 2 from Africa (both from South Africa) [27,28] and 1 from Asia (1 Singapore) [29], all of them cited in Table 1. Additionally, two guidelines focusing specifically on post-tracheostomy care were included. (1 from France and 1 from Spain) (Table 2) [25,30]. Data from other Asian countries, Middle East, South, Central America and the Caribbean were not available online. These guidelines were examined and compared, results are summarized in Tables 1–3.

Appraisal of guidelines

The AGREE-II domain percentages for each guideline are shown in table 3. None of those selected guidelines stated the methods used in the literature search, quality of evidence, and strengths of recommendations reported.

Scope and purpose

With this quality domain, the aim of the guideline under scrutiny is determined [12]. A total of 8 guidelines obtained a score of 100% [14,15,21–26,29], 7 a score $> 80\%$ [17–20,24,27,28], and 2 a score < 70 [13,16]. Therefore, 15 of the reviewed guidelines had a clearly described scope and purpose.

Stakeholder involvement

Stakeholder involvement examines the extent to which the guidelines have been developed by the appropriate stakeholders and takes into account the views of the intended users and target population [12]. No guidelines scored $> 80\%$ [13,30], with that no guidelines including the views and preferences of the patients and users. Most guidelines do not provide details about the participants during the developmental process. In general, the target audience is generally specified in the guideline procedure.

Rigor of development

The rigor of development “relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them. [12] Details about the research strategy, evidence rating scales and evidence selection criteria were not described in any guidelines [13–29]. The update was indicated in 2 guidelines [15,23].

Clarity of presentation

The clarity of the presentation examines “the language, structure, and format of the guideline [12]. All guidelines provided a clear presentation and summary of recommendations. One of them offered an algorithm [26].

Applicability

Applicability addresses barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying guidelines, meaning the degree to which the implementation of recommendations in practice and in a particular context may be facilitated or hindered by different factors like equipment, skills or

economic resources [12]. All guidelines offered elements regarding applicability in the context of operative room or ICU setting, and protective measures were provided to healthcare workers. Also, elements concerning implementation were described on each guideline. Only one guideline provides recommendations in a resource-constrained setting [27].

Editorial independence

Editorial independence “is concerned with the formulation of recommendations not being unduly biased with competing interests [12]. The overall mean domain score and SD were $79 \pm 6.3\%$. No guidelines provided information about interest or financing. However, almost all come from institutions or national societies and this information is not relevant for tracheostomy in the context of the pandemic.

Overall assessment

Fifteen (88%) guidelines were assessed and recommended for use during COVID-19 pandemic, since their quality scores were 6 or more, and met the AGREE II criteria for providing good recommendations for clinical practice [14,15,17–29], representing good-quality guidelines. The 2 remaining guidelines had scores between 5 and 6 [13,16]. These guidelines were recommended for COVID-19 attention, but not as tracheostomy guidelines.

The mean scores (range; SD) for the domains were: scope and purpose 93.8% (66.6–100%; SD 10.22); stakeholder involvement 70.8% (62.2–78.5%; SD 4.18); rigor of development 54.4% (51.4–59.5%; SD 2.61); clarity of presentation 81.4% (61.1–88.8%; 7.91); applicability 84.6% (69.4–91.6%; SD 5.30) and editorial independence 79.6% (75–87.5%; 6.33). The kappa values ranged from 0.47 (95% CI 0.39–0.56) to very good 0.92 (95% CI 0.73 to 0.99). The overall inter-rater agreement was intraclass correlation = 0.89 (95% CI 0.81–0.94), indicating very good strength of agreement.

Statements

The following statements reflect the current practice of surgical airway management in patient suffering from severe COVID-19 infection. Given the dynamic nature of scientific information and technology and the emergence of new data during and after the outbreak, the information herein presented should be managed carefully. Periodic reviews, updates, and revisions are required and expected. Tracheostomy surgical steps and technical notes are beyond the scope of this paper.

Is it relevant to know COVID-19 status before performing a tracheostomy?

The availability to test patients differs among countries. Ideally, being able to assess COVID-19 status prior to performing a tracheostomy is of paramount importance. PCR or serology tests are scarce due to the outbreak and the limited resources in some settings need to be taken into consideration. Moreover, information regarding viral load in the upper airway (nasopharynx and oropharynx) is conflicting. Early information suggest a higher viral load in the early phase of the disease, between days 9 to 15 [31,32]. However, new evidence suggests viral load detection in secretions up to 2–3 weeks after onset of symptoms [33].

According to guidelines reviewed; some recommend performing a test before any elective tracheostomy [13–21,27,28]. Furthermore, for SARS-CoV-2 positive patients, there is a strong recommendation against performing a tracheostomy in patients who are infectious and have a high viral burden. One guidelines specifies that during the pandemic patients should be considered positive (until proven otherwise) and full PPE needs to be used during each procedure [18]. Other guidelines do not specify or mention the need of a recent test prior to a tracheostomy [23–26]. All guidelines recommend, as expected, proceeding in case of emergency or crash tracheostomy regardless of COVID-19 status, using all full PPE [13–29].

What precautions and measures are needed to perform a tracheostomy?

During the outbreak, barrier precautions are critical in order to protect healthcare workers from contamination or infection. All the consulted guidelines recommend full PPE due to the high risk of infection, including N95 or N99 (USA), FFP2 or FFP3 (Europe) mask, the use of double gloves, goggles or eye protection, face shield and an apron or gown [13–29]. Three guidelines also recommend the use of a Powered air-purifying respirator (PAPR) [17,21,29]. Careful hand hygiene is recommended with hydroalcoholic solution [13–29]. After every tracheostomy, careful PPE removal following the sequential centers for disease control and prevention (CDC) protocol is important to avoid contamination [34]. Also of note, as highlighted by the Centre for Disease Control (CDC) protocol, a designated person to closely supervise this step, is mandatory [35].

What is the role of patient comorbidities?

None of the reviewed guidelines mention a higher risk with any associated comorbidities in the post-operative course or outcomes of patients undergoing tracheostomy. This however, is relevant, as COVID-19 patients with specific comorbidities have a poorer prognosis when compared to COVID-19 patients without comorbidities [36]. A recent meta-analysis identified hypertension, diabetes, chronic obstructive pulmonary disease, cardiovascular disease, and cerebrovascular disease as significant risk factors for mortality in COVID-19 patients. Identifying high risk groups is therefore essential during the decision-making process, and in particular when proceeding with a high-risk procedure like a tracheostomy [37]. Nevertheless, the Italian experience have informed us that elderly patients had a higher mortality compared to younger patients (36%vs 15%; difference, 21% [95%CI, 17–26%]; $P < 0.001$) [38].

What are the risks related to performing a tracheostomy in COVID-19 positive patients?

Open and percutaneous tracheostomy represent aerosol-generating procedures (AGP) related to an increase in potential viral exposure for the healthcare workers [39]. It is attributed to aerosolized viral particles, which can stay up to 3 h [40]. Furthermore, after tracheostomy, there is an increased potential for virus exposure to the ICU team who perform several bedside procedures from simple examination to suctioning, dressing changes and other routine post-tracheostomy care [15].

According to Wuhan epidemic data, affected healthcare workers represented 3.8% of the infected patients and 14.8% were categorized as severe disease, with an overall mortality rate of 0.6% [6,41,42]. In Italy, 15% of responding healthcare workers were infected [43]. However, consistent data regarding the risk of contracting COVID-19 from tracheostomy was not described in any guideline or across the indexed literature.

Is there any evidence regarding indications and timing for elective tracheostomy?

Indications and timing represent the most controversial issue. Is important to highlight that indications come from Intensivists or Anesthesiologists managing patients since there are a lot of parameters that need to be taken into consideration. It is necessary to establish a multidisciplinary team (Intensivist, Anesthesiologist, ENT or Head & Neck Surgeon) to discuss every case. Our findings present a high variability in national guidelines and protocols guidelines. European guidelines excluding British guidelines propose a more aggressive approach (early tracheostomy) [23,24,25], maybe attributed the high volume of cases during the pandemic. By contrast British, North American, Singaporean and South-African guidelines propose a more

conservative approach, suggesting waiting for at least 14 days of ventilation or a COVID-19 negative test (PCR or two negative pharyngeal swabs) before performing an elective tracheostomy. They also recommend avoiding tracheostomy in COVID-19 positive or suspected patients during periods of respiratory instability or heightened ventilator dependence [13–22,27–29]. Moreover, none of the guidelines discuss or differentiate specifically why a tracheostomy might be indicated in COVID-19 patients.

Looking at previous reports, benefits of performing an early tracheostomy in critically ill COVID-19 patients are unclear, and based on the SARS-CoV-1 outbreak with a similar coronavirus, the need for mechanical ventilation was associated with a 46% mortality [44]. In addition, during the SARS-CoV-1 outbreak physicians were unable to identify the exact time-point when afflicted patients either improve, remain stable, or progress toward death due to pulmonary complications. As the mean time from onset to death was 23.7 days, there was a very low potential benefit of tracheostomy prior to this time [45].

Early evidence from Wuhan shows that the mean time from admission to time of death was 11 days with a median of 5 days. However, this data was not statistically significant ($p = 0.56$) [46]. Givi et al. suggests delaying most tracheostomy procedures beyond 14 days, given the high infectious risks during the procedure, arguing that early phases of COVID-19 infection may carry a higher viral load. Furthermore, after 14 days the rate of recovery is higher, with subsequent ventilator weaning as the primary goal of care [9].

Data collected from non COVID-19 patients in a recent systematic review suggested that early tracheostomy, performed in the first 7 days after orotracheal intubation, is associated with a reduction of mechanical ventilation duration, mortality rate and length of stay in ICU irrespective of reason for admission [47]. Furthermore, a meta-analysis of randomized controlled clinical trials in non COVID-19 patients with trial sequential analysis performed by Ruohui et al., compared with early with late tracheostomy. Findings indicated early tracheostomy presented a lower incidence of ventilator-associated pneumonia, shorter duration of mechanical ventilation, and shorter ICU stay. A cumulative meta-analysis, however, indicated that this evidence was unreliable and inconclusive [49]. In contrast, a previous randomized clinical trial of non COVID-19 patients, did not show an improved mortality rate or reduced length of ICU stay in patients on mechanical ventilation that underwent early tracheostomy [48].

More studies are therefore needed to compare the benefit of early versus late tracheostomy placement in COVID-19 patients.

What is the best option to choose: Percutaneous or surgical tracheostomy?

Recommendations against and in favor of both techniques were found. Six guidelines did not specify the type of technique recommended [13,15,19,20,28,29], 3 guidelines recommend open tracheostomy [14,21,26], 1 recommended percutaneous tracheostomy [17] and 6 recommended both techniques [16,18,22,23,25,29]. Nevertheless, data about aerosol diffusion or droplets during percutaneous or open tracheostomy are not available across the literature. Low-level evidence from SARS-CoV1 outbreak was in favor of open tracheostomies (OT) [50,51].

Those who argue against percutaneous tracheostomy (PT) suggest that the procedure hypothetically involves a more extensive airway manipulation, due to the need for bronchoscopy and/or serial dilations during trachea entry and put the patient's airway in direct contact with the surgeons from the beginning. These factors are noted to increase aerosolization risks when compared to the operating room, where there is no contact with the patient's airway during dissection of the neck and the tracheal opening is performed quickly with an incision. Aerosolization risks can be mitigated with some specific measures like distally advancing the endotracheal tube with the cuff inflated and below incision site before opening the trachea. More recently, an improved method to perform a PT was proposed [52,53]. Authors suggests

the use of a double lumen endotracheal tube (DLET) for PT in critically ill patients [53]. DLET is equipped with an upper channel that allows passage of a bronchoscope during the percutaneous tracheostomy and with a lower channel exclusively dedicated to patient ventilation [53]. The lower channel is equipped with a distal cuff positioned just above the carina that may allow a safe mechanical ventilation by keeping stable gas-exchange and limiting the spread of aerosol during the procedure [52,53]. The authors recommend considering either open tracheostomy or percutaneous tracheostomy at the discretion of the faculty performing the procedure, and according to departmental experience.

Where is the best place to do it: The operating room or the ICU?

All the reviewed guidelines emphasize the importance of a proper surgical setting [13–29]. Evidence from the SARS-CoV-1 outbreak highlight the role of bedside tracheostomy in the ICU in negative-pressure rooms [50,51,54,55]. These measures are directed to avoid unnecessary transport of patients and repeated handling (connection and disconnection) of ventilatory circuits during transfer, which may increase the risk of contamination. Nevertheless, some guidelines recommend establishing a dedicated COVID-19 operating room (OR) to perform tracheostomy. In this case, it should ideally be a negative pressure OR, with well-demarcated areas and routes for patient transport [26,29,56]. Nevertheless, most ORs are positive pressure environments and none of the reviewed guidelines mentioned this. From our group, we also strongly suggest increasing PPE measures and reduce the number of healthcare workers during a tracheostomy to minimize risk.

Who should perform the tracheostomy?

Seventeen guidelines recommended minimal staff during the procedure [13–29], composed of two surgeons, one anesthetist or intensivist, one scrub nurse and a second nurse as a runner. All guidelines recommended a skilled surgical team (COVID-19 Airway team) composed of a senior consultant (ENT or Head & Neck Surgeon) to lead the surgery, assisted by a skilled assistant (junior faculty or consultant), who needs to be familiar with all the surgical steps of tracheostomy, to minimize the time spent in the contaminated room [29].

What type of dissection is recommended?

Surgical smoke is created when the electrocautery instrument is used to cut, coagulate, or ablate tissue. The tissue is heated to the boiling point of its constituent fluids, causing membranes to rupture, releasing a bioaerosol [57]. The use of an efficient, filtered evacuation system is indicated, particularly when there is the possibility of dissemination of viral particles [58]. Only 6 guidelines mentioned the use of cold or diathermy dissection. Five guidelines recommended avoiding the use of diathermy [15,21,23,25,26]. One guideline recommended minimizing its use [24].

What precautions should we take before opening the trachea?

A single British guideline made specific recommendations regarding precautions before opening the trachea [21]. The first step recommended is the suction of oropharyngeal, hypopharyngeal and tracheal secretions with a Yankauer suction tip and an in-line suction system [21]. Prior to making the tracheal window, neuromuscular blockade should be confirmed with the anesthetist in order to avoid swallowing and cough reflexes. Maximum oxygenation must be achieved before to open the trachea. Once the anterior wall of the trachea is exposed, the anesthetist or intensivist needs to: 1) reduce the oxygen-percentage of the insufflated air to 21%, 2) blindly advance the endotracheal tube as caudally as possible with cuff inflated, looking for

signs of right main bronchial intubation and 3) hyper-inflate the cuff to ensure lower airway isolation thereby reducing the risk of aerosoling [59]. Prior to making the tracheal window an additional dose of muscle relaxant can be useful and ventilation must be stopped to avoid aerosolization in case of cuff puncture [21].

Are there any recommendations about post-tracheostomy care and first change?

Post-tracheostomy care should be performed by trained nursing staff [29]. Safe suction with a closed airway circuit and regular checks of cuff-pressure is recommended [29]. No dressing change is recommended unless evidence of local infection. Cannula cuff should not be deflated to avoid any risk of air leakage from the stoma. Recommendation about first change varies among clinical guidelines. Italian guidelines suggest that the first change should be planned 7–10 days later using the same standards (PPE utilization and airflow interruption), and subsequent cannula change can be delayed after a further 30 days [26]. Spanish Guidelines suggest waiting 14–21 days [23]. British guidelines from the BLA suggest waiting almost 4 weeks [21], and by contrast ENT-UK guideline suggests making the first change in the first 7–10 days [22]. South-African ENT Society and the AAO-HNS guidelines suggest delaying routine post-operative tracheostomy tube changes until COVID-19 testing is negative [15,27,28]. Other North American guideline suggest avoiding tube changes unless clinically indicated [17]. Those that support delaying the first change, based their decision on reducing the risk of infection for healthcare workers. By contrast, authors hypothesized that those that suggest an early change based their decision on minimising tracheal injury by replacing the cuffed tube with an uncuffed one.

Is there any recommendation about filters and protective measures in a tracheostomy patient?

All guidelines suggest using Heat and Moisture filters (HME) after tracheostomy [13–30]. Commercial filters are described and recommended for laryngectomy patients and for patients after elective tracheostomy, given that many are asymptomatic carriers [60]. Both products have an effective electrostatic filter that can protect against > 99% of viruses and bacteria, according to the composition.

Study limitations

The absence of prospective data regarding indications, timing and relevance of tracheostomy in COVID-19 patients is limiting the level of evidence used to provide robust guidelines. Additionally, this review may not include all existing guidelines since many are not available online.

Conclusions

Tracheostomy represents a high-risk AGP due to constant exposure to droplets and aerosol leakage that is infected with of SARS-CoV-2, during the surgical procedure. Full PPE is mandatory and the creation of a COVID-19 airway team is essential. Otolaryngologist - Head & Neck Surgeons performing tracheostomies should be aware that they are in the highest risk category together with ICU nurses and intensivists. Collecting data about indications, clinical outcomes and safety for healthcare providers of tracheostomies performed in the setting of SARS-CoV-2 outbreak will help build more robust evidence-based recommendations.

YO-IFOS tracheostomy recommendations:

- Is important to understand that all these recommendations are based on limited evidence.
- All cases should ideally be discussed in a multidisciplinary team to

evaluate the risks to benefits of the procedure.

- Intensive hand hygiene with hydroalcoholic solution. Full PPE due to the high risk of infection, including N95 or N99 (USA), FFP2 or FFP3 (Europe) mask, the use of double gloves, goggles or eye protection, PARP, face shield and an apron or gown is recommended in all patients.
- Elderly, hypertension, diabetes, chronic obstructive pulmonary disease, cardiovascular disease, and cerebrovascular disease are significant risk factors in COVID-19 patients.
- Available evidence from non COVID-19 patients suggests considering tracheostomy after 14 days of invasive mechanical ventilation.
- Consider either open tracheostomy or percutaneous tracheostomy according to the faculty performing the procedure and the institutional resources.
- Establish a specific COVID-19 Airway team.
- Minimizing or avoiding the use of diathermy, is recommended.
- Follow a Minimal-Staff policy on each tracheostomy.
- HME are mandatory after tracheostomy.
- Delay first tracheal change.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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