A systematic review of the literature on the role of tracheostomy in COVID-19 patients

P. PIOMBINO¹, S. TROISE¹, M. VARGAS², A. MARRA², P. BUONANNO², S. FUSETTI³, F. APOLLONI³, S. CRIMI⁴, A. BIANCHI⁴, D. MARINIELLO¹, L. CALIFANO¹

Abstract. – The Coronavirus Disease 2019 (COVID-19) is a viral infection caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), which emerged in East Asia and spread around the world from December 2019. The most severe stage of COVID-19 pathology is characterized by respiratory distress requiring intubation. In specific cases, tracheostomy is indicated to ensure the safety of the procedure. The aim of our study was to analyze the scientific literature identifying the indications for tracheostomy and safety precautions to reduce contamination. We analyzed the literature from February 2003 to April 2020, including papers on pandemics of other coronaviruses, such As Severe Acute Respiratory Syndrome Coronavirus 1 and Middle East Respiratory Syndrome Coronavirus, to obtain a variety of relevant information. We focused on indications for tracheostomy in patients affected by COVID-19 or related viruses and the measures adopted to perform a safe procedure. We included 35 papers, of which 24 (68.57%) discussed guidelines for tracheostomy indications. All 35 studies discussed the procedures for performing tracheostomy safely. Data obtained indicated that the authors generally agreed on safety measures but expressed different opinions about indications. Therefore, we provided guidelines addressing safety recommendations. After the pandemic has been resolved, we plan to conduct an international retrospective study to identify the criteria for tracheostomy indications.

Key Words:

COVID-19, Oral and maxillofacial surgery, SARS-CoV-2, Pandemic safety, Healthcare protection, New coronavirus.

Introduction

The Coronavirus Disease 2019 (COVID-19) is a highly virulent, highly transmissible viral in-

fection caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). It first appeared in humans in Southeast Asia on November 17 in Jinyintan hospital, Wuhan, China, and spread rapidly worldwide since December 2019¹. The typical clinical signs and symptoms reported in affected patients are fever (83.3%), cough (60.3%), and fatigue (38.0%)². Older age and comorbidities are reported to be risk factors for death². Roughly, 14% of patients develop severe problems (acute respiratory disease syndrome; multiorgan failure, such as acute kidney and cardiac injury; sepsis; and septic shock), requiring hospitalization and oxygen support. Five percent have to be shifted to the intensive care unit (ICU) for mechanical ventilation, requiring 20 to 30 days in the ICU and up to 14 to 16 days of intubation^{3,4}.

To improve the condition of these patients and ensure redistribution of limited medical resources, the intensive care anesthesiology team may decide to perform a tracheotomy⁴⁻⁶. It is possible that requests to perform tracheostomy on patients with COVID-19 will increase in the near future^{2,4,7,8}. However, tracheostomy and tracheal intubation are the riskiest procedures for airway management because they generate aerosol particles, directly exposing surgical teams to secretions and thereby increasing the risk of spread to healthcare providers9. Thus, for the safety of both medical personnel and patients, it is advisable to have guidelines for the right indications and the appropriate technique to perform this procedure, which could limit the risk of infection^{10,11}.

In this study, we analyzed the existing literature on the indications and advantages of tracheostomy in COVID-19 patients and the precautions involved

¹Department of Neurosciences, Reproductive and Odontostomatological Sciences, Maxillofacial Surgery Research Unit, University "Federico II" of Naples, Naples, Italy

²Department of Neurosciences, Reproductive and Odontostomatological Sciences, Intensive Care Research Unit, Federico II University of Naples, Naples, Italy

³Maxillofacial Surgery Department, Padua Hospital, University of Padua, Padua, Italy

⁴Department of General Surgery and Medical-Surgery Specialities, University of Catania, Catania, Italy

in safely performing this procedure¹²⁻¹⁷. We also analyzed papers on past pandemics of coronaviruses, such as Severe Acute Respiratory Syndrome Coronavirus 1 (SARS-CoV-1) and Middle East Respiratory Syndrome Coronavirus (MERS-CoV), to obtain more relevant information.

Thus, the goal of our study was to review the literature in order to provide evidence-based guidelines for healthcare workers and the entire population, since tracheostomy could facilitate patient admission to sub-intensive care units, thereby reducing the pressure on ICUs and allowing more optimal use of medical resources.

Materials and methods

Study Design

In this literature review, we identified records focusing on tracheostomies in patients with pulmonary disease caused by coronavirus infection.

Search Strategy

This study used PubMed to identify research published from February 2, 2003 to April 20, 2020. The articles were searched primarily from the online database of the U.S. National Library of Medicine within PubMed. The medical subject headings we used were Tracheostomy, Tracheotomy, COVID-19, Coronavirus, SARS, MERS, and Airway Management. For the literature search, the three keywords "Tracheostomy," "Tracheotomy," and "Airway AND Management" were paired sequentially as follows: "tracheostomy AND coronavirus," "tracheostomy AND SARS," "tracheostomy AND COVID19," "tracheostomy AND MERS," "tracheotomy AND SARS," "tracheotomy AND coronavirus," "tracheotomy AND COVID19," "tracheotomy AND MERS," "airway AND management AND SARS," "airway AND management AND COVID19," "airway AND management AND coronavirus," and "airway AND management AND MERS." Additional articles not present in PubMed were added using Google as the secondary search engine, putting the terms "tracheostomy" and "COVID-19" in the search bar. We formulated this review in compliance with recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)8.

Eligibility Criteria

The PubMed search results were screened, and duplicate articles were eliminated. Studies con-

ducted on humans and published in English with complete access were considered. Every study referring to global, such as viral pandemics, was included in the review. Titles and abstracts of the records were screened independently by two authors (ST and PP) using the inclusion criteria. Articles not included in the initial search but cited in the reference lists of the selected articles, were studied for content to determine if they should be added. We also included one article written in Italian, due to its content.

We found 109 records after the PubMed search. In addition, five useful papers were added from a careful Google search for the latest guidelines on tracheostomy and COVID-19, but two duplicates were excluded. The PubMed search results were screened by carefully by reading the articles. Twenty-eight items were excluded due to irrelevant titles, and 43 items were excluded based on the abstract. Among the 41 remaining PubMed studies, nine that were not in English and one that did not refer to humans were excluded. Four other studies that were found in the bibliographies of the selected studies and had topics of interest were added. Thus, the final number of records included in our review was 35. The study selection process is summarized in Figure 1.

Data Extraction

Data extracted from each manuscript mostly pertained to indications or contraindications for performing a tracheostomy, surgical precautions observed during the procedure, and safe management of the procedure. Other considered data included the department of provenance, nationality, and type of study, setting, and the specific type of infection. The number of patients undergoing tracheostomy was also recorded if reported. For the purposes of this study, the primary outcome was reported as the indications for tracheostomy in patients with virus-related severe respiratory disorders, while the secondary outcome was the identification of precautions that all healthcare personnel should follow in order to limit the spread of the virus pre-surgery, during the procedure, and post-surgery.

Results

A careful analysis of the 35 selected articles showed that 24 (68.57%) studies evaluated the indications to perform a tracheostomy in affected patients with pneumonia (primary outcome) (Table I). In particular, the majority of authors (87.50%)

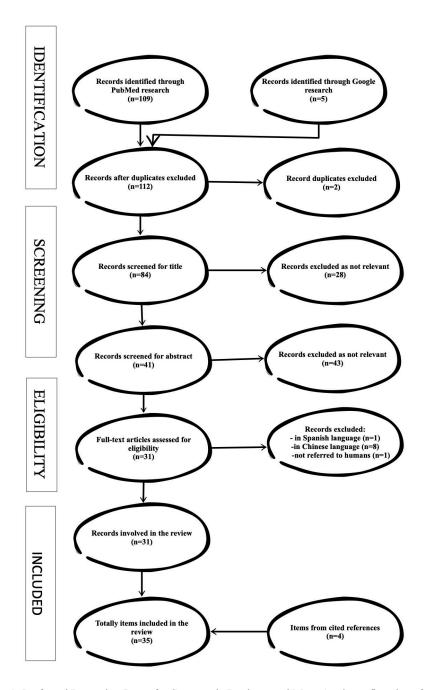


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart for the study.

stated that a prolonged time of intubation was the main indication for tracheostomy. Eleven other papers also provided an indicative time beyond which the procedure must be practiced: 20-28 days was reported as the average time of intubation. Other reported indications were failed primary intubation (6/24; 25%), need for ventilator weaning (6/24; 25%), irreversible airway obstruction (5/24; 20.83%), respiratory failure (3/24; 12.5%),

need for sedation level reduction (3/24; 12.5%), high risk of primary extubation failure (3/24; 12.5%), and the need for improved pulmonary hygiene in patients with high mucus and secretion production (2/24; 8.33%). Minor indications included the reduction of the ratio of arterial oxygen partial pressure to fractional inspired oxygen (PO₂/FiO₂), use of high-flow oxygen, and a high risk of tracheal stenosis.

Authors and year	Article	Indications to tracheostomy	Clarifications of subtypes trachestomy
Balakrishnn et al ¹¹ 2020	COVID-19 Pandemic: What Every Otolar- yngologist-Head and Neck Surgeon Needs to Know for Safe Airway Management.	Prolonged endotracheal intubation and mechanical ventilation Respiratory failure Need of ventilator weaning High risk of primary extubation failure	Intubation period > 20 days
Givi et al ¹³ 2020	Safety Recommendations for Evaluation and Surgery of the Head and Neck During the COVID-19 Pandemic.	In general, tracheotomy is not recommended or in any case it can be considerated in patients with prolonged intubation time when the acute phase has passed.	Percutaneous tracheotomy is preferred because it is a minimally invasive procedure.
Kligerman et al ¹⁴ 2020	Managing the Head and Neck Cancer Patient with Tracheostomy or Laryngectomy During the COVID-19 Pandemic. A Review of the Literature and Recommendations for Risk Reduction	Long-term intubation alone is not sufficient to justify tracheostomy - Only urgent tracheostomy is justified in particularly cases or when head and neck cancers coexist.	
Cui et al 15 2020	Approaching Otolaryngology Patients during the COVID-19 Pandemic	Prolonged endotracheal intubation is not sufficient alone to justify a tracheotomy, but associated to: Need of ventilator weaning High risk of primary extubation failure Irreversible airway obstruction	Intubation period > 14 days
Wei et al ¹⁶ 2003	Safe tracheostomy for patients with severe acute respiratory syndrome.	Prolonged endotracheal intubation and mechanical ventilation - unsuccessful endotracheal intubation	In case of unsuccessful endotracheal intubation and reduction of oxygen saturation level, there is indication for an emergency tracheotomy - intubation period > 14 days
Vukkadala et al ¹⁷ 2020	COVID-19 and the otolaryngologist – preliminary evidence-based review	Prolonged endotracheal intubation and mechanical ventilation Irreversible airway obstruction High production of mucus and secretion	In case of irreversible airway obstruction emergency tracheotomy is performed. In case of many secretion, tracheostomy improves pulmonary toilet Intubation period > 28 days
Foster et al ¹⁸ 2020	Novel Approach to Reduce Transmission of COVID-19 During Tracheostomy	Prolonged endotracheal intubation and mechanical ventilation	Intubation period > 28 days
Schultz et al ¹⁹ 2020	French consensus regarding precautions during tracheostomy and post-tracheostomy care in the context of COVID-19 pandemic	Prolonged endotracheal intubation and mechanical ventilation Unsuccessful endotracheal intubation Need of ventilator weaning	Percutaneous tracheotomy is preferred because it reduces aerosolization. In case of anatomical contraindications surgical tracheotomy is performed. Tracheostomy under local anesthesia is not recommended
Zhong et al ²⁰ 2020	How to avoid nosocomial spread during Tracheostomy for Covid-19 patients.	Prolonged endotracheal intubation and mechanical ventilation	Percutaneous tracheotomy is preferred because it is a minimally invasive procedure. In case of case of unfavorable neck anatomy or neck contracture surgical tracheotomy is performed
Miles et al ²¹ 2020	Tracheostomy during COV-SARS-CoV-2 pandemic: Recommendations from the New York Head and Neck Society	Prolonged endotracheal intubation and mechanical ventilation High risk of tracheal stenosis	Intubation period > 21 days Percutaneous tracheotomy is preferred because it reduces aerosolization. In case of anatomical contraindications surgical tracheotomy is performed
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Table I. Continued/. Indications for tracheostomy.

Authors and year	Article	Indications to tracheostomy	Clarifications of subtypes trachestomy
Chee et al ²² 2004	Infection Control Measures for Operative Procedures in Severe Acute Respiratory Syn- drome–related Patients	Prolonged endotracheal intubation and mechanical ventilation	Open tracheostomy was selected over percutaneous tracheostomy because it entailed a lower risk of aerosolization of airway secretions.
Tay et al ²³ 2020	Surgical Considerations for Tracheostomy During the COVID-19 Pandemic Lessons Learned From the Severe Acute Re- spiratory Syndrome Outbreak	Prolonged endotracheal intubation and mechanical ventilation	Percutaneous tracheotomy is not preferred because it increases airway manipulation and aerosolization risks compared to surgical tracheotomy
Engels et al ²⁴ 2020	Recommendations from the CSO-HNS Taskforce on Performance of Tracheotomy During the COVID-19 Pandemic	Prolonged endotracheal intubation and mechanical ventilation - insufficient airway by endotracheal tube - irreversible airway obstruction	In case of irreversible airway obstruction emergency tracheotomy is performed
Harrison et al ²⁵ 2020	Guidance for Surgical Tracheostomy and Tracheostomy Tube Change during the COVID-19 Pandemic	Difficult airway guidance to intubation Use of high flow oxygen- irreversibile airway obstruction	In case of irreversible airway obstruction emergency tracheotomy is performed
Chao et al ²⁶ 2020	Tracheotomy in ventilated patients with COVID-19	Prolonged endotracheal intubation and mechanical ventilation Reduction of sedation level Accelerate ventilator weaning Improve pulmonary toilet in patients with a lot of secretions	Intubation period > 21 days
SIO 27 2020	Tracheostomy in COVID-19 patients (LINK)	High risk of primary extubation failure Need of high flow oxygen therapy Non-invasive ventilation Need of reduction of level sedation	
Parker et al ²⁸ 2020	Tracheotomy Recommendations During the COVID-19 Pandemic	Prolonged endotracheal intubation and mechanical ventilation Reduction of sedation level Accelerate ventilator weaning	Unless emergency, tracheostomy must be performed only after ascertaining of Covid-19 status Intubation period >24 days
Crossley et ³³ al 2020	Surgical Considerations for an Awake Tracheotomy During the COVID-19 Pandemic	Prolonged endotracheal intubation and mechanical ventilation	Intubation period > 21 days
Ahmed et al ³⁵ 2005	Open tracheostomy in a suspect severe acute respiratory syndrome (SARS) patient: brief technical communication	Prolonged endotracheal intubation and mechanical ventilation Primary intubation failure	
Bassin et al ³⁶ 2020	Michigan Medicine Tracheostomy Guidelines in COVID-19 Era	Prolonged endotracheal intubation and mechanical ventilation Primary intubation failure Irreversible airway obstruction	In case of irreversible airway obstruction emergency tracheotomy is performed.
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Table continued

Clarifications of subtypes trachestomy Prolonged endotracheal intubation and mechani- Intubation period > 25 days Prolunged endotracheal intubation and mechan- Intubation period > 25 days Prolonged endotracheal intubation and mechani-Prolonged endotracheal intubation and mechanical ventilation Indications to tracheostomy Respiratory failure Accelerate ventilator weaning Reduction of PO2/FiO2 Ratio Respiratory failure ical ventilation cal ventilation cal ventilation Performing tracheostomy during the Covid-19 pandemic: guidance and recommendations from the Critical Care and Acute Care Surgery Committees of the American Association for the Surgery of Trauma Improving staff safety during tracheostomy in COVID-19 patients Elective and Emergency Surgery in Patients With Severe Acute Respiratory Syndrome (SARS) Tracheostomy in a patient with severe acute respiratory syndrome. Article Authors and year Michetti et al⁴⁵ 2020 Vargas et al⁴⁸ 2020 Kwan et al⁴¹ 2005 Tien et al⁴⁷ 2005

Table I. /Continued/. Indications for tracheostomy.

With respect to the secondary outcome, all studies provided information on the strategies to practice tracheotomy safely (Table II). All 35 papers defined essential safety and protection strategies: 1) use of personal protective equipment (PPE) consisting of N95 or FFP3 masks, surgical cap, eye protection, gown, double pairs of gloves, shoe covers, and positive air-powered respirator (PAPR); 2) limiting patient movement to the operative room and performing the procedure at the bedside in a negative pressure room with a high air-change rate (25/h); 3) limiting staff to no more than two surgeons and one anesthesiologist; and 4) decontaminating PPE and cleaning the room 20 min after the procedure.

In addition, 97.14% (34/35) of papers proposed the following measures: 1) general anesthesia with

preoxygenation (100% for 5 min); 2) deep neuro-muscular blockade to avoid swallowing; and 3) cessation of ventilation before the tracheostomy window and resumption only after the cuff has been inflated. In addition, 88.57% (31/35) suggested the use of a non-fenestrated cuffed tracheostomy tube; 80% (28/35) suggested limiting suction during the procedure and ensuring a closed system, using a viral filter if necessary; 73.52% (25/35) suggested the use of senior experienced surgical and anesthesiology staff to reduce operative time; 54.28% (19/35) proposed the use of a supine system with an extended neck; and 48.57% (17/35) proposed the limited use of the electrocautery to minimize aerosol particles dispersion.

Other less frequently reported recommendations were related to the post-operative protocol:

Table II. Recommendations to perform safe tracheostomy as reported in the papers.

Recommendation for a safe tracheostomy	
	Covering with personal protective equipment (PPE) consisting in N95 or FFP3 masks, surgical cap, eye protection, gown, double pairs of gloves, shoe covers.
Pre-operative advices	Limit patients movement to Operative Room: perform the procedure by bedside in a negative pressure room with high air-changes (25/h).
	Limit staff: no more than two surgeons and one anesthetists involved. If possible, Senior Experienced Surgical and Anesthesiological Staff are preferred.
	When possible, use a sterile transparent interface between the patient and the surgeon, in order to limit the risk of contamination
	Use deep neuromuscular blocking drugs in order to avoid cough.
	Patient must be in supine positionwith extended neck during tracheotomy while the surgeon quickly incides trachea avoiding damaging cuff.
Intra operative settings	Inject with 2% lidocaine with 1:100,000 epinephrine to minimize bleeding and need for suctioning
	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).
	Stop ventilation before to perform tracheostomy window and resume ventilation only after the cuff has been inflated.
	Use of non-fenestrated cuffed tracheostomy tube. the fenestration allow air flow upward increasing the risk of infection.
	Limit the use of electrocautery in order to avoid dissipating of aereosol particles.
	Limit suction as possible during the procedure or if not possible use closed system with viral filter.
	Use of non-fenestrated cuffed tracheostomy tube. the fenestration allow air flow upward increasing the risk of infection.
	Withdraw endotracheal tube under appropriate guidance; consider Doppler to determine airflow as ETT pulled back
	Decontamination of PPE and clean room (20 minutes) after the procedure by a personal expert.
Post-operative advices	Non-disposable objects must be carefully sterilized by expert and specially trained personnel.
1 ost-operative advices	Airway management should be performed by qualified nurses. The change of the tracheal cannula must be carried out by personnel with PPE in a closed airway circuit.

ensuring that the tube was not prone or turned, avoiding humidified oxygen if possible, using only closed suction circuits at all times, and delaying the first tube change until at least 7-10 days, when the COVID-19 test was negative.

In addition to the evaluation of primary and secondary outcomes, the countries from which the studies originated were as follows: 28.57% (10/35) from the USA; 17.14% (6/35) multicenter studies; 11.43% (4/35) from China; 11.43% from the United Kingdom; 8.57% (3/35) from Italy, Canada, and Singapore; and the rest were from France and Saudi Arabia. The departments mentioned were the Departments of Otorhinolaryngology-Head & Neck Surgery in 62.85% (22/35) of cases, the Anesthesia and Intensive Care Unit in 17.14% (6/35), the Unit of Surgery and Care Medicine in 14.28% (5/35), the Departments of Pathology & Laboratory Medicine (2.86%), the Departments of Physical Medicine (2.86%), and the Departments of Rehabilitation (2.86%). Most of the studies (17/35; 48.57%) included guidelines based on expert opinions and experiences. The other types of studies were systematic reviews (6/35; 17.14%), observational studies (9/35; 25.71%; six case series and three case reports), and letters to the editor/editorials (3/35; 8.57%) (Table III).

Discussion

COVID-19 is a respiratory tract infection related to an emergent viral strain in the coronavirus family, SARS-CoV-2, which was first identified in Wuhan, China, in December 2019^{1,2}. Data obtained from genetic sequencing of the virus established that SARS-CoV-2 is a "betacoronavirus" that is closely linked to SARS-CoV-1, responsible for the 2003 Severe Acute Respiratory Syndrome (SARS) pandemic. Recently published literature suggests that the clinical features of COVID-19 are not very different from those of the two previous major COV-related epidemics, SARS and MERS. While the three diseases share multiple etiological, pathological, clinical, and morbidity-related characteristics, the fatality rate of COVID-19 (2.3%) is lower than that of the others: SARS (9.5%) and MERS (34.4%)³⁻⁷. Nevertheless, we included papers on SARS and MERS in the review to ensure sufficient data and to use past pandemic information in the current situation. Therefore, we searched the literature from February 2003, when the first study on SARS was published.

The main aim of the study was to focus on the indications for tracheostomy in COVID-19 patients and the adequate safety measures to be considered while performing this procedure. Due to insufficient data regarding tracheostomy and the COVID-19 disease, we included papers on the same topic published about the MERS and SARS pandemic. We aimed to provide appropriate guidelines that could be useful for head and neck surgeons as well as the entire medical community involved in this pandemic; therefore, we chose keywords that seemed to be more coherent with our goal.

Tracheostomy is the topic of this paper, because it is one of the tasks performed by head and neck surgeons in this COVID-19 emergency. Tracheostomy, as the literature confirms, offers numerous advantages: improvement in comfort and reduction in the patient's sedative demand; possibility of articulated language, which could reduce anxiety and increase well-being; opportunity for oral nutrition; facilitation of weaning from mechanical ventilation by reducing dead space, airway resistance, and work of breathing; and improving the removal of secretions¹².

Since the pandemic spread initially in China, we expected to find many articles by Chinese authors who provided their experiences. Our hypothesis was confirmed but some of those papers were published only in their native language; therefore, we excluded them from review but analyzed abstracts written in English, if they were available. Three papers appeared to be quite interesting (Table IV), so their translation would benefit the scientific community. We have also included one paper written in Italian and cited it in the references, because it provides very interesting, useful information and guidelines, considering that Italy has been one of the countries where SARS-CoV-2 has spread the most. Analysis of the 35 English papers showed that a large proportion (28.57%) of the COVID-19 studies (Figure 2), were written by US authors, reflecting the extent of the pandemic in the USA, with 983,457 cases and 50,492 deaths to date (information obtained from https://www. who.int/emergencies/diseases/novel-coronavirus-2019 on April 29).

The majority of studies (62.85%) involved head and neck surgical units, indicating that surgical staff can provide valid support to the anesthesiology team in the decision-making process about tracheostomies in COVID-19 cases. In particular, we observed that studies from head and neck surgery units mainly focused on tracheostomy and safety

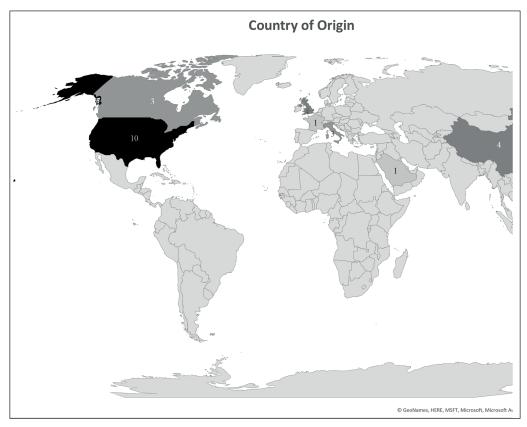


Figure 2. Countries of origin of the articles assessed in the study.

measures while papers from other departments, mostly anesthesia and ICUs, focused on general airway management while providing some information about tracheostomy.

Furthermore, we noticed that a majority of the studies (48.47%) included guidelines proposed by experts based on their direct experience in the management of COVID-19 positive patients. We found that retrospective observational studies (25.71%) were mostly about SARS-CoV-1 (6 of 9 studies) rather than SARS-CoV-2, testifying that it is still too early to obtain statistically significant scientific evidence for COVID-19, which should ideally come from a large cohort of patients. We included two case reports and one case series on SARS-CoV-2, covering eight patients undergoing tracheostomy. The exact number of patients treated in each of the nine observational studies is reported in Figures 3 and 4.

For our primary outcome, we found that 68.57% papers offered data on indications for tracheostomy. Almost all of these (87.50%) proposed a long period of intubation as the main indication for tracheostomy. Givi et al¹³ affirmed

that tracheostomy is not recommended in general until the acute phase has passed, while Kligerman et al¹⁴ and Cui et al¹⁵ affirmed that a long period of intubation alone does not justify the execution of a tracheostomy but should be accompanied by other reasons. Eleven of these 24 papers provided information about the duration of the intubation period beyond which it is necessary to proceed with tracheostomy. The median period was >20.28 days, ranging from a minimum of 14 days^{15,16} to a maximum of 28 days^{17,18}. We noted much discordance in the decisional process between surgical and percutaneous tracheostomy: Givi et al¹³, Shultz et al¹⁹, Zhong et²⁰ al and Miles et al²¹ proposed percutaneous tracheostomy as the first option, considering it a minimally invasive practice that reduces aerosolization. Surgical tracheostomy was indicated only in cases with anatomical contraindications or neck contractures. In contrast, Chee et al²² and Tay et al²³ affirmed that percutaneous tracheostomy involves greater manipulation, aerosolization, and airway secretion production, so an open tracheostomy is preferable.

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Table III. Main features of 35 papers.

Reference	Title	Hospital Unit / Department	Country	Viral Strain	Type of Article
Butt et al 20169	Infection control and prevention practices implemented to reduce transmission risk of Middle East respiratory syndrome-coronavirus in a tertiary care institution in Saudi Arabia	Department of Emergency Medicine	Saudi Arabia	MERS-CoV	Observational case series
Cook et al 2020 ¹⁰	Consensus guidelines for managing the airway in patients with COVID-19	Anaesthesia and Intensive Care	UK	SARS-CoV-2	Expert opinion/Guidelines
Balakrishnan et al 2020 ¹¹	COVID-19 Pandemic: What Every Otolar- yngologist-Head and Neck Surgeon Needs to Know for Safe Airway Management	ENT	USA	SARS-CoV-2	Expert opinion/Guidelines
Givi et al 2020 ¹³	Safety Recommendations for Evaluation and Surgery of the Head and Neck During the COVID-19 Pandemic	ENT	USA	SARS-CoV-2	Expert opinion/Guidelines
Kligerman et al 2020 ¹⁴	Managing the Head and Neck Cancer Patient with Tracheostomy or Laryngectomy During the COVID-19 Pandemic. Subtitle: A Review of the Literature and Recommendations for Risk Reduction	ENT	Multicenter	SARS-CoV-2	Review/Guidelines
Cui et al 2020 ¹⁵	Approaching Otolaryngology Patients during the COVID-19 Pandemic	ENT	Multicenter	SARS-CoV-2	Observational case series
Wei et al 2003 ¹⁶	Safe tracheostomy for patients with severe acute respiratory syndrome	ENT	China	SARS-CoV	Observational case series
Vukkadala et al 2020 ¹⁷	COVID-19 and the otolaryngologist – preliminary evidence-based review	ENT	USA	SARS-CoV-2	Review/Guidelines
Foster et al 2020 ¹⁸	Novel Approach to Reduce Transmission of COVID-19 During Tracheostomy	Surgery	USA	SARS-CoV-2	Observational case report
Schultz et al 2020 ¹⁹	French consensus regarding precautions during tracheostomy and post-tracheostomy care in the context of COVID-19 pandemic	ENT	France	SARS-CoV-2	Expert opinion/Guidelines
Zhong et al 2020 ²⁰	How to avoid nosocomial spread during Tracheostomy for Covid-19 patients	ENT	Multicenter	SARS-CoV-2	Letter to editor/Guidelines
Miles et al 2020^{21}	Tracheostomy during COV-SARS-CoV-2 pandemic: Recommendations from the New York Head and Neck Society	ENT	USA	SARS-CoV-2	Expert opinion/Guidelines
Chee et al 2004 ²²	Infection Control Measures for Operative Procedures in Severe Acute Respiratory Syn- drome-related Patients	ENT	Singapore	SARS-CoV	Observational case series
					Table continued

Table III. (Continued). Main features of 35 papers.

Reference	Title	Hospital Unit / Department	Country	Viral Strain	Type of Article
Tay et al 2020 ²³	Surgical Considerations for Tracheostomy During the COVID-19 Pandemic Lessons Learned From the Severe Acute Respiratory Syndrome Outbreak	ENT	Singapore	SARS-CoV-2	Review/Guidelines
Engels et al 2020 ²⁴	Recommendations from the CSO-HNS Task-force on Performance of Tracheotomy During the COVID-19 Pandemic	ENT	Canada	SARS-CoV-2	Expert opinion/Guidelines
Harrison et al 2020 ²⁵	Tracheostomy guidance during the COVID19 Pandemic	Surgery	UK	SARS-CoV-2	Expert opinion/Guidelines
Chao et al 2020 ²⁶	Tracheotomy in ventilated patients with COVID-19	ENT and Anesthesiology	USA	SARS-CoV-2	Review/Guidelines
SIO 2020 ²⁷	La tracheostomia in pazienti affetti da CO-VID-19 (LINK)	ENT	Italy	SARS-CoV-2	Expert opinion/Guidelines
Parker et al 2020 ²⁸	Tracheotomy Recommendations During the COVID-19 Pandemic	ENT	USA	SARS-CoV-2	Expert opinion/Guidelines
Crossley et al 2020 ³³	Surgical Considerations for an Awake Tracheotomy During the COVID-19 Pandemic	ENT	USA	SARS-CoV-2	Observational case report
Frauenfelder et al 2020 ³⁴	Practical insights for paediatric otolaryngology surgical cases and T performing microlaryngobronchoscopy during the COVID-19 pandemic	Pediatric ENT	Multicenter	SARS-CoV-2	Expert opinion/Guidelines
Ahmed et al 200435	Open tracheostomy in a suspect severe acute respiratory syndrome (SARS) patient: brief technical communication	Surgery	Canada	SARS-CoV	Observational case report
Bassin et al 2020 ³⁶	Michigan Medicine Tracheostomy Guidelines in COVID-19 Era	ENT	USA	SARS-CoV-2	Expert opinion/Guidelines
Broderick et al 2020 ³⁷	Surgical tracheostomies in Covid-19 patients: important considerations and the "5Ts" of safety	ENT and Anesthesiology;	UK	SARS-CoV-2	Expert opinion/Guidelines
Hui et al 2013 ³⁸	Severe acute respiratory syndrome (SARS): lessons learnt in Hong Kong	Respiratory Medicine	China	SARS-CoV	Expert opinion/Guidelines
Jacob et al 2020^{39}	A framework for open tracheostomy in COVID-19 patients	ENT	UK	SARS-CoV-2	Lettert to editor/Guidelines
Kowalski et al 2020 ⁴⁰	COVID-19 pandemic: Effects and evidence-based recommendations for otolaryngology and head and neck surgery practice	ENT	Multicenter	SARS-CoV-2	Review/Guidelines
Kwan et al 2020 ⁴¹	Tracheostomy in a patient with severe acute respiratory syndrome	Anesthesiology; Surgery; Intensive Care	China	SARS-CoV-2	Observational case series

Table continued

SARS-CoV-2 | Expert opinion/Guidelines Expert opinion/Guidelines SARS-CoV-2 | Expert opinion/Guidelines SARS-CoV-2 | Expert opinion/Guidelines Observational case series Editorial/Guidelines SARS-CoV-2 | Review/Guidelines ype of Article Viral Strain SARS-CoV-2 SARS-CoV SARS-CoV Multicenter Country Singapore Canada China USA Italy Italy Impact of a viral respiratory epidemic on the Physical Medicine and Rehabiliparctice of medicine and rehabilitation: severe tation and Intensive Hospital Unit/Department Surgery and Care Medicine Improving staff safety during tracheostomy in Anesthesiology COVID-19 patients Pediatric Airway Management in COVID-19 Anesthesiology patients - Consensus Guidelines from the Society for Pediatric Anesthesia's Pediatric Difficult Intubation Collaborative and the Cana-Intubation and Ventilation amid the COVID-19 | Anesthesiology Performing tracheostomy during the Covid-19 Surgery pandemic: guidance and recommendations ENT Elective and Emergency Surgery in Patients With Severe Acute Respiratory Syndrome CORONA-steps for tracheotomy in COVID-19 patients: A staff-safe method for from the Critical Care and Acute Care Surgery Committees of the American Association for dian Pediatric Anesthesia Society Outbreak: Wuhan's Experience acute respiratory syndrome airway T management the Surgery of Trauma Michetti et al 202045 Vargas et al 202048 Meng et al 2020^{44} Pichi et al 202046 Tien et al 2004⁴⁷ Lim et al 2004⁴² Matava et al 2020^{43} Reference

Fable III. (Continued). Main features of 35 papers.

Table IV. Potentially interesting Chinese articles that were not included in the review.

Paper Reference	English Abstract (summary)
Deng ZF, Zhu T, Ding YJ, et al Zhonghua Er Bi Yan Hou Tou Jing Wai Ke Za Zhi. Application of Tracheotomy in the Treatment of Severe Cases of COVID-19	Tracheotomy for severe cases of COVID-19 can achieve certain curative effect, but the occurrence of tracheotomy related complications and nosocomial infection should be effectively controlled, and the risk benefit ratio of tracheotomy should be carefully weighed before surgery
Gong ZY, Huang YG, Wang JJ, et al Zhongguo Yi Xue Ke Xue Yuan Xue Bao. Evaluation of Tracheal intubation in Critical SARS Patients	The patient should be intubated or received tracheotomy if non-invasive respiratory support has no effect. Standard protection could protect medical staff from infection under tracheal intubation
Respiratory care committee of Chinese Thoracic Society. Zhonghua Jie He He Hu Xi Za Zhi. Expert Consensus on Preventing Nosocomial Transmission During Respiratory Care for Critically Ill Patients Infected by 2019 Novel Coronavirus Pneumonia	With the aim to reduce the nosocomial transmission and optimize the treatment for the COVID-19 pneumonia patients, using dual limb ventilator with filters placed at the ventilator outlets, or using heat-moisture exchanger (HME) instead of heated humidification in single limb ventilator. When tracheotomy patients are weaned from ventilator, HME should be used, avoid using T-piece or tracheostomy mask

Furthermore, all authors generally advised against performing emergency tracheostomies, because safety measures may not be guaranteed in such procedures. They recommended performing emergency tracheostomy only in cases of irreversible airway obstruction or failed primary intubation in patients with respiratory distress or with head and neck cancers, like transglottic masses^{13,15,17,21,24,25}. In 8.33% papers, the authors^{17,26} specified that the classic endotracheal intubation hinders adequate pulmonary hygiene in patients with high mucus and secretion production, so tracheostomy is justified in these patients, because it allows more direct aspiration of secretions through the cannula and improves pulmonary hygiene.

Furthermore, in 12.5% of studies, the authors justified the need to reduce sedation as an indication for tracheotomy for general improvement of the patient's condition²⁶⁻²⁸. In fact, several authors²⁹⁻³² have shown that reduced sedation levels improve the possibility of awakening the patient, because it reduces the duration of mechanical ventilation, improves renal function by increasing diuresis, and enhances sleep quality while alleviating muscle atrophy. In addition, the risk of over infection is reduced. In such cases, performing tracheostomy could improve the general condition of the patient.

It is important to note that, among the 35 works included in the review, those that provide indications for tracheotomy were mainly from head and neck surgery units: this confirms the importance of the support provided by surgical staff to the anesthesiology team in the management

of COVID-19 emergencies. Thus, the number of qualified staff assisting the patient could increase and the management of limited resources could improve. According to the literature9, all the works assessed tracheostomy as a high-risk procedure, considering the possible contamination associated with endotracheal tube manipulation and aerosolization of viral particles. Therefore, every study focused on precautional procedures to ensure safe tracheostomies; thus, each study contributed to our secondary outcome related to measures of safety. Essential safety and protection strategies reported by all authors are as follows: 1) use of PPE consisting of N95 or FFP3 masks, surgical cap, eye protection, gown, double pairs of gloves, shoe covers, and PAPR; 2) limiting patient movement in the operating room and performing the procedure at the bedside in a negative pressure room with a high air-change rate (25/h); 3) limiting staff to no more than two surgeons and one anesthesiologist; and 4) decontamination of PPE and the clean room for 20 min after the procedure. All authors agreed that these steps could ensure a more sterile environment and avoid the risk of external contamination.

In 34 cases, tracheostomy was performed under general anesthesia and 100% preoxygenation for 5 min with deep neuromuscular blockade to avoid swallowing and muscle reflexes that could spread particles into the whole setting. Only Crossley et al³³ reported a single case of awake tracheostomy in a patient with a transglottic mass, who could not be intubated. He was then sedated with midazolam but breathed spontaneously, showing that

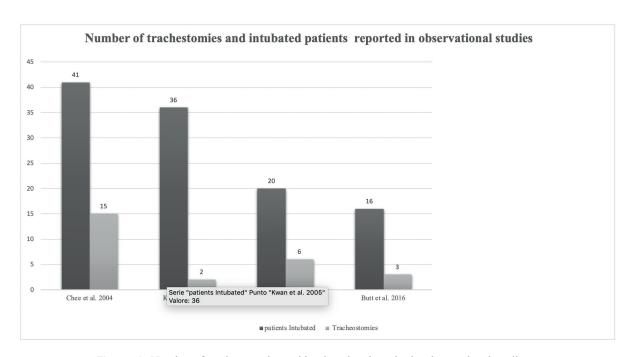


Figure 3. Number of tracheostomies and intubated patients in the observational studies.

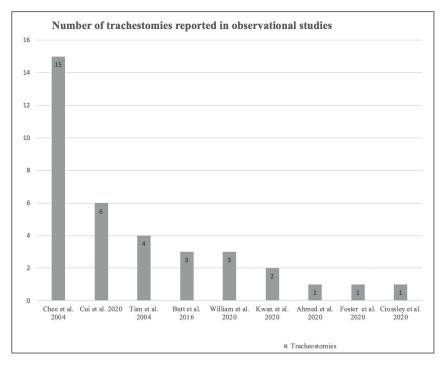


Figure 4. Number of tracheostomies reported in the observational studies.

tracheostomy can be also performed under sedation in rare cases, even if the risk of contamination is greater.

The primary recommendations were to involve senior, experienced surgical and anesthesi-

ology staff in order to reduce the operative time (73.52%), use a supine position with an extended neck (54.28%) and limitation of suction during the procedure, or, if necessary, use a closed system with a viral filter (80%). Almost all authors

suggested using non-fenestrated cuffed tracheostomy tubes (88.57%), stopping ventilation before the tracheostomy window, inserting the tracheal cannula up to the carina, and resuming ventilation only after the cuff was inflated (97.14%). Thus, the air circuit remains closed and the risk of contamination is reduced. Another recommendation suggested by 48.57% studies was to limit the use of electrocautery to avoid the dispersion of aerosol particles. The authors recommended the use of sutures instead of bipolar devices and scalpel or scissors instead of monopolar devices to reduce aerosolization.

The less common reported recommendations were related to the post-operative period: ensuring that the tube is not prone or turned, avoiding humidified oxygen if possible, using only closed suction circuits at all times, and delaying the first tube change for at least 7-10 days, when the COVID-19 test was negative. With respect to oxygen humidification of the endotracheal tube, opinions differed for cases involving adults and children. While the practice should be avoided in adult patients, oxygen humidification is preferable in children since they require small-sized tubes to avoid crust formation³⁴. After careful evaluation of each paper, we affirmed that these simple safety measures are very important for infection containment and that the surgical and anesthesiology staff should follow them. These measures were obviously elaborated after initial contact with the virus, so we expect that at the end of Phase 2. studies will provide more complete descriptions of these measures and specify other methods, based on worldwide gained experiences. In fact, one limitation of our review is that the data were obtained during the course of the pandemic rather than after it.

Conclusions

Data obtained from this review highlights different opinions among several authors regarding the indications for tracheostomy. While the authors seemed to agree on the safety precautions for performing safe tracheostomies and reducing the risk of contamination, there was disagreement regarding the risks and benefits of practicing tracheostomy and, therefore, its actual necessity. This review offers guidelines to ensure safety during tracheostomy surgical procedures and provides the direct experiences of authors involved in the pandemic, but at present, it does not provide

guidelines regarding the indications for tracheostomy with the same certainty. We aim to postpone the conclusions pertaining to the guidelines for tracheostomy indications to the end of the first outbreak period, when ICUs will start discharging intubated patients. At that stage, we hope to proceed with an international and retrospective study of the criteria for tracheostomy during the COVID-19 pandemic.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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