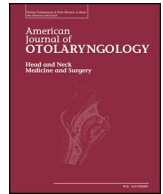




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Tracheostomy in the intensive care unit: Guidelines during COVID-19 worldwide pandemic

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ABSTRACT

Purpose: COVID-19 has become a pandemic with significant consequences worldwide. About 3.2% of patients with COVID-19 will require intubation and invasive ventilation. Moreover, there will be an increase in the number of critically ill patients, hospitalized and intubated due to unrelated acute pathology, who will present underlying asymptomatic or mild forms of COVID-19. Tracheostomy is one of the procedures associated with an increased production of aerosols and higher risk of transmission of the virus to the health personnel. The aim of this paper is to describe indications and recommended technique of tracheostomy in COVID-19 patients, emphasizing the safety of the patient but also the medical team involved.

Materials and methods: A multidisciplinary group made up of surgeons with privileges to perform tracheostomies, intensive care physicians, infectious diseases specialists and intensive pulmonologists was created to update previous knowledge on performing a tracheostomy in critically ill adult patients (> 18 years) amidst the SARS-CoV-2 pandemic in a high-volume referral center. Published evidence was collected using a systematic search and review of published studies.

Results: A guideline comprising indications, surgical technique, ventilator settings, personal protective equipment and timing of tracheostomy in COVID-19 patients was developed.

Conclusions: A safe approach to performing percutaneous dilational bedside tracheostomy with bronchoscopic guidance is feasible in COVID-19 patients if appropriate security measures are taken and a strict protocol is followed. Instruction of all the health care personnel involves is key to ensure their safety and the patient's favorable recovery.

1. Introduction

In December 2019, authorities in the city of Wuhan, China, reported 27 cases of pneumonia of unknown cause. Most of the cases were related to a market of marine products and other animals. From these cases, a new Coronavirus (SARS-CoV-2) was identified. Since then, the outbreak has led to a pandemic with almost 3,000,000 cases reported globally, in which > 80% are associated with mild respiratory disease (COVID-19) while 17% develop severe COVID-19 with acute respiratory distress syndrome (ARDS) [1,2]. A mortality rate of 2% is estimated [3], lower than other coronavirus epidemics (approximately

10% for SARS-CoV and 40% for MERS-CoV) but significantly higher than the 2009 H1N1 influenza A pandemic (0.026%) [4].

The SARS-CoV-2 virus is known to be spread between people through respiratory drops and by contact. Droplet transmission occurs when a person is in close direct contact (1 m) with someone who has respiratory symptoms (cough or sneeze) and therefore is at risk of having their mucosa (mouth and nose) or conjunctiva (eyes) exposed to potentially infectious respiratory droplets (> 5–10 μm in diameter). It can also occur by indirect contact with surfaces in the immediate environment or with objects used by the infected person [5]. On the other hand, aerosol transmission refers to the presence of microbes within the

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droplet nuclei (particles < 5 μm in diameter) that result from the evaporation of larger droplets. They can remain in the air for long periods of time and can be transmitted over distances of > 1 m. As has been demonstrated in previous coronavirus epidemics, such transmission is more prevalent in critical care hospital settings where aerosolizing procedures are performed; these include endotracheal intubation, tracheostomy and other surgeries of the upper airway and craniofacial structures, non-invasive ventilation with positive pressure and mask ventilation [6]. Airway endoscopy, open suction, disconnection of the patient from the ventilator tubing and cardiopulmonary resuscitation may also be mentioned [7,8]. This mechanism explains the high risk to which the physicians in charge of its performance are potentially exposed if they do not have specific safety guidelines, protocols and adequate personal protective equipment.

According to data recently reported in Wuhan and northern Italy, at least 10% of COVID-19 patients require hospitalization in critical care units and around 3% require mechanical ventilation through an endotracheal tube sometime in the course of their illness due to respiratory insufficiency [9,10]. Moreover, the increase in viral circulation in the communities according to the dynamics of transmission of the infection [11], brings about an increase in the prevalence of patients with acute critical pathology and requirement for mechanical ventilation who also have mild or asymptomatic COVID-19 as an underlying morbidity, but are still infectious, creating a risk for the health personnel involved in their treatment. Both groups are made up of patients who, under normal conditions, would benefit from performing an open or percutaneous tracheostomy with or without endoscopic guidance, according to the usual indications [12].

Even though there are descriptions in the literature of cases of patients with SARS-CoV-1 disease who underwent tracheostomies during the 2002–2004 outbreak [13–15], there are few recent publications describing specific considerations for tracheostomy in patients with SARS-CoV-2 infection [16,17]. Controversy concerning timing of tracheostomy, open or percutaneous technique and bronchoscopic assistance is seldom addressed. The development of clear guidelines is of fundamental importance considering the increasing number of patients with severe COVID-19 who require mechanical ventilation and patients who are hospitalized for severe underlying pathologies not related to the pandemic, but have SARS-CoV-2 as a concomitant infection. The aim of the present paper is to describe the updated indications for tracheostomy and its surgical technique, with the appropriate biosecurity measures, prioritizing the protection of health personnel amidst the COVID-19 outbreak. Secondly, we intend to highlight the relevance of intraoperative bronchoscopic guidance, which facilitates a more secure and expeditious procedure.

2. Material and methods

A multidisciplinary group made up of surgeons with privileges to perform tracheostomies - thoracic surgeon, head and neck surgeon, otorhinolaryngologist - (SPT), intensive care physicians, infectious diseases specialists and intensive pulmonologists was created to update and expand previous knowledge on performing a tracheostomy in critically ill adult patients (> 18 years) in the new context of the SARS-CoV-2 pandemic. An evidence-based approach was used. Published evidence was collected using a systematic search and review of published studies from the PubMed, Google Scholar and LILACS databases. The search was limited to studies in Spanish and English. The MeSH (Medical Subject Headings) terms used in the bibliographic search in both Spanish and English were coronavirus, COVID19, SARS-CoV2, SARS, severe acute respiratory syndrome, tracheostomy, technique, transmission, aerosolization, personal protection equipment. The evidence was reviewed and recommendations formulated.

The experience of the work group is based on the assistance of critically ill patients in a high-volume and referral center for patients that require prolonged mechanical respiratory care. The center has 116 intensive care beds available (Intermediate Therapy Unit, Adult Intensive Care Unit, Cardiology Intensive Care Unit) and approximately 120 tracheostomies are performed each year.

The development of these guidelines was supervised and approved by the Infectious Diseases Control Committee at Hospital Italiano de Buenos Aires.

3. Results

3.1. Indications

The most frequent criteria for the indication of tracheostomy is prolonged weaning from mechanical ventilation [18], which is a process that requires more than three tests of spontaneous ventilation or a period of at least seven consecutive days.

Other indications for tracheostomy are serious injuries to the anatomy of the upper airway such as obstructions or stenosis, inhalation of smoke or vapor of corrosive materials and paralysis of deglutatory muscles, causing higher risk of aspiration-induced lung injury [12].

However, percutaneous tracheostomy (PT) is a high risk procedure for operators due to the generation of aerosols and it may be prudent to delay the procedure until active COVID-19 disease is resolved [19].

Key point

During the COVID-19 pandemic, the decision to perform a tracheostomy ought to be agreed between the surgical team, the critical care medical team and/or anesthesiologists.

Based on the available evidence and the recommendations of scientific societies recommendations are [20–22]:

- Avoid tracheostomy in patients with suspected or confirmed COVID-19.
- Tracheostomy can be considered in patients with COVID-19 in who are expected to obtain a substantial benefit, assessing the high infectious risk to which the acting team is exposed.
- Ideally, it should be performed 21 days after intubation and with negative COVID-19 tests [23].

3.2. Contraindications

It is highlighted that percutaneous tracheostomy in most circumstances is an elective procedure, therefore risks and benefits must be analyzed in each patient. However, contraindications have been described, which can be considered as relative depending on the clinical context of the patient:

1. Hemodynamic instability
2. Hypoxemia ($\text{PaO}_2/\text{FiO}_2 < 200$)
3. High intracranial pressure (> 20 mmHg)
4. Multi-organ failure
5. Coagulopathy
6. Platelet antiaggregation or anticoagulation
7. Surgical site infection
8. History of major cervical surgery that alters cervical flexion-extension
9. Abnormal cervical anatomy



Fig. 1. Surgical sterile level 3 personal protection equipment (PPE) recommended by the Infection Control Committee of the Hospital Italiano de Buenos Aires, for the performance of percutaneous tracheostomy (PT) in patients with suspected or positive COVID-19.

Key point

This group infers then that COVID-19 patients who would be suitable candidates for a tracheostomy are those who, after 21 days of intubation and with a negative test, do not present hypoxemia, multiple organ failure or requirement of vasoactive drugs or any of the contraindications above mentioned. Patients' stable clinical status should allow physicians to predict a benefit of the tracheostomy in terms of weaning from mechanical ventilation and subsequent hospital discharge, increasing the availability of mechanical ventilation equipment.

3.3. Personal protective equipment (PPE)

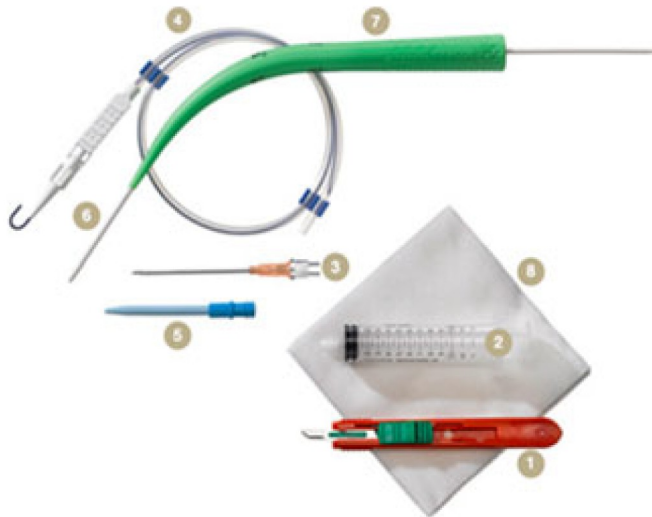
For COVID-19, contact and droplet precautions are recommended, however, the connection and disconnection from mechanical ventilation during the PT can produce aerosolized secretions, with the risk of viral dispersion through the air. Taking this into account, all procedures involving COVID-19 patients, are carried out bedside in a negative-pressure room in the intensive care unit. Therefore, level #3 protection

for the physician who performs the bronchoscopy and for the SPT who performs the procedure with the necessary adaptation of the sterile surgical equipment, is recommended (Fig. 1). The nurse in charge of the patient will assist from inside the negative-pressure operating room, dressed in PPE #3, with medication ready to be prepared and administered if necessary. Instructions were prepared, then SPTs were instructed on the correct way to place and remove them. A step-by-step manual was prepared and all the nurses and medical personnel involved were instructed to ensure the proper donning and doffing procedures are being followed at all times.

- There will be only two operators within the room:
 - 1) Physician with privileges to perform bronchoscopy (PPB): Intensive care practitioner, pulmonologist, anesthesiologist, SPT.
 - 2) SPT.
- It is recommended to perform the procedure in a negative pressure respiratory infection isolation room with a HEPA (High Efficiency Particulate Air) filter.

3.4. Materials

- Percutaneous tracheostomy set, preferably with single dilating horn (Fig. 2)



Percutaneous tracheostomy set:

1. Scalpel
2. Syringe
3. 14 G puncture teflon catheter
4. Seldinger guidewire
5. Short 12 Fr dilator
6. Guide-catheter
7. Hydrophilic dilator
8. Gauze

Fig. 2. Percutaneous tracheostomy set.

Table 1

Bronchoscopy-assisted percutaneous tracheostomy technique.

Surgical technique	Ventilator setting
1.) Endoscopic exploration of the airway and aspiration of secretions.	Expiratory apnea (necessary pre-oxygenation)
2.) Withdrawal of the endotracheal tube to the subglottic cone without completely deflating the cuff.	
3.) Transverse cervicotomy above the jugular notch.	Ventilator breath cycling
4.) Blunt dissection of subcutaneous tissue. ^a	
5.) Digital opening of the cutaneous muscle of the neck (platysma).	
6.) Divulsion of pretracheal muscles.	
7.) Palpation of tracheal rings.	
8.) Second and third tracheal cartilage recognition.	
9.) Tracheal puncture using abbocath 14 G.	Expiratory apnea (necessary pre-oxygenation)
10.) Guidewire progression.	
11.) Dilatation of the anterior aspect of the trachea with a short dilator according to the Seldinger technique.	
12.) Dilatation of the anterior aspect of the trachea with a "horn-type" hydrophilic dilator.	
13.) Placement of the tracheostomy tube.	
14.) Cuff inflation.	
15.) Tracheostomy tube connection to ventilator tubing.	Ventilator breath cycling
16.) Fixation of the tracheostomy tube.	
17.) Endoscopic verification of the cannula placement site.	Expiratory apnea (necessary pre-oxygenation)
18.) Placement of closed suction systems.	
19.) Dressing.	Ventilator breath cycling

^a Low-energy electric scalpel with suction adaptation may be used in certain cases, such as patients with aberrant topographic neck anatomy, increased local vascularization due to collateral circulation and/or other situations in which abnormal intraoperative bleeding is expected.

- Disposable flexible video bronchoscope with remote display.
- Tubing set with functioning central aspiration.
- Pair of clamps for blunt dissection.
- Low-energy electric scalpel with suction adaptation, console and patient return electrode ("dispersive pad"). These will only be necessary in certain cases, such as patients with aberrant topographic neck anatomy, increased local vascularization due to collateral circulation and/or other situations in which abnormal intraoperative bleeding is expected.
- Sterile disposable surgical drapes.
- Sterile gauze.
- Chlorhexidine soap cloth for pre-surgical surgical site washing.
- Alcohol-based chlorhexidine solution for surgical scrub.
- Sterile physiological solution.
- Absorbable multifilament 3.0 suture (Polyglactin™).
- Absorbable multifilament 1.0 suture (Polyglactin™).

3.5. Preoperative preparation

In order to reduce personnel exposure as much as possible, all procedures should only be performed by two operators (SPT and

physician in charge of airway patency control) with appropriate PPE. It is suggested to optimize the following conditions prior to the start of the procedure:

- Corroborate signed informed consent, which must comprehend the wider variety of risks, possible outcomes of the procedure and postoperative complications amidst the COVID-19 pandemic.
- Verify adequate functioning of suction systems.
- Verify that the ventilator has a heat and moisture exchanger with an electrostatic filter (HMEF).
- Set the ventilator in volume control mode to obtain a ventilation of 6 ml/kg of theoretical weight.
- Set respiratory rate adjusted to arterial pH.
- 100% FiO₂ for adequate pre-oxygenation.
- Set ventilator alarms.
- Place Mount catheter with double rotating mechanism between the ventilator tubing and the orotracheal tube, without making incisions in it. Perform this maneuver with the ventilator in standby mode (patient in expiratory apnea).
- Deep sedation with bolus of ketamine (1 to 2 mg/kg) and propofol in continuous infusion (dose of 1.8 mg/kg/h).

- Neuromuscular blockade with rocuronium bolus (1 mg/kg).
- Place the patient's head at 0°.
- Turn off the alternating pressure mattress.
- Interscapular projection to achieve greater cervical extension.
- Perform checklist.

The configuration of the ventilation modality, the infusion of medications, the positioning of the patient and the preoperative surgical preparation (antisepsis and sterile fields) should be carried out by the two practitioners who are inside the room equipped with EPP #3.

3.6. Surgical procedure

A percutaneous bronchoscopy-assisted technique ought to be used. It is detailed in relation to the necessary mechanical ventilation parameters in [Table 1](#).

3.7. Postoperative care

It is suggested to optimize the following post-procedure conditions:

- Discard procedural material
 - SPT: Discard sharp material, tracheostomy kit remnants and surgical drapes.
 - Airway physician: Discard endotracheal tube, aspiration and bronchoscope processing.
- Adjust FiO₂ to the patient's requirements.
- Set respirator alarms.
- Maintain deep sedation for at least an hour to avoid waking up under neuromuscular block. After that period, reevaluate target sedation level.
- Make sure that the closed suction system is correctly adapted. Intermittent subglottic suction through tracheostomy cannula ought to be avoided since to prevent aerosolization maneuvers outside a closed suction system.
- Place humidification systems.
- Request a control chest radiograph.
- Make a report of the procedure.
- Turn on the alternating pressure mattress.

4. Discussion

The objective of this guide is to establish recommendations regarding the performance of tracheostomies that focus on the well-being of the patient and safety of the health care professionals during the COVID-19 pandemic with minimization of the time and risk of viral exposure and depletion of material resources that make up personal protective equipment (PPE). This document is intended to provide background, considerations and recommendations based on published literature that is under constant review and front-line information at this early stage of the pandemic. These recommendations may require individualization depending on the region, institution, resources and specific patient characteristics.

Studies carried out in China have shown that most of those who become seriously ill with COVID-19 do so due to the rapid progression of pneumonia to acute respiratory distress syndrome, which can lead to respiratory failure and death [9,24–27]. According to the SARS-1 outbreak caused by another coronavirus, the need for mechanical ventilation was associated with a 46% mortality [28]. The available data do not clarify the benefits of performing an early tracheostomy in critically ill patients with COVID-19. However, as an aerosol-generating procedure, tracheostomy increases potential viral exposure to nurses, technicians and practitioners, who require adequate PPE, which is currently a scarce resource [14,15]. There is also increased exposure to the virus among those who perform checks, suctioning, changes in dressings and other post-tracheostomy care. Despite these difficulties, reducing the

risk of in-hospital outbreak amplification through transmission of COVID-19 to other patients and healthcare workers is of critical importance.

Among the benefits of tracheostomy are the possibility to decrease sedation, reduce sedation-related delirium, improve patient comfort and move towards spontaneous ventilation tests, which would impact ventilator shortages in the context of the pandemic; laryngotracheal stenosis after prolonged intubation is a known risk, but it has not been shown to significantly decrease in patients treated with early tracheostomy in some systematic reviews (generally < 10 days) [29,30]. Overall, the duration of mechanical ventilation has the potential to be significantly shortened by early tracheostomy and result in considerably shorter intensive care unit stays [31]. On the other hand, although the incidence of ventilator-associated pneumonia would decrease, overall mortality would not clearly improve with early tracheostomy [32].

Regarding the choice of the most opportune time to perform the tracheostomy, there is no identified time point in which the patients with COVID-19 improve, remain stable or progress towards death due to pulmonary complications. In the SARS-1 epidemic, the average time from onset to death was 23.7 days [33], suggesting a low potential benefit of tracheostomy before this time. Patients who do not show clinical or radiological remission within 10 days may be more likely to require continuous ventilation and have a more severe course of the disease, including death [27]. There is no certified time lapse for viral clearance and critically ill patients may have positive tests for longer periods, lasting at least 2–3 weeks [26]. Regarding this, the American Academy of Otorhinolaryngology - Head and Neck Surgery established in March 2020 that unless it is an emergency, surgical procedures should only be performed after establishing the patient's SARS-CoV-2 serology status.

Finally, the use of bronchoscopic guidance during percutaneous tracheostomy has been a controversial subject even prior to the present pandemic. However, this group believes that intraoperative direct airway visualization adds to the technical security of the procedure, mainly reducing the risk of inadvertent injuries to the posterior wall of the trachea by facilitating the location of the most suitable tracheostomy site [34]. Such major complication in a COVID-19 patient would bring about, not only a severe increase in the patient's morbidity and mortality, but also a higher risk of viral exposure to the healthcare practitioners involved in the procedure and subsequent treatment of the complication. Altogether, fibre optic bronchoscopy-guided percutaneous dilatational tracheostomy allows for a faster, more secure and efficient procedure [35].

5. Conclusions

- Decision-making regarding tracheostomy must take into account the criteria of the surgical team and intensivists, as well as institutional policy.
- It would be good practice to avoid tracheostomy in SARS-CoV-2 + patients or with suspected COVID-19 during periods of respiratory instability or increased dependency on the ventilator.
- Tracheostomy can be considered in patients with respiratory and ventilatory stability, but should not be performed before 2–3 weeks after intubation, and preferably with negative COVID-19 tests.
- It must strictly adhere to the procedures for placement and removal of PPE based on institutional protocols.
- It is recommended to limit the number of health workers participating in the procedure (2) and in post-procedure airway management.
- It is important to keep the tracheostomy cannula cuff properly inflated after the procedure to avoid leakage.
- Avoid circuit disconnections and minimize secretions aspiration through the closed circuit.
- If available, fit a heat and moisture exchanger when the

tracheostomy tube is disconnected from mechanical ventilation.

- Delay routine changes to the tracheostomy cannula until the COVID-19 test is negative.

Author statement

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- San Román, Juan E.: Writing - review & editing.
- García Fornari, Gustavo: Writing - review & editing.
- Figari, Marcelo: Writing - review & editing.

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