



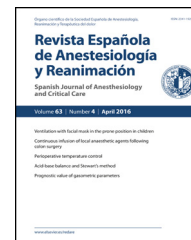
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Revista Española de Anestesiología y Reanimación

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CONSENSUS STATEMENT

Consensus Document of the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC), the Spanish Society of Otorhinolaryngology and Head and Neck Surgery (SEORL-CCC) and the Spanish Society of Anesthesiology and Resuscitation (SEDAR) on Tracheotomy in Patients with COVID-19 Infection^{☆,☆☆}



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Available online 16 November 2020

[☆] Please cite this article as: Villalonga Vadell R, Martín Delgado MC, Avilés-Jurado FX, Álvarez Escudero J, Aldecoa Álvarez-Santuyano C, de Haro López C, et al. Documento de consenso de la Sociedad Española de Medicina Intensiva, Crítica, y Unidades Coronarias (SEMICYUC), la Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello (SEORL-CCC). . Rev Esp Anesthesiol Reanim. 2020;67:504–510.

^{☆☆} This article is published simultaneously in Medicina Intensiva (<https://doi.org/10.1016/j.medin.2020.05.001>), in Acta Otorrinolaringológica Española (<https://doi.org/10.1016/j.otorri.2020.04.002>) and in the Spanish Journal of Anesthesiology and Critical Care (<https://doi.org/10.1016/j.redar.2020.05.001>), with the consent of the authors and editors.

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Received 6 May 2020; accepted 10 May 2020

Available online 16 November 2020

KEYWORDS

Mechanical ventilation;
Tracheotomy;
COVID-19;
Pandemic

Abstract: The current COVID-19 pandemic has rendered up to 15% of patients under mechanical ventilation. Because the subsequent tracheotomy is a frequent procedure, the three societies mostly involved (SEMICYUC, SEDAR and SEORL-CCC) have setup a consensus paper that offers an overview about indications and contraindications of tracheotomy, be it by puncture or open, clarifying its respective advantages and enumerating the ideal conditions under which they should be performed, as well as the necessary steps. Regular and emergency situations are displayed together with the postoperative measures.

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PALABRAS CLAVE

Ventilación mecánica;
Traqueotomía;
COVID-19;
Pandemia

Documento de consenso de la Sociedad Española de Medicina Intensiva, Crítica, y Unidades Coronarias (SEMICYUC), la Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello (SEORL-CCC) y la Sociedad Española de Anestesiología y Reanimación (SEDAR) sobre la traqueotomía en pacientes con COVID-19

Resumen La alta incidencia de insuficiencia respiratoria aguda en el contexto de la pandemia por COVID-19 ha conllevado el uso de ventilación mecánica hasta en un 15%. Dado que la traqueotomía es un procedimiento quirúrgico frecuente, este documento de consenso, elaborado por tres Sociedades Científicas, la SEMICYUC, la SEDAR y la SEORL-CCC, tiene como objetivo ofrecer una revisión de las indicaciones y contraindicaciones de traqueotomía, ya sea por punción o abierta, esclarecer las posibles ventajas y exponer las condiciones ideales en que deben realizarse y los pasos que considerar en su ejecución. Se abordan situaciones regladas y urgentes, así como los cuidados posoperatorios.

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Introduction

In intensive care units (ICU), tracheotomy is a common procedure in patients with respiratory failure who require mechanical ventilation.¹

In the recent pandemic, COVID-19 in its most severe form presents with acute respiratory failure that can progress to acute respiratory distress syndrome (ARDS), which in many patients requires mechanical ventilation. Between 9.8% and 15.2% of these patients required mechanical ventilation in different series published.^{2–4} Surgical tracheotomy is the most common procedure in critically ill patients with COVID-19.⁵

Mortality among patients with COVID-19 on mechanical ventilation can be as high as 50%.⁶ These patients require ventilation strategies that call for deep analgesic sedation, and even muscle relaxation, protective ventilation, recruitment manoeuvres and prone positioning, in the initial phases.⁷ This means that many patients will remain on mechanical ventilation for several days, and will be at high risk of developing ICU-acquired weakness, making it difficult to wean them from the ventilator. The use of specific antiviral drugs can interact with sedatives and analgesics and prolong their effects.⁸ The appearance of delirium, common in this type of patient, can also affect weaning from mechanical ventilation.

SARS-CoV-2 has shown a high rate of infection, especially by airborne and droplet transmission. Specific recommendations on personal protective equipment (PPE) and airway management involving intubation and mechanical ventilation have been established. The risk of contagion is high when performing aerosol-generating procedures, among which tracheal intubation, fiberoptic bronchoscopy and tracheostomy are considered to involve the highest risk.⁹

Different recommendations for tracheotomy techniques in patients with COVID-19 have been published, but there is insufficient evidence on the optimal timing of the procedure, the type of approach (surgical vs. percutaneous tracheotomy), or the subsequent treatment of these patients.

Although some authors have published case series describing their experience with tracheotomy in patients with COVID-19, there is still insufficient evidence to support firm recommendations; therefore, expert consensus and a review of the literature in the context of routine practice can help establish guidelines for performing tracheotomy in this disease.

The following recommendations have been drawn up by the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC), the Spanish Society of Otorhinolaryngology and Head and Neck Surgery (SEORL-CCC) and the Spanish Society of Anaesthesiology and Critical Care (SEDAR). These recommendations may be changed as new scientific evidence emerges, and can be adapted to the resources available at any given time.

Methodology

The development of the COVID-19 pandemic and the need to establish recommendations that would help professionals make decisions regarding certain clinical procedures, in this

Table 1 Indications for tracheotomy in the intensive care unit.

- Prevention of intubation-induced laryngeal and upper airway damage in patients undergoing prolonged mechanical ventilation
- Easy access to the airway for removal of secretions
- Reduction of dead space
- Obstruction of the airway
- Whenever endotracheal intubation after urgent cricothyrotomy is impossible in patients with difficult airways
- Accelerate weaning from mechanical ventilation

Source: Añón et al.¹⁰.

Table 2 Contraindications for tracheotomy.

- Existence of advance directives refusing the procedure
- End-of-life situation
- Uncontrolled septic shock and multi-organ dysfunction with high risk of death
- The procedure should be delayed or the high risk taken into account in certain circumstances:
 - Very high ventilatory requirements: FiO₂ > 70% and/or PEEP > 12 cmH₂O
 - Need for prone position during the preceding 48 h
 - Haemodynamic instability requiring vasoactive support
 - Coagulopathy with high bleeding risk
 - Impossibility of obtaining informed consent

PEEP: positive end expiratory pressure.

case tracheotomy, led to the creation of an *ad hoc* group of experts from the SEMICYUC, the SEORL-CCC and the SEDAR. The group drew up a series of consensus recommendations based on the results of a review of the literature.

Results

Tables 1 and 2 describe the relative indications and contraindications for tracheotomy.

Timing of tracheotomy in COVID-19 patients

In routine practice, outside the context of COVID-19, there is no conclusive evidence for the optimal timing of tracheotomy in critically ill patients. This is due to the heterogeneity of the patients included in studies, the different definitions of early and late tracheotomy, and even faulty randomisation of patients in the clinical trials performed. Because of this, it is impossible to definitively establish the impact of tracheotomy timing in critically ill patients. In the context of COVID-19 patients, it would be reasonable to define early tracheotomy as that performed in the first 10 days, and late as that performed thereafter.

Post-intubation tracheal stenosis is a well-known risk factor for prolonged orotracheal intubation, but systematic reviews have not shown stenosis to be significantly reduced in patients undergoing early tracheotomy.^{11,12}

It could be said that early tracheotomy does not provide benefits in variables such as ventilator-associated pneumonia or mortality, but due to its benefits over to intubation in terms of well-being, length of ICU stay, and time under mechanical ventilation, it seems reasonable to perform it in patients with a high probability of prolonged mechanical ventilation.¹³ A recent meta-analysis only found early tracheotomy to be associated with a shorter duration of sedation.¹⁴

Early tracheotomy can increase the risk of infection in patients testing positive for COVID-19 on PCR with a higher viral load. Although the exact rate of viral clearance is not known, infection could persist for 2–3 weeks in critically ill patients.¹⁵ This is why some scientific societies have established negative PCR as a criterion for tracheotomy, the only exception being patients in whom orotracheal intubation has been unsuccessful.^{16,17} When certain resources, such as ventilators, are in short supply, early tracheotomy would reduce the duration of mechanical ventilation and free up resources for other patients needing this therapy. In these circumstances, early tracheotomy can facilitate treatment and nursing care.

In a recent study (data pending publication), both early (<10 days) and late tracheotomy allowed mechanical ventilation to be withdrawn after only 4 days on average.

At the other end of the scale, delaying tracheotomy can give a more accurate picture of which patients would not benefit from the procedure due to late complications that increase the risk of death, such as dysfunction of other organs, and which have a better prognosis, are likely to make good progress, and can be extubated. It appears that patients who do not show clinical or radiological remission within 10 days are more likely to require long-term ventilation, present more severe course, and are at higher risk of mortality.¹⁸

We recommend performing tracheotomy in patients with positive PCR for COVID-19 from day 14 of orotracheal intubation, and to consider early tracheotomy only in stable patients with low oxygen demand in whom prolonged mechanical ventilation is expected for other reasons. Early tracheotomy could be considered in order to optimize intensive care resources.

Surgical vs. percutaneous tracheotomy

Outside the context of COVID-19, there is currently no evidence to support a recommendation for any particularly tracheotomy technique. The only criteria for choosing one technique over any other are clinical status, experience and availability. In the current situation in which intensive care resources are stretched to the limit, surgical tracheotomy performed by specific surgical teams can expedite the procedure and prevent unnecessary delays. The decision between open or percutaneous tracheotomy (PT) is taken by the multidisciplinary team, based on the hospital's experience in either technique and the resources available. If, based on experience and a multidisciplinary team decision, PT is considered best, the known contraindications should be taken into account.

Although the use of fiberoptic bronchoscopy (FOB) could reduce the risks associated with PT,¹⁹ it is not advised in

patients with COVID-19 because it increases the number of participants in the room and has a high risk of aerosol generation. If, however, FOB is performed, we recommended using a sealed port and considering the use of disposable bronchoscopes.^{20,21}

In these cases, although there is insufficient evidence to recommend ultrasound, it could reduce FOB-related complications by indicating the correct puncture site in patients in whom anatomical structures are hard to identify.²²

In both cases, the equipment used should be cleaned according to established recommendations.

In necks without significant anatomical alterations, PT can be considered the technique of choice, taking into account existing recommendations and the availability of professionals trained in this technique. Surgical tracheotomy would allow more controlled and rapid airway management than the percutaneous technique in patients at high risk of complications.²³ It can be considered during stages of the pandemic when the burden of care is greatest for intensive care professionals.

Where tracheotomy should be performed

Bedside PT reduces the need for transfer and disconnection from mechanical ventilation if it can be performed in individual or negative pressure rooms.

We recommend performing the tracheotomy in an ICU room or nearby location (such as the operating room) that has an isolation system and negative pressure, using the appropriate equipment for the procedure. It should not be performed in COVID-19 wards without isolation rooms. If it is performed in the operating room, special patient transit routes and special specific tracheotomy areas should be marked.²⁴

Surgical technique^{25–28,29}

General recommendations

- Use standard tracheotomy surgical material.
- The use of electrical, ultrasonic or any other cutting and coagulation systems that can spread particulate matter should be avoided as far as possible. It is best to use cold material and conventional haemostasis systems, unless this will unduly delay performance of the technique.
- Use closed circuit suction systems with antiviral filters.
- Only essential personnel should remain in the room during the tracheotomy.
- The procedure should be performed as quickly as possible by the most experienced clinician available.
- Use adequate protection measures. PPE: disposable, waterproof gown, cap and boots; disposable plastic splash-proof full face screen; FFP2 or FFP3 mask or equivalent (N95) covered by a surgical mask. Double gloving is advised.
- Goggles, hazard suits or the like are usually splash-proof. We recommend using anti-fog spray or similar to prevent fogging.

- Choose between PT or surgical tracheotomy on the basis of the standard protocol in place in the hospital.

Recommendations for scheduled tracheotomy (intubated patient)

- 1 Before opening the trachea:
 - Pre-oxygenate the patient (100% oxygen, 5 min).
 - Administer muscle relaxants to ensure the patient is immobile throughout the procedure, particularly during extubation and decannulation, to avoid coughing and aerosolization.
 - Withdraw mechanical ventilation before tracheal opening.
- 2 Perform the tracheotomy, withdraw the endotracheal tube, without completely removing it, until the cuffed tube can be inserted; inflate the cuff.
- 3 Connect the ventilator and, when correct ventilation is verified (preferably by capnography), remove the endotracheal tube and secure the tracheotomy tube with tape and stitches. The cuff of the tracheotomy tube should never be deflated once mechanical ventilation has begun.
- 4 Collect all tracheotomy material.
- 5 Surgeons must doff their protective material inside the operating room or room, according to prevailing regulations.
- 6 Exit the operating room or room according to prevailing rules.

Recommendations in urgent tracheotomy (non-intubated patient)

Emergency tracheotomy may be required in a non-intubated patient with breathing difficulty. In these cases, a cricothyrotomy kit should be used.

Emergency tracheotomy should be avoided whenever possible, since it is performed in conditions that are far from ideal. Good communication channels should be maintained between intensivists, anaesthesiologists and emergency services, and help should be offered in anticipated difficult intubations:

- 1 Pre-oxygenate the patient (100% oxygen, 5 min).
- 2 Administer muscle relaxants to immobilise the patient and prevent coughing.
- 3 Insert the tracheotomy tube and inflate the cuff.
- 4 Connect the ventilator and stabilize the patient.
- 5 Secure the cannula.
- 6 If tracheotomy is impossible, perform standard cricothyrotomy.
- 7 If a cricothyrotomy has been performed, once the patient has been stabilized and the airway secured, perform a surgical tracheostomy using a different incision. Close the cricothyrotomy incision after the anterior cannula has been removed and the tracheostomy tube is in place.
- 8 Follow points 4–6 of the previous section (scheduled tracheostomy).

Table 3 Recommendations for tracheotomy in patients with COVID-19.

- In a patient under prolonged mechanical ventilation, tracheotomy is indicated after the 14th day of orotracheal intubation if the patient is clinically stable and the procedure is not contraindicated.
- Early tracheotomy may be considered in stable patients who are expected to require prolonged mechanical ventilation for other reasons
- Percutaneous tracheostomy is still the technique of choice for critically ill patients, provided it is not contraindicated. Surgical tracheostomy should take precedence over the percutaneous approach when intensive care staff are overloaded.
- Non-fenestrated cuffed tubes with interchangeable inner cannulas should be used, and the cuff should be kept inflated with the use of closed suction systems
- Delay the first cannula change as long as possible
- Evaluate the risk/benefit when establishing the schedule for changing the inner cannula or cleaning the tracheostomy tube
- Exercise extreme precaution and use the recommended PPE when deflating the cuff and starting weaning procedures
- If T-tubes are unavoidable, high-efficiency antimicrobial filters and heat exchangers should be used

PPE: personal protective equipment.

Recommendations for tracheotomy care

Caring for tracheotomized COVID-19 patients can increase staff exposure to infection and promote the spread of the virus:

- Place patients in COVID-19 cohort rooms, depending on the risk of infection.
- Preferably in individual and negative pressure rooms, if available.
- Staff caring for patients with tracheotomy, particularly those that are still PCR positive, must always use the PPE indicated for performing aerosol-generating procedures, including splash-proof gown, FFP2 or FFP3 filtering mask, splash-proof goggles and gloves. Proper hand hygiene must be performed before donning and after doffing the PPE.¹⁰
- Tracheotomy patients must have a surgical mask placed over the tracheostomy or over the nasal prongs or oxygen mask if the tracheostomy is closed.
- In life-threatening emergencies, prioritise PPE donning and ask for help.
- Extra PPE must be available in areas allocated to tracheotomized patients.
- Minimize tracheotomy manipulations and the number of professionals involved.
- Consider delaying the first change of the tracheostomy tube, and perform successive changes after tests are negative for COVID.
- Always consider using an inner cannula.

- Always keep the cuff inflated.
- Use closed suction systems.
- Evaluate the risk/benefit when establishing the schedule for changing the inner cannula or cleaning the tracheostomy tube.
- Avoid active humidification and assess the risk/benefit associated with cannula obstruction.
- Use high-efficiency antimicrobial filters and heat exchangers when disconnecting mechanical ventilation.
- Avoid T-tubes, fenestrated cannulas and cuff deflation as far as possible, until virus testing is negative.
- We recommend creating multidisciplinary teams trained in the management of tracheostomy tubes to care for these patients.
- Specific equipment should be available to repeat the tracheotomy in the event of decannulation failure.
- A system for alerting the otolaryngology service must be in place.
- PPE can hinder vision and communication between the team. Tracheotomy procedures should be planned and short briefings held.

Table 3 summarizes the main conclusions of the consensus on tracheotomy in patients with COVID-19.

All these recommendations are based on the available evidence and the knowledge accrued by specialists involved in treating acute respiratory failure secondary to COVID-19 pneumonia. It is likely that some indications will need to be changed or adapted to the resources available in hospitals over the course of the pandemic.

Conflict of interests

The authors declare that they have no conflict of interest.

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