Optimal Timing for Performing Tracheotomy in Patients with Acute Respiratory Failure

Tracheotomy is a routine surgical procedure that enables airway access through an incision made below the larynx. The procedure is often performed to place an endotracheal tube in patients who need long-term or permanent mechanical ventilation. Critically ill patients in acute respiratory distress typically receive mechanical ventilation through an endotracheal tube advanced through the mouth at first. There is general agreement that patients should be switched to a tracheotomy tube if ventilation is likely to last several weeks or longer; however, consensus is lacking on how long to wait before switching when the patient’s prognosis is unclear, and the definition of “early” tracheotomy varies widely (by days). This report assesses the clinical evidence available to guide decisions to perform tracheotomy in intubated, critically ill patients with acute respiratory disease.

The optimal timing for performing tracheotomy in patients with acute respiratory disease, including COVID-19, cannot be determined from available evidence. We identified only 2 very-low-quality retrospective studies that reviewed cases of patients who had received earlier tracheotomy (i.e., within 7 to 10 days of intubation) and compared them with patients who had received later tracheotomy. The studies reported improved survival, shorter hospitalization, and reduced costs with earlier tracheotomy, but the studies are at high risk of bias and provide no data on the burden of tracheotomy reversal. Two evidence-based guidelines from India and France disagree on early tracheotomy’s (within 4 to 7 days) effectiveness in critically ill patients. No evidence-based guidelines specific to COVID-19 are possible, but consensus guidance is mixed: 3 guidelines from France and Spain recommend early tracheotomy, while 15 guidelines from Asian, European, North America, and African medical societies, hospitals, and universities recommend delaying tracheotomy >14 days because of COVID-19 infection risks and the poor prognosis associated with mechanical ventilation in patients with COVID-19.

Evidence limitations: The two studies are at high risk of bias from lack of randomization, retrospective design, and single-center focus. One of the studies is also at risk of bias from small sample size, and in the other study, one or both tracheotomy groups may have included patients with nonrespiratory disease etiologies. Larger prospective, controlled studies are needed to assess early tracheotomy’s potential benefits and harms in patients with severe acute respiratory disease and report on recovery time, physical function, and quality of life (QOL) after discharge from the intensive care unit (ICU). Studies should also assess potential harms (i.e., transmission) to clinical staff performing early tracheotomy for critically ill patients with COVID-19 whose prognosis may be very poor.

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Executive Summary

Findings

We assessed 2 studies that reported on survival, life support duration, and hospitalization length and costs.

- One retrospective study (Kang et al. 2020) from South Korea reported lower 90-day mortality (31.2% versus 47.8%, p = 0.012) in critically ill, mechanically ventilated patients who had respiratory disease and received tracheotomy within 10 days of intubation compared to patients receiving later tracheotomy. Patients given earlier tracheotomy had shorter median ventilation time (23 versus 28 days), ICU stay (24 versus 33), and hospitalization length (43 versus 54 days) and lower overall costs ($26,609 versus $36,973 per patient).

- One retrospective study (DiChiacchio et al., 2020) from the United States of patients with acute respiratory distress syndrome (ARDS) reported that extracorporeal membrane oxygenation (ECMO) support was shorter (12 versus 21 days; p = 0.005) when patients underwent tracheotomy within 7 days of intubation. Earlier tracheostomy also reduced overall costs ($3,624 versus $5,603 per patient).

Evidence

Search dates: January 1, 2015, to May 21, 2020. We identified 2 studies and reviewed 1 study as full text and 1 study abstract reporting on 290 patients.

- We focused on respiratory failure and included only studies in which ≥85% of patients had respiratory disease as the primary indication for mechanical ventilation. We included studies that compared patient groups who underwent tracheotomy at different times after intubation or that correlated tracheotomy timing and clinical outcomes by means of regression analysis. We review a full-text article available with open access and the abstract of another study.

- One retrospective study (Kang et al. 2020, n = 575) reviewed cases to compare mortality, ventilation and ICU stay length, and ICU costs in critically ill patients who underwent intubation only (n = 285) or intubation followed by tracheotomy within or after 10 days of intubation (n = 240). We included here only the tracheotomy groups. The proportion of patients with respiratory disease was listed for the full cohort (86.4%) but not for the tracheotomy groups. Thus, 1 or both tracheotomy groups may include patients with other etiologies.

- One retrospective study (DiChiacchio et al., 2020, n = 50) reviewed cases to compare outcomes of patients with ARDS who underwent tracheotomy within 7 days with outcomes of those who underwent the procedure after 7 days of ECMO initiation. The study reported ECMO duration and cost.

Guidelines, Position and Consensus Statements

Searched PubMed, EMBASE, and ECRI Guidelines Trust® (EGT) for relevant documents published between January 1, 2016, and May 21, 2020. We identified 6 documents.

Guidelines Supported by Systematic Reviews

- We sought guidelines that are clearly supported by published systematic reviews (SRs) or included in EGT. EGT is a publicly available online repository of guidelines supported by SRs and developed by nationally and internationally recognized medical organizations and specialty societies. These guidelines must meet certain U.S. National Academy of Medicine criteria. We found 2 relevant guidelines supported by SRs (none in EGT) and 2 other documents.


- Indian Society of Critical Care Medicine Organization (2020). The guideline endorses tracheotomy within 7 days of intubation as effective to reduce hospitalization and ventilation duration in critically ill patients.

Other Documents


- 3 guidance documents published in the United States by 1 medical society and 2 universities recommend delaying tracheotomy by 14 to 21 days in patients with COVID-19 because of typically poor outcomes and contamination risks.
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Background

Airway Access in Mechanical Ventilation

Mechanical ventilation of patients who cannot breathe on their own requires an airtight seal between the patient and the ventilator’s breathing circuit. In alert patients, air can be delivered with face-fitting mask or helmet interface. Typically, however, critically ill patients who need mechanical ventilation are unconscious or sedated and cannot maintain their airway open and clear of secretions. In these patients, clinicians isolate the airway with a balloon-cuffed tube that they then connect to the breathing circuit. Clinicians can place the tube through the mouth or through a tracheotomy (i.e., an incision through in the neck and trachea). (For more information, see the chapter Airway Management in ICU Settings in Intensive Care)

Intubation through the mouth is the standard initial airway access method in critical care. Intubation takes seconds to perform and reverse and is thus ideal for emergency use. However, tube placement is traumatic for the larynx and can cause erosion, bleeding, infection, and vocal cord paralysis or stenosis over time. Repeated intubation is particularly risky and thus not ideal for ventilation weaning, which may require several trials. Oral intubation does not permit drinking, eating, or talking, and alert patients may not tolerate it for more than a few hours or days. (For more information, see Airway Management in ICU Settings and the review Tracheostomy in Special Groups of Critically Ill Patients: Who, When, and Where?)

Tracheotomy is indicated in patients with oral or laryngeal obstruction or injury. Clinicians place the tube below the larynx through an open surgical incision or a through a puncture with the help of dilators. Open tracheotomy requires a surgical suite; puncture (“percutaneous”) tracheotomy is a bedside procedure but requires an experienced practitioner. Tracheotomy allows for drinking, eating, and talking and facilitates airway secretion clearance and ventilator weaning and is thus also indicated for long-term mechanical ventilation (months to years). (For more information, see Tracheostomy in Special Groups of Critically Ill Patients: Who, When, and Where?)

Timing of Tracheotomy

In critically ill patients, clinicians may choose initial tracheotomy instead of intubation when mechanical ventilation is not urgently needed and is expected to last for at least several weeks. However, tracheotomy involves surgical complication risks (e.g., infection, bleeding), and reversing the tracheotomy after recovery is a complex process that may take weeks or even months. De-cuffing and de-cannulation needs to be stepwise because of risks of aspiration and occlusion, and some patients may have difficulty regaining control of their airway. Because of the risks and burden of reversal, initial intubation and subsequent replacement with tracheotomy remains the standard approach. (For more information, see the review Tracheostomy 2: Managing the Weaning of a Temporary Tracheostomy.)

Clinical experts and medical societies have yet to reach consensus on how long clinicians should wait to transition critically ill patients from intubation to tracheotomy. A large literature base on the subject is available, and meta-analyses of clinical studies have found that tracheostomy after one to two weeks reduces ICU mortality and speeds recovery and ventilator weaning (See Adly et al. [2020] and McCredie et al. [2017].) However, these studies do not consider the burden of tracheotomy reversal, which increases with earlier tracheotomy. Furthermore, the analyses do not consider risk specific to certain etiologies—for instance, the risk of airborne pathogen spread when tracheotomy is performed on patients with highly infectious respiratory diseases, such as SARS, MERS, or COVID-19. This report focuses on what evidence supports as the optimal time for performing tracheotomy in critically ill patients with respiratory disease.

Guidelines, Position and Consensus Statements

Searches of PubMed, EMBASE, EGT, and other web-based resources identified six relevant guidelines and documents published between January 1, 2016, and May 21, 2020. We sought guidelines that are clearly supported by published SRs or included in EGT. EGT is a publicly available online repository of guidelines supported by SRs and developed by nationally and internationally recognized medical organizations and specialty societies. These guidelines must meet certain U.S. National Academy of Medicine criteria. We found two relevant guidelines supported by SRs and four other documents.
Guidelines Supported by Systematic Review

  
The incidence of VAP [ventilator-associated pneumonia] does not change with early (within 7 days of ventilation) or late tracheostomy ([Level of evidence] 1 [Strength of recommendation] A).
  
  Early Tracheostomy should not be used as a strategy to reduce the incidence of VAP (1 A).
  
  Early tracheostomy may result in reduction of ICU length of stay as compared to late tracheostomy (1 A).
  
  Early Tracheostomy may reduce the duration of mechanical ventilation and may result in more ventilator free days in critically ill patients (2 B).
  
  There is no difference in short term and long term mortality between early and late tracheostomy (1 A).
  
  Patients with stroke and those undergoing decompressive craniectomy may have reduced short term mortality with early tracheostomy (3 B).

  
  Tracheotomy in intensive care should not be performed before the fourth day of mechanical ventilation… Early tracheotomy (in general before the fourth day of mechanical ventilation) is not associated with decreases in mortality, the incidence of ventilator-associated lung injury, or the duration of mechanical ventilation.

Other Documents

We identified a MedRxiv preprint document by Chiesa-Estomba et al. titled *Systematic Review of International Guidelines for Tracheostomy in COVID-19 Patients* that describes 15 guidance documents published between January and April 202 and addressing the timing of tracheotomy in patients with COVID-19. The publisher warns that, “This article is a preprint and has not been peer-reviewed. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.”

The document states:

None of those selected guidelines stated the methods used in the literature search, the quality of the evidence, and the strengths of the recommendations reported.

Our findings present a high variability in national guidelines and protocols guidelines. European guidelines propose a more aggressive approach (early tracheostomy), maybe attributed the high volume of cases at this moment of the outbreak. 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.

This review includes the following guidance documents:


- American College of Surgeons. *COVID 19: Considerations for Optimum Surgeon Protection Before, During, and After Operation*.


We also identified three additional guidance documents based on consensus:

- **American Association for the Surgery of Trauma.** *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*, 2020. The guideline states:

  In the absence of large-scale triage, the decision to perform a tracheostomy in a patient with Covid-19 currently should be made on a case-by-case basis and with multidisciplinary input, maintaining a patient-centered and family-centered and caregiver safety-focused approach. It should be emphasized that data on tracheostomy in this population are very limited. Patients with severe disease likely are not physiologically stable enough to undergo the procedure, and patients who are recovering from the disease may benefit from traditional ventilator weaning and liberation strategies. At this time, we recommend against performing tracheostomy in patients with active Covid-19 disease.

  Consider pharmacological pretreatment and perform viral load testing first to confirm non-transmissibility of the disease.16 if testing is negative for Covid-19, proceed with tracheostomy.

- **University of California San Francisco.** *Tracheostomy Guidelines Developed at a Large Academic Medical Center during the COVID-19 Pandemic*, 2020. The document states:

  The decision to proceed with tracheostomy should involve a multidisciplinary discussion and should be supported by multiple [Otolaryngology-Head and Neck Surgery] team members. Notably, survival is reported to be extremely poor (<20%) in patients with COVID-19 requiring mechanical ventilation, which argues against early tracheostomy. When the determination is
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made to perform tracheostomy, a delay in timing from 14 days postintubation to 21 days postintubation should be considered to allow for sufficient decline in viral load.


Tracheotomy before 21 days should not be routinely performed in COVID-19 patients solely for prolonged ventilator dependence, given the high risk of transmission and poor prognosis of patients requiring intubation and ventilation in the existing literature. It may be considered before 21 days in patients with increased requirement for pulmonary toilet or high levels of sedation, or if incoming data from Europe suggests an improved prognosis over the current data cited herein.”

Clinical Literature

We searched PubMed, EMBASE, CINAHL, Google Scholar, and selected web-based resources for documents relevant to this topic and published between January 1, 2015, and May 21, 2020. Our search strategies included the following keywords: tracheostomy, tracheotomy, early, delayed, late, timing, ARDS, coronavirus, COVID-19, respiratory distress, respiratory failure. Please see the Selected Resources and References section for detailed search strategies.

We focused on severe acute respiratory failure and included only studies in which at least 85% of patients had respiratory disease as the primary cause of intubation and mechanical ventilation. We included any studies comparing clinical outcomes in patients who underwent tracheotomy at different times after intubation. We also included single-arm studies that correlated tracheotomy timing and clinical outcomes by means of regression analysis.

We identified and reviewed one full-text publication available with open access and a published abstract, as follows:

1 retrospective study (Kang et al. 2020, n = 575) compared mortality, ventilation and ICU stay length, and ICU costs in cases of critically ill patients who received mechanical ventilation with intubation alone (n = 285) or intubation followed by tracheotomy within 10 days (n = 125) or after 10 days (n = 115).(1) The authors stated that 86.4% of patients (497) had respiratory disease. We include here only the patients who underwent tracheotomy (n = 240), although the authors do not list the proportion of those with respiratory disease in this subgroup.

1 retrospective study (DiChiacchio et al., 2020, n = 50) compared ECMO duration and cost in patients with ARDS who had received tracheotomy within 7 days and cases of patients who received it after 7 days of ECMO initiation.(2)

See Table 1 for study details. We also identified but excluded from review two studies that did not list underlying patient etiologies.(3,4)

Evidence limitations: The two studies are at high risk of bias from lack of randomization, retrospective design, and single-center focus. One of the studies is also at risk of bias from small sample size, and in the other study, one or both tracheotomy groups may have included patients with nonrespiratory disease etiologies. Larger prospective, controlled studies are needed to assess potential benefits and harms of early tracheotomy in patients with severe acute respiratory disease and report on recovery time, physical function, and QOL after ICU discharge. Studies should also assess potential harms (i.e., transmission) to clinical staff performing early tracheotomy for critically ill patients with COVID-19 whose prognosis may be very poor.
Table 1. Clinical Studies

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Study Type and Patients</th>
<th>Intervention</th>
<th>Findings Reported by Authors</th>
<th>Authors' Conclusions</th>
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</thead>
<tbody>
<tr>
<td>Kang et al. 2020(1)</td>
<td>Retrospective, single-center study of 575 patients treated in a tertiary intensive care unit (ICU) and who received mechanical ventilation for &gt;4 days; 497 (86.4%) had pulmonary diseases; 240 (41%) had tracheotomy and are included in our analysis.</td>
<td>Early (2 to 10 days after intubation, n = 125) or late (&gt;10 days after intubation, n = 115) tracheotomy</td>
<td>“The 90-day cumulative mortality rate was 47.5% (n=273) and 258 patients (44.9%) underwent tracheostomy. In comparison with the late group (n=115), the early group (n=125) had lower 90-day mortality (31.2% vs. 47.8%, p=0.012), shorter stays in hospital and ICU, shorter ventilator length of stay (median, 43 vs. 54; 24 vs. 33; 23 vs. 28 days; all p&lt;0.001), and a higher rate of transfer to secondary care hospitals with post-intensive care settings (67.2% vs. 43.5% p&lt;0.001). Also, the total medical costs of the early group were lower during hospital stays than those of the late group (26,609 vs. 36,973 USD, p&lt;0.001).”</td>
<td>“Early tracheostomy was associated with lower 90-day mortality, shorter ventilator length of stay and shorter lengths of stays in hospital and ICU, as well as lower hospital costs than late tracheostomy.”</td>
</tr>
<tr>
<td>DiChiacchio et al. 2020(2)</td>
<td>Retrospective, single-center study of 50 patients with acute respiratory distress syndrome who received mechanical ventilation and extracorporeal membrane oxygenation (ECMO)</td>
<td>Early (within 7 days of ECMO, n = 21) or late (after &gt;7 days of ECMO, n = 29) tracheotomy</td>
<td>“Duration of [ECMO] support was significantly shorter in the early tracheostomy group (12 vs. 21 days; p = 0.005). Median [ECMO]-related costs were significantly decreased in the early tracheostomy group ($3,624 vs. $5,603, p = 0.03).”</td>
<td>“Early tracheostomy placement is associated with decreased time on [ECMO] support and reduced [ECMO]-related costs in this cohort.”</td>
</tr>
</tbody>
</table>

Selected Resources and Reference

Search Summaries

Our master’s-level medical librarians searched the following databases to identify the literature and related materials.


Search Strategy: tracheostomy; tracheotomy; respiratory distress; respiratory failure

Results: We identified two related reports and numerous records in the Healthcare Product Alerts database.

- The Ins and Outs of Tracheostomy Care and Maintenance. [PSO Plus]. 2020 Jan 2.
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Healthcare Product Alerts database. [Searched January 1, 2017, through May 21, 2020]. Note: we identified several records for tracheotomy products. To access, search the database using the terms: tracheostomy OR tracheotomy.


Search Strategy:

- #1 tracheostomy[mh] OR tracheotomy[mh] OR tracheost*[ti] OR tracheotom*[ti]
- #3 "coronavirus infections"[mh] OR COVID-19[nm] OR "severe acute respiratory syndrome coronavirus 2"[nm] OR "respiratory tract infections"[mh] OR "corona virus*" OR coronavirus* OR "COVID-19" OR COVID19 OR nCoV OR CoV-2 OR "respiratory distress" OR "respiratory failure" OR "respiratory syndrome" OR SARS*
- #4 #1 AND #2 AND #3

Results: We identified 72 records.


Search Strategy:

- #1 tracheostomy/de OR 'tracheostomy device'/exp OR tracheotomy/de OR (tracheostom* OR tracheotom*):ti
- #2 (day OR days OR delay* OR earl* OR late OR later OR month* OR predict* OR respiratory OR soon* OR timing OR week* OR when):ti
- #3 'coronavirus infection'/de OR 'coronavirus disease 2019'/de OR 'respiratory tract infection'/exp OR 'corona virus*’ OR coronavirus* OR 'COVID-19' OR COVID19 OR nCoV OR CoV-2 OR 'respiratory distress' OR 'respiratory failure' OR 'respiratory syndrome' OR SARS*
- #4 #1 AND #2 AND #3

Results: We identified 10 unique records.


Search Strategy:

- #1 TI tracheostom* OR TI tracheotom*
- #2 TI day OR TI days OR TI delay* OR TI earl* OR TI late OR TI later OR TI month* OR TI predict* OR TI soon* OR TI timing OR TI week* OR TI when
- #3 #1 AND #2

Results: We identified one unique record.

Selected Guidelines, Position and Consensus Statements [searched January 1, 2016, through May 21, 2020].

Search Strategy: tracheotomy; tracheostomy

Results: We identified six relevant documents.

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American Association for the Surgery of Trauma. Michetti CP. 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. *Trauma Surg & Acute Care Open (BMJ).* 2020;5:e000482. Note: see section titled, Considerations for indications and timing.


- UC San Francisco, Department of Otolaryngology. David AP et al. Tracheostomy guidelines developed at a large academic medical center during the COVID-19 pandemic. *Head Neck.* 2020. Note: see section titled, 3.4 Indications and timing for tracheostomy in the COVID-19 positive patient or PUI.


**Search Strategy:** tracheostomy OR tracheotomy

**Results:** We did not identify any relevant national or local pending coverage analyses, determinations, articles, or policies.

**Selected Web Resources.** [searched May 21, 2020].

**Other Selected Web Resources**

- ClinicalTrials.gov. [searched 2020 May 21]. Note: we identified over 100 trials; see the comprehensive list of ongoing, completed, and terminated trials.

- Medscape. [cited 2020 May 21]. Note: may require free registration to view documents.
  - Harman EM, Riley LE. *Acute respiratory distress syndrome (ARDS).* [updated 2020 Mar 27].

**References Reviewed (PubMed, EMBASE, CINAHL search dates were January 1, 2015, through May 21, 2020)**


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Policy Statement

The information presented in this Clinical Evidence Assessment is highly perishable and reflects the state of the literature on this topic at the time at which searches were conducted and the Clinical Evidence Assessment was prepared. Clinical Evidence Assessments provide a guide to the published clinical literature and other information about a topic on which we received a client inquiry. The scope is customized to address the specific information needs of the requestor. The content reflects the information identified from searches of the available, published, peer-reviewed scientific literature, gray literature, and websites at the time the searches were conducted. Publications referenced in this Clinical Evidence Assessment are generally limited to the English language. Clinical Evidence Assessments are developed by a multidisciplinary staff of doctoral level research analysts, clinicians, and medical librarian information specialists. For quality assurance, all reports are subject to review within ECRI before publication. Neither ECRI nor its employees accept gifts, grants, or contributions from, or consult for medical device or pharmaceutical manufacturers. The Clinical Evidence Assessment may be based on review of abstracts of published articles as well as full text articles. Abstracts do not always accurately reflect the methods and findings of full-length articles and limit full interpretation of published data. This Clinical Evidence Assessment is not intended to provide specific guidance for the care of individual patients. ECRI implies no warranty and assumes no liability for the information contained in the Clinical Evidence Assessment.

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