



Modernizing Tracheostomy Practice to Improve Resource Utilization and Survivorship Outcomes

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13.1 Introduction

Tracheostomy has attracted increasing attention in recent years, owing to progress in team-based care and demonstrable advances in weaning and decannulation. A cardinal objective of the intensive care unit (ICU) is to stabilize critically ill patients, but it is increasingly recognized that the quality of life that patients and their families experience after an ICU stay is also important. Many patients who require invasive mechanical ventilation will manifest long-lasting physical, cognitive and/or mental health impairments. While many factors that affect survivorship after an ICU stay are poorly understood, tracheostomy plays an important role in alleviating this burden through reducing cumulative sedation dose, expediting physical therapy and rehabilitation, and potentially allowing patient-focused benefits such as earlier eating, drinking, talking and mobilization. Such observations highlight the importance of modernizing tracheostomy practice using evidence-based approaches.

Tracheostomy is associated with significant healthcare expenditure as well as high personal and social costs secondary to reduced quality of life and dependency. Improved practices around tracheostomy care, weaning, and decannulation reduce ICU

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and hospital lengths of stay. The coronavirus disease 2019 (COVID-19) pandemic, which has seen a surge in patients requiring tracheostomy for prolonged mechanical ventilation, has underscored the importance of effective tracheostomy practice in efficient resource allocation and optimizing survivorship outcomes following ICU stay.

13.2 What is the Pre-COVID-19 Evidence for Early Tracheostomy?

Conflicting results regarding timing of tracheostomy were reported in meta-analyses published in 2015 [1–4], and repeated in 2018 [5, 6], with no major trials published between them. Most recently, a meta-analysis of 17 randomized trials and 3145 participants found that early tracheostomy in adults receiving invasive mechanical ventilation was associated with a decrease in the occurrence of ventilator-associated pneumonia (VAP), more ventilator-free days, and fewer ICU days [7]. However, the evidence suggests limited, if any, benefit on survival rates with early compared to later tracheostomy.

Despite the marked heterogeneity across trials, there are populations who benefit from early tracheostomy (e.g., selected patients with burns, trauma, or stroke), and there are also populations who are well-served by attempts at extubation without increasing length of ICU stay or duration of mechanical ventilation. Several mechanisms may account for this benefit from early tracheostomy. Tracheostomy reduces the cumulative sedation dose administered [8] and allows for earlier rehabilitation and physical therapy, thereby reducing the likelihood of venous thromboembolism and risk for critical illness myopathy. Early tracheostomy also allows for earlier walking, talking and eating [9]. Earlier extubation also reduces the risk of numerous airway complications that may arise from prolonged translaryngeal intubation, including laryngeal diastasis, scarring, tracheomalacia, and tracheal stenosis.

Nonetheless, an important caveat remains the heterogeneity found among trials. Studies vary in the patients recruited, definition of ‘early’ tracheostomy, and outcomes studied. Tracheostomy is performed for a variety of indications, and patients differ widely in their underlying disorders and morbidities. Furthermore, studies span multiple ICU settings: findings for stroke patients in the neuro-ICU may not generalize to patients with respiratory failure within the medical ICU. Randomized controlled trials conducted over several years may have confounders relating to evolving practices and protocols. The literature also reflects a wide range of disease severity. Finally, a critical knowledge gap remains on how to predict whether a patient will require prolonged mechanical ventilation.

13.3 What Does ‘Early’ Tracheostomy Really Mean?

Definitions of early tracheostomy range from <4 to 15 days [10, 11], and criteria are invariably time-delimited, rather than linked to physiological parameters or phase of illness. This observation reflects our limited mechanistic understanding of the

factors that determine weaning and course of illness. Studies that have found benefit with early tracheostomy have often reported reduced before-tracheostomy time or reduced weaning time only, not necessarily modifying the period spanning from onset of invasive mechanical ventilation to initiation of weaning [12, 13], thus making results difficult to compare depending on case-mix. To our knowledge, no trial has defined ‘early’ based on this more physiological concept, which is notable as weaning time may account for nearly 40% of total time on ventilator.

Some aspects of COVID-19 can substantially modify time on ventilator: first, time to tracheostomy may be delayed due to perceived risk for infection transmission to healthcare workers; second, the need for prone position during the early stage of the disease may delay tracheostomy; third, the surge conditions in overwhelmed units may modify bedside decisions over the course of successive pandemic waves; fourth, COVID-19 has a high prevalence of late complications (e.g., delirium, ICU-associated weakness, secondary nosocomial infections, etc.) prolonging the weaning time and posing difficulties in establishing when weaning attempts were initiated. Therefore, it has proven challenging to define the optimal early-timing for tracheostomy in the pre-COVID-19 era and even harder during the COVID-19 surges.

13.4 What Respiratory Parameters or Criteria Ensure It Is Safe to Perform a Tracheostomy?

Ensuring adequate pulmonary reserve was a key prerequisite for early tracheostomy prior to the COVID-19 era. A large randomized trial comparing early (after 6–8 days of endotracheal intubation) versus late (after 13–15 days of endotracheal intubation) tracheostomy, in which 46% of patients had primary respiratory failure, excluded patients from having a tracheostomy if they had recovered lung function up to a $\text{PaO}_2 > 60$ mmHg with a $\text{FiO}_2 < 50\%$ and a positive end-expiratory pressure (PEEP) < 8 cmH_2O [11]. The reason for this exclusion was to reduce the number of unnecessary tracheostomies. Using these criteria, 28.3% of enrolled patients did not receive a tracheostomy because they were close to fulfilling weaning criteria before day 15 (21.3% before day 11). Abe et al. [14] reported a 12.9% rate of tracheostomy after a median time of 14 days in a large population of patients with acute respiratory distress syndrome (ARDS), with a median $\text{PaO}_2/\text{FiO}_2$ ratio of 156 with a median PEEP of 8 cmH_2O at ARDS onset. Moreover, in a randomized clinical trial comparing early (within 4 days) versus late (after 10 days) tracheostomy, Young et al. [10] included patients for tracheostomy if they had been receiving mechanical ventilation for less than 4 days and were expected by the attending physician to need mechanical ventilation for at least 7 more days, with no pre-specified ventilator setting limitation. This led to the exclusion from statistical analysis after randomization of 53.7% of the patients in the late tracheostomy group because they did not meet the attending physician criteria.

After the COVID-19 pandemic started in 2020, respiratory safety criteria for performing a tracheostomy changed, mainly because the overriding concern was to

reduce unnecessary tracheostomies but to protect healthcare workers and unstable patients. Bier-Laning et al. [15] found, in their state-of-the-art review, 14 different protocols listing unstable respiratory status criteria contraindicating tracheostomy. Late tracheostomy is not usually limited by unstable respiratory conditions, but safety protocols for early tracheostomy demonstrate a wide range of criteria, from an apnea test [16] to definitions of very high ventilatory requirements (e.g., $\text{FiO}_2 > 60\text{--}70\%$ and/or $\text{PEEP} > 12 \text{ cmH}_2\text{O}$) [17, 18].

There are several reasons for these pre- and post-COVID-19 differences. First, pre-COVID-19 randomized trials on this topic recruited patients in whom the tracheostomy was performed for indications other than primary respiratory failure. Such studies had a low percentage of patients with ARDS, limiting comparisons with COVID-19 evidence for early tracheostomy [10, 11]. Second, prioritization of healthcare worker safety resulted in modifications to procedural recommendations (e.g., disconnecting patients from mechanical ventilation before opening the trachea or delaying reconnection through tracheal cannula after cuff is inflated). These modifications result in a longer apnea period, often with total depressurization of the tracheal tree, thus putting patients at risk for respiratory deterioration. Third, some expert panels recommended the open technique, probably resulting in longer procedure times. In light of these observations, it seems that very high ventilatory requirements did not limit early tracheostomies, and severe deterioration was not reported after early tracheostomies in many experienced centers [13, 19].

13.5 What Does Predicting Prolonged Mechanical Ventilation Really Mean?

Traditional models for predicting prolonged mechanical ventilation aim to estimate at the earliest time point on mechanical ventilation the likely duration the patient will remain on the ventilator, ranging from 1 day to 21 days [20]. In addition, only one study has prospectively validated a model capable of predicting patients needing mechanical ventilation for more than 14 days [21]. This model loses close to 20% of the patients when optimizing specificity at 100%.

As already mentioned, a large UK trial aimed at elucidating a possible benefit for early tracheostomy, assessed the attending physicians' ability 4 days after intubation to predict 7 additional days on the ventilator [10]. Others have randomized patients 3 days after endotracheal intubation, including those with persistent respiratory failure fulfilling gasometric criteria of moderate ARDS (PO_2/FiO_2 ratio < 120 with a $\text{FiO}_2 \geq 50\%$ and $\text{PEEP} \geq 8 \text{ cmH}_2\text{O}$) [11]. Importantly, this trial excluded patients with a respiratory infection mainly because of the increased difficulty in accurate prediction in these cases. Under these conditions, those trials lost 48.4% [10] and 18.6% [11] of the randomized patients because of clinical improvement.

In the case of COVID-19 patients, guidelines recommend performing a tracheostomy when the expected total duration of mechanical ventilation is greater than 10 days [16]. The median duration of mechanical ventilation in COVID-19 patients has been reported according to the severity of ARDS at onset, ranging from 12 (6–18)

days in mild ARDS to 14 (10–19) days in severe cases, with tracheostomy rates ranging from 10% to 7% respectively [22]. Anticipating the clinical course of patients remains challenging, although innovations continue to emerge, including those arising from machine learning in tracheostomy [23] and more broadly in critical care [24].

13.6 Why Has Prone Position Been Considered a Limitation For Early Tracheostomy?

Prone positioning has traditionally been considered a relative contraindication for tracheostomy because of an increased risk for cannula displacement or accidental decannulation [25]. Prone ventilation has been extensively used in ARDS patients with COVID-19 with up to 80% of patients receiving at least one session in severe cases [22]. Most guidelines have recommended 12–16 h per day sessions and the median number of sessions reported in many large cohort studies is 3–4 (2–6) [22, 26], similar to that described previously in non-COVID-19 patients [27]. This observation means that around 25% of patients are definitively turned supine by day 3 after intubation and around 75% of patients who need prone positioning finish this therapy before the first week on mechanical ventilation. Some studies on tracheostomy in COVID-19 patients have reported pronation rates up to 80% within the first 14 days [13]. Although some COVID-19 patients require prolonged prone position therapy, it seems that most can safely receive a tracheostomy within the first 14 days after intubation without the need to modify postural therapies.

13.7 What Is the Real Risk for Healthcare Workers Performing Tracheostomies During the COVID-19 Pandemic?

Tran et al. [28] performed a systematic review of the risk of transmission of acute respiratory infections to healthcare workers during aerosol-generating procedures during the 2003 severe acute respiratory syndrome (SARS) pandemic, reporting an increased risk for tracheostomy (odds ratio 4.2 [1.5–11.5]). Notably, only one case-control study was included [29]. Moreover, tracheostomy was not independently related to the risk of infection transmission when the multivariable analysis included a logistic regression. Comparable data have not been published for COVID-19. The observational studies on tracheostomy during the COVID-19 pandemic have shown no infection or rates of infection no higher than the base rate for individuals involved in non-aerosol generating procedures. Most tracheostomies have been performed in a scheduled fashion, with minimal emergent techniques. The data on rates of healthcare worker infections associated with tracheostomies have largely demonstrated limited or absent viral transmission; however, many reports are anecdotal case series. Another limitation is that in cohorts with tracheostomy performed by proceduralists, viral transmission in the broader team was not reported.

Even when infection occurs in healthcare professionals involved in performing tracheostomy, the source of infection is often unclear, as evident in the study by Rosano and colleagues, who collected data on severe acute respiratory coronavirus 2 (SARS-CoV-2) infection in ICU nurses and physicians involved in 121 percutaneous tracheostomies and compared it to the prevalence of SARS-CoV-2 infection in ICU healthcare professionals not participating in tracheostomies. The 7.7% prevalence of infection in doctors and nurses performing tracheostomies was not significantly different from the 11.5% prevalence of infection in healthcare worker not involved in any tracheostomy procedure [30].

13.8 Post-tracheostomy Care

Most recent advances to accelerate weaning and decannulation in patients with a tracheostomy tube include aerosol-generating protocol modifications (e.g., disconnection from mechanical ventilation, increasing effective airway diameter including cuff deflation, use of tracheal high flow therapy) [31–33]. During the COVID-19 pandemic, perceived risk for healthcare workers took precedence, and guidelines on COVID-19 management have recommended against cuff deflation during the pandemic to protect healthcare workers [16–18]. We can interpret this information in two different ways: on the one hand, the risk for healthcare workers remains a challenge, and on the other hand, it can be assumed that the risk for infection transmission has declined by the time patients with a tracheostomy tube can be considered for disconnection from mechanical ventilation. Performing a tracheostomy in a COVID-19 patient has been delayed to a median time of about 19–20 days since symptom onset [16], and the first weaning attempts are delayed to about 28–30 days [13], thus likely increasing safety for healthcare workers.

Another important aspect of post-tracheostomy care is related to the expected probability of meaningful recovery. Many healthcare systems manage these patients in step-down units or long-term care centers, aiming to improve the quality of life of the patients with little hope of a full recovery [31]. However, recent advances in centers managing patients with a tracheostomy tube in high-dependency units report higher expectations for final decannulation when more aggressive protocols are applied [33].

Jubran et al. [31] reported several important results: first, close to 30% of patients with a tracheostomy tube were transferred to a chronic center without previous clear effort to advance in the disconnection process; second, it was not possible to wean 22.5% of a general population of tracheostomized patients under these conditions; third, patients with a limited pulmonary reserve detected by delayed failure after first disconnection were more prone to respond to aerosol-generating protocols. Hernandez et al. [33] found that reducing the effective airway diameter not only during weaning but also during the decannulation period reduced successful progression to final decannulation, as a prolonged capping trial seems to impose a

limitation for secretion management, even increasing the probability of delayed weaning failure.

These recent advances in the management of patients with a tracheostomy tube include some aspects that must be taken into account [32]. A more proactive approach to early detection and treatment of the limiting factors for decannulation involves pre-emptive diagnostic testing. Both airway patency problems and risk of aspiration should be detected not after weaning but at its beginning, as clinically significant stenosis (secondary to inflammation due to the prolonged presence of the artificial airway or directly because the tracheal cannula reduces the effective airway diameter) calls for specific treatment or a down-sized tracheal cannula and severe risk for aspiration precludes some measures facilitating the weaning process (e.g., deflating the tracheal cuff).

Diagnostic testing for impaired swallowing can be performed using a clinical test (e.g., deglutition test or FEES [fiberoptic endoscopic evaluation of swallow]), allowing for detection of severe cases of swallowing dysfunction. Mild and moderate swallowing dysfunction limit progression to oral intake, but do not delay progression to weaning and decannulation. Endoscopic procedures can confirm and specifically diagnose anatomical injuries needing direct attention by Head and Neck surgical teams. In addition, deflating the cuff has been associated with an improved recovery of swallowing function [32]. Although this result is hypothesis-generating and must be confirmed, reduced vertical movement of the trachea while swallowing with the cuff inflated could explain, at least in part, the frequent swallowing dysfunction observed in patients with a tracheostomy tube. Early restoration of trans-laryngeal airflow promotes laryngeal rehabilitation, coughing, swallowing and of course vocalization—all of which can have a positive physical and psychological benefit in those recovering from prolonged critical illness.

Conditioning the gases inhaled directly through the trachea helps accelerate both weaning and decannulation [32, 33] by improving secretion management and reducing the respiratory infection rate. Surprisingly, deflating the cuff significantly reduced the respiratory infection rate during weaning when combined with tracheal high flow. Although explanations for these results remain speculative, high flow seems to facilitate avoiding micro-aspirations around the cannula. This result was confirmed in a second study during the decannulation process [33].

These modifications taken together can increase the weaning and decannulation success rate by up to 93% and 95%, respectively [32, 33]. The subgroup of patients with a tracheostomy tube in which these aggressive protocols are limited are those with low level of consciousness, mainly because of a high risk of aspiration. Although level of consciousness is frequently recovered later in the course of the ICU or hospital admission, these patients are usually analyzed in specific studies and excluded from general trials because the time for recovery is difficult to predict and the time sensitive analysis of the trials could report spurious results depending on the case-mix. However, after these patients recover a good level of consciousness, the protocols could be applied without modification.

13.9 What Are the Implications of Tracheostomy for COVID-19 Survivorship?

Advances in critical care medicine are to be credited for the many survivors of severe COVID-19 (Table 13.1). Among such advances are the benefits of use of small tidal volumes, prone ventilation, conservative fluid management, lung protective ventilation, and other principles of the Surviving Sepsis Campaign guidelines for management of critically ill patients with COVID-19 [34]. However, despite this success, approximately 80% of patients surviving critical illness after mechanical ventilation in the ICU will experience physical, cognitive and/or mental health impairments, which are recognized as the post-intensive care syndrome (PICS).

Timely tracheostomy, when indicated, may shorten the duration of ICU stay and thereby potentially reduce the impairments associated with PICS [35]. For some aspects of survivorship after critical illness, a longer duration of critical illness is associated with greater impairment. Patients' survivorship experience reflects the complex interplay of critical illness and the iatrogenic effects of aggressive treatment. For example, the cumulative effects of sedation and restraints on the neuromuscular system, cognition, and overall rehabilitation are sometimes under-recognized. These are summarized in Figure 1. Temporary or permanent effects of translaryngeal intubation on dyphonia, dysphagia, and airway patency may not be recognized until long after the acute phase of illness and are increasingly documented in patients with COVID-19 [36]. Other physical impairments after critical illness may include joint contractures and critical illness-associated neuropathy or myopathy.

Table 13.1 Core principles for modernizing tracheostomy care

Principle	Practical implementation
Overarching drivers for improved tracheostomy care	<ul style="list-style-type: none"> • Multidisciplinary care and rounds • Engagement of patient and family members • Standardized protocols • Broad-based staff education • Data collection and analysis (e.g., globaltrach.org)
Critical care best practices	Instituting evidence-based use of prone ventilation, conservative fluid management, lung protective ventilation, pre-tracheostomy oxygenation
Assessing readiness for tracheostomy (COVID-19 era)	Initial assessment by day 10 of invasive ventilation. Patient should demonstrate clinical improvement; apnea test can verify pulmonary reserve
Best practices for technique and postoperative care	Appropriate personal protective equipment (PPE) and coordinated postoperative care including multidisciplinary collaboration with defined protocols, education, and data tracking
Enhanced decannulation protocols	High-flow oxygen with suctioning to accelerate tracheostomy decannulation
Early rehabilitation and transition from ICU	Interprofessional collaboration for comprehensive rehabilitation across specialties to help survivors of COVID-19 attain full and meaningful lives

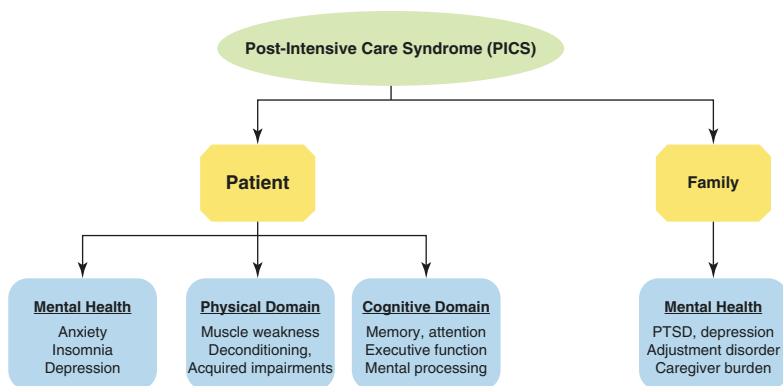


Fig. 13.1 Post-intensive care syndrome (PICS) affects patients and family members, affecting mental health, physical, and cognitive domains. From [35] with permission

Modernizing tracheostomy care can serve as a catalyst for improving efficiencies in resource utilization and enhancing survivorship outcomes. Evidence-based, multidisciplinary critical care plays a critical role in improving patients' long-term quality of life. Awareness of these survivorship considerations is important for all members of the healthcare team, including clinicians as well as patients and families, to maximize the likelihood of restoring fulfilling and meaningful lives (Figs. 13.1 and 13.2). Lack of coordination of care is a major factor in prolonged ICU stay and delayed decannulation. Patients may suffer persistent sleep impairment, pain, fatigue, and overall degraded health-related quality of life. Patients' loved ones have significant rates of mental health impairment.

13.10 Lessons from COVID-19

The COVID-19 pandemic has overwhelmed ICUs around the world, affecting not only healthcare workers, but also ICU capacity including ICU beds and ventilators. What mainly defines an ICU bed is the attending staff and the supplies and equipment required to manage a patient with endotracheal intubation, so the limiting factor for ICU equipment capacity in this context is availability of ventilators. Unfortunately, few measures can help optimize this capacity, including considering transport ventilators, operating room equipment, military supplies, long-term ventilators, veterinary ventilators, magnetic resonance imaging compatible ventilators, non-invasive ventilators, or even prolonged manual ventilation [37, 38]. These recommendations are based on best practice statements, except the recommendation against using one ventilator for multiple patients (strong recommendation with low quality evidence), that was based on animal or mechanical models [38].

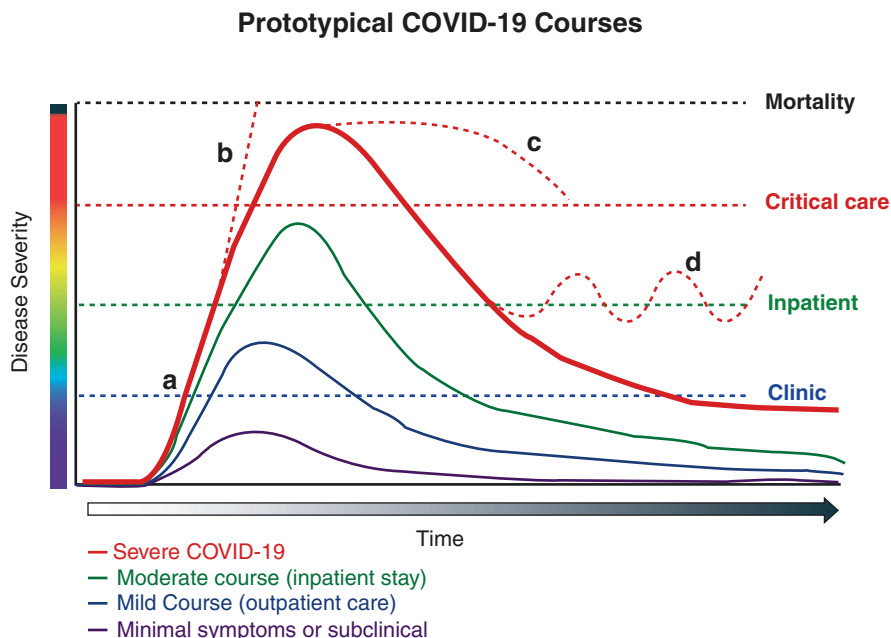


Fig. 13.2 Clinical courses of patients with COVID-19. **a.** Prototypical course of severe COVID-19, **b.** Progressive multiorgan failure; **c.** Protracted critical illness requiring extracorporeal membrane oxygenation (ECMO), **d.** Relapsing course requiring readmission. Other survivorship streams also depicted. Reproduced from [35] with permission

There is limited evidence for early timing of tracheostomy before the COVID-19 pandemic. There are many explanations for this paucity of evidence: first, the difficulty for physicians to predict prolonged mechanical ventilation and limited internal validity of randomized trials; second the great variability in definition of early tracheostomy, increasing the heterogeneity in meta-analyses, and the heterogeneous outcomes analyzed, with different results for duration of mechanical ventilation and ventilator-free days [2]. The reason for this disparity in results depending on the outcome analyzed could be the high mortality of patients needing prolonged mechanical ventilation, modifying the results when a failure-free days composite end-point is used instead of the duration of mechanical ventilation. A meta-analysis published in 2015 showed a significant increase in ventilator-free days with early tracheostomy (mean difference for ventilator-free days 2.12, 95% CI 0.94 to 3.30) [2], and others confirmed a reduced duration of mechanical ventilation with a trial-sequential analysis (mean difference -0.91, 95% CI -1.45 to -0.38) [5] in 2019. These results have been confirmed in a recent meta-analysis by Chorath et al. [7].

Specific data regarding COVID-19 patients is scarce, as performing a randomized trial is difficult under surge conditions. Some studies suggest a benefit for early tracheostomy in COVID-19 patients. Aviles-Jurado et al. [13] reported the

possibility of decreased use of ICU beds during the pandemic when tracheostomy is properly indicated early in the course of the disease. Possible reasons for this include the following: first, it is easier to predict prolonged mechanical ventilation in this population, second the high volume of patients with low heterogeneity facilitate the statistical analysis.

Recommended ventilator settings for safely performing an early tracheostomy during the COVID-19 pandemic are the following: PEEP <12 cmH₂O, FiO₂ <60%, respiratory rate <30 bpm, PaCO₂ <60 mmHg, and able to tolerate a period of apnea, but more relaxed approaches have shown good results. In their single center study, Aviles-Jurado et al. [13] performed tracheostomies within the first 8 days in patients with PEEP of 10 cmH₂O and PaO₂/FiO₂ about 200.

13.11 Conclusion

Despite important recent advances in tracheostomy and post-tracheostomy care, we have a long way to go before we can confidently answer important questions about the insertion and subsequent management of tracheostomy for the maximum benefit of our patients and for our healthcare systems. We have detected a slowing down in progression, but the window for improvement remains open. The COVID-19 pandemic has increased our understanding of many aspects of tracheostomy care, but our learning must go on.

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