Published in final edited form as:

Semin Respir Crit Care Med. 2015 December ; 36(6): 851–858. doi:10.1055/s-0035-1564872.

To Trach or not to Trach: Uncertainty in the Care of the Chronically Critically Ill

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Abstract

The number of chronically critically ill patients requiring prolonged mechanical ventilation and receiving a tracheostomy is steadily increasing. Early tracheostomy in patients requiring prolonged mechanical ventilation has been proposed to decrease duration of mechanical ventilation and ICU stay, reduce mortality, and improve patient comfort. However, these benefits have been difficult to demonstrate in clinical trials. So how does one determine the appropriate timing for tracheostomy placement in your patient? Here we review the potential benefits and consequences of tracheostomy, the available evidence for tracheostomy timing, communication surrounding the tracheostomy decision, and a patient-centered approach to tracheostomy. Patients requiring >10 days of mechanical ventilation who are expected to survive their hospitalization likely benefit from tracheostomy, but protocols involving routine early tracheostomy placement do not improve patient outcomes. However patients with neurologic injury, provided they have a good prognosis for meaningful recovery, may benefit from early tracheostomy. In chronically critically ill patients with poor prognosis, tracheostomy is unlikely to provide benefit and should only be pursued if it is consistent with the patient's values, goals and preferences. In this setting, communication with patients and surrogates regarding tracheostomy and prognosis becomes paramount. For the foreseeable future, decisions surrounding tracheostomy will remain relevant and challenging.

Keywords

Prolonged mechanical ventilation; tracheostomy; health outcomes; patient-centered outcomes; comparative effectiveness; chronic critical illness

Introduction

The number of patients requiring prolonged mechanical ventilation (PMV) after acute illness or injury is steadily increasing; by the year 2020, over 600,000 patients in the United States will require PMV.¹ PMV, the most common condition associated with chronic critical illness (CCI), consumes a high proportion of healthcare resources for hospitals and post-acute care facilities and is associated with high costs and emotional burdens for patients and families.^{2,3} Patients requiring PMV have a 50-60% mortality at 1 year.^{2,4,5} Given this information, a method of standardizing delivery of mechanical ventilation in order to minimize mortality, decrease duration of intensive care unit (ICU) and hospital stay, and improve patient comfort is attractive. Tracheostomy placement is one method that has been proposed to achieve these goals, and its use has been increasing over time.⁶ The suggested benefits of tracheostomy come with some risk and complications; it is likely not appropriate for all patients requiring PMV. In addition, for those patients in whom a tracheostomy is appropriate, an adequate guideline for the appropriate patient selection and timing of tracheostomy remains elusive.

One possible explanation for this difficulty lies in the differences among critically ill patients. While ICU practices are becoming increasingly standardized, ICU patients are becoming increasingly diverse. Many conditions treated in the ICU are not specific diseases, but “syndromes”, e.g. sepsis or acute respiratory distress syndrome (ARDS). Lumping distinct patients into loosely defined groups does not always clarify best practices or outcomes. Further research identifying distinct subtypes within syndromes of critical illness may lead to improved care and decision making over time.⁷ However, we must make patient care decisions now based on available evidence, clinical judgment, and patient preferences.

Here we will discuss the benefits and complications of tracheostomy, the available evidence surrounding timing of tracheostomy, communication surrounding the tracheostomy decision, and a view for the next five years.

Overview of Tracheostomy

Suggested benefits of tracheostomy include: improved patient comfort, easier oral care and suctioning, reduced need for sedation or analgesia, reduced accidental extubation, improved weaning from mechanical ventilation, easier facilitation of rehabilitation, earlier communication and oral nutrition, and facilitated transfer to lower level of care.^{8,9} There has never been a large, randomized trial confirming any of the commonly proposed benefits of tracheostomy. Patient comfort was evaluated in only one clinical trial of tracheostomy.¹⁰ Thirteen patients who underwent tracheostomy were asked to compare tracheostomy with translaryngeal intubation: all 13 preferred the tracheostomy. For the remainder of the proposed benefits, consensus remains the best available guide.

Tracheostomy placement is not without risks and consequences including: scarring, short-term patient discomfort from an invasive procedure, long-term airway injury and complications.^{8,9} Perhaps the largest problem with tracheostomy is that it may be unnecessary if the patient improves quickly. Thus the timing of tracheostomy remains a critical factor when considering placement.

Timing of Tracheostomy

Before Day 10 of Mechanical Ventilation

There have been over 20 randomized trials evaluating early versus late tracheostomy (see Table 1), and 8 systematic reviews, 5 in the last year.¹⁰⁻³¹ The clinical trials vary widely in methodology, definitions of early and late, and measured outcomes. Yet all systematic reviews to date have come to similar conclusions:

1. There is no demonstrated benefit of early tracheostomy on mortality;
2. There is minimal to no benefit on duration of mechanical ventilation or ICU length of stay;
3. There is minimal to no benefit on sedation use.^{11,17,18,20,21,32-34}

To date, only one single center randomized trial has demonstrated an improvement in mortality, with 31.7% mortality in the early tracheostomy group (4 days) compared to 61.7% mortality in the late tracheostomy group (14 days).²³ However, the >60% mortality in the control group is significantly higher than that seen in any other trial, suggesting a significant difference in how patients were selected for the trial.

The largest clinical trial to date, the TracMan Randomized Trial, enrolled nearly 1000 patients – almost the total of all other studies combined.³⁰ In the TracMan trial, patients were identified within 4 days of hospitalization, and were deemed eligible for the trial if the treating physician determined that they were likely to require at least 7 more days of mechanical ventilation. Eligible patients were then randomized either to receive a tracheostomy in the first 4 days (early) or to receive a tracheostomy after 10 days, but only if still necessary (late). There was no difference in mortality at 30 days (~31% in both groups). Perhaps most striking in the TracMan trial is the finding that less than half the patients randomized to late tracheostomy ultimately required a tracheostomy. This finding pervades all trials since the original 1976 study, where 80% of late patients did not require a tracheostomy.¹⁶ Clinicians struggle to accurately predict which patients will require PMV; perhaps this is the major factor impacting the effectiveness of a uniform early tracheostomy protocol for mechanically ventilated patients. Based on the available evidence, routine placement of tracheostomy prior to day 10 of mechanical ventilation is not indicated.

Specific Population Exceptions Supporting Early Tracheostomy

With that in mind, let us turn to specific populations where early tracheostomy may be beneficial. Patients with neurologic injury, e.g. stroke or traumatic brain injury, are a distinct subset of mechanically ventilated patients. Often the reason for PMV is related to poor mental status, inability to protect the airway, and related pulmonary complications.³⁵ Several observational studies suggest that there is a benefit in mortality and length of stay with early tracheostomy for neurologically injured patients, especially traumatic brain injured patients in trauma ICUs.³⁵⁻³⁸ These observational studies could be impacted by significant indication bias. Patients who are stable for early tracheostomy are more likely to survive. In a small randomized clinical trial enrolling stroke patients, placement of tracheostomy within 3 days compared to 7-14 days resulted in a reduction in ICU (10% vs.

47%) and 6-month (27% vs. 60%) mortality, as well as decreased sedation use.¹³ The potential benefits for this population seem to stem from easier pulmonary care and fewer pulmonary complications.³⁵ Pulmonary complications are associated with increased mortality in trauma and stroke; reducing their occurrence should reduce mortality.³⁹⁻⁴¹ Thus, patients with neurologic injury could benefit from early tracheostomy. Unfortunately, two clinical trials designed for this study population [clinical trials.gov # NCT00292097 and NCT01176214] were terminated early due to difficulty enrolling patients. Perhaps more important to these patients is the potential for neurologic recovery. If patients with neurologic injuries have a very poor prognosis for meaningful recovery, it is unlikely they would benefit from tracheostomy regardless of timing, and communication with the patient or their surrogate becomes paramount.

Day 10-21 of Mechanical Ventilation

After day 10 of mechanical ventilation, the situation becomes more complex. General consensus is that a tracheostomy should be placed after day 10 if the patient is likely to require more than a few additional days of ventilation.⁴² Yet by this point the patient is approaching the condition of chronic critical illness. Before initiating another invasive procedure, a consideration of the patient's prognosis and burden of discomfort should be undertaken relative to their values and wishes for prolonged invasive care.

Communication Surrounding Tracheostomy

The course of chronic critical illness is almost invariably long, and outcomes are usually poor, regardless of the venue of care. Yet, at the time of tracheostomy for failure to liberate from the ventilator in the ICU, most patients and families lack a meaningful understanding of what lies ahead.^{2,43,44} In particular, they may not know of the heavy burden of physical and psychological symptoms experienced by the chronically critically ill.⁴⁵ They are often unaware that, even if the patient survives the hospital and resumes breathing without mechanical ventilation, there is only a small chance of regaining functional independence.^{3,46,47} Or worse, that cognitive dysfunction affecting many patients during chronic critical illness can persist for months – or even permanently.^{46,48} Many patients and families are also unaware of alternatives to indefinite continuation of intensive care therapies, including limitation of life supports while preserving the patient's comfort.⁴⁴

To optimize communication, clinicians themselves need a clear understanding of the nature and typical course of chronic critical illness. Evidence suggests, however, that ICU physicians may fail to appreciate the gravity of this syndrome,² perhaps partly because chronically critically ill patients tend to be transferred out of ICUs to long term acute care hospitals or post-acute facilities.^{49,50} Subsequent complications and ultimate outcomes are rarely followed by the original ICU. In addition, clinicians may lack training and skills required to communicate about the complexities of critical illness in ways that laypeople can comprehend, absorb and integrate in their decision-making.⁵¹⁻⁵³ ICU physicians miss opportunities to address strong emotions, such that patients and families are unable to process prognostic information.⁵¹ Patients and families can carry forward long-term psychological distress including post-traumatic stress disorder, prolonged grief, and decisional regret.⁵⁴⁻⁵⁸ Although most surrogates of ICU patients accept that uncertainty

about prognosis is unavoidable and wish to discuss expected outcomes with clinicians even if unfavorable,^{59,60} many clinicians are reluctant to conduct discussions that they believe will heighten anxiety, diminish hope, or engender hostility.

Communication about chronic critical illness should begin before its onset and, ideally, as early as the initiation of mechanical ventilation (or even at decision-making about whether to initiate ventilation). As mortality from common types of acute critical illness continues to decrease while increasing evidence emerges about ICU survivors' impairments, it is important to approach patients and families from the outset. Clinicians should inform not only of the risk of death in the ICU, but also the chance the patient might survive this first phase but remain dependent on the ventilator and other intensive therapies for a prolonged period. These initial discussions allow a longer time for clinicians to “cultivate prognostic awareness” – i.e., the capacity to understand prognosis and the likely illness trajectory – and help patients and families prepare psychologically and practically for further developments.⁶¹ Integration of prognostic information is difficult after a single meeting; patients or families may be more able to make informed decisions through a sequence of iterative discussions that attend to emotions and develop a trusting relationship for shared decision-making.

A clinician's decision to recommend tracheostomy if intensive care will continue represents a crucial juncture that should not pass without full discussion of the potential burdens as well as potential benefits of such care.^{43,44} Although communication at this point is often limited to risks and benefits of the tracheostomy procedure, as required for informed consent, a broader discussion about chronic critical illness is necessary because consideration of tracheostomy in these circumstances reflects the clinical judgment that the patient will neither be liberated from the ventilator nor die in the near future – i.e., the patient is chronically critically ill.⁶² As the patient approaches two weeks on the ventilator with no expectation of weaning or dying within a few days, use of the ProVent model⁶³⁻⁶⁵ along with other evidence and judgment can assist clinicians to identify patients at particularly high risk of poor outcome as well as those for whom one-year survival and better functional recovery is likely. The ProVent score was developed to predict the 1-year mortality of patients receiving prolonged mechanical ventilation. Using 5 patient variables (Table 2) the clinician can obtain an accurate prognosis for their patient. For example, of two patients admitted for ARDS, now on day 14 of mechanical ventilation:

1. A 45 year-old trauma patient on no vasopressors, not requiring dialysis, and with a normal platelet count on day 14 has an expected mortality of only 5% at one year.
2. A 68 year-old patient with pneumonia requiring dialysis at day 14 has an expected mortality of 90% at one year.

Patient 1 is likely to benefit from tracheostomy placement to improve comfort and potentially ease the ventilator liberation process. Patient 2 *could* benefit, but only if continued invasive care in the setting of a poor prognosis was in accordance with their values and preferences.

As a first step in each meeting with patients/families, the clinician should elicit the present understanding of the patient's condition and of expectations for the future course.^{66,67} Asking whether they would like additional information can convey empathy and respect; it can also identify patients and families who may wish to defer discussion of prognosis.⁶⁶ When the patient or family is receptive, prior research has illuminated the type of information that is felt to be important and thus should be communicated by clinicians to support decision-making about continuation of intensive care therapies when critical illness becomes chronic (Table 3).^{43,44,68} ICU clinicians tend to dominate meetings with families, whereas families are more satisfied when the proportion of clinician speech is lower and the family has an opportunity to ask questions and express their concerns.⁶⁹ Thus, listening and exploring by clinicians are key strategies for effective communication, as are explicit expressions of empathy,⁷⁰ which can serve to moderate emotions, encourage patient and family participation, and establish a framework for decisions about the appropriate plan of care. Clinicians should provide reassurance that, whatever the decision, they will attend to the patient's comfort and continue supporting the family.⁷¹ To ensure that information shared by the clinician has actually been heard and understood, it is helpful to ask the patient or family for a summary of what was said.

Like all major decisions about treatment, decision-making about continuation of intensive care therapy into the chronic phase of critical illness should incorporate the patient's values, goals, and preferences.^{72,73} Patients in these circumstances usually lack decisional capacity,^{74,75} and may lack a specific advance directive,⁷⁴ but sensitive and skillful communication can elicit an understanding of the patient as a person, which provides the touchstone for treatment decisions. Since most older patients with multiple organ dysfunction fail to recover functional independence after becoming chronically critically ill, knowledge that the patient would consider permanent custodial care unacceptable is very significant in deciding whether to continue mechanical ventilation and other life supports after failure to wean in the ICU.^{76,77} Individual patients have varying, distinct, values and goals. Those goals, and not the specific treatments, should be the primary focus of discussion between clinicians and families.⁷³ Based on an understanding of goals and values, clinicians can collaborate with families to establish an appropriate and achievable plan of care.

Evidence indicates challenges as well as opportunities to improve communication about chronic critical illness. Optimally, communication in the ICU is an interprofessional effort that incorporates the input not only of physicians, but nurses, social work, chaplaincy, and others with valuable input as a team.^{78,79} Specialists in palliative care, who are specifically trained in skills for communication about serious illness, are available at an increasing number of institutions.⁸⁰ Results will soon be available from a clinical trial [clinical trials.gov # NCT01230099] comparing communication with families at the onset of chronic critical illness by a palliative care physician and nurse practitioner with usual care and communication by the ICU team. Families in both arms in this trial received a printed brochure about chronic critical illness that is available from the Society of Critical Care Medicine.^{68,81}

Five-year View

With the continued expected growth in the utilization of prolonged mechanical ventilation, the desire to find the best approach to managing these patients will likewise grow.¹ Yet the way we evaluate treatments in the ICU is likely to evolve over the next five years. How we describe outcomes in the intensive care unit is likely to move from simply “alive at X days” or “days free of mechanical ventilation” to outcomes that incorporate functional status and patient comfort as elements of quality of life and productivity. The sum total of the literature with regards to early tracheostomy has yielded an important answer: the day of mechanical ventilation on which you perform a tracheostomy has little impact on mortality in prolonged mechanical ventilation and minimal impact on healthcare resources. So in the next five years, we should move beyond just asking when to perform the tracheostomy, and focus more on “Should we perform a tracheostomy?”

There are several approaches to this question. First, like many clinical trials in critical care, early tracheostomy interventions have been tested in rather heterogeneous groups of patients, defined only by location in the hospital (ICU), or by a general process (mechanical ventilation). It is likely that the practice of early tracheostomy is more appropriate to some subgroups (e.g. traumatic brain injury patients needing an endotracheal tube only for prolonged airway protection), whereas other subgroups will present challenges due to difficulty in predicting duration of ventilation (e.g. ARDS). Future clinical trials focused on specific subgroups may be more informative.

Second, only one of the recent clinical trials evaluated patient comfort.¹⁰ Of the 13 respondents that experienced both endotracheal intubation and tracheostomy, all felt tracheostomy was more comfortable – none felt intubation was more comfortable! Based on this finding, given the option, patients may choose earlier tracheostomy in order to have improved comfort while undergoing mechanical ventilation. But even this stops short of other factors such as the impact of a tracheostomy on whether a patient can be discharged home rather than to a nursing home, or the emotional impact of a visible scar. A broader patient-centered question may be: “How many extra days of translaryngeal intubation would you accept in order to avoid a tracheostomy?” By involving patients' beliefs and values in the decision-making process, we move from practice driven by large trials in diverse patient populations to individualized medicine, and we evaluate patient centered outcomes that could have a more important impact than one or two extra days of mechanical ventilation.

Third, the 30 day and 1-year mortality for patients in the TracMan trial were high (31% and 47%, respectively), consistent with other studies of patients requiring PMV. Despite this high mortality rate, only 2 (0.4%) of the patients in the late tracheostomy group had life sustaining treatments withdrawn by day 10. Perhaps this is reflective of excluding patients from the trial if they were likely to die before needing a tracheostomy, but it could also reflect a reluctance to discuss prognosis in severely ill patients.^{2,82} In addition to developing better models for predicting the need for PMV, work should continue on refining objective models for determining prognosis in PMV, preferably incorporating functional outcomes in addition to mortality. Research is also continuing on improving the communication of these prognoses in the setting of shared decision-making in the ICU.

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Table 1

Characteristics and Results of Randomized Controlled Trials

	ICU Population	Day of Early Placement	Day of Late Placement	Number of patients	Primary endpoint	Benefit
Young 2013 ³⁰	General, Cardiothoracic	4	10	899	30-day mortality	No
Bösel 2013 ¹³	Neuro (stroke)	1-3	7-14	60	ICU LOS	No
Zheng 2012 ³¹	Surgical	3	15	119	Ventilator free days	Yes
Koch 2012 ¹⁹	Neuro, neurosurgical, surgical	4	6	100	Hospital mortality	No
Trouillet 2011 ²⁸	Cardiac surgical	5	19	216	Ventilator free days	No
Terragni 2010 ²⁷	General	6-8	13	419	VAP incidence	No
Blot 2008 ¹⁰	Medical, Surgical	4	Never/ 14*	123	28-day mortality	No
Barquist 2006 ¹²	Trauma	7	29	60	Duration of MV	No
Rumbak 2004 ²³	Medical	2	14-16	120	Pneumonia	No
Bouderka 2004 ¹⁴	Trauma	5-6	Never	62	Duration of MV	Yes
Saffle 2002 ²⁴	Burn	Next OR day	14	44	Duration of MV	No
Sugerman 1997 ²⁶	Trauma	3-5	10-14	112	ICU LOS	No
Rodriguez 1990 ²²	Surgical	7	8	106	Duration of MV	Yes
Dunham 1984 ¹⁵	Trauma	3-4	14	74	Laryngotracheal pathology	No
El-Naggar 1976 ¹⁶	General	3	10-11	52	Patient characteristics	No

* Study did not require late tracheostomy, but if placed had to be after day 14.

ICU = intensive care unit; LOS = length of stay; VAP = ventilator-associated pneumonia; MV = mechanical ventilation; OR = operating room;

Table 2
ProVent14 Score and Associated Mortality

Patient Characteristics	Points	Score	1-year Mortality % (95% CI)
Age 50-64	1	0	4 (0, 9)
Age 65	2	1	28 (19, 37)
Requiring hemodialysis	1	2	43 (35, 51)
Requiring vasopressors	1	3	61 (52, 70)
Platelet count 100	1	4-6	92 (84, 100)
Non-trauma	1		

Adapted from Hough CL, Caldwell ES, Cox EC et al. Development and Validation of a Mortality Prediction Model for Patients Receiving 14 Days of Mechanical Ventilation. *Crit Care Med.* 2015. In press.

Table 3
Topics and Strategies for Communication of Chronic Critical Illness

Relevant information for patients and families facing chronic critical illness^{2,43,68,82}	
Why the patient is dependent on mechanical ventilation	
How tracheostomy might affect ability to eat	
How tracheostomy might affect ability to speak	
Chances of liberation from mechanical ventilation	
Symptoms during continued treatment	
Complications that might develop	
Risk of death during hospitalization	
Expected functional status after hospitalization	
Expected cognitive status after hospitalization	
Risk of death at one year	
Potential dependence for daily activities/need for custodial care	
Strategies for emotional support and patient-focused decision-making^{66,67,69-71}	
Attentiveness to emotion	
Response to emotion with explicit empathy rather than medical information	
Exploration of patient values and goals	
Listening to patient/family questions and concerns	
Assurance of comfort and non-abandonment	