Should Tracheostomy Be Performed as Early as 72 Hours in Patients Requiring Prolonged Mechanical Ventilation?

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Advances in treating the critically ill have resulted in more patients requiring prolonged airway intubation and respiratory support. If intubation is projected to be longer than several weeks, tracheostomy is often recommended. Tracheostomy offers the potential benefits of improved patient comfort, the ability to communicate, opportunity for oral feeding, and easier, safer nursing care. In addition, less need for sedation and lower airway resistance (than through an endotracheal tube) may facilitate the weaning process and shorten intensive care unit and hospital stay. By preventing microaspiration of secretions, tracheostomy might reduce ventilator-associated pneumonia. There is controversy, however, over the optimal timing of the procedure. While there have been many randomized controlled trials on tracheostomy timing, most were insufficiently powered to detect important differences, and systematic reviews and meta-analyses are limited by the heterogeneity of the primary studies. Based on the available data, we think it is reasonable to perform early tracheostomy in all patients projected to require prolonged mechanical ventilation. Unfortunately, identifying those patients can be difficult, and for many patient populations we lack the necessary tools to predict prolonged ventilation. We propose an early-tracheostomy decision algorithm. *Key words: respiratory failure; tracheostomy; intubation; mechanical ventilation; weaning; critical care; timing*. [Respir Care 2010;55(1):76–83]

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Introduction

Advances and improvements in treating the critically ill have resulted in more patients requiring prolonged airway intubation and respiratory support. In the recent past it was generally recommended that if intubation is projected to be longer than several weeks, tracheostomy should be performed. The decision to perform a tracheostomy in a critically ill patient should be individualized to the patient and pathology, balancing the patient's wishes, expected recovery course, risk of continued translaryngeal intubation, and surgical risks. Tracheostomy offers several important benefits over continued translaryngeal intubation, including improved patient comfort, better oral hygiene, improved ability to communicate, opportunity for oral feeding, and easier, safer nursing care. Less need for sedation and analgesia[1] and lower airway resistance (than through an endotracheal tube) may facilitate the weaning process[2] and help avoid ventilator-associated pneumonia.

The primary reason to place a tracheostomy is to avoid the complications of prolonged translaryngeal intubation, which include dental damage, sinus obstruction, sinus infection, mouth injury, laryngeal trauma, cricoid cartilage damage, tracheal injury (from cuff and tube tip), and ventilator-associated pneumonia. Accidental extubation with airway loss and tube occlusion are additional risks of prolonged translaryngeal intubation. These latter, potentially lethal risks, are believed to be less likely with tracheostomy. The risks of continued translaryngeal intubation need to be balanced with the acute surgical risks of performing tracheostomy and its long-term complications. One of the serious problems of balancing the risks and benefits of tracheostomy is that all studies of tracheostomy outcomes include a variable period of translaryngeal intubation prior to tracheostomy. This makes it impossible to separate the risk contributions from the endotracheal tube versus the tracheostomy. The risks of translaryngeal intubation undoubtedly increase with duration of intubation, but the magnitude and speed of the risk increase are influenced by patient, disease process, and environmental factors. Thus, when to perform a tracheostomy is open to debate. Optimal timing (early vs late tracheostomy) remains controversial.

One difficulty in resolving the tracheostomy timing issue is that there is no uniformity in the literature about the definition of "early" tracheostomy. In the 1980s a tracheostomy was considered "early" if it was performed before 21 days of translaryngeal intubation.[3] But the timing of tracheostomy has changed over the last several years, and now many suggest tracheostomy within 2–10 days. This definition of "early" corresponds to that proposed by the otorhinolarygologists, who have always suggested tracheostomy within several days to prevent laryngeal injury from even these short periods of intubation.[4] Lack of common definitions for "early" and "late" tracheostomy makes comparison of published studies difficult. To frame the debate in this paper, we will define early tracheostomy as within 3–5 days of translaryngeal intubation, though the literature we discuss will include longer periods.

While there have been many randomized controlled trials (RCTs) on tracheostomy timing, most have been insufficiently powered to detect important differences. The meta-analyses have been limited by the different definitions of "early," inconsistent use of weaning protocols, different tracheostomy techniques, differences in blinding of clinicians to group assignment, and other important study differences. These issues make it difficult to come to a clear conclusion about tracheostomy timing.

Advantages of Tracheostomy

Table 1 lists potential advantages of tracheostomy over continued translaryngeal intubation. Patient comfort is important. In a follow-up study of patients who were randomized either to remain translaryngeally intubated for a prolonged period or to receive early tracheostomy, Blot and colleagues reported that oral comfort scores, feeling of mouth uncleanliness, perception of change in body image, feelings of safety, and overall comfort were lower in the prolonged-intubation group.[5] All 13 thirteen patients who survived to hospital discharge and were able to answer (6 in the early-tracheostomy group and 7 in the prolonged-intubation group) and who had undergone both translaryngeal intubation and tracheostomy reported tracheostomy as the more comfortable airway. Improved patient comfort alone may be enough to justify early tracheostomy rather than continuing with translaryngeal intubation and eventually performing a tracheostomy.

Tracheostomy may allow for more rapid weaning from mechanical ventilation. In a prospective trial with 74 surgical/trauma patients who were unable to pass a spontaneous breathing trial after 72 hours of mechanical ventilation, the subjects were divided into 2 groups: continued translaryngeal intubation, and immediate tracheostomy prior to attempting weaning.[6] In both groups, weaning was carried out with the same protocol of gradual reduction in pressure support. There were 21 patients in the early-tracheostomy group and 54 in the continued-translaryngeal-intubation group, 25 of whom eventually underwent tracheostomy. Only early tracheostomy and the rapid shallow breathing index predicted more rapid weaning; in the early-tracheostomy group the odds ratio was 2.1 for being weaned in 3 days versus 6 days. Although mortality was different (0% in the early-tracheostomy group and 10% in the other group), that difference was not significant ($P = .15$).

Table 1. Potential Advantages of Translaryngeal Intubation Versus Tracheostomy

Translaryngeal Intubation	Tracheostomy
Ease and rapidity of initial placement of device	Safety of reinsertion after stomal maturation
Avoidance of acute surgical complications	Less skilled care environment
Bleeding	Earlier mobilization
Tracheal injury	Reduced laryngeal damage
Nerve injury	Laryngeal stenosis less likely
Barotrauma	Less voice damage
Low initial cost of device placement	Better oral hygiene
Lower resource use for placement	Better pulmonary secretion removal
Avoidance of late surgical complications	Less likely tube occlusion
Stoma infection	Better ability to communicate
Vascular erosion	Lip reading
Nerve injury	Speaking valve
Stomal stenosis	Less oral-structure injury (teeth, tongue, lips)
	Better patient comfort
	Less sedation needed
	Lower incidence of sinusitis
	Preservation of glottic competence
	Lower aspiration risk
	Less risk of ventilator-associated pneumonia
	Better swallowing function
	Earlier oral feeding
	More rapid weaning from mechanical ventilation
	Lower airway resistance to breathing
	Less dead space
	Lower work of breathing

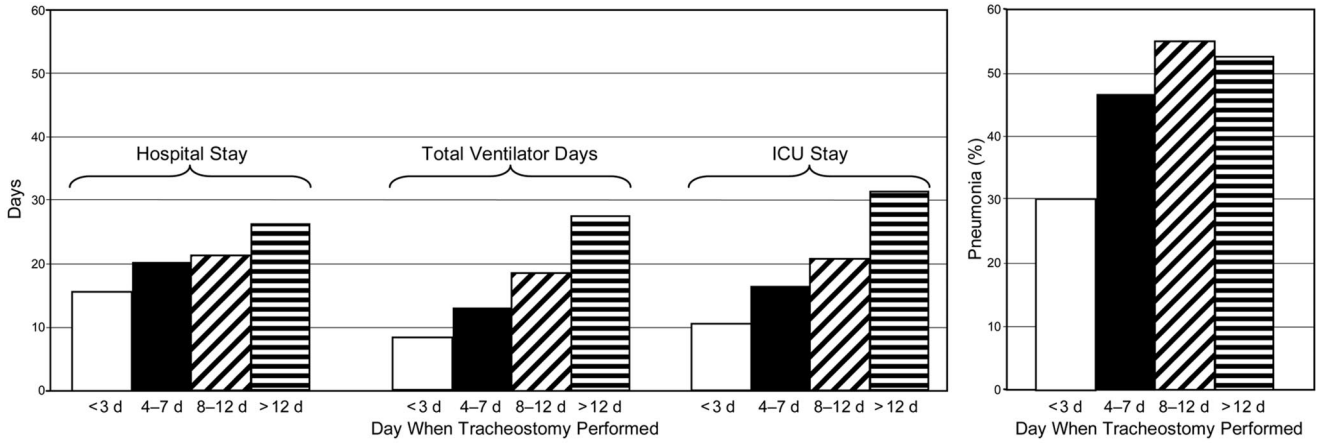

Fig. 1. Relationship between day when tracheostomy was performed and hospital stay, total days of ventilation, intensive care unit (ICU) stay, and frequency of pneumonia. (Adapted from Reference 7.)

Non-randomized Trials of Early Versus Late Tracheostomy

Some trials suggest better outcomes with earlier tracheostomy in selected patients. In a review of a large trauma database, tracheostomy timing influenced duration of mechanical ventilation, hospital and intensive care unit (ICU) stay, and incidence of pneumonia.[7] The earlier the tracheostomy was performed, the greater the benefit (Fig 1), but mortality was not different with early tracheostomy. Interestingly, mortality was higher with earlier tracheostomy in those patients predicted unlikely to survive. This is probably due to clinician bias in providing tracheostomy early to the sickest patients, most commonly in conjunction with emergency exploratory surgery.

Flaatten and colleagues reported prolonged translaryngeal intubation and tracheostomy experience in a single Norwegian ICU over a period of 5 years.[8] They found better survival up to 1 year and better severity-of-illness-corrected mortality in patients who received tracheostomy, but there were differences in subject demographics, and this was not a prospective trial. Flaatten et al also compared the 462 patients (equally divided) who received tracheostomy before versus after day 6. While the later-tracheostomy group had minimally higher Simplified Acute Physiology Score on admission (48.3 vs 44.4), the early-tracheostomy group was slightly older (55.1 y vs 51.9 y). Hospital mortality (22.2% vs 32.5%), 1-year mortality (33.9% vs 40.7%), and standardized mortality ratio (0.63 vs 0.78) were significantly better in the early-tracheostomy patients. Ventilator days, hospital and ICU stay, and costs were lower in the early-tracheostomy group.

A report from Morocco showed similar results. Aissaoui et al[9] described a retrospective clinical study in a 12-bed ICU in January 2001 to June 2005. All patients in respiratory failure who received a tracheostomy were divided into 2 groups: tracheostomy on or before day 7, and tracheostomy after day 7. During the 4-year study period, 112 patients underwent tracheostomy, and 62 had tracheostomy before day 7. Earlier tracheostomy was associated with a significantly shorter period of sedation (10 ± 3 d vs 17 ± 5 d, $P < .001$), shorter mechanical ventilation (21 ± 19 d vs 29 ± 17 d, $P = .02$) and shorter ICU stay (33 ± 22 d vs 42 ± 18 d, $P = .042$). Several nonsignificant trends also favored early tracheostomy: pneumonia rate (21% vs 31%, $P = .13$), successful weaning (50% vs 36%, $P = .19$), and mortality (38% vs 54%, $P = .15$).

Do the Randomized Trials Support Early Tracheostomy?

Bouderka et al prospectively randomized 62 patients with severe head injury and Glasgow coma scores of ≤ 8 to early tracheostomy (5th or 6th day of admission, $n = 31$) or prolonged endotracheal intubation ($n = 31$).[10] They found shorter mechanical ventilation, by 3 days, with early tracheostomy. There was no difference in pneumonia or mortality. The control group continued endotracheal intubation for a mean ± SD 17.5 ± 10.6 d. With current practices some of those patients would be expected to receive a tracheostomy within 10–14 days. But Bouderka et al did not describe their weaning methods, which raises concern about the validity of their finding of shorter mechanical ventilation with early tracheostomy. It is certainly possible that the providers were more aggressive in their weaning attempts once a tracheostomy was performed.

Rodriguez et al[11] prospectively randomized 106 surgical ICU patients to early tracheostomy (within 7 days of admission, $n = 51$) or late tracheostomy (> 7 days after admission, $n = 55$). Although early tracheostomy was defined as within 7 days, all the patients assigned to this group received tracheostomy on or before the fifth day of admission. The participants were not critically ill (average Acute Physiology and Chronic Health Evaluation II score 10), and included trauma and non-trauma patients. Early tracheostomy was associated with shorter ICU stay, hospital stay, and mechanical ventilation. But Rodriguez et al used quasi-randomization, did not describe their methods for ventilator liberation, and excluded from analysis many patients randomized to late tracheostomy who were extubated prior to requiring the procedure, which would bias the results toward the early-tracheostomy group.

Sugerman et al[12] prospectively randomized 127 patients to either early tracheostomy (day 3–5 of admission) or prolonged intubation. The participants included a mix of patients, including head trauma, multiple trauma, and non-injured surgical patients. There was no difference in the risk of death, pneumonia, or ICU stay. The study had important limitations, including incomplete data for all randomized patients, quasi-randomization, and significant physician bias toward patient enrollment.

Rumbak et al[13] prospectively studied 120 medical patients in the ICU. These patients were critically ill and had Acute Physiology and Chronic Health Evaluation II scores > 25, approximately 50% had chronic obstructive pulmonary disease, and the majority were on high-dose vasopressors. They were randomized to either early tracheostomy (within 2 d of admission, $n = 60$) or late tracheostomy (day 14–16 of admission, $n = 60$). The projected need for prolonged intubation was indicated as a specific inclusion criteria, but Rumbak et al did not describe the method by which these patients were identified. Early tracheostomy was associated with lower mortality, less pneumonia, and shorter time in the ICU and on mechanical ventilation. The generalizability of this study is limited by the inclusion of only a very specific group of severely ill medical patients.

Saffle et al[14] performed a prospective randomized trial of early tracheostomy in 44 burn patients. The timing of early tracheostomy was not specifically defined, but tracheostomy occurred at a mean of 4 days after burn injury, and the control group received prolonged intubation, then tracheostomy, at a mean of 14.8 days. They used a previously validated prediction equation to predict which patients would require prolonged mechanical ventilation. There were no differences in survival, pneumonia, duration of ventilation, or ICU stay.

Blot et al[5] recently conducted a well designed RCT with 123 severely ill medical, surgical, and trauma ICU patients, comparing early tracheostomy (within 4 days of intubation, $n = 61$) to prolonged intubation (tracheostomy after ≥ 14 days of endotracheal intubation, $n = 62$). This trial was closed early, due to difficulties with enrollment, because providers were hesitant to follow the study pro-

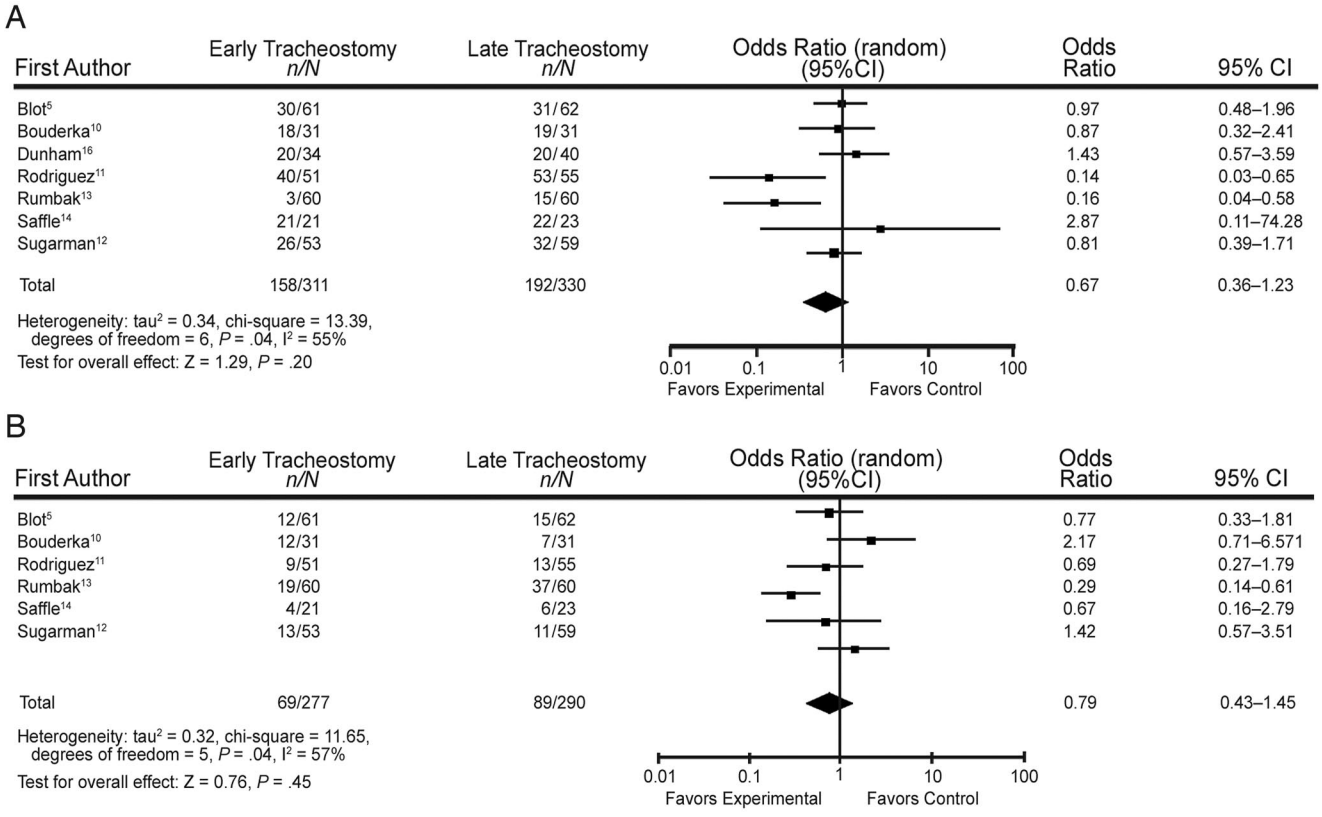

Fig. 2. Meta-analysis of all the included studies of early versus late tracheostomy. A: Pneumonia rate. B: Mortality.

tocol and had difficulty predicting the need for prolonged intubation. The study was underpowered to detect differences in predefined outcomes. However, the study did suggest better patient comfort with early tracheostomy.

What Do the Meta-analyses Suggest?

Griffiths et al[15] meta-analyzed 5 trials,[10,11,13,14,16] in which the time to early tracheostomy ranged from zero to 7 days after initiation of mechanical ventilation or ICU admission, and the study participants included general trauma, head trauma, surgical, medical, and burn patients. Two of the trials used quasi-randomization techniques.[13,16] The meta-analysis found shorter mechanical ventilation and ICU stay, but no difference in mortality or pneumonia rates with early tracheostomy.

Dunham and Ransom[17] systemically reviewed and meta-analyzed trials of early tracheostomy in trauma patients and found no difference in mortality with early tracheostomy among retrospective studies and RCTs. Meta-analysis of the randomized prospective trials found no difference in pneumonia or mortality. In the studies reviewed there was a wide variation in time to early tracheostomy and duration of prolonged endotracheal intubation in the control arms, and several limitations in individual study design.

Maziak et al[18] systemically reviewed 3 RCTs and 2 retrospective reviews and were unable to make conclusions regarding outcomes with early tracheostomy. Similar to the other meta-analyses, there were important differences between the study populations and inclusion criteria, and the trials used flawed randomization techniques.

Does the Evidence Justify Early Tracheostomy?

Most of the RCTs of early tracheostomy have found no important benefits with early tracheostomy in patients who may require prolonged intubation. Rumbak et al[13] found improvements in meaningful outcomes, including mortality and pneumonia rates, but that trial was conducted on a very selected group of critically ill medical ICU patients, and they did not specify their method for predicting prolonged intubation. A few trials have found improvements in less important outcomes, such as duration of mechanical ventilation and ICU stay, but these studies had important design limitations and did not indicate or control their weaning methods. The meta-analyses by Griffiths et al[15] also suggested improvement in less important outcomes, but included trials with substantially different inclusion and exclusion criteria, definition of early tracheostomy, and variable study quality. These issues limit the external

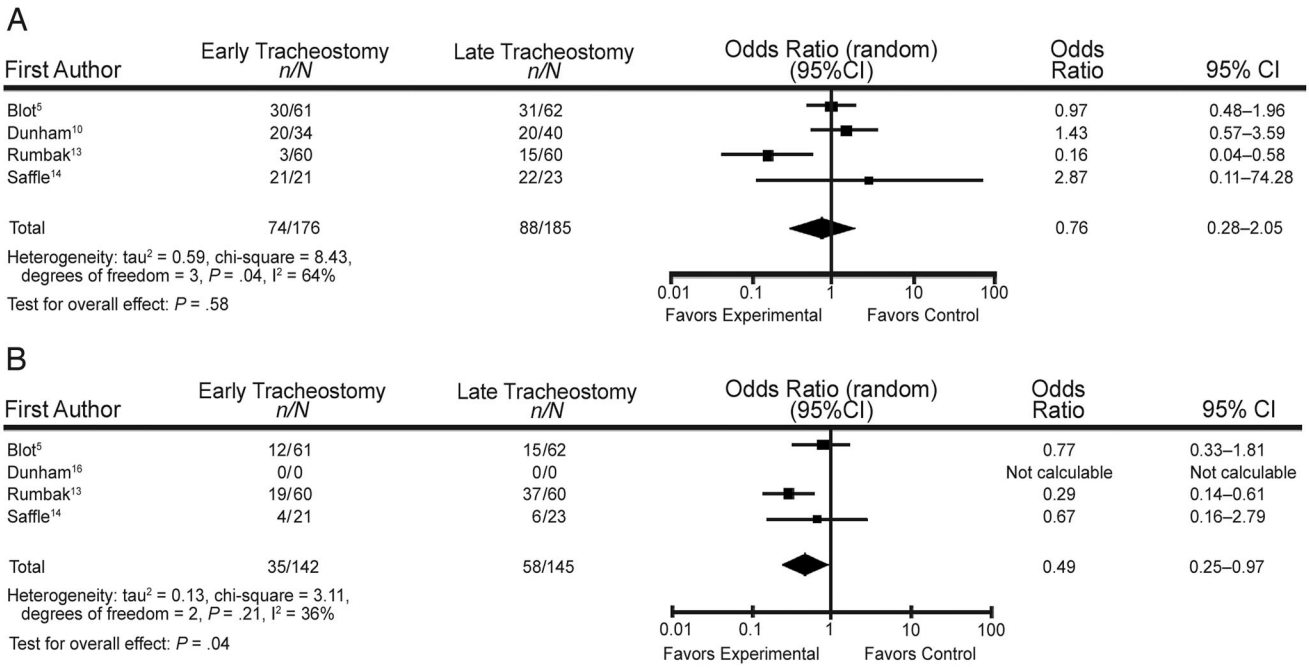

Fig. 3. Meta-analysis of only the high-quality studies of early versus late tracheostomy. A: Pneumonia rate. B: Mortality.

validity of those studies and make it difficult to apply them to a general ICU population.

Because of the limitations of the earlier reviews, we conducted our own meta-analysis of RCTs of early versus late tracheostomy or prolonged translaryngeal intubation. We performed an initial subgroup analysis and included only the trials that defined early tracheostomy as within 5 days from initiation of mechanical ventilation. We then narrowed that analysis further by including only studies of high-quality design. We felt these subgroup analyses would produce clinically useful data, because 5 days is sooner than might be expected in conventional practice and would reduce heterogeneity in the definition of early tracheostomy.

Our meta-analysis found the following results. Seven studies were identified,[5,10-14,17] which comprised 641 patients (311 patients in the early-tracheostomy arm and 330 patients in the late-tracheostomy or prolonged-translaryngeal-intubation arm). Six of these trials performed tracheostomy within 5 days. Two trials used quasi-randomization and had additional important design limitations. If we include all the studies, early tracheostomy did not significantly affect mortality (odds ratio [OR] 0.79, 95% confidence interval [CI] 0.3–1.45) or risk of pneumonia (OR 0.67, 95% CI 0.36–1.23) (Fig. 2).

When the analysis was restricted to the 5 studies in which tracheostomy was performed within 5 days, there was no difference in mortality (OR 0.66, 95% CI 0.37–1.17), risk of pneumonia (OR 0.62, 95% CI 0.3–1.3), or duration of mechanical ventilation (−7.32 d, 95% CI −15.3 to 0.65).

Restricting the analysis to trials of acceptable design with tracheostomy performed within 5 days, mortality was significantly lower (OR 0.49, 95% CI 0.25–0.97), but there was no effect on duration of mechanical ventilation (−3.13 d, 95% CI −11.74 to 5.47) or risk of pneumonia (OR 0.76, 95% CI 0.28–2.05) (Fig. 3). Only 3 trials evaluated ICU stay, and our analysis indicated significantly shorter ICU stay (−10.96 d, 95% CI −17.42 to −4.38) with early tracheostomy.

In our analysis we attempted to mitigate the differences in tracheostomy timing and study quality in the available literature. When we restricted the analysis to studies with true early tracheostomy (≤ 5 d) and high-quality designs, there was a statistically significant reduction in mortality. However, this finding should be interpreted with caution. The analysis included only 3 trials and was heavily influenced by the study by Rumbak et al,[13] whereas the other 2 trials found near equivalency in mortality risk. The Rumbak et al trial may not be generalizable because of its very narrow patient population. To conclude that early tracheostomy reduces mortality based primarily on that one study would be premature.

Our analysis also found shorter ICU stay with early tracheostomy. This also included data from only 3 trials, but each study favored or at least trended toward shorter ICU stay. However, 2 of these trials used quasi-randomization, which may limit the validity of this finding.

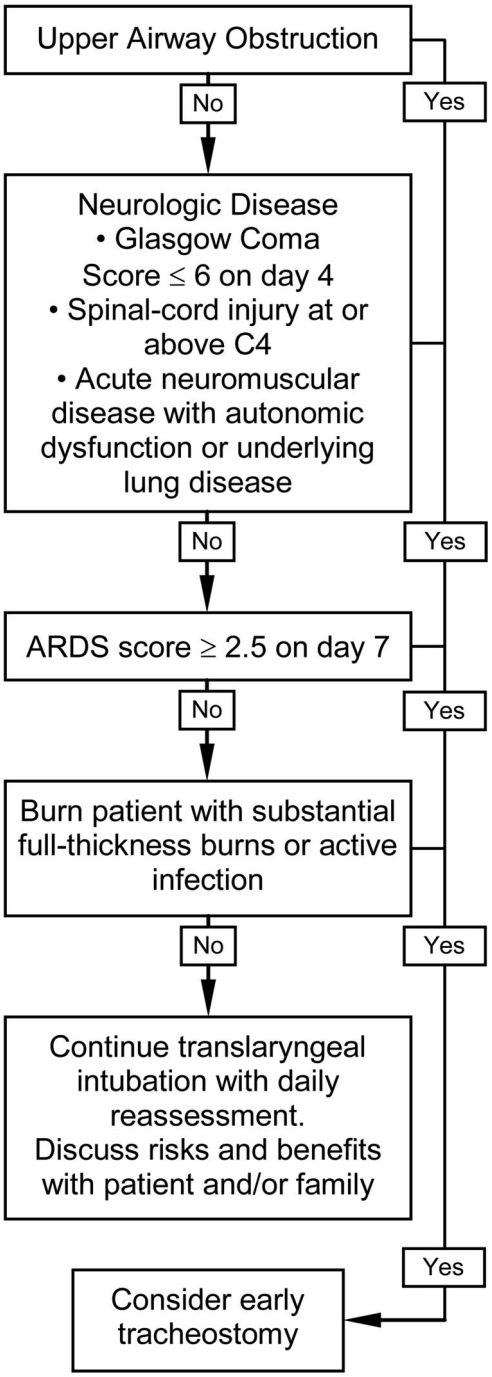

Fig. 4. Suggested tracheostomy algorithm. The acute respiratory distress syndrome (ARDS) score is based on data collected on day 4 and day 7 of ARDS, and includes ratio of arterial to alveolar P_{O_2}, required positive end-expiratory pressure, and chest radiograph progression.

One mechanism by which early tracheostomy could reduce ICU stay is by shortened duration of mechanical ventilation. Our meta-analysis did not indicate a statistically significant reduction in days of mechanical ventilation, although there was a trend toward this when all trials were included. The shorter ICU stay indicated by our meta-analysis may be affected by shorter mechanical ventilation, given the near significance of that difference. Alternatively, shorter stay may be due to earlier transfer out of the ICU while still on mechanical ventilation, as many institutions will accept tracheostomized patients, who require less intensive care than translaryngeally intubated patients. In the study by Rumbak et al,[13] in the early-tracheostomy group the mean duration of mechanical ventilation exceeded the mean ICU stay, whereas it did not in the late-tracheostomy group. The importance of this method for expedited ICU discharge is unknown. Our analysis does call into question prior meta-analyses' finding of shorter mechanical ventilation, because this trend is less near to significance if only high-quality trials are included, which suggests this previously reported outcome may be due to study design flaws.

Does Lack of Harm, Patient Comfort, or Cost Justify Early Tracheostomy?

One reason to consider early tracheostomy might be the fact that studies have not indicated harm, and some even suggest improved patient comfort and reduced need for sedatives. However, little is known about the longer-term risks and cost of early tracheostomy. To apply a uniform policy of early tracheostomy it is important to be able to predict which patients will require prolonged intubation, which remains challenging. Additionally, studies have used various (or not described) criteria when including patients predicted to require prolonged ventilation, so it is difficult to estimate the proportion of patients unnecessarily tracheostomized early or to use the literature to guide tracheostomy decision making. Patients unnecessarily tracheostomized might have an artificial airway longer than required and thus have higher risks and costs. Some data suggest lower ICU and hospital costs with early tracheostomy, but this is based on prospective cohort studies, which are subject to substantial bias. To date, no randomized controlled studies have examined longer-term costs. Few have evaluated longer-term risks, and these have produced limited findings. These uncertainties raise concern about viewing early tracheostomy as a non-inferior alternative to conventional prolonged endotracheal intubation, and about using improvements in less important short-term outcomes as justification for early tracheostomy.

Summary

The substantial heterogeneity and study design limitations of the available literature prohibit its application to all patients. Our meta-analysis attempted to control for these effects. Although it is influenced heavily by one

study, we did find lower overall mortality with early tracheostomy. In addition, no reports suggest worse outcome with early tracheostomy. Two fairly large RCTs have just been completed that are likely to confirm this finding.[19,20] Based on the current data, we think it is reasonable to perform early tracheostomy in all patients projected to require prolonged mechanical ventilation. Unfortunately, identifying these patients is difficult, and we lack the needed prediction tools for many patient populations. Patients with neuromuscular causes for respiratory failure, severe head injury, burn, or upper-airway obstruction are more easily identified as candidates for early tracheostomy.[21] Heffner et al[22,23] have proposed a scoring system to predict the likelihood of prolonged ventilation in patients with acute respiratory distress syndrome, which, if validated, may allow identification of patients who will benefit from early tracheostomy. Figure 4 shows our suggested algorithm for deciding when to perform tracheostomy in critically ill patients.

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Discussion

MacIntyre: In the meta-analysis figures you presented I was struck that the one that keeps driving it towards positive is the Rumbak et al trial,[1] which I think was one of the larger trials. Why was that trial so different and very positive, whereas the others were borderline at best? I thought it seemed like a pretty good trial.

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Durbin: I think that trial was with medical patients, who presumably had a higher incidence of chronic obstructive pulmonary disease, and used treatment protocols. Some of the reported results didn't show much improvement, and the trial was not used in several of the meta-analyses because of a lack of relevant outcome information.

Moores: Right, it didn't report all the outcomes.

Durbin: So there wasn't a lot of data to add in most categories. The one review in which it was included it probably contributed 30% of the patients, and that's why it seems to have such an impact. This study probably includes a more homogenous group of patients, so it makes sense that it would have a more predictable outcome.

Gay: What these studies seem to forget is that these are the most expensive patients in the hospital, and there haven't been very good cost/benefit analyses of them. These patients can be in the hospital for many days, and whether tracheostomy saves you anything needs to be much clearer.

Moores: That's an interesting point. When we finished this meta-analysis, we said, wow! Although we did it a little bit differently, and we thought we were more strict in our definitions, we came up with the same thing as Griffiths et al.[1] Then we thought that maybe one spin on this would be to look at cost-effectiveness and decision making. The tough thing is that when you try to do modeling and cost-effectiveness analyses, you need a difference in some outcome, and the only differences we see are in ICU stay and duration of ventilation, which may be important. We decided to hold off and include the data from the 2 new trials coming out, and then try to add cost into that.

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Gay: The 21-days rule came from the chronic ventilator project. You couldn't get a tracheostomy for a MediCare patient unless you waited 21 days to move them to one of these facilities. Part of this tracheostomy argument would be, can you get them out of the hospital quicker and get them to a rehabilitation area faster? Otherwise, all we're doing is generating huge expenses.

Hess: Have any of the trials looked at how many of these patients leave the hospital with a tracheostomy? When these patients get off the ventilator and probably don't need the tracheostomy anymore, there seems to be reluctance about just taking out the tracheostomy tube.

Gentile: Dean, we looked at 125 patients who went home with a tracheostomy and found that, unless they had some kind of spinal injury or head injury, for the most part the tracheostomy was removed if they weren't on a ventilator. So the tracheostomy was removed rather quickly. A lot of times we enrolled them and then shortly thereafter, or even before they left the hospital, they weaned and were off the tracheostomy.

Hess: I think it varies a lot from hospital to hospital. An observation we've made is that there's a reluctance to take out the tracheostomy tube. We have some survey data[1] that shows that, once you go to rehabilitation, the likelihood of getting decannulated really goes down.

1. Stelfox HT, Crimi C, Berra L, Noto A, Schmidt U, Bigatello LM, Hess D. Determinants of tracheostomy decannulation: an international survey. Crit Care 2008;12(1):R26.

Sessler: I would think that local practice patterns would influence it. For example, if you don't have a ventilator skilled nursing facility available, the costs don't matter as much if the patient is out of the ICU but remains in the hospital. If you have a readily available ventilator skilled nursing facility, then you have an exit plan that might influence the timing of tracheotomy.

The availability of percutaneous tracheotomy may play a role as well. I think the Rumbak study was with percutaneous tracheotomy, which are probably the majority of ICU tracheotomies nowadays. Easy availability might influence it because it's in our hands, we do it, and we don't have to wait for an operating-room date.

Moores: I agree. Current practice is all over the place, so I didn't focus on that. I just compared one to the other. But the reviews of practice patterns suggest they're affected by what's available. The people who do a lot more percutaneous tracheotomies are doing a lot more tracheotomies, and some of them earlier.

Epstein: Lisa, you pointed out that it's not possible to blind these studies. How many of these studies used rigorous protocols for weaning and sedation? I see a strong possibility of bias.

Moores: I agree, and I think not many of them describe it well enough, so there's a possibility of bias. When you look at the duration of mechanical ventilation, not only do we say the sedation comes off more quickly, but they also wean more quickly. Most of us are probably less afraid of weaning a patient with a tracheostomy more quickly. There's not much to lose if we disconnect them from the ventilator and they don't do well: we just put them back on. But extubation and having to re-intubate has a lot more risk.

How much of that goes into people's decision making and how much it affects how aggressive they are in the tracheostomy arm in getting them off the ventilator is impossible to discern. Only one trial described any set protocol. I didn't know whether the TracMan [Tracheostomy Management in Critical Care] trial[1] had a set weaning protocol. I think they did, but I didn't find it.

1. Tracheostomy management in critical care (TracMan). http://www.tracman.org.uk. *Accessed October 20, 2009.*

Durbin: In that trial the primary investigators had an agreed-upon plan, but the study included about 55 institutions, so it's unlikely that the weaning plan was rigorously applied.

MacIntyre: Maybe it's a false positive, but if it makes you do the right thing, then maybe it's OK.

Durbin: We don't have data to say that an early tracheotomy is a bad thing. I remember people saying that was true years ago when I talked about this. My perspective was, do we have data that suggests it's bad to do an early tracheotomy? Now, anybody who does tracheotomies knows that every once in a while you have a bad outcome and that can turn you off to doing tracheotomies, especially in a patient who only needed it for a week. But the published data does not suggest that bad outcomes are particularly common, and they certainly aren't as common as they were 20 years ago, and some of these data go back 20 years.

We're comparing apples and oranges; there've been huge changes in our practice in the past 15 years. Meta-analysis of all those studies that look for things such as sedation fail because there was no concern about sedation 15 years ago: we just did it. There was no understanding of how much that contributes to our process of weaning and extubation.

Epstein: I'm not sure that would force you to go faster. For example, you might make the argument that a tracheotomy might in some ways slow you down, because there are now a couple of studies that looked at patients who were transferred to long-term weaning units. One was an Italian study, by Vitacca et al.[1] The other one is Bigatello's study from the unit at Massachusetts General Hospital.[2] That study found that about 10%, and Vitacca's study found that about a third of patients who got to the unit were weaned from the ventilator within 24 to 48 hours.

That makes me think that as soon as the tracheostomy has been placed in the acute setting, people slow down and say, "they're going to get transferred, so they'll take care of it at the long-term acute care facility." So I wonder which way the bias would go?

1. Vitacca M, Vianello A, Colombo D, Clini E, Porta R, Bianchi L, et al. Comparison of 2 methods for weaning patients with chronic obstructive pulmonary disease requiring mechanical ventilation for more than 15 days. Am J Respir Crit Care Med 2001;64(2):225-230.
2. Bigatello LM, Stelfox HT, Berra L, Schmidt U, Gettings EM. Outcome of patients undergoing prolonged mechanical ventilation after critical illness. Crit Care Med 2007; 35(11):2491-2497.

Moores: I think it could go either way, but your point is valid: it's not measured. We don't know what's going on in that decision making process, and there weren't standard protocols for weaning in most of these studies. The duration of mechanical ventilation is important in several ways and affects cost, but I think it's much harder to interpret in this setting. I don't know what to do with them, so I'm focusing more on pneumonia and mortality.

Fessler: It seems that all these studies focus on the short-term costs and benefits of one approach or the other, but there are also long-term costs, such as the risk of tracheal stenosis, which may be more common, and the risk of injury to the vocal cords, which may be less common but is harder to repair. A complete analysis of costs and benefits has to follow patients longer and determine the true incidence and costs of those complications.

Siobal: In the trials where the goal was to enroll large numbers of patients, why did they stop early? Was it lack of enrollment? Was it that families wouldn't consent or the physicians didn't want their patients tracheotomized early or late, or they wanted to make those decisions themselves?

Moores: In the brain-injury trial it sounded like people had their own thoughts about doing early tracheotomies, so they didn't want to enroll their patients and possibly have them randomized into the delayed-tracheotomy arm. The TracMan report didn't say, or I didn't find it. The TracMan Web site shows their enrollments at each month. Each month they sent out flyers and gave this smiley-face award to the center that enrolled the most each month. It certainly looks like they did a good job of trying to meet their enrollment goals. The numbers were just not there, and they don't say why. Hopefully, when they release the data, they'll explain that problem.

MacIntyre: I suspect that it's like the CORTICUS [Corticosteroid Therapy of Septic Shock] trial.[1] People have prejudices about what they think is right. With percutaneous tracheotomies and reimbursement rates being what they are, I think people are just unwilling to enroll.

1. Sprung CL, Annane D, Keh D, Moreno R, Singer M, Freivogel K, et al; CORTICUS Study Group. Hydrocortisone therapy for patients with septic shock. N Engl J Med 2008;10;358(2):111-124.

Epstein: It seems to me we need a reliable way to predict who will require prolonged mechanical ventilation. We certainly don't want to do a tracheotomy on day 3 on a person who's going to be off the ventilator on day 5, or the person who's going to die on day 5 either, because that's just needless cost, pain, and suffering. Is anybody here confident that we have a good system for predicting prolonged mechanical ventilation? The exception is the patient with Guillain-Barré syndrome and rapid deterioration; we know that person's going to be on a ventilator for weeks.

MacIntyre: That was one of the things that impressed me about the Rumbak study. They seemed remarkably good because most of the group that got randomized to late tracheotomy ended up getting a tracheotomy. So their criteria seemed to work.

Epstein: I think there's a problem with that study. I don't have the data, but I'm not so sure about what you said.

Hess: No, I don't think Rumbak was like that at all.

Epstein: I don't think so either.

MacIntyre: No, most—the majority—of patients who got randomized to late tracheotomy, got tracheotomies.

Hess: But they got extubated in the first 7 days, as I recall.

Epstein: I think that was the problem. They had a very hard time accurately predicting.

Moores: Maybe that's a reasonable argument against it: to say that we can't even decide *who* first of all. There are some data from some populations that can help us, mostly neurologic patients and a small group of burn patients. Heffner and Zamora did some work[1] with patients with ARDS, but it was about 10 years ago and I haven't seen it used much or validated much beyond that original work, so I don't have tons of confidence in it.

After reviewing the literature on this, I think we are really no further along than when Heffner wrote the same thing 16 years ago.[2] You have to individualize it and do your best when predicting the likelihood of prolonged ventilation. Sometimes we'll be right; sometimes we won't.

1. Heffner JE, Zamora CA. Clinical predictors of prolonged translaryngeal intubation in patients with the adult respiratory distress syndrome. Chest 1990;97(2):447-452.
2. Heffner JE. Timing of tracheotomy in mechanically ventilated patients. Am Rev Respir Dis 1993;147(3):768-771.

Sessler: There were 2 criteria. One was a low Glasgow coma score, and the other was something like a very high APACHE [Acute Physiology and Chronic Health Evaluation] score plus a low P_{aO_2}/F_{IO_2}. I'm not sure how useful these are for predicting when early tracheotomy is attractive; I don't think they have been validated.

Fessler: Maybe the best predictor would be a tracheostomy scar.

Siobal: About percutaneous tracheotomies: if they were done at San Francisco General Hospital, a lot more tracheotomies would be done earlier. How many of your institutions do percutaneous tracheotomies at the bedside? Almost everybody.

Durbin: I think the review suggests that now we are further along, because now "early" tracheotomy means 3 or 4 days, not 7 to 14 days, because we're more comfortable with tracheotomy placement and removal than we were 15 years ago. That's probably good, but it has a down side, which is that we don't really know what the long-term problems might be.

We certainly haven't evaluated the economic impact of either doing or not doing tracheotomy. At my institution it's about getting patients out of the ICU quicker, which lets us get more people in, and that number has fallen—not because we have data that early tracheotomy is a good thing to do—but, instead, because we can get the next patient in, which has been a problem for the past 10 years.

Gentile: Tracheostomy is not usually done during the acute illness, unless it's a trauma or in the surgical ICU. While they're there they'll do a tracheotomy if they know the patient's going to be there a long time. It might be the patient who's sort of "smoldering" for a long time, versus one on higher ventilator settings, when you're just trying to see if they're going to survive. Do you agree? I wrote an editorial in 2004 that said a lot of what's being said here today, so I feel pretty smart right now.[1]

1. Gentile MA, Cheifetz IM. Optimal positive end-expiratory pressure: the search for the Holy Grail continues (editorial). Crit Care Med 2004;32(12):2553-2554.

Gay: Depending on what hat I'm wearing, there may be different goals. I may have a sole goal of getting them out of the ICU one week and then saying, "what are you doing to me?" the next week when I'm on the chronic ventilator side. The person who did the tracheotomy may have had little discussion about placement, and this is what on the other end of these long-term complicated patients is killing us financially. The outcome that's happening more often than I'd like to see is the patient who spends weeks or months getting weaned off, and then you read their obituary the following week, after they went home, or you must place them in a skilled facility far from their home and they decide to withdraw instead.

Sessler: For predicting who might be good early-tracheotomy candidates, in 1992 Johnson et al[1] used P_{aO_2}/F_{IO_2} less than 175 mm Hg and Glasgow coma score less than 9 at 48 hours, and reported a positive predictive value of 91% and a negative predictive value of 96%, but that was long ago. Rumbak's entry criteria included APACHE score $>$ 25, which means pretty darn sick patients, in terms of his randomization. Among those randomized to late tracheotomy, 10 of 60 were extubated by day 14.

1. Johnson SB, Kearney PA, Barker DE. Early criteria predictive of prolonged mechanical ventilation. J Trauma 1992 Jul;33(1):95-100.

MacIntyre: What happened to the other 50?

Sessler: I don't know.

MacIntyre: I think most of those got a tracheotomy.

Moores: Ten patients randomized to the delayed group did not receive tracheotomy; 2 of those 10 died before tracheotomy. The remaining 8 were extubated. So the rest got tracheotomy.

MacIntyre: So the majority *did* get tracheotomized. That was my point. Whatever he was doing, he seemed to be pretty good at predicting who was going to eventually get a tracheotomy. Maybe it's because he had a population with very high APACHE scores, who were quite ill. That may not be typical of what we see in general.

Photograph by David J Pierson