Impressive advances in the understanding and treatment of disease increasingly make it possible to bring patients back from the brink of death. Nowhere is this more obvious than in intensive care units (ICUs), where the focus is on preventing death of patients who previously had poor prognoses. This progress allows us to help patients survive, but it has also brought forth many questions. One such question concerns the optimal timing of tracheotomy in a patient who requires prolonged mechanical ventilation.

Although some studies have reported improved outcomes in patients who receive early tracheotomy (generally between the first 3 to 6 days of mechanical ventilation) compared with late (after about 2 weeks), others have found no difference between early and late timing of the procedure. In 2004, one group reported that early tracheotomy decreased mortality by 50% (1). Furthermore, the unconventional early timing of this intervention decreased duration of mechanical ventilation, length of ICU stay, incidence of pneumonia, and requirements for sedation (1). However, other studies, including the large multicenter TracMan (Tracheostomy Management in Critical Care) trial, have not been able to consistently reproduce all of these benefits (2–4). In this issue, Trouillet and colleagues (5) attempt to resolve the controversy surrounding optimal timing of tracheotomy in a randomized trial that studied patients who were likely to require prolonged mechanical ventilation after cardiac surgery.

This thoughtfully designed study represents a commendable effort to identify and address key questions in this debate. The researchers implemented a standardized, goal-directed sedation protocol using the Richmond Agitation Sedation Scale paired with daily awakenings (6, 7). They also implemented a mechanical ventilator weaning protocol and predefined strict criteria for ventilator-associated pneumonia. Furthermore, they conducted an a posteriori evaluation of long-term consequences, including quality-of-life and psychosocial evaluations. As such, they succeeded in taking a comprehensive approach to determining the net benefit of early tracheotomy.

Trouillet and colleagues found that early compared with late tracheotomy did not improve outcomes in their primary end point of ventilator-free days or in many of the secondary end points. Although some studies have shown the benefits of early tracheotomy in the past, findings in other studies parallel the authors’ findings. One group recently found that early tracheotomy (mean of 7 days after intubation) in a mixed medical–surgical critical care population resulted in fewer days on a ventilator and in the ICU but did not meet the primary end point of a lower incidence of pneumonia (4). Another group found no benefit to early tracheotomy, but their study was terminated early because of difficulty in recruitment, which they attributed to an inability to predict confidently which patients would require prolonged ventilation (3). The multicenter TracMan trial (2) is also expected to report similar results, although a peer-reviewed manuscript has not yet been published.

Despite their best efforts, Trouillet and colleagues did encounter an unanticipated obstacle and acknowledge that an unexpectedly high number of ventilator-free days in the control group (late tracheotomy) resulted in the study being underpowered for the primary end point. Potential factors contributing to the high number of ventilator-free days in the control group include a more standardized approach to sedation and liberation from the ventilator, but patient selection may have played a role as well. A recurrent flaw in almost all of the early versus late tracheotomy studies has been the failure to specifically state the criteria for determining if a patient is expected to require prolonged intubation.

In Trouillet and colleagues’ study, an inclusion criterion was a clinician’s expectation that the patients would require 7 days or more of mechanical ventilation. The authors cite previous work from their own group that studied factors associated with prolonged ventilation in this sample of patients, but they do not specify if these or other strict criteria were used for patient selection (8). Of interest, only 29% of patients required tracheotomy at day 15 or later. This is compared with a previous study in which 83% of the late tracheotomy group had the procedure at day 14, 15, or 16 (1). Perhaps the post–cardiac surgery population is more likely than others to require mechanical ventilation for only 1 to 2 weeks, even when prolonged intubation is required. It is also possible that clinicians have limited intuitions about the clinical course a patient will take (9). Until we can better characterize criteria that predict prolonged mechanical ventilation, it will be impossible to reach firm conclusions about the value of early tracheotomy or to generalize findings beyond the study setting.

Although this trial was largely unable to provide definitive answers about the primary and many of the secondary outcomes, it does offer several observations that warrant further discussion and investigation. First, it showed that sedation, analgesia, and antipsychotic medication needs are reduced in patients who have early versus late tracheotomy. Although less medication was not accompanied by significant changes in mechanical ventilation or duration of ICU and hospital stay, patients who received this intervention were able to transfer from bed to chair and eat by mouth sooner than control participants. A growing body of literature supports an early initiation of physical and occupational rehabilitation (10–12), and it would be interesting to examine whether early tracheotomy can facilitate an even earlier return to independence when paired with an aggressive mobilization protocol. Furthermore, with growing evidence supporting the relationship...
between ICU delirium and sedative administration (13), it would be interesting to know if the patients who had early tracheotomy had reduced delirium. The long-term physical and cognitive functional effects of early tracheotomy are another area worthy of further study (14). Of interest, only 1 patient in this study reported being embarrassed by the tracheotomy scar compared with 7% in a study of long-term outcomes for 109 survivors of the acute respiratory distress syndrome (15). This may reflect the use of a percutaneous dilatation technique in this protocol, which was found in a meta-analysis to have a lower likelihood to cause unfavorable scarring than open tracheotomy (16).

As standards for optimal management of the critically ill patient evolve, we must be careful to weigh the evidence for each intervention in light of the limitations of available evidence. Although there was initial enthusiasm in support of early tracheotomy to improve patient outcomes, repeated studies have been unable to reproduce such robust benefits. We do not know if this reflects that early tracheotomy truly does not improve outcomes, that other interventions (such as protocolized approaches to sedation and ventilator weaning) improve overall outcomes to a larger degree than early tracheotomy, or that our ability to predict a patient’s need for prolonged care is inadequate. Future studies must aim to elucidate characteristics of patients that predict who will require prolonged ventilation and enable appropriate patient selection in studies, such as that of Trouillet and colleagues (5), that aim to answer important questions. In the meantime, it is our opinion that the critical care community should temper enthusiasm for early tracheotomy.

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