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Early vs Late Tracheotomy in ICU Patients

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Endotracheal intubation is the most common procedure for airway control for patients requiring mechanical ventilation. Extubation is performed once patients have improved so that mechanical ventilation can be discontinued. For patients who require prolonged mechanical ventilation, replacement of the endotracheal tube with a tracheotomy is often considered. The most common reason for tracheotomy insertion in the intensive care unit (ICU) is to provide access for prolonged mechanical ventilation. From observational data, between 6% and 11% of mechanically ventilated patients receive a tracheotomy after a median of 9 to 12 days; however, there is significant variability around both patient selection and timing.1,3

Tracheotomy practice is variable in large part because what constitutes prolonged mechanical ventilation (ie, the optimal timing for tracheotomy) is not known.4 Defining and predicting the need for prolonged ventilation has been a major methodological challenge. Research on tracheotomy timing involves evaluating a 2-part study question. First, is it possible to prospectively identify patients who will require prolonged mechanical ventilation and could potentially benefit from tracheotomy? Second, does tracheotomy actually provide benefit for these patients? The key challenge is to avoid performing tracheotomy on patients who are close to extubation (ie, an unnecessary procedure) or who are not likely to survive (ie, a futile procedure), and instead find patients who might benefit.

The anticipated benefits of tracheotomy for patients undergoing prolonged ventilation include improved patient comfort due to reduced oropharyngeal and laryngeal stimulation (and possibly less damage to the larynx), which may in turn reduce sedation requirements and possibly delirium. These and other posited advantages, including improved pulmonary toilet and decreased resistance to breathing, might accelerate weaning from mechanical ventilation, decrease the risk of ventilator-associated pneumonia (VAP), and perhaps shorten the duration of mechanical ventilation. Thus, early tracheotomy in place of longer-term oral endotracheal intubation could conceivably lead to desirable downstream effects including shorter ICU and hospital stays, reduced costs, or even lower mortality. The problem with routinely performing tracheotomy early is that some patients who do not require tracheotomy undergo an unnecessary procedure. In addition, the presence of a tracheotomy may convey a sense of greater medical vulnerability and need, and could result in such patients being transferred to long-term care facilities, when this otherwise might have been avoided.1,2

In this issue of JAMA, Terragni and colleagues5 report the results of a trial of tracheotomy timing from 12 Italian ICUs in patients with ongoing severe respiratory failure 24 hours after intubation. Of 600 patients studied, 419 did not significantly improve or worsen according to standardized criteria evaluated 48 hours after enrollment. These patients were randomized to receive percutaneous tracheotomy after 6 to 8 days (early group) or after 13 to 15 days (late group) of laryngeal intubation. The primary endpoint was development of VAP; there was a statistically nonsignificant trend toward a reduction in VAP with early tracheotomy. However, even if this trend were real (and the trial was underpowered to confirm it), the clinical benefit would appear small; earlier tracheotomy was not associated with reductions in mortality (at 28 days or 1 year) or hospital length of stay.

Although it may be seen as largely negative, this study is important and has several strengths. It is the largest published trial to date to evaluate tracheotomy timing. Monitoring for VAP was standardized and assessed by blinded adjudicators in an effort to minimize ascertainment bias. Compared with previous trials, the algorithm used to predict which patients would require prolonged mechanical ventilation was explicit, stepwise, and reasonably accurate. This is important because the inability to predict which patients will require ongoing mechanical ventilation has led to the premature termination of some trials,6 whereas unclear patient selection processes have limited the generalizability of others.7 Even in the current trial by Terragni et al,3 many of the randomized patients (31% in the early group and 43% in the late group) did not undergo tracheotomy. The reasons they did not were evenly split between actual or impending extubation vs actual or impending death. This reinforces the point that a strategy of early tracheotomy is inevitably a strategy of more vs fewer tracheotomy procedures.

This trial supports the findings of previous studies and meta-analyses suggesting that earlier tracheotomy is unlikely to reduce mortality.8,9 Even though ventilator-free days
and ICU-free days (but not hospital stay) were both improved, these endpoints are difficult to interpret and are less important when mortality or overall costs are not reduced. Other researchers have shown that cost savings for reduced ICU length of stay are small, especially if hospital length of stay is unchanged.\textsuperscript{10} This trial also suggests that tracheotomy timing does not affect the use of long-term care, at least in the Italian health care system; similar numbers of patients in each group required long-term care after hospital discharge. This finding suggests that previous observations of increased long-term care use by patients who had undergone tracheotomy are more likely associations by indication, rather than causal.\textsuperscript{11}

However, the effects of tracheotomy timing on resource use in other health care systems, including the United States in which long-stay ICU patients are frequently transferred to dedicated weaning facilities, is unclear. In the United States, it is possible that the health care system may contribute to the use and timing of tracheotomy. For instance, patients who are ventilated for 96 hours and also have a tracheotomy, are assigned a high-paying diagnosis-related grouping (003 and 004, formerly 483).\textsuperscript{11} This raises the possibility that an unintended consequence of current compensation schemes may be to create an incentive for performing earlier tracheotomies (ie, on or around day 4 of mechanical ventilation). Given the documented differences in resource use across health care systems for other aspects of critical care,\textsuperscript{12} these and other questions related to tracheotomy use remain interesting topics for future research.

Early tracheotomy may be associated with other benefits, such as improved patient comfort, that were not measured by this trial. Clinical experience supports this contention, but objective data have been inconsistent.\textsuperscript{8,13} Thus, if the only remaining benefit of earlier tracheotomy might be improved patient comfort, but the procedure does not reduce VAP, hospital length of stay, or mortality, these factors need to be weighed against procedural risks and other disadvantages. In the trial by Terragni et al,\textsuperscript{5} 39% of patients had procedural complications, although these were mostly minor and none were fatal. However, there is a well recognized but infrequent incidence of serious complications from the procedure, including tracheoinnominate artery fistula, posterior tracheal perforation, and death.\textsuperscript{14,15}

Perhaps the most important finding from the study by Terragni et al\textsuperscript{5} is that despite best efforts to predict which patients will require prolonged mechanical ventilation, many patients were successfully managed without tracheotomy. This creates a compelling argument for waiting at least 2 weeks to be certain that a patient has an ongoing need for mechanical ventilation or assistance with pulmonary toilet before proceeding to tracheotomy. The recently completed but as yet unpublished TracMan trial,\textsuperscript{16} in which 900 patients were randomly assigned to tracheotomy within 4 days vs after 10 days, may provide additional information to guide clinical decision making; preliminary communications suggest the results will be congruent with those of Terragni et al.\textsuperscript{5} Future research might establish whether other patient groups would benefit from the procedure, such as patients with spinal cord injuries or head injuries who require little or no assistance from the mechanical ventilator yet still require airway protection or pulmonary toilet, or patients who have failed an attempt at primary extubation.

The study by Terragni et al\textsuperscript{5} in this issue of JAMA represents an important contribution to caring for mechanically ventilated patients. Their algorithm for predicting which patients will require prolonged mechanical ventilation is a step forward, and could be adopted into clinical practice to help with prognosis. The findings also serve as a reminder that in the complex arena of randomized controlled trials in the ICU, correctly defining the target population is equally important as ensuring other key markers of methodological quality. This trial should convince clinicians that routine early tracheotomy most likely will not lead to reduced VAP, shorter hospital stay, or lower mortality. Most importantly, it shows that performing tracheotomy for perceived weaning failure must be tempered by the knowledge that many patients will improve with additional time. Sometimes physicians just need to wait.

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REFERENCES