



critical care

The Timing of Tracheotomy*

A Systematic Review

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Study objective: To examine the impact of the timing of tracheotomy on the duration of mechanical ventilation, the secondary changes to the trachea, and the clinical course of critically ill patients in the ICU.

Design: A systematic review of the literature.

Methods: Two independent reviewers conducted a MEDLINE search for relevant literature in the form of randomized or observational controlled clinical studies. Studies were selected for review by criteria determined *a priori*; and the methodologic quality of selected studies was evaluated by duplicate independent review, also using criteria determined *a priori*.

Results: Five studies were identified, of which three were quasirandomized and none were blinded. Agreement between reviewers of methodologic quality was high ($\kappa=0.87$).

Conclusions: There is insufficient evidence to support that the timing of tracheotomy alters the duration of mechanical ventilation or extent of airway injury in critically ill patients.

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Key words: systematic review, tracheotomy, timing

Treatment of acute respiratory failure may require endotracheal intubation. However, even after a few hours of intubation, damage to the oropharynx and larynx can occur from translaryngeal intuba-

For editorial comment see page 361

tion.¹⁻⁷ In the 1960s, early recognition of this problem led to the performance of tracheotomy within 48 h.⁴ With the advent of less traumatic tubes and ventilatory equipment, tracheotomy was delayed. It is common practice in North America to delay the performance of a tracheotomy for 2 weeks. Nonetheless, there exists controversy as to which mode of tracheal intubation, translaryngeal or tracheotomy, causes more frequent and/or severe laryngotracheal damage.⁵

Numerous prospective studies published in the

1980s addressed the issue of tracheotomy and airway damage.¹⁻⁷ Patients who received a tracheotomy were found to have more serious airway and laryngeal injury than patients without tracheotomy, yet most authors attributed the excess damage in the tracheotomy group to the preceding prolonged translaryngeal intubation.¹⁻⁷

In 1989, at the Consensus Conference on Artificial Airways in Patients Receiving Mechanical Ventilation,⁴ the indications for placement of nasal and oral endotracheal tubes as well as tracheotomy tubes were forged. The consensus conference issued the following statement: "If the need for an artificial airway is anticipated to be greater than 21 days, a tracheotomy is preferred."⁴ Research opportunities were outlined, including the need for a multicenter cooperative study comparing long-term translaryngeal intubation to early conversion to tracheotomy. The objective of such a study would be to better define the indications, limitations, and complications of each of the various routes of securing the airway for mechanical ventilation.

The need for such a study persists because the issue goes beyond the incidence of tracheal damage.

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Patients with respiratory failure requiring prolonged mechanical ventilation consume considerable hospital resources.^{8,9} Currently, tracheotomy plays a vital role in the care of ventilator-dependent ICU patients. Despite the 4,000-year history of tracheotomy as a medical application, few data are available to define the impact of the timing of tracheotomy on the duration of mechanical ventilation, ICU stay, or hospital stay. Furthermore, the available data are conflicting.

We sought to examine the impact of the timing of tracheotomy on the duration of mechanical ventilation and the clinical course of critically ill patients in the ICU. Accordingly, we conducted a systematic review of the literature to determine the effect of the timing of conversion to tracheotomy with respect to (1) the patient's course in the ICU and (2) laryngeal and tracheal injury.

MATERIALS AND METHODS

We searched MEDLINE, from 1966 to December 1996, to identify all trials investigating the timing of tracheotomy. The terms *tracheotomy* and *tracheostomy* were used as Medical Subject Headings (MeSH terms) and text words. Citations were limited to human studies. In addition, the reference lists of all relevant articles obtained from these searches were reviewed to identify additional papers. We did not contact investigators and we did not attempt to identify unpublished data.

Two independent reviewers performed the search using published criteria for a comprehensive standardized review.^{10,11} In all instances where the titles indicated to either reviewer that an article might be relevant, the papers were obtained. These articles were then reviewed and considered for inclusion in the overview. The following inclusion criteria were applied: (1) patient population: mechanically ventilated patients in the ICU; (2) intervention: a tracheotomy at a selected time interval in the course of the ICU stay; (3) outcomes of interest: duration of mechanical ventilation; duration of hospitalization; airway trauma sustained; and incidence of ventilator-associated pneumonia; and (4) study design: all study designs were considered for inclusion.

Agreement between reviewers in the rating of papers was calculated and reported using the kappa statistic (a measure of agreement beyond that which can be expected by chance).¹¹ Disagreements were resolved by discussion.

The reviewers independently assessed the methodologic quality of the included studies according to the following 10 methodologic issues:

1. Clarity of objectives: Was there a statement that specifically outlined the question?
2. Search methods: Did the authors clearly state how they assessed the relevant medical literature?
3. Method of randomization: Did the authors indicate whether the trial was randomized? If so, did they outline the method of randomization?
4. Blinding: Was the evaluation of the outcome data blinded as to the results of randomization?
5. Description of the statistical analysis: Did the methods section outline and justify the statistical methods?
6. Inclusion and exclusion criteria: Were these specifically noted?

7. Similarities of patients between groups: Did the authors report demographic and patient characteristics that would define the groups to note whether there were any statistical differences?
8. Management of dropouts: Were all dropouts accounted for?
9. Management of follow-up: Were all patients followed up and accounted for?
10. Reporting of secondary outcomes: Were all measured variables adequately reported in a comprehensive manner?

Items were scored as follows: yes=2; partially=1; and no/not stated=0. For the two items related to randomization, a score of 0 was assigned if the study was not randomized and not blinded. All other possible responses for these two items were assigned a score of 1. The possible range of total scores was 0 to 18. Scores were calculated for each reviewer. Disagreements were resolved by discussion.

Data from each study were extracted by two reviewers using customized data forms. The information that was abstracted included method of randomization, population of interest, study population comorbidities, definition of timing of tracheotomy (early vs late), method of tracheotomy, length of ventilation, hospitalization, ICU morbidities and mortality, and length of follow-up.

RESULTS

The MEDLINE search yielded 8,153 citations. From this list, 48 articles were identified that might be relevant to the review. Five of the 48 articles¹²⁻¹⁶ met the inclusion criteria.

The articles' methodologic quality scores ranged from 8 to 12 (possible range, 0 to 18). Weighted kappa statistics calculated between the two reviewers showed a high degree of agreement (kappa=0.87). Table 1 summarizes the methodologic quality of the five articles.

Table 2 summarizes the results of these articles. Two of the five articles did not state the results of the primary outcome, and none of the studies described long-term complications (*ie*, anytime after discharge from the hospital) of tracheotomy or endotracheal intubation.

In the article by Rodriguez et al,¹² entitled "Early Tracheostomy for Primary Airway Management in the Surgical Critical Care Setting," 106 trauma patients admitted to the ICU over a 12-month period were randomized to one of two groups according to the day of admission. Group 1 (51 patients admitted on odd-numbered days) underwent tracheotomy within 7 days of admission; 24% underwent tracheotomy within 2 days and 76% did so within 3 to 7 days. Group 2 (55 patients admitted on even-numbered days) underwent tracheotomy at least 8 days after admission; 82% underwent tracheotomy 8 to 14 days after admission and 18% did so within 15 to 21 days. There was a statistically significant reduction in length of ventilation, duration of ICU and hospital

Table 1—Summary of Methodologic Quality of Studies*

Items	Rodriguez ¹²	Lesnik ¹³	Blot ¹⁴	Dunham ¹⁵	El-Naggar ¹⁶
Question stated	Yes	Yes	Yes	No	Partially
Explicit search methods	No	No	No	No	No
Randomization	Yes	No	No	Yes	Yes
Blinding	No	No	No	No	No
Inclusion/exclusion criteria	Yes	Yes	Yes	Yes	Yes
Patients matched	Yes	Yes	No	Partially	Partially
Dropouts accounted for	Partially	Yes	Yes	Yes	No
Follow-up complete	No	Yes	Yes	Not stated	Not stated
Secondary outcomes stated	Yes	No	No	Yes	Partially
Statistical analysis	Yes	Yes	Yes	Yes	Yes
Total score (0-18)	12	12	12	10	8

*Resolved results of the two reviewers; kappa=0.87.

stay, and incidence of pneumonia in group 1 compared with group 2 (p<0.05; relative risk=0.588). Long-term complications were not reported.

In the article by Lesnik et al,¹³ “The Role of Early Tracheostomy in Blunt, Multiple Organ Trauma,” the authors conducted a retrospective chart review of 101 adult patients who were admitted following blunt injuries and who underwent a tracheotomy at some time during the course of their hospitalization. Patients were arbitrarily divided into two groups

according to the timing of the tracheotomy. Group 1 (early) consisted of 32 patients who had undergone a tracheotomy within the first 4 days, and group 2 (late) consisted of 69 patients who underwent tracheotomy after 4 days. Indications for tracheotomies were not described, nor were the surgical techniques (open vs percutaneous). The two groups were matched for age and comorbidities. The authors found that the mean duration of ventilatory support was 6.0 days in group 1, vs 20.6 days in group 2

Table 2—Summary of Study Results

Data Point	Rodriguez ¹²	Lesnik ¹³	Blot ¹⁴	Dunham ¹⁵	El-Naggar ¹⁶
Randomization method	Yes	None	None	Yes	Yes
Population	Adult (n=106)	Adult (n=111)	Adult (n=53)	Adult (n=74)	Adult (n=52)
Early tracheotomy defined	≤7 d (n=51)	≤4 d (n=32)	2 d (n=20)	3-4 d (n=34)	3 d (n=26)
Late tracheotomy defined	≥8 d (n=55)	>4 d (n=69)	≥7 d (n=33→12)	>14 d (n=40→20)	>10-11 d, as needed (n=26→?)
Long-term follow-up	Hospital stay	ICU only	Hospital stay	4-12 mo	ICU only
Length of ventilation, d*					
E	12±1	6±3.4	23.8±21.1	N/A	N/A
L	32±3	20.6±12.2	13.3±12.2	N/A	N/A
Length of ICU stay, d*					
E	16±1	N/A	28.2±24.2	N/A	N/A
L	37±4	N/A	18.8±17.8	N/A	N/A
Hospital stay, d*					
E	34±4	N/A	30.5±25.9	N/A	N/A
L	51±4	N/A	22.6±20.8	N/A	N/A
Complications from tracheotomy, %					
E	4	yes	5	N/A	N/A
L	4	yes	N/A	N/A	N/A
Death from tracheotomy, %					
E	0	0	N/A	N/A	N/A
L	0	0	N/A	N/A	N/A
Incidence of pneumonia, %					
E	78	19	10	N/A	N/A
L	96	59	9	N/A	N/A
Incidence of tracheal stenosis, %					
E	2	N/A	N/A	17.6	N/A
L	2	N/A	N/A	12.5	N/A
Long-term complications	N/A	N/A	N/A	N/A	N/A

*Data are expressed as mean±SD.

E=early tracheotomy group; L=late tracheotomy group; N/A=data point not mentioned in the article.

($p < 0.001$). The incidence of pneumonia was lower in group 1 than in group 2 (19% vs 59%; relative risk=0.3156). The length of ICU stay, duration of hospitalization, and overall mortality were not reported.

In "Early Tracheotomy in Neutropenic, Mechanically Ventilated Patients: Rationale and Results of a Pilot Study" by Blot et al,¹⁴ a retrospective chart review of 53 consecutive ventilated neutropenic patients was reported. The patients were divided into two groups for comparison. Group 1 included 20 patients who had undergone a tracheotomy within 48 h of beginning mechanical ventilation, and group 2 included 33 patients who either were tracheotomized later (>7 days) or remained endotracheally intubated until death or extubation. In the latter group, the number of patients who underwent a tracheotomy was only 12. The differences between the two groups in the incidence of nosocomial pneumonia and death in the ICU and hospital were not statistically significant, but the length of hospital stay and length of ventilation were significantly longer in the early tracheotomy group ($p < 0.05$).

In "Prolonged Tracheal Intubation in the Trauma Patient" by Dunham et al,¹⁵ 74 trauma patients were prospectively randomized over a 15-month period into early and late tracheotomy groups. Quasirandomization was determined by the last digit of the patient's hospital number. The early tracheotomy group (tracheotomy 3 to 4 days after initiation of ventilation) comprised 34 patients, and the late tracheotomy group (tracheotomy >14 days after the initiation of ventilation if continuation of intubation was needed) comprised 40 patients. Only 20 patients in the late group actually had tracheotomies performed. Although the mean duration of mechanical ventilation was not reported for each group, the groups were subdivided according to the number of patients ventilated at discrete intervals, the longest interval being >21 days. There was no significant difference in the incidence of major laryngotracheal pathology between the early and late groups. Each group was then subdivided according to injury: no head injury, head injury with rigid posture, or head injury without rigid posture. They found that there was no difference between early and late tracheotomy groups in the incidence of major laryngotracheal pathology with various injuries. However, there was a significantly higher incidence of major laryngotracheal pathology in the rigid, head-injured patients. Patients were interviewed 4 to 12 months after extubation and "no tracheal pathology" was found in any of the patients.

In "Factors Influencing Choice Between Tracheostomy and Prolonged Translaryngeal Intubation in Acute Respiratory Failure: A Prospective Study" by El-Naggar et al,¹⁶ on day 3 after admission to the

ICU, 52 adult ventilated patients who were believed to require continued intubation were alternately allocated into two groups. Group 1 consisted of 26 patients managed by continued ventilation for 10 to 11 days, after which a tracheotomy would be performed if needed; in group 2, 26 patients were assigned to undergo tracheotomy after day 3 of mechanical ventilation. The authors compared percentages of the cumulative number of patients who were extubated or who died in the two groups; more patients in group 1 (late) were weaned from mechanical ventilation ($p < 0.05$). However, the number of tracheotomies actually performed was not reported.

DISCUSSION

Despite the frequent practice of tracheotomy in the management of respiratory failure, there is little agreement on the optimal timing of the procedure in mechanically ventilated patients. The issue is important for two reasons. First, the route of tracheal intubation may influence the process and timing of weaning. A significant difference could have profound implications in duration of ventilation and hospital costs. Second, trauma to the airway can be devastating and the timing of tracheotomy may be important in the evolution of airway damage. There is abundant literature concerning the risks and benefits of tracheotomy compared with translaryngeal intubation, but there have been very few prospective studies evaluating the timing of tracheotomy. Although the recommendations of the Consensus Conference of 1989 included conversion to tracheotomy if the anticipated need for mechanical ventilation is >21 days, the need for a multicenter randomized trial to definitely resolve this question was acknowledged.⁴

Our search resulted in the selection of five studies. Although three of the five studies stated that patients were randomly allocated to early or late tracheotomy, their methods of randomization were substandard; randomization relied on alternative allocation, the day of admission, or the patient's medical record number. None of the studies were blinded. Follow-up was complete in only two of the studies, and two did not comment on follow-up. All papers clearly stated the inclusion and exclusion criteria and outlined the method of statistical analysis of the data. The three randomized trials reached different conclusions. Although the study by Rodriguez et al¹² suggested that there was a reduction in the duration of mechanical ventilation, ICU stay, and hospital stay, the authors did not comment on the immediate or long-term sequelae of intubation vs tracheotomy. In addition, the patient population was restrictive (*ie*, young trauma patients). In contrast, Dunham et al¹⁵

found no difference with respect to important clinical outcomes. They did, however, note that the incidence of major laryngotracheal damage was similar for early and late tracheotomy. Conversely, in the third randomized trial, El-Naggar et al¹⁶ found that the late tracheotomy group had a higher percentage of extubation and a lower incidence of airway lesions. Clearly, these trials taken in isolation or together yield insufficient information to permit a reasonable conclusion about early vs late tracheotomy.

The two retrospective reviews of early vs late tracheotomy (Lesnik et al¹³ and Blot et al¹⁴) are at odds with each other. The findings likely reflect institutional bias in the timing of tracheotomy or certain bias within the population.

This review of the literature indicates a lack of rigorous controlled studies to support the recommendations of the 1989 Consensus Conference.⁴ The basis for current practice derives from quasi-randomized trials and observational studies examining the complications of prolonged endotracheal intubation in comparison with tracheotomy. A definitive randomized, controlled trial is still required.

Why has this not yet been accomplished? The first problem is the fact that each group of authors has focused on only one aspect of the problem; either laryngotracheal damage or duration of ventilation and length of stay. A definitive study would require a more comprehensive analysis that accurately assesses both of these outcomes. The assessment of laryngotracheal damage by endoscopy is time-consuming and costly, which has precluded an accurate analysis. In the future, randomized trials must focus on functional outcomes of dyspnea and voice, as well as provide for surveillance endoscopy during the randomization process in order to ensure quality control.

Second, the matter of cost containment and duration of ICU stay are important issues in the 1990s. The techniques for a proper economic analysis are costly and have precluded the design of several trials. Third, ICU patients are a heterogeneous group, as suggested by Dunham et al.¹⁵ The incidence of laryngotracheal damage may be affected by the etiology of respiratory failure and other complicating clinical conditions. Likewise, one might surmise that the duration of ventilation could be influenced by factors other than the timing of tracheotomy. A randomized trial would require a tight study design with specific inclusion and exclusion criteria, stratification where deemed appropriate, and standardized weaning practices. The need for stratification suggests a large population. Standardization of weaning might be difficult to achieve when several institutions are involved.

The issue of tracheotomy timing remains critically

important. Early tracheotomy might benefit patients because it might accelerate the process of weaning and thus lead to a reduction in the duration of ventilation, length of hospitalization, and cost. Alternatively, tracheotomy may provide no benefit to patients with respect to survival and duration of mechanical ventilation, but might lead to an increase in airway injury. A randomized, prospective study is required to examine the need for and the timing of tracheotomy in patients requiring prolonged mechanical ventilation. The findings of such a study would have significant impact on clinical practice and hospital costs. Until that time, physicians can approach the problem only on an individual, case-by-case basis and with anecdotal information.

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