A prospective, randomized, study comparing early percutaneous dilational tracheotomy to prolonged translaryngeal intubation (delayed tracheotomy) in critically ill medical patients*

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Objective: **The timing of tracheotomy in patients requiring mechanical ventilation is unknown. The effects of early percutaneous dilational tracheotomy compared with delayed tracheotomy in critically ill medical patients needing prolonged mechanical ventilation were assessed.**

Design: **Prospective, randomized study.**

Setting: **Medical intensive care units.**

Patients: **One hundred and twenty patients projected to need ventilation >14 days.**

Interventions: **None.**

Measurements and Main Results: **Patients were prospectively randomized to either early percutaneous tracheotomy within 48 hrs or delayed tracheotomy at days 14–16. Time in the intensive care unit and on mechanical ventilation and the cumulative frequency of pneumonia, mortality, and accidental extubation were documented. The airway was assessed for oral, labial, laryngeal, and tracheal damage. Early group showed significantly less mortality (31.7% vs. 61.7%), pneumonia (5% vs. 25%), and accidental extubations compared with the prolonged translaryngeal group (0 vs. 6). The early tracheotomy group spent less time in the intensive care unit (4.8 ± 1.4 vs. 16.2 ± 3.8 days) and on mechanical ventilation (7.6 ± 2.0 vs. 17.4 ± 5.3 days). There was also significantly more damage to mouth and larynx in the prolonged translaryngeal intubation group.**

Conclusions: **This study demonstrates that the benefits of early tracheotomy outweigh the risks of prolonged translaryngeal intubation. It gives credence to the practice of subjecting this group of critically ill medical patients to early tracheotomy rather than delayed tracheotomy. (Crit Care Med 2004; 32:1689–1694)**

KEY WORDS: tracheostomy; tracheotomy; critical care; dilational/methods; pneumonia/etiology; comparative study; intensive care units; hospital mortality; intraoperative complication; postoperative complication; prospective study; questionnaire; respiratory insufficiency/therapy; tracheal stenosis; treatment outcome

Tracheotomy is performed some time during the ventilation of patients who fail to wean easily. The timing is controversial (1–6). Prolonged translaryngeal intubation has the disadvantages and complications of injury to the mouth, larynx, and trachea as well as the dangers of self-extubation and malposition, parasinusitis, extreme physical discomfort, and need for increased sedation (1, 2, 7–9). A tracheotomy provides a relatively stable, well-tolerated airway. It makes oral feedings possible, enhances communication, permits earlier ambulation, and facilitates pulmonary toilet and oral hygiene (3–5, 10, 11). Unfortunately, tracheotomy is associated with such complications as stomal infection, pneumothorax, subcutaneous emphysema, hemorrhage, tracheal stenosis, tracheomalacia and granulation tissue, and rarely death (4, 5, 11, 12).

Studies have compared the risks of prolonged intubation to early tracheotomy but lacked good study design and appropriate controls, had selection bias, and involved small sample sizes. Many were nonrandomized and retrospective (13). One concluded that early tracheotomy has an overall risk comparable to translaryngeal intubation and that those receiving early tracheotomy remained on mechanical ventilation and in intensive care for less time (3).

We (14–18) and others (19–23) have documented improved safety of percutaneous tracheotomy compared with conventional tracheotomy. To our knowledge, there has been no published study comparing the benefits of early to delayed percutaneous tracheotomy. Therefore, we performed a prospective, randomized study comparing the benefits and risks of percutaneous tracheotomy within 48 hrs vs. 14–16 days in critically ill medical patients who were projected to require ventilation for ≥14–16 days.

PATIENTS AND METHODS

Patients. Patients were recruited from the Medical Intensive Units at the Baptist Memorial Hospital, University of Tennessee, Memphis, TN, and Tampa General and the James A. Haley Veterans Administration Hospital, University of South Florida, Tampa, FL. The institutional review boards approved the protocol. All medical patients in these closed intensive care units who were intubated and

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mechanically ventilated for acute respiratory failure were screened to see if they met the following inclusion criteria: a) >18 yrs old; b) projected to need ventilation support for >14 days; c) initial Acute Physiology and Chronic Health Evaluation (APACHE) II score >25; d) informed consent obtained from the patients' surrogates. The patients were excluded for the following reasons: a) anatomical deformity of the neck, including thyromegaly and cervical tumors; b) previous tracheotomy; c) existence of platelet count <50,000/mm^2, an activated partial thromboplastin time or prothrombin time >1.5 times, or bleeding time greater than twice normal; d) soft tissue infection of the neck; e) mechanical ventilation with a positive end-expiratory pressure >12 cm H_2O; f) intubated >48 hrs; and g) having a neck on which it was technically difficult to perform a percutaneous tracheotomy (e.g., morbidly obese patients with difficult to palpate landmarks or short, fat necks).

Independent group randomization was placed in sequentially numbered envelopes to be open once consent was signed. One hundred and thirty-five patients qualified for the study to enroll 120 patients. The reason for not enrolling patients was failure to obtain consent.

Protocol. The duration of intubation, ventilation, intensive care stay, and mortality by each approach was recorded. Patients were followed for cardiac arrhythmias, oxygen desaturation, and the occurrence of operative complications such as tracheal tube misplacement, uncontrolled hemorrhage, subcutaneous emphysema, pneumothorax, and death. Clinical circumstances determined whether patients who were randomized to receive a delayed tracheotomy at days 14–16 after intubation actually received one (13).

Airway Assessment. The airway was assessed for oral, laryngeal, and tracheal damage by physical examination, fiberoptic bronchoscopy, and linear radiographic tomography with tracheotomy and extubation at 10 wks postintubation. The trachea was assessed by the method previously described by us (24). The bronchoscope was advanced into the upper trachea and the diameter noted. The diameter of the trachea at the level of the carina reflects the native diameter. By pulling back through the damaged area, an accurate correlation with the damaged area, the carina, and sublaryngeal diameter is made.

Oral-Labial Ulceration. Oral-labial ulceration was scored as none, 0; superficial mucosal ulceration <5 mm, 1; superficial mucosal ulceration >5 mm, 2; and deep ulceration, 3.

Laryngeal Damage. Swelling, hemorrhage, subglottic stenosis, and mucosal disruption to the vocal cords were recorded (none, 0; swelling, 1; mucosal disruption, 2; and hemorrhage, 3).

Choice of Tracheotomy Tube. The size of the tracheotomy was determined by the size of the trachea on the portable chest radiograph film. The Perfit by Portex (Keene, NH) was used. The minimum leak technique was used (24). The inner cannula was changed daily. Suctioning was performed according to routine respiratory care using a closed suction system.

Percutaneous Dilational Tracheotomy Procedure. Patients were monitored with telemetry, pulse oximetry, and blood pressures monitored noninvasively (every 3 mins) if no intra-arterial catheter was present. Patients were placed on 100% oxygen. The ventilator rate and tidal volume were adjusted to ensure adequate ventilation of the patient. The peak pressure alarm was increased to 120 cm H_2O. All were sedated with midazolam and morphine and paralyzed with pancuronium. Before the endotracheal tube cuff was deflated, the posterior pharynx was thoroughly suctioned. Nasogastric tubes were removed because they restrict posterior displacement of the tracheal wall during the insertion of the dilating catheter, predisposing the tracheal wall to damage. The procedure was performed under bronchoscopic surveillance. The endotracheal tube was moved proximally to allow the needle to penetrate the anterior tracheal wall without inserting itself into the tube. Once the guiding catheter was inserted, it was stabilized to avoid displacement when the dilating catheter was advanced over it (25–27). There is a learning curve with this procedure, and only the authors (except SWS) performed the procedures modified by Hazard et al. (14, 15).

Ventilation and Weaning Protocol. Patients with acute lung injury were ventilated with low tidal volumes and were weaned in a similar fashion to the acute respiratory distress syndrome network (28, 29). All patients were sedated with fentanyl 50 μg/hr. Propofol was used to keep the patients sedated but arousable. Every morning the sedation was stopped for 1 hr and a T-piece tried if the patients had a good level of consciousness, a positive end-expiratory pressure of 8 cm, and 40% oxygen. After 2 hrs the patients were extubated or placed on a tracheotomy collar. A patient was considered weaned if off ventilation >48 hrs. Tracheostomized patients were then decannulated. The trial was terminated and ventilation resumed if the patient developed a respiratory rate >30 per minute, if blood pressure increased by 10%, if patients were sweating or using accessory respiratory muscles, or if the respiratory rate divided by tidal volume >105. Patients were rested for 24 hrs on assist-control mode and weaning was reinstituted the next day.

Time in the ICU. Narcotics and sedation were continued for 1 day posttracheotomy. The patients were moved out of intensive care once the airway was secured, the patients were hemodynamically stable, and there was no reason to keep the patients in intensive care (3, 30–34).

Prevention, Diagnosis, and Treatment of Ventilator-Associated Pneumonia. Hands were washed before and after patient contact (35). The head of the bed of patients was raised to 45°. This was reinforced with signs on the doors, at the bottom of the monitors, and on the ventilators in intensive care. In-services were given daily to nursing and house staff. Patients were fed with a small, soft nasogastric tube. Pneumonia was confirmed by bronchoscopy using semiquantitative cultures from protected specimen brushes (>1000 organisms/mL) or bronchoalveolar lavage (>10,000 organisms/mL) (36, 37). Antibiotics were started for pneumonia depending on the Gram-negative stain. A negative brush or lavage allowed us to stop the antibiotics and search for a nonpneumonia cause for the fever (37, 38). Appropriate antibiotics were continued for 7–10 days and stopped when the repeat brush or lavage was culture negative.

Data Analysis. The sample size (60 in each group) was determined for a 50% reduction in pneumonia from a baseline frequency of 50% (two-sided, power = 0.8). There was no interim analysis of the data. Unadjusted comparison between groups was made using a Student's *t*-test for continuous variables and Cochran-Mantel chi-square statistic for dichotomous variables. Risks of dying were also compared between groups using a logistic regression (Proc Genmod in SAS version 8) that adjusted for demographics and APACHE II score. The low prevalence of pneumonia in the early group precluded a meaningful, adjusted analysis for this outcome. Lengths of stay in intensive care and of ventilation were compared between groups with a linear regression adjusted for demographics and APACHE II score. Kaplan Meier curves were plotted (Fig. 1) and differences in survival were tested using a log-ranked test corroborated with a Wald statistic proportional hazards model.

RESULTS

The groups were similar in mean age, proportion of women and African Americans, APACHE II score, and underlying diseases (Table 1). Sixty patients underwent tracheotomy in the early tracheotomy group. Fifty of 60 (83.3%) patients randomized to the delayed tracheotomy group were subjected to a tracheotomy on days 14–16. Ten patients randomized to the delayed group did not receive a tracheotomy. Two of the ten died before tracheotomy, and the remaining eight were extubated before day 14 according to the weaning protocol.

Fifty-six of the total 120 (31.6%) patients died. Nineteen of 60 (31.6%) patients in the early tracheotomy group died, whereas 37 of 60 (61.7%) of patients in the delayed group died (Table 2). The mortality was 50% lower in the early tracheotomy compared with the delayed group ($p < .005$). The cause of death in each group is listed in Table 3.

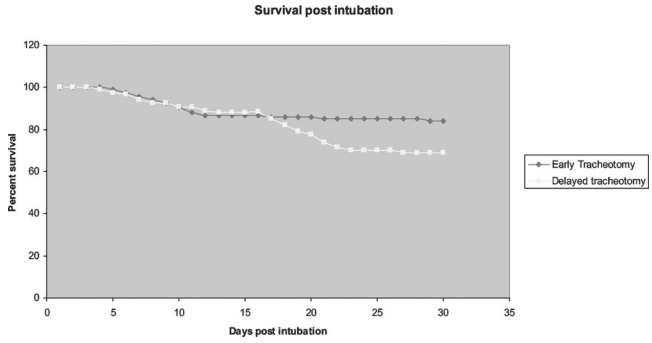

Figure 1. Kaplan-Meier curve. The time to death is displayed here. There is a significantly better mortality rate in the early tracheotomy group than the prolonged translaryngeal group at 30 days ($p > .005$).

Table 1. Baseline characteristics

Baseline Characteristics	Early Tracheotomy (n = 60)	Prolonged Translaryngeal Intubation (n = 60)
Age, yrs ± SD	63 ± 10.4	63 ± 9.3
Male, n (%)	31 (51.7)	34 (56.7)
Body mass index, kg/m^2	20.8 ± 8	21.9 ± 9
APACHE II score ± SD	27.4 ± 4.2	26.3 ± 2.6
African American, n (%)	25 (41.7)	28 (46.7)
White, m (%)	20 (33.3)	21 (35)
Hispanic, n (%)	15 (25)	11 (18.3)
Human immunodeficiency virus[a]	2	3
Diabetes mellitus[a]	5	4
Coronary artery disease[a]	3	3
Malignancy[a]	3	3
Respiratory failure[a]	60	60
Renal failure (new onset)[a]	27	25
Severe sepsis[a]	42	40
Organ failure (≥3)[a]	35	33
High-dose vasopressor use (dopamine ≥5 $\mu \cdot kg^{-1} \cdot min^{-1}$ or norepinephrine)[a]	51	50
Overt disseminated intravascular coagulation[a]	51	50
Lactic acidosis[a]	32	33
Initial platelet count <50,000[a]	25	23
Community-acquired pneumonia[a]	15	16
Chronic obstructive lung disease[a]	32	31
Congestive heart failure[a]	10	9
Diabetic ketoacidosis[a]	4	3
Aspiration pneumonia[a]	12	11
Urinary tract infection[a]	11	13

APACHE, Acute Physiology and Chronic Health Evaluation.

[a]Some patients had more than one baseline characteristic and, therefore, the total number is >120. There were no significant differences observed in the baseline characteristic between the two groups.

Mean intensive care stay was 9.4 ± 2 days and mean ventilation duration was 8.4 ± 2 days. Some patients were moved to a step-down or a ventilator floor while still on mechanical ventilation, so the time on ventilation was sometimes longer than the time in the ICU. The cumulative frequency of pneumonia in early tracheotomy group was 80% lower than the delayed group ($p < .001$). Length of intensive care stay and ventilator use were also less in the early vs. the late tracheotomy group (Table 2). There was more damage to the larynx and lip in the delayed group. Orolabial ulceration in the early group was rated between 0 and 1 and in the delayed group between 2 and 3. Statistically, there was no difference in damage to the trachea or larynx between the two groups. There was a trend favoring the early tracheotomy group (Table 4). Self-extubation was more frequent in the delayed group (6 vs. 0). Sedation per day before the tracheotomies was the same in both groups. The overall sedation was longer in the delayed group. The type, proportion, and frequency of bacteria causing pneumonia were the same in both groups (Table 2).

DISCUSSION

Our findings demonstrate that early tracheotomy has advantages over delayed tracheotomy in critically ill medical patients who were predicted to need ventilation >14 days. The early group spent significantly less time in the intensive care unit, spent less time on ventilation, and had significantly lower mortality rate and ventilator-associated pneumonia (Table 2). They experienced less damage to the mouth and larynx and less loss of airway control. There were no significant differences in tracheal damage (Table 4). Pneumonia was 80% less in the early group compared with the delayed group. Pooled secretions above the endotracheal cuff are aspirated from the oropharynx through the vocal cords, kept open by the tube. The secretions are transported around the cuff and aspirated into the distal airway, and the reflux moves into the inner part of the tube where the developing biofilm becomes infected (35, 39). Suctioning and ventilation allow infected secretions to disseminate through the lungs (35, 39). The inner cannula of the tracheotomy was changed daily to prevent biofilm buildup.

In keeping with other studies (31–34), most patients who developed pneumonia and died were in the delayed group (Tables 2 and 3). Patients in the early tracheotomy group had a 50% reduction in mortality rate compared with the delayed group, confirming the study of Kollef et al. (30) (26.4% vs. 13.7%). The higher mortality rate in this study is explained by the fact that our patients were sicker than Kollef et al.'s (mean APACHE II scores of 27 and 26 vs. 19.2 and 17.8) and had a shorter early group (2 vs. 7 days). We speculate that the shorter the time the endotracheal tube is in the trachea, the less the pneumonia and mortality rate. This is in keeping with studies where noninvasive face mask ventilation was used to prevent or reduce endotracheal tube time and the duration of ventilation in patients with respiratory failure, (40) immunosuppression (41), and solid organ transplant (42) or to wean patients faster from ventilation (43). Pneumonia, intensive care stay, and mortality rate were reduced.

Table 2. Outcome measures

Outcome Measurement	Early Tracheotomy (n = 60)	Prolonged Translaryngeal Intubation (n = 60)
Died (%)	19 (31.7)	37 (61.7)[a]
Pneumonia (%)	3 (5)	15 (25)[a]
Days in ICU ± SD	4.8 ± 1.4	16.2 ± 3.8[b]
Days mechanically ventilated ± SD	7.6 ± 4.0	17.4 ± 5.3[b]
Days sedated ± SD	3.2 ± 0.4	14.1 ± 2.9[b]
Days on high-dose pressors	3.5 ± 4	3.0 ± 4.5
Organism(s) causing pneumonia: Methicillin-resistant *Staphylococcus aureus*, *Pseudomonas aeruginosa* mixture	1 1 1	5 5 5

[a] $p < .005$; [b] $p < .001$. There was a significant difference between the early tracheotomy groups and the prolonged translaryngeal intubation group in outcome measures. Some patients were sent to a step-down while still on mechanical ventilation.

Table 3. Causes of death by treatment group

Cause of Death	Early Tracheotomy (n = 19)	Delayed Translaryngeal Intubation (n = 37)
Ventilator-associated pneumonia	2	9
Gastrointestinal bleed	1	3
Acute myocardial infarction	2	4
Pulmonary embolus	1	1
Intractable septic shock	4	8
Withdrawal of life support	2	1
Respiratory failure	7	11

More patients died of ventilator-associated pneumonia in the prolonged translaryngeal group than the early tracheotomy group.

Table 4. In-hospital and 10-week evaluation of the trachea

	In-Hospital Evaluation		Ten-Week Evaluation	
Tracheal Stenosis (%)	Early Tracheotomy No. (%)	Prolonged Translaryngeal Intubation No. (%)	Early Tracheotomy No. (%)	Prolonged Translaryngeal Intubation No. (%)
0–20	52 (86.7)	41 (70.7)	26 (63.4)	13 (56.5)
21–50	6 (10)	12 (20.7)	10 (24.3)	6 (26)
>50	2 (3.3)	5 (8.6)	5 (12.2)	4 (17.4)

There were no significant differences observed in the in-hospital or 10-wk postintubation evaluation of the trachea between the two groups. Significance is $p > .05$. The original size of the trachea was assessed by looking at its diameter below the vocal cords and just proximal to the main carina. The abnormal diameter is estimated as the bronchoscope is moved from just below the cords to the carina and back (24) and tomography with which it correlated well.

The only prospective study that differs from ours is that of Sugerman et al. (44), who found that early tracheotomy did not significantly decrease the length of stay or prevalence of pneumonia in trauma patients. They noted a bias toward enrollment of patients in their study. Physicians were reluctant to enroll patients in the early tracheotomy group unless they had a poor prognosis.

Although the amount of sedation per day before tracheotomy was the same in both groups, there was significantly more sedation in the delayed group as a function of prolonged ventilation. The time on mechanical ventilation between the two groups was striking. Quicker extubation can also be explained by more sedation in the prolonged translaryngeal intubation group (45) and apparent less work of breathing (46) and better lung mechanics in the tracheotomized patients (47).

Early tracheotomy in critically ill medical patients who undergo ≥14 days of ventilation may have significant benefits over delayed tracheotomy.

In keeping with the literature (2), no patients in our early group self-extubated whereas 10% of the other group did. Complications of delayed tracheotomy included orolabial ulcerations, laryngeal edema, and hemorrhage. The damage was the result of the duration of translaryngeal intubation. Tracheal damage assessed during the in-hospital and at 10 wks postintubation was statistically the same. There were insufficient patients to demonstrate a significant difference between groups, if it exists (type II error). There was one perioperative complication of the tracheotomy. A suture was placed adjacent to the incision to control the mild bleeding. The procedure was otherwise free from complications. This is in keeping with previous studies on our patients and reflects the care taken to minimize complications and the experience of the authors (17, 21, 22, 25–27).

These results are significant and the groups are indeed similar with respect to the diseases that predict mortality (Table 1) (46–48). Patients who were randomized to the delayed tracheotomy group had a mortality rate of 61.7%, which is higher than that predicted by the APACHE II score for nonoperative patients of 25–30. The mortality rate should be a little in excess of 50%. Lactic acidosis, number of organ failures, or high dose vasopressors predict a higher mortality rate than the APACHE II score suggests (Table 1) (49–51). Caution should be used when translating these results to the general critically ill population as the study was performed in a highly select group.

CONCLUSIONS

Early tracheotomy in critically ill medical patients who undergo ≥14 days of ventilation may have significant benefits over delayed tracheotomy. These include reduction in mortality rate, frequency of pneumonia, duration of mechanical ventilation, and length of time in intensive care. The findings of this study, and those of others (32, 35, 52, 53), suggest that the risks and benefits of early tracheotomy are preferable to delayed tracheotomy in critically ill medical patients. This may be performed open or percutaneously, depending on the experience of the operator.

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The authors designed this study. They and their study nurses (employed by Drs. Adams and Hazard or the University of South Florida) collected data. The authors had unrestricted access to the data analyzed it and wrote the article. Drs. Hazard and Rumbak were paid consultants to SIMS Portex. Nobody has stock in the sponsor's company. The abstract was also a finalist for the Alfred Stoffer award.

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