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Outcomes of Early Versus Late Tracheostomy: 2008–2010

Jennifer A. Villwock, MD; Kristin Jones, MD

Objectives/Hypothesis: The ideal timing of tracheostomy varies. This study sought to determine demographic, management, and outcome differences in patients undergoing early tracheostomy (ET) versus late tracheostomy (LT) (<10 days vs. >10 days postintubation, respectively).

Study Design: Retrospective review of the 2008 to 2010 Nationwide Inpatient Sample for patients with extreme severity of illness who underwent tracheostomy.

Methods: Patients were subdivided based on the timing of tracheostomy placement (days 1–5, 6–10, 11–15, 16–20, 21–25). ET and LT were defined using a 10-day cutoff. Descriptive statistics were obtained for hospital and patient demographics. Multivariate models analyzed the effect of tracheostomy timing on primary outcomes of in-hospital morbidity/mortality, length of stay (LOS), and charges.

Results: A total of 124,990 tracheostomy cases met inclusion criteria. Of the total cases, 53,749 underwent ET, and 71,244 underwent LT. Significant predictors ($P < .01$) of ET included patient age <65 years (odds ratio [OR]: 1.136), admission to a Midwest hospital (OR: 1.430), neurologic disorder (OR: 1.196), paralysis (OR: 1.264), and admission to a government, nonfederal hospital (OR: 1.434). Significant predictors of LT included admission to a small hospital (OR: 1.150), acute respiratory failure (OR: 1.601), and acute chronic respiratory failure (OR: 1.349). The economic outcomes of hospital costs and LOS increased linearly and significantly with time to tracheostomy, as did mortality ($P < .001$). ET was associated with a significantly increased rate of discharge to home ($P < .001$) and decreased rate of sepsis ($P < .001$) and ventilator-associated pneumonia ($P < .001$).

Conclusions: Efficient and effective healthcare delivery is paramount in today's economic climate. Identification of patients likely to need prolonged ventilator support and ET may prove to be a cost- and morbidity-saving measure and deserves further prospective examination.

Key Words: Tracheostomy, outcomes tracheostomy, early tracheostomy.
Level of Evidence: 2c.

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INTRODUCTION

Indications for tracheostomy include inability to protect the airway, excessive secretions, or inadequacy of spontaneous ventilation.[1] Despite the relative frequency with which tracheostomy is performed, the timing of tracheostomy placement is variable. In 1989, a consensus statement advised tracheostomy if ventilator support was expected to exceed 21 days. In an effort to balance the morbidity associated with long-term endotracheal intubation and the operative risk of tracheostomy, the prevailing tendency since then has been to perform tracheostomy after 14 days of mechanical ventilation (MV).[2–5] Recently, multiple studies have shown a benefit to performing tracheostomy at even earlier time points, and much debate remains regarding the ideal timing of tracheostomy.[2–5]

Common complications of prolonged endotracheal intubation include trauma to the larynx and trachea,[6,7] need for sedation, and hospital-acquired ventilator-associated pneumonia (VAP)[8–10] The latter condition accounts for >50% of antibiotic prescriptions in the intensive care unit (ICU) and adds a minimum of 10 days to MV and ICU stay.[8,11] Additionally, VAP prevention is a national patient safety goal and is being considered as a condition of nonreimbursement by the Centers for Medicare and Medicaid Services.[11] However, tracheostomy is not without complications. Historic concerns center on airway stenosis and formation of granulation tissue, although these have significantly decreased as advances in tracheostomy materials, design, and management have occurred.[12,13]

Currently, there is a growing consensus for "individualized assessment with a predilection for earlier tracheotomy."[6,14] However, the definition of early tracheostomy (ET) varies.[6,15] We compare the end points of treatment outcome, morbidity and mortality, length of stay (LOS), and cost of admission and treatment, as well as demographic data among patients receiving tracheostomy on MV days 1 to 5, 6 to 10, 11 to 15, 16 to 20, and 21 to 25, with the goal of further elucidating the ideal timing of tracheostomy. As the definition of an ET is

From the Department of Otolaryngology, SUNY–Upstate Medical University, Syracuse, New York, U.S.A.

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Send correspondence to Jennifer Villwock, MD, Department of Otolaryngology, SUNY–Upstate Medical University, 750 East Adams Street, Syracuse, NY 13210. E-mail: villwocj@upstate.edu

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variable in the literature, for the purposes of comparing ET versus late tracheostomy (LT) in the present study, a cutoff of 10 days is used.[2,3]

MATERIALS AND METHODS

Discharge data from the Nationwide Inpatient Sample (NIS) database (Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality) were analyzed. This database represents approximately a 20% sample of US hospitals. Detailed information on the design of the NIS database is available at http://www.hcup-us.ahrq.gov. Data from 2008, 2009, and 2010 were included in the present study.

Patients receiving tracheostomy were identified using International Classification of Diseases, Ninth Revision (ICD-9) codes 31.74, 31.1, and 31.29. Separate subgroups for analysis were then created based on timing of tracheostomy with respect to number of days of MV. The duration of MV was calculated as the difference between the day of tracheostomy and the day of tracheal intubation (ICD-9 96.04). ET was defined as tracheostomy within 10 days of initiation of MV. LT was defined as tracheostomy after 10 days of MV. Additional subgroups were also analyzed as follows:

Tracheostomy between days 1 and 5 of MV,
Tracheostomy between days 6 and 10 of MV,
Tracheostomy between days 11 and 15 of MV,
Tracheostomy between days 16 and 20 days of MV,
Tracheostomy between days 21 and 25 days of MV.

Patients receiving tracheostomy after 25 days were excluded due to excessively prolonged intubation of unknown reason (n = 10,725). Patients receiving a tracheostomy on the day of intubation were excluded, as the procedure was likely performed in an emergency situation (n = 11,594). Patients with a missing procedure code of intubation were excluded from analysis as we could not calculate duration of MV prior to tracheostomy (n = 208,770). Comparisons between timing groups were performed only in patients with an extreme severity of illness (All Patient Refined Diagnosis-Related Groups severity of illness classification: 4). There were 89,436 tracheostomies performed on patients with a severity of illness <4 that were excluded from this analysis so as to match patients in both groups.

Hospital and patient demographic data were evaluated. The method of comorbidity extraction using inpatient datasets has been described and validated previously.[8] Sepsis was identified using the methodology described by Martin et al.,[16] which utilized ICD-9-Clinical Modification codes 020.0, 790.7, 117.9, 112.5, and 112.81. The LOS and associated hospital charges were only calculated for patients who did not die during their hospital course. This was done to eliminate the artificial shortening of these variables in cases involving a withdrawal of care or potentially unrelated cause of death.

Statistical Analysis

Data were analyzed using SPSS version 17 (IBM Corp., Armonk, NY). To obtain national estimates, discharge weights were applied. Patient discharge data and hospital demographics were compared using Mann-Whitney U tests and χ^2 tests, as appropriate. Total hospital charges from 2008 and 2009 were compounded yearly at an inflation rate of 3% to standardize charges at 2010 levels. Hospital charges were converted to costs using the group average all-payer inpatient cost/charge ratio.

Multivariate models were used to compare the effect of ET versus LT on outcome measures and to examine the predictors of ET. The analysis considered the following patient-specific factors: age, gender, race, number of comorbidities, number of diagnoses, number of procedures, patient income (<\$39,000, \$39000–\$47,999, ≥\$48,000), and payer (Medicare, Medicaid, private insurance, self-pay, or no charge). The analysis also considered hospital-level factors including: region (Northeast, Midwest, South, West), teaching status, hospital-bed size (small, medium, large), hospital location (rural or urban), and hospital ownership (public, private nonprofit, private for profit). The model that examined the predictors of ET additionally included the Elixhauser comorbidities.[17] Continuous variables were transformed into categorical variables dichotomized about the median. Binary logistic regression was used to analyze the clinical outcomes. Backward stepwise regression was performed with variable entry when probability was <0.05 and removal when probability exceeded .10. Odds ratio (OR) and 95% confidence interval (CI) were reported. Generalized linear models with the use of generalized estimated equations were used to analyze the economic measures. To meet the distributional requirements of a generalized linear model, we used the logarithm of LOS and the logarithm of total inflation-adjusted costs as targeted outcomes in analyses. The effect ratio was expressed as the exponential parameter estimate along with the 95% CIs. A probability value of .01 was considered statistically significant to nominally control for type I error.

RESULTS

There were 378,000 tracheostomies reported by the NIS between from 2008 to 2010. Of these, 124,490 were eligible for inclusion in the study—extreme severity of illness (All Patient Refined Diagnosis-Related Group severity of illness classification: 4) and tracheostomy performed within 1 to 25 days of initiation of MV.

A total of 53,749 received ET compared to 71,244 who underwent LT. Multiple demographic and outcome measures were significantly different in patients receiving ET versus LT (Table I). Costs and LOS increased with increasing time to tracheostomy (Fig. 1). The rates of mortality, death, and sepsis increased linearly as the time to tracheostomy increased (Fig. 2).

Multivariate models were constructed to evaluate the economic outcomes while controlling for confounding factors. Similar to univariate analysis, ET resulted in significantly reduced LOS (effect ratio = 0.772, 95% CI: 0.758-0.786, $P < .001$) and hospital costs (effect ratio = 0.778, 95% CI: 0.765-0.791, $P < .001$).

In addition to differences in economic outcomes, ET was associated with increased the odds of discharge home (OR: 1.256, 95% CI: 1.113-1.418, $P < .001$) and decreased the odds of in-hospital mortality (OR: 0.766, 95% CI: 0.717-0.819, $P < .001$). Additionally, ET patients had an associated reduction in the odds of VAP (OR: 0.923, 95% CI: 0.873-0.975, $P = .004$) and sepsis (OR: 0.734, 95% CI: 0.694-0.776, $P < .001$). However, ET was also associated with increased odds of tracheostomy-related complications such as subglottic stenosis, glottic web, and granuloma formation (OR: 1.443, 95% CI: 1.240-1.679, $P < .001$).

Binary logistic regression revealed multiple predictors of ET and LT (Tables II and III).

DISCUSSION

The ideal timing of tracheostomy and its impact on clinical and economic outcomes is unknown. To address

TABLE I.
Demographics and Patient Outcomes in Early and Late Tracheostomy Recipients.

	Early	Late	*P*
Age, yr	63 (51-75)	65 (52-76)	<.001
Gender, female	22,727 (42.3%)	32,989 (46.3%)	<.001
Median income level			
<$39,000	16,580 (31.7%)	21,849 (31.5%)	
$39,000-$47,999	13,211 (25.2%)	16,493 (23.8%)	<.001
≥$48,000	22,587 (43.1%)	30,944 (44.7%)	
Hospital-bed size			
Small	3,320 (6.3%)	5,187 (7.4%)	
Medium	11,437 (21.6%)	16,149 (22.9%)	<.001
Large	38,196 (72.1%)	49,058 (69.7%)	
Hospital location			
Rural	1,845 (3.5%)	2,300 (3.3%)	.036
Urban	51,109 (96.5%)	68,094 (96.7%)	
Hospital region			
Northeast	11,827 (22.0%)	17,697 (24.8%)	
Midwest	8,035 (14.9%)	8,387 (11.8%)	<.001
South	22,518 (41.9%)	29,629 (41.6%)	
West	11,370 (21.2%)	15,532 (21.8%)	
Medicare	28,130 (52.3%)	39,281 (55.1%)	<.001
Teaching hospital	31,413 (59.3%)	40,647 (57.7%)	<.001
Patient factors			
Average number of days until tracheostomy	7 (5-9)	15 (13-18)	
>7 chronic conditions	21,386 (39.8%)	29,028 (40.7%)	.001
>18 diagnoses	22,290 (41.5%)	34,163 (48.0%)	<.001
>9 procedures	23,835 (44.3%)	37,431 (52.5%)	<.001
Acute respiratory failure	32,681 (60.8%)	48,279 (67.8%)	<.001
Chronic respiratory failure	541 (1.0%)	544 (0.8%)	<.001
Acute on chronic respiratory failure	7,751 (14.4%)	9,732 (13.7%)	<.001
Outcomes			
Discharged home	3,150 (5.9%)	3,132 (4.4%)	<.001
VAP	2,429 (4.5%)	3,576 (5.0%)	<.001
Sepsis	14,833 (27.6%)	25,341 (35.6%)	<.001
Tracheostomy complications	1,824 (3.4%)	1,756 (2.5%)	<.001
Mortality	8,947 (16.7%)	15,466 (21.7%)	<.001
Length of stay, d	24 (17-36)	33 (24-47)	<.001
Total charges, $	247,387 (157,197-394,910)	345,240 (227,643-525,302)	<.001
Cost, $	82,415 (53,797-126,448)	112,007 (77,239-165,227)	<.001

Continuous variables are presented as median (interquartile range), and categorical variables are presented as n (%).
VAP = ventilator-associated pneumonia.

this knowledge gap, we analyzed the NIS to provide a nationwide analysis of outcomes following ET and LT. Although the definition of ET remains debatable, a cutoff of 10 days was used. The rationale for 10 days was twofold. First, multiple studies investigating ET have utilized the 10-day cutoff.[2–5] Second, the 10-day cutoff allowed us to keep the sizes of the two groups analyzed relatively similar so as to avoid skewed population sizes.

Our study is largely in agreement with prior studies reporting that ET was significantly associated with decreased LOS and decreased hospital charges.[2,18,19] Multiple studies have found ET to reduce the LOS in intensive care.[18,20,21] Although the NIS does not differentiate ICU stay from total hospital stay, we found a similar reduction of overall LOS in patients receiving ET. The economic impact of reduced LOS, and in particular ICU stay, is significant. According to Dasta et al., the average ICU cost per day was $31,574 in patients receiving MV. After adjusting for patient and hospital characteristics, the mean incremental cost of MV in ICU patients was over $1,500 per day.[22]

With respect to MV and tracheostomy-related complications, multiple prior studies have reported a decreased incidence of VAP with ET.[20,21] We also found a

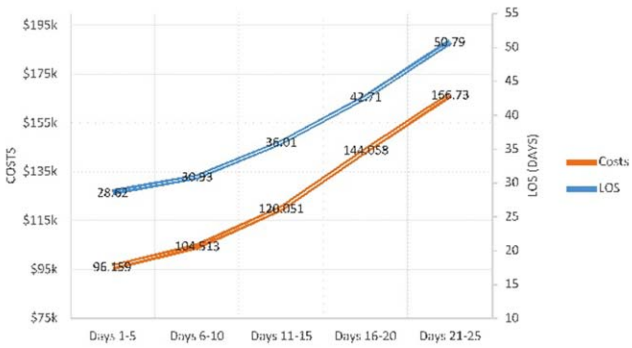

Fig. 1. Costs and length of stay (LOS) with respect to day of tracheostomy. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

1.5% decreased incidence of VAP in patients receiving ET. Considering the relatively large numbers of patients who receive tracheostomy and the cost associated with ICU stays, the economic impact cannot be ignored. This is particularly true as each case of VAP is estimated to add $40,000 per patient to the cost of hospitalization.[23] Furthermore, VAP has been proposed as a nonreimbursable complication by the Centers for Medicare and Medicaid Services.[24,25]

Although some prior studies have shown no impact on mortality,[5,26] our study is in agreement with those showing a significant association between increased time to tracheostomy and increased in-hospital mortality.[3,19] The likelihood of discharge home was highest in those receiving ET (10.5% vs. 4.5%). Similar to mortality, this finding may represent inherent differences in the ability to receive ET or social factors that impact patient discharge status. However, we cannot ignore the possibility that ET, in and of itself, may impact discharge status.

Interestingly, we did note an increase in the tracheostomy-related complications of subglottic stenosis, glottic webs, and granuloma formation in those receiving ET. It is difficult to ascertain the exact reason for this. Because there is no way to know the temporal relationships between diagnosis codes (i.e., which diagnosis came first), it is possible that some of the patients who underwent ET had preexisting stenosis or granulomas. Also, as laryngeal injury can be seen as early as 7 days after laryngeal intubation,[6] it is possible that intubation, rather than ET, is the cause of these complications. Our findings are in contrast to a 2012 study by Tong et al., which showed an increase in complications in those receiving LT, defined in their study as 7 days after MV. The complications reported included stomal bleeding, tracheitis, self-decannulation, stomal wound complication, and mucus plugging.[18] Unfortunately, we are unable to determine the incidence of these specific complications in our study population due to limitations in the NIS database. Further investigation is needed.

Several significant predictors of ET and LT were identified. It may seem counterintuitive that the most common diagnoses for both ET and LT—acute, chronic, and acute on chronic respiratory failure—are predictors of LT. However, this may be reflective of an overall trend toward LT, with more than double the amount of respiratory-failure patients receiving LT versus ET. The comorbidities found to be associated with ET are those unlikely to quickly respond to treatment, and intuitively, are likely to require prolonged intubation. In cases of metastatic cancer and solid tumors—depending on location—without debulking, resection, or neoadjuvant therapy, any associated airway compromise would be unlikely to resolve spontaneously, thus making ET an appropriate choice. Paralysis and neurologic disorders are similarly unlikely to resolve quickly.

The recently published TracMan (Tracheostomy Management in Critical Care) trial is the latest prospective, randomized trial examining the effect of ET on mortality and ICU LOS, in this case within 4 days of intubation, versus LT (7–14 days). This study included 909 critical-care patients and compared the end points of ICU stay, complications, and mortality. Although the study failed to show a significant benefit of ET, it should be cautioned that this trial was stopped prematurely, not for statistical reasoning, but due to lack of funding. Additionally, a narrow set of outcome measures was used, and they did not assess other factors important when considering benefit to the patient including other tracheostomy-related complications such as stenosis and the course of subsequent voice, swallowing, and airway rehabilitation.[27] Complications were reduced in the ET group (5.5% vs. 7.8%) but not significantly so. This trial also serves to highlight the lack of definitive guidelines for tracheostomy placement and resultant issues. The decision to randomize a patient was based on the predicted need for 7 additional days of MV, a fairly liberal inclusion criteria, especially when this prediction is made shortly following placement on MV. Only 45% of patients assigned to the LT group eventually received tracheostomy.[28] This would suggest that the ability of clinicians to predict which patients will require prolonged intubation is limited.

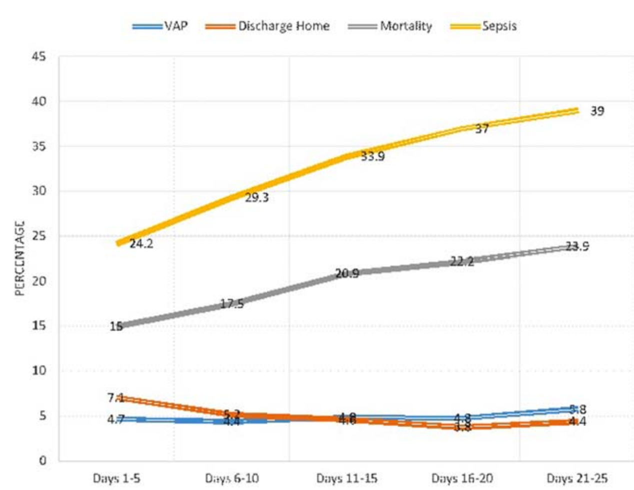

Fig. 2. Patient outcomes with respect to day of tracheostomy. VAP = ventilator-associated pneumonia. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

A scoring tool to aid the clinical decision of when to perform tracheostomy is both desirable and lacking. Several studies have previously attempted to establish criteria for tracheostomy. Major et al.[29] attempted to identify positive predictors of need for tracheostomy in blunt head trauma patients. They found the Glascow Coma Scale (GCS) and Simplified Acute Physiology Score (SAPS) highly predictive and concluded that patients with a GCS <7 and a SAPS >15 on hospital day 4 should undergo tracheostomy as soon as they can tolerate the procedure.[29] Holmgren et al.[30] analyzed over 1,000 patients with facial fractures who required tracheostomy. They found that the facial injury severity score was significantly higher in those who underwent tracheostomy. Overall, patients requiring tracheostomy had injuries that were more severe, specifically single or multiple mandible fractures or Le Fort III fractures.[30] Although these studies may help guide clinical decision making, they studied specific patient populations, in both cases trauma patients, and a widely applicable and validated scoring tool is still needed.

The current study documents a nationwide association between ET and reduced complications of MV such as VAP and improved economic outcomes. However, this study is not without limitations. It is a retrospective analysis of a large administrative database; determination of tracheostomy receipt was not randomized. This limits the ability to adequately match the population in each group across a wide variety of patient- and disease-specific variables. For example, though increasing numbers of diagnoses and procedures were both predictors of LT, analysis may have been confounded as more complex patients are inherently more likely to require lengthier and more intensive hospital courses with subsequently increased hospital costs. Alternatively, this may indicate that other medical conditions needed to be stabilized prior to tracheostomy, and that optimization of these other conditions may have been done prior to considering tracheostomy. However, this approach does reduce potential bias in patient selection, as data analysis is completely isolated from patient management. Additionally, the scope of the study was limited to outcomes occurring prior to hospital discharge; it is impossible to know how these patients ultimately fared. For example, progression to, and timing of, tracheostomy decannulation is unknown. Similarly, as long-term follow-up was not possible, long-term incidence of complications such as airway stenosis and granulation tissue could not be assessed. Additionally, there are other important factors when determining the outcome of tracheostomy that cannot be gleaned from the NIS database. For example, multiple prior studies showed ET resulted in significantly more ventilator-free, sedation-free, and ICU-free days.[1,15,20,21,26] Perhaps most importantly, the data collected from the NIS do not take into account the clinical acumen of the treating physician(s) or the myriad of individual factors that play into the determination of treatment course.

TABLE II.
Predictors of Early Tracheostomy.

Early Predictors	Odds Ratio	95% CI	*P*
Age <65 years	1.136	1.078–1.197	<.001
Midwest hospital	1.430	1.324–1.543	<.001
Government, nonfederal hospital	1.094	1.016–1.177	.017
Number of chronic conditions, >7	1.202	1.125–1.284	<.001
Cancer with metastases	1.164	1.015–1.336	.030
Neurologic disorder	1.196	1.119–1.278	<.001
Paralysis	1.264	1.174–1.362	<.001
Solid tumor without metastases	1.263	1.086–1.470	.003

CI = confidence interval.

TABLE III.
Predictors of Late Tracheostomy.

Late Predictors	Odds Ratio	95% CI	*P*
No. of diagnoses, >18	1.273	1.192–1.360	<.001
No. of procedures, >9	1.401	1.327–1.479	<.001
Small hospital	1.150	1.042–1.269	.005
Acute respiratory failure	1.601	1.501–1.708	<.001
Acute on chronic respiratory failure	1.349	1.234–1.474	<.001
Liver disease	1.278	1.126–1.451	<.001
Lymphoma	1.478	1.158–1.887	.002
Fluid and electrolyte disorder	1.174	1.111–1.241	<.001
Psychoses	1.185	1.052–1.336	.005
Renal failure	1.125	1.051–1.203	.001

CI = confidence interval.

CONCLUSION

Effective and efficient healthcare delivery is paramount both for optimizing patient care and decreasing cost. ET is significantly associated with reduced complications, hospital stay, and total charges, while increasing the likelihood of discharge home. Additional randomized, prospective studies are needed to more fully evaluate the impact of ET. Additionally, due to difficulties in ability to predict the need for prolonged intubation, development of a standardized scoring tool to aid in tracheostomy decision making would be helpful.

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