DISCLAIMER: These guidelines were prepared by the Department of Surgical Education, Orlando Regional Medical Center. They are intended to serve as a general statement regarding appropriate patient care practices based upon the available medical literature and clinical expertise at the time of development. They should not be considered to be accepted protocol or policy, nor are intended to replace clinical judgment or dictate care of individual patients.

TIMING OF TRACHEOSTOMY

SUMMARY

The appropriate timing of tracheostomy in the patient suspected to require prolonged mechanical ventilation remains a subject of controversy. Multiple retrospective and prospective studies have been performed to evaluate this clinical question. These studies suggest that early tracheostomy (within 7-10 days of intubation), especially among patients with traumatic brain injury, is associated with significant improvements in duration of mechanical ventilation, intensive care unit and hospital length of stay, reduced ventilator-associated pneumonia, reduces hospital costs, and improves patient survival.

RECOMMENDATIONS

- Level 1
- None
- Level 2
 - Tracheostomy should be considered in patients who require more than 7-10 days of mechanical ventilation in order to reduce the duration of mechanical ventilation and decrease intensive care unit and hospital length of stay, duration of sedation, and hospital cost.
 - The reason for mechanical ventilation should be considered when deciding the timing of tracheostomy.

• Level 3

- Tracheostomy before 7 days is contraindicated in patients with a probability of survival less than 25%.
- > Early tracheostomy may reduce the risk of ventilator-associated pneumonia and may improve patient survival.

INTRODUCTION

Airway access for mechanical ventilation can be provided either by endotracheal or tracheostomy tube. During episodes of acute respiratory failure, patients are generally ventilated through an endotracheal tube. The transition to a tracheostomy tube is often considered when the need for mechanical ventilation is expected to be prolonged. The most common indications for tracheostomy are acute respiratory failure and need for prolonged mechanical ventilation and traumatic or catastrophic neurologic insult requiring airway control, mechanical ventilation or both. Upper airway obstruction is a less common indication for tracheostomy. Observational studies document that approximately 10% of mechanically ventilated patients will require tracheostomy, but there is significant variability regarding optimal timing and patient selection.

LITERATURE REVIEW

Several retrospective and prospective studies have been performed to examine the optimal timing for

EVIDENCE DEFINITIONS

- Class I: Prospective randomized controlled trial.
- Class II: Prospective clinical study or retrospective analysis of reliable data. Includes observational, cohort, prevalence, or case control studies.
- Class III: Retrospective study. Includes database or registry reviews, large series of case reports, expert opinion.
- Technology assessment: A technology study which does not lend itself to classification in the above-mentioned format. Devices are evaluated in terms of their accuracy, reliability, therapeutic potential, or cost effectiveness.

LEVEL OF RECOMMENDATION DEFINITIONS

- Level 1: Convincingly justifiable based on available scientific information alone. Usually based on Class I data or strong Class II evidence if randomized testing is inappropriate. Conversely, low quality or contradictory Class I data may be insufficient to support a Level I recommendation.
- Level 2: Reasonably justifiable based on available scientific evidence and strongly supported by expert opinion. Usually supported by Class II data or a preponderance of Class III evidence.
- Level 3: Supported by available data, but scientific evidence is lacking. Generally supported by Class III data. Useful for educational purposes and in guiding future clinical research.

tracheostomy. These studies evaluated the potential benefits of reduced length of stay (LOS), mortality, and intensive care unit (ICU) stay. A 2020 study performed at a tertiary medical center showed that patient's managed by Trauma and Neurology services had a significantly shorter time to tracheostomy than those managed by other services (1). In addition to the objective data points studied in most of the following studies, a study in Australia showed that patients who received tracheostomy had earlier returns to walking, talking, out of bed exercise, and required less sedation and analgesia. This study however compared patients with tracheostomy to intubated patients (2).

Arabi et al. published a retrospective study of 531 mechanically ventilated subjects in a mixed medical/surgical ICU (3). The mean time to tracheostomy was 12 days and mean ICU LOS was 23 days. Time to tracheostomy was associated with an increased duration of mechanical ventilation, ICU LOS, and hospital LOS for each day tracheostomy was delayed. Time to tracheostomy was not associated with increased ICU or hospital mortality.

Beltrame et al. performed a single-center study evaluating the outcomes of bedside percutaneous dilatational tracheostomy (PDT) and surgical tracheostomy (ST) (4). Five hundred twenty-eight mechanically ventilated patients underwent tracheostomy. 161 patients received ST and 367 underwent PDT. STs were performed significantly later than PDT (12.4 days vs. 8.7, p<0.05). Overall ICU LOS (18.4 vs. 23.3 days, p< 0.05) and mean duration of mechanical ventilation (14.2 vs. 20.1 days, p<0.05) were lower in the PDT than in the ST group.

Möller et al. performed a study to determine whether early tracheostomy (ET) of severely injured patients reduces duration of mechanical ventilation, the frequency of ventilator-associated pneumonia (VAP), and ICU LOS (5). The study was a retrospective review that included 185 surgical ICU patients with acute injuries requiring mechanical ventilation and tracheostomy. There were no differences in the rate of acute respiratory distress syndrome (ARDS) or acute lung injury between groups. ET was defined as \leq 7 days, and late tracheostomy (LT) as > 7 days. The incidence of VAP was significantly higher in the LT group (42.3% vs. 27.2%, respectively; p<0.05). They also found that APACHE II scores, hospital and ICU LOS, and the number of ventilator days were significantly higher in the LT group.

In 2005, a systematic review and meta-analysis included 5 randomized controlled trials (RCT) evaluating the timing of tracheostomy in 406 adult patients on ventilatory support (6). ET did not significantly alter mortality (relative risk 0.79, 95% confidence interval 0.45 to 1.39) or the risk of pneumonia (0.90, 0.66 to 1.21). ET did however significantly reduce the duration of mechanical ventilation (weighted mean difference 8.5 days) and ICU LOS (weighted mean difference 15.3 days).

In 2008, a large retrospective analysis from Ontario compared mechanically ventilated patients who underwent ET vs. LT. A total of 10,927 patients received tracheostomy during the study of which one-third (n=3758) received ET \leq 10 days) and two-thirds (n=7169) received LT (>10 days). Patients in the ET group had lower unadjusted 90-day (34.8% vs. 36.9%; p=0.032), 1 year (46.5% vs. 49.8%; p=0.001), and study mortality (63.9% vs. 67.2%; p<0.001) than patients in the LT group (7).

Terragni et al. conducted a multicenter prospective RCT in 12 Italian ICUs from June 2004 to June 2008 (8). The study enrolled 600 adult patients without pneumonia who had been ventilated for 24 hours. Subjects were monitored for 48 hours and those with worsening respiratory failure and no pneumonia were then randomized to either early (6–8 days, n=209) or late tracheostomy (13–15 days, n=210). The study included both medical and surgical subjects with no demographic differences. Thirty-one percent in the early group and 43% of the late group did not undergo tracheostomy due to proximity to either extubation or death. In the early group, 69% underwent tracheostomy compared with 57% in the late group. All tracheostomies were performed using bedside percutaneous techniques (Griggs technique in 72% early vs. 73% late, PercuTwist technique in 25% vs. 22%). VAP developed in 14% of early vs. 21% of late tracheostomy group, but 28-day survival (74% vs. 68%; p=0.25) did not differ. The authors concluded that early tracheostomy did not result in significant reduction in the incidence of VAP compared with late tracheostomy and was associated with an adverse event related to the tracheostomy procedure in more than one third of subjects. It should be noted that both percutaneous insertion techniques utilized in this

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study have been noted in other studies to have an increased rate of procedural complications.

Young et al. performed the largest open multi-center randomized controlled trial on timing of tracheostomy (9). This study was conducted from 2004 through 2011 in 70 general adult and 2 cardiothoracic ICUs in 72 hospitals in the United Kingdom. Nine hundred nine patients were enrolled. Inclusion criteria were mechanically ventilated subjects in adult ICUs who were identified in the first 4 days after admission as likely to require at least an additional 7 days of mechanical ventilation. Exclusion criteria included those patients receiving immediate tracheostomy or were contraindicated due to anatomical or other reasons or those with respiratory failure due to chronic neurological diseases. Patients were randomized to either ET (within 4 days after intubation, n=455) or LT (after 10 days if still indicated, n=454). Most subjects were admitted with a medical diagnosis (79.2%), with respiratory failure as the primary admission diagnosis (n=59.5%). Interestingly, in the early group, 91.9% of subjects received tracheostomy as planned as compared to the late group where only 45.5% of subjects required tracheostomy. Many subjects in the late tracheostomy group no longer required mechanical ventilation and were successfully extubated. Ninety percent of the tracheostomies were performed by the percutaneous technique, with 88.7% performed in the ICU at the bedside, and the majority (77.3%) performed by the single tapered dilator technique. There was no difference in 30-day mortality (30.8% ET vs. 31.5% LT), 2-year mortality (51.0% vs. 53.7%), or median ICU stay among survivors (13.0 days vs. 13.1 days). There was also no difference in hospital stay or duration of mechanical ventilation between the two groups. However, ET was associated with significantly decreased sedation use. The median number of days during which any sedatives were received in survivors at 30 days after randomization was 5 days in the early group and 8 in the late group (p<0.001), with a mean difference between groups of 2.4 days (95% CI 1.6–3.6).

Patient selection is a key factor in determining timing to tracheostomy. Barquist et al. performed one of the few prospective RCTs looking at timing to tracheostomy in trauma patients (10). This was a single-center trial comparing trauma patients who received a tracheostomy within 8 days of intubation vs. those whose tracheostomy was delayed until after day 28. The study was halted after the first interim analysis (after 60 patients) as there was no significant difference between groups in number of mechanical ventilator days, ICU length of stay, incidence of VAP, or hospital mortality. They concluded that tracheostomy before day 8 post-injury in trauma patients did not reduce the number of days of mechanical ventilation, frequency of pneumonia or ICU LOS as compared with a tracheostomy strategy involving the procedure at 28 days post-injury or more.

In 2009, Schauer et al. performed a retrospective multi-institutional study looking back over a 5-year period (11). They analyzed the relationship between the timing of tracheostomy in trauma patients and mortality, ICU and hospital LOS, and incidence of pneumonia. This relationship was investigated in the context of expected survival based on probability of survival (Ps) greater than 25%. The study examined 685 trauma patients who received tracheostomy and stratified patients into low and high probability of survival and early (0–3 days), early intermediate (4–7 days), late intermediate (8–12 days), and late (>12 days) tracheostomy. ET was associated with decreased ICU stay, hospital stay, total ventilator days, and rates of pneumonia among trauma patients with a high Ps. There was a significantly higher mortality rate (48.9%) associated with patients with low Ps (<25%) receiving tracheostomy less than 4 days injury. This study demonstrated that ET in patients with low Ps may not be beneficial given the high mortality rate before post injury day 4. However, in patients with high probability of survival, there is an increased benefit to ET.

Arabi et al. also showed a benefit to ET (12). They evaluated trauma patients who received tracheostomy over a 5-year period. Tracheostomy was considered early if it was performed by day 7 of mechanical ventilation. Multivariate analysis was performed on duration of mechanical ventilation, ICU LOS, and outcome between ET and LT patients. Six hundred fifty-three trauma ICU patients were identified, of which 21% required tracheostomy. Twenty-nine patients underwent ET and 107 received LT. ET patients were more likely to have maxillofacial injuries and to have a lower Glasgow Coma Scale score. Duration of mechanical ventilation was significantly shorter with ET (mean 9.6 versus 18.7 days; *p*<0.0001). Similarly, ICU LOS was significantly shorter (10.9 vs. 21.0 days; p<0.0001). There was no significant difference regarding ICU LOS after tracheostomy. ICU and hospital mortality rates were similar. LT was found to be an independent predictor of prolonged ICU stay (>14 days).

These results were duplicated by Hyde et al. (13). ET was defined as a tracheostomy performed by the fifth hospital day. Patients in the ET group had significantly shorter ICU LOS (21.4 vs. 28.6 days, p<0.0001) and significantly fewer ventilator days (16.7 vs. 21.9 days, p<0.0001) compared to the LT group. ET patients also had significantly less VAP (34% vs. 64.2%, p=0.0019). In the current era of increased healthcare costs, the authors concluded that ET significantly decreased both pulmonary morbidity and critical care resource utilization translating to a cost savings of \$52,173 per patient. They concluded that for trauma patients requiring prolonged ventilator support, ET should be performed.

Patients with traumatic brain injury (TBI) commonly tracheostomy. In 2004, Bouderka et al. published a study that evaluated whether ET (by the fifth day post-injury) reduces duration of mechanical ventilation, ICU LOS, incidence of VAP, and mortality in comparison with prolonged intubation among patients with head injury (14). Randomization was performed on the fifth day into two groups: ET and prolonged endotracheal intubation (PEI). The two groups were comparable in terms of age, sex, and Simplified Acute Physiologic Score (SAPS). The mean time of mechanical ventilation was shorter in the ET group (14.5 days) vs. PEI group (17.5 days) (p=0.02). After pneumonia was diagnosed, mechanical ventilatory time was 6 days for the ET group vs. 11.7 days for PEI group (p=0.01). There was no difference in frequency of pneumonia or mortality between the two groups. Khan et al. recently demonstrated that in patients with cervical spine injuries without traumatic brain injury (TBI), ET (prior to intubation day 7) had lower rates of VAP, shorter duration of mechanical ventilation, and ICU and hospital LOS (15).

Rizk et al. collected data from the Pennsylvania Trauma Society Foundation statewide trauma registry from January 1990 until December 2005 (16). 3,104 patients met criteria for inclusion in the study (GCS \leq 8, documented TBI, and tracheostomy). Patients in the ET group (< 7 days) had higher ISS and lower GCS scores when compared to the LT group (> 7 days). ICU and hospital LOS were significantly lower and functional independence at discharge significantly greater in the ET group. However, LT patients were more likely to be discharged alive (93% vs. 85%, p<0.0001). The authors concluded that a strategy of ET (1-7) days, particularly when performed on patients with a reasonable chance of survival, results in a better overall clinical outcome than when the tracheostomy is performed in a delayed manner.

In a small 2002 study, Saffle et al. randomized patients to either ET, or to conventional therapy with tracheostomy on intubation day 14. They showed that although there were some benefits in terms of patient comfort, there was no benefit in mortality (17). This work was seemingly confirmed by a 2018 study by Tsuchiya et al. who retrospectively reviewed severely burned patients who underwent ET. They initially predicted that those patients would have improved outcomes with decreased mortality, but no difference in mortality was demonstrated between the groups (18)

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