Tracheostomy Tube Change Before Day 7 Is Associated With Earlier Use of Speaking Valve and Earlier Oral Intake

Daniel F Fisher MSc RRT, Dhimiter Kondili, June Williams MSc SLP,
Dean R Hess PhD RRT FAARC, Edward A Bittner MD PhD, and Ulrich H Schmidt MD PhD

BACKGROUND: Presence of a tracheostomy tube often decreases the patient's ability to communicate and to tolerate oral intake. The initial tracheostomy tube change is often recommended between day 7 and 14 post insertion. Local guidelines permit tracheostomy tube change 5 days after insertion. OBJECTIVE: We hypothesized that changing tracheostomy tubes before day 7 is associated with earlier use of a speaking valve as well as earlier oral intake, compared to changing tracheostomy tubes after 7 days. METHODS: We prospectively enrolled 130 admitted subjects, after tracheostomy placement to a respiratory care unit between July 2008 and May 2010. Subject data were recorded from the electronic medical record. The primary end point was the time from tracheostomy tube placement to tolerating speaking valve. The secondary end point was the time from tracheostomy tube placement to tolerating oral intake. Complications of tracheostomy tube change were recorded. RESULTS: Thirty-eight subjects had the first tracheostomy tube change before 7 days (early group), and 92 subjects had the first tracheostomy tube change after 7 days (late group). The early group tolerated a speaking valve significantly sooner than the late group (7 d vs 12 d, $P = .001$). The early group also tolerated oral intake significantly sooner (10 d vs 20 d, $P = .04$). After change of the tracheostomy tube, the time to tolerating oral feeding was 5.5 days in both groups. There was no significant difference in time to decannulation between the groups. The early group had a shorter respiratory care unit stay (11 d vs 17 d, $P = .001$) and a shorter hospital stay ($P = .05$) than the late group. There was no difference in survival. There were no complications associated with tracheostomy tube change. CONCLUSIONS: Tracheostomy tube change before day 7 is associated with earlier ability to tolerate speaking valve and oral intake. In this series, early tracheostomy tube change was not associated with an increased rate of complications. *Key words: tracheostomy; mechanical ventilation; respiratory failure; outcomes; safety.* [Respir Care 2013;58(2): 257–263. © 2013 Daedalus Enterprises]

Introduction

Tracheostomy tubes are placed in over 10% of patients who require more than 3 days of mechanical ventilation.[1]

The presence of a tracheostomy tube often decreases the patient's ability to communicate and to tolerate oral in-

take.[2,3] Since sufficient flow and pressure generation are needed for effective vocalization by the patient with a tracheostomy, it is common to downsize the outer diameter of the airway prior to employing either a speaking valve or decannulation cap.[2] The initial tracheostomy tube change is commonly recommended between day 7 and 14 post insertion.[4] In our hospital there is wide variation among clinician opinions regarding when to downsize the tracheostomy tube. Some, but not all, feel that an earlier downsize of the tube allows for earlier verbal communication and oral intake. We therefore undertook a prospective observational study to determine whether tracheostomy tube change before day 7 is associated with earlier use of speaking valves and oral intake, compared to tracheostomy tube change after day 7.

We hypothesized that first tracheostomy tube change before day 7 is associated with earlier use of a speaking valve and earlier oral intake, compared to the first tracheostomy tube change after 7 days.

Methods

Setting

This study was performed in the Respiratory Acute Care Unit (RACU) of the Massachusetts General Hospital. The RACU is a 10-bed unit providing care of mechanically ventilated patients who are hemodynamically and metabolically stable. The focus of the RACU is liberation of patients from mechanical ventilation.[5,6] Ventilated patients are transferred from other ICUs. After liberation from the ventilator they are either transferred to the wards for continued care of their underlying disease, or transferred to rehabilitation facilities. The RACU uses a transitional model that includes a medical director, intensivists from the Department of Anesthesia and Critical Care Medicine, and intensivists from the Department of Pulmonary and Critical Care Medicine. There is one nurse for every 2 patients. A respiratory therapist and attending intensivist are on-site 24 h/d. Patient care is provided by a multidisciplinary team including speech and language pathologists and physical therapists, in addition to physicians, respiratory therapists, and nurses.

The care model incorporates guidelines for liberation from mechanical ventilation, downsizing of tracheostomy tubes for speech and oral feeding, and tracheostomy tube decannulation. Specifically, guidelines for tracheostomy tube change state that the tubes can be changed 5 days after placement. The first tube change is by an attending intensivist, or by a fellow in critical care medicine under direct supervision of an attending physician. Additionally, a respiratory therapist assists with the first tube change, and a nurse is in attendance. The decision to change the tracheostomy tube is made by the attending physician. A

QUICK LOOK

Current knowledge

The presence of a tracheostomy tube often decreases the patient's ability to communicate and to tolerate oral intake. The optimal timing for elective change of a tracheostomy tube is unknown.

What this paper contributes to our knowledge

Tracheostomy tube change before day 7 is associated with earlier ability to tolerate placement of a speaking valve and oral intake. In this series, early tracheostomy tube change was not associated with an increased rate of complications.

speech and language pathologist is assigned to the RACU to assist with speech in patients with a tracheostomy tube, and to assess their ability to swallow. Subjects were treated following institutional guidelines. Speech and language pathologists performed a formal consultation and assessment before oral feeding. The consistency of the diet was altered according to their assessment. All subjects were followed by nutritionists to assure that the subjects received adequate nutrition. Following institutional guidelines, speaking valve trials were performed after assuring that the tracheal pressure was acceptable. Full cuff deflation and adequate air flow were assessed in all subjects. Subjects were closely supervised by respiratory care and nursing staff during speaking valve trials.

During the study period there were no changes in policies related to tracheostomy change. There were no changes in attending physician staff or mid-level providers. Nursing, speech pathology, and respiratory therapy staff were also stable during this time.

Study Design

The study was approved by the institutional review board of the Massachusetts General Hospital. The need to obtain subject consent for the study was waived by the institutional review board. The investigators were not directly involved in the decision-making regarding the timing of change of tracheostomy tubes.

We included only the first admission of tracheostomized subjects to the RACU of the Massachusetts General Hospital from July 2008 through May 2010.

Patients were excluded from analysis if they were transferred from an outside institution with a tracheostomy in place, if they did not undergo a tracheostomy tube change, if they had progressive neuromuscular weakness requiring long-term mechanical ventilation (long-term tracheos-

tomy), or if they underwent an emergency tracheostomy tube change. All other patients were included. Local institutional guidelines permit elective tracheostomy tube change 5 days after tracheostomy placement. We predefined an early group as subjects who underwent a change of the tracheostomy tube before day 7 and a late group as subjects who underwent tracheostomy tube change more than 7 days after tracheostomy placement.

Demographic Factors

Age, sex, number of hospital days, number of days in the RACU, and admission service (medicine, surgery, neurology) were recorded. Acute Physiology and Chronic Health Evaluation II scores were recorded. Comorbidities were identified from the medical record (eg, coronary artery disease, congestive heart failure, neurological disease, renal insufficiency, COPD, asthma) and summarized using the Charlson comorbidity index. These data were extracted by 2 authors, both of whom have been extensively trained and have experience with this task. Data extraction was overseen and validated by 2 other authors. All investigators completed the Collaborative Institutional Training Initiative, as directed by the institutional review board.

Study End Points

The primary end point was the time from tracheostomy tube placement to successfully tolerating a speaking valve. Tolerating a speaking valve was defined as not needing to discontinue use of the valve due to respiratory distress. The subjects were able to clear secretions and did not require suctioning. Phonation was assessed in all subjects, and oxygenation was within the pre-described range.

The secondary end point was the time from tracheostomy placement to time of tolerating oral intake. Tolerating oral intake was defined as not discontinuing oral intake due to respiratory distress. We also recorded complications of tracheostomy tube change.

The following complications were predefined: inability to insert a tracheostomy tube; bleeding at the tracheostomy site and/or substantial subject discomfort, defined as either the subject's communication of substantial discomfort; coughing that required intervention; or an increase in breathing frequency to > 30 breaths/min.

Statistical Analysis

All data analysis was performed using statistics software (Stata 10, StataCorp, College Station, Texas). Continuous variables with a normal distribution are expressed as mean ± SD. Ordinal variables are expressed as median and interquartile range. Baseline demographic characteristics, tracheostomy data, and outcomes of the 2 groups
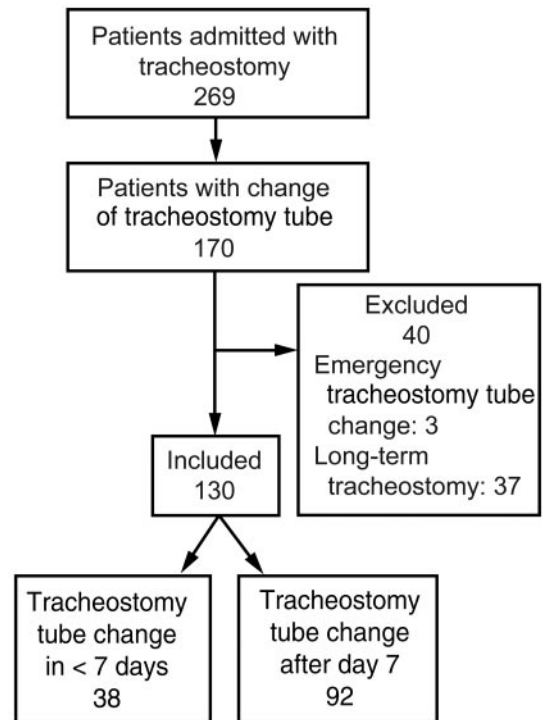

Figure. The flow of subjects enrolled in the study.

were compared by unpaired t test for normally distributed variables, and by Wilcoxon rank sum test for variables that were not normally distributed. The chi-square test was used to compare absolute numbers and proportions.

Results

During the study period, 269 patients were admitted to the RACU with a tracheostomy tube in place (Figure). There were 99 patients who did not have a tracheostomy tube, who were excluded from the study. Of the remaining 170 patients, 40 were excluded because they either underwent an emergency tracheostomy change or had long-term tracheostomies placed. There were 130 subjects who had their tracheostomy tube changed from the original postsurgical airway to a tube with a smaller outer diameter. Of these, 38 subjects had the first tracheostomy tube change before day 7 (early group) and 92 subjects had the first tracheostomy tube change after day 7 (late group). Table 1 summarizes demographic and other care-related data. There was no difference in age, sex, or severity of disease between the groups, as measured by Acute Physiology and Chronic Health Evaluation II and Charlson score. At the time of tracheostomy change, 53% of subjects in the early group were mechanically ventilated, and 43% in the late group ($P = .47$). There was also no statistical difference between subjects mechanically ventilated on day 6 post tracheostomy placement (early group 45%, late group 59% $P = .09$).

Table 1. Subject Characteristics

	Early Tracheostomy Tube Change (< 7 d) (n = 38) no. (%)*	Late Tracheostomy Tube Change (≥ 7 d) (n = 92) no. (%)*	P
Demographic			
Age, mean ± SD y	64.1 ± 17.8	62.6 ± 16.0	.53
Female	12 (32)	36 (39)	.55
Hospital Admitting Service			
Medicine	11 (29)	33 (36)	.35
Surgery	17 (45)	34 (37)	.37
Neurology	10 (26)	25 (27)	.80
ICU Type†			
Medical	11 (29)	28 (31)	.74
Surgical	13 (34)	26 (29)	.61
Other	14 (37)	40 (43)	.61
Clinical			
Body mass index, mean kg/m²	26.3	28.7	.11
Comorbidities			
Coronary artery disease	13 (34)	33 (36)	.72
Congestive heart failure	14 (37)	39 (42)	.43
Peripheral vascular disease	4 (11)	9 (10)	.97
Neurological disease	23 (61)	61 (66)	.49
History of malignancy	8 (21)	17 (18)	.83
Renal insufficiency	12 (32)	40 (43)	.15
Diabetes	11 (29)	36 (39)	.20
COPD	16 (42)	33 (36)	.64
Asthma	4 (11)	19 (21)	.14
Connective tissue disease	1 (3)	13 (14)	.046
Gastrointestinal disease	23 (61)	45 (49)	.35
Charlson comorbidity index score, mean ± SD	3 ± 2.7	3 ± 2.3	.56
APACHE II score, mean ± SD	10 ± 7–15	11 ± 8–15	.50
Etiology of Respiratory Failure			
ARDS	17 (45)	47 (51)	.37
Chronic lung disease with acute lung injury	9 (24)	18 (20)	.69
Neurological disease	7 (18)	17 (18)	.98
Congestive heart failure	2 (5)	5 (6)	.92
Other	3 (8)	6 (7)	.48
Tracheostomy			
Time to first tracheostomy change, mean ± SD, d	5.0 ± 1.2	12.8 ± 6.1	< .001
Duration of mechanical ventilation prior to tracheostomy, mean ± SD, d	16.9 ± 15.5	15.1 ± 9.3	.49
Percutaneous tracheostomy technique	32 (84)	71 (77)	.81
Mechanically ventilated day 6 post tracheostomy	17 (45)	54 (59)	.09
Mechanically ventilated on day of tracheostomy change	20 (53)	40 (43)	.47
Days to tracheostomy change after liberation from mechanical ventilation, mean ± SD	2.21 ± 1.18	3.98 ± 4.76	.007

* Values are number and percent unless otherwise indicated.
† Two subjects were admitted to 2 ICUs during their hospital stay.

All tracheostomy tubes had been placed before transfer to the RACU. A percutaneous technique was used in 79% of the cases. A Shiley percutaneous tracheostomy tube (inner diameter 8 mm and outer diameter 12.2 mm) was used for all percutaneous placements. The remaining 21% were either Shiley single cannula or Portex disposable inner cannula, placed with an open technique. All tracheostomy tubes were downsized to a tube with an inner

Table 2. Outcome Data*

	Early Tracheostomy Tube Change (< 7 d) (n = 38)	Late Tracheostomy Tube Change (≥ 7 d) (n = 92)	P
Oral intake days after tracheostomy	10 (9–18)	20 (15–25)	.04
Oral intake days after tracheostomy tube change	5.5 (3–12)	5.5 (3–9)	.65
Speaking valve days after tracheostomy placement	7 (6–10)	12 (10–19)	< .001
Speaking valve days after tracheostomy tube change	2 (0–6.5)	1 (0–3)	.17
Decannulation days from tracheostomy tube change	13.5 (10–17)	17 (13–22)	.28
ICU stay, d	11 (7–15)	17 (12–23)	.001
Hospital stay, d	14.5 (6–26)	24 (8–34)	.05
Survival, no. (%)	34/38 (89)	79/82 (96)	.15
At discharge	37/38 (97)	80/82 (98)	.95
30 d post-discharge	34/38 (89)	76/82 (93)	.55
60 d post-discharge	34/38 (89)	74/82 (90)	.90
120 d post-discharge	33/38 (87)	67/82 (82)	.48

* Values are median and IQR unless otherwise indicated.

diameter of 7.0 mm and an outer diameter of 9.6 mm. We used tracheostomy tubes with air cuffs in all subjects.

There was less time between liberation from the ventilator and toleration of speaking valve in the early group (2 d vs 4 d, P = .007). The early group tolerated a speaking valve significantly sooner than the late group (7 d vs 12 d, P = .001). The early group also tolerated oral intake significantly sooner (10 d vs 20 d, P = .04). The adequacy of caloric intake was monitored by the nutritionists and deemed adequate for all patients. After change of the tracheostomy tube, the time to tolerate oral feeding was 5.5 days in both groups. There was no significant difference in time to decannulation between the groups. The early group had a shorter RACU stay (11 d vs 17 d, P = .001) and a shorter hospital stay (P = .05) than the late group. There was no significant difference in survival between the groups. There were 125 subjects (96%) discharged to a rehabilitation facility, and 5 subjects (4%) were discharged home. Outcome data are summarized in Table 2.

Complications

During the study period there were no complications with changing of the tracheostomy tube, including bleeding at the tracheostomy site or complaints of substantial subject discomfort reported during the procedure. The pain score in all subjects was < 3, and the Richmond Agitation and Sedation Scale score was between −1 and 0 in all subjects.[7]

Discussion

The main finding of our study was that the first change of a tracheostomy tube before day 7 was associated with an earlier tolerance of a speaking valve and earlier oral feeding. Early first change of the tracheostomy tube before day 7 was not associated with important complications.

Tracheostomy tubes are electively changed for a variety of reasons, including downsizing, and to allow placement of a speaking valve and thereby facilitate speech[8] and oral intake.[9] The ability to speak is an important patient benefit. Flow though the upper airway for speech needs to be > 50 mL/s.[10] In tracheostomized patients this flow is determined by the relationship between the inner diameter of the trachea to the outer diameter of the tracheostomy tube. With the cuff deflated, a tracheostomy tube with a smaller outer diameter will allow more flow through the upper airway.

However, the outer diameter of the tracheostomy tube is often too large to allow sufficient air flow for quality speech when the cuff is deflated. Therefore, downsizing the tracheostomy tube is required to facilitate speech.[2] Our data provide evidence that decreasing the outer diameter of the tracheostomy tube will allow the patient to better tolerate a speaking valve. Placement of a tracheostomy speaking valve has also been associated with a decreased risk of aspiration.[9] Thus, it has been our practice to place a speaking valve before allowing oral intake. The data presented here provide evidence that tracheostomy change before day 7 is associated with earlier ability to tolerate speaking valve and oral intake. While ability of earlier oral intake and use of speaking valves might increase nutritional intake, reduce anxiety, and improve patient satisfaction, we did not measure these factors. We can only speculate that the ability to communicate and earlier oral intake will positively impact the patient's overall well-being.

One might argue that tracheostomy tubes with a small diameter should be placed initially, bypassing the need for a tracheostomy downsize to facilitate placement of a speaking valve. In our hospital, tracheostomy tubes are usually placed in critically ill patients requiring mechanical ventilation. To allow for bronchoscopy, the initial tracheostomy tubes used have an inner diameter of 8 mm. This inner diameter also minimizes the impact of secretions on resistance through the tube, and facilitates airway clearance.[11,12]

The optimal timing for elective change of a tracheostomy tube is unknown. A 7–14 day time after surgical placement has been suggested to allow the stoma to mature.[4] From a survey of otorhinolaryngology training programs, Tabaee et al reported that tracheostomy tubes are first changed between days 3 and 7.[13] However, 25% of respondents reported that they were aware of a lost airway during a change, and 15% were aware of death during a tracheostomy tube change. Our hospital guidelines allow for tracheostomy tube change 5 days after tracheostomy placement. We did not observe any complications with tracheostomy tube changes. This might be due to our multidisciplinary team approach and institutional guidelines. In contrast to Tabaee et al,[13] which reported that junior residents changed tracheostomy tubes, in our RACU, tracheostomy tube changes are performed by an experienced team consisting of an intensivist, respiratory therapist, and nurse. Due to our small sample size it is difficult to generalize our findings and exclude the possibility of potential complications during early tracheostomy change in a larger cohort.

Our results were not due to differences between the early and late tracheostomy tube change groups. We did not identify any difference in demographic parameters, severity of disease, between the 2 groups (see Table 1). While most comorbidities were similar, there was a significantly higher percentage of patients with connective tissue disorder in the late group (14% vs 3%). Some connective tissue disorders, such as relapsing polychondritis, have been associated with respiratory tract chondritis, leading to tracheal stenosis.[14] While none of our subjects had this disease, it is possible that a clinically important manifestation of connective tissue disorder might lead to a delay in tracheostomy change. There was no difference in time of mechanical ventilation and ventilator liberation between the 2 groups. While there might be unidentified clinical parameters precluding the early downsize of the tracheostomy tube, our results provide evidence that early tracheostomy tube change is feasible and associated with earlier use of a speaking valve and earlier oral intake.

Limitations

Our study was observational; it was not a randomized controlled trial. Randomized controlled trials are best suited to investigate cause-effect relationships. However, especially in situations that do not investigate a direct cause-effect relationship, observational studies have an important role. These studies better reflect routine care and help to start improvement initiatives, including care of tracheostomized patients.[15] While the subjects in both groups were similar, we cannot exclude the possibility that there are patient factors that influenced the decision to change a tracheostomy tube that were not apparent in our subjects. While we did not observe any important complications during early tracheostomy tube change, our sample size is too small to exclude the possibility of potential complications during early tracheostomy tube change. We reported only subjects who transferred to our respiratory care unit in a tertiary care center. These mechanically ventilated subjects were metabolically and hemodynamically stable. In our unit we have adequate physician, respiratory therapy, nursing, and speech pathology staff. We also have aggressive protocols in place to encourage the use of speaking valves and oral nutrition. Whether or not our results can be generalized to other settings with different cultures, staffing models, and patient populations is unknown.

Conclusions

In this study, tracheostomy tube change before day 7 after initial placement was associated with earlier ability to tolerate a speaking valve and earlier oral intake. An adequately powered randomized controlled trial is needed to determine whether early tracheostomy tube change leads to better outcomes.

REFERENCES

1. Durbin CG Jr. Tracheostomy: why, when, and how? Respir Care 2010;55(8):1056-1068.
2. Hess DR. Facilitating speech in the patient with a tracheostomy. Respir Care 2005;50(4):519-525.
3. Dettelbach MA, Gross RD, Mahlmann J, Eibling DE. Effect of the Passy-Muir valve on aspiration in patients with tracheostomy. Head Neck 1995;17(4):297-302.
4. De Leyn P, Bedert L, Delcroix M, Depuydt P, Lauwers G, Sokolov Y, et al. Tracheotomy: clinical review and guidelines. Eur J Cardiothorac Surg 2007;32(3):412-421.
5. Schmidt U, Hess D, Kwo J, Lagambina S, Gettings E, Khandwala F, et al. Tracheostomy tube malposition in patients admitted to a respiratory acute care unit following prolonged ventilation. Chest 2008; 134(2):288-294.
6. Bigatello LM, Stelfox HT, Berra L, Schmidt U, Gettings EM. Outcome of patients undergoing prolonged mechanical ventilation after critical illness. Crit Care Med 2007;35(11):2491-2497.
7. Sessler CN, Gosnell MS, Grap MJ, Brophy GM, O'Neal PV, Keane KA, et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. Am J Respir Crit Care Med 2002;166(10):1338-1344.
8. White AC, Kher S, O'Connor HH. When to change a tracheostomy tube. Respir Care 2010;55(8):1069-1075.

9. Suiter DM, McCullough GH, Powell PW. Effects of cuff deflation and one-way tracheostomy speaking valve placement on swallow physiology. Dysphagia 2003;18(4):284-292.

10. Holmberg EB, Hillman RE, Perkell JS. Glottal airflow and transglottal air pressure measurements for male and female speakers in soft, normal, and loud voice. J Acoust Soc Am 1988;84(2):511-529.

11. Shah C, Kollef MH. Endotracheal tube intraluminal volume loss among mechanically ventilated patients. Crit Care Med 2004;32(1):120-125.

12. Shapiro M, Wilson RK, Casar G, Bloom K, Teague RB. Work of breathing through different sized endotracheal tubes. Crit Care Med 1986;14(12):1028-1031.

13. Tabaee A, Lando T, Rickert S, Stewart MG, Kuhel WI. Practice patterns, safety, and rationale for tracheostomy tube changes: a survey of otolaryngology training programs. Laryngoscope 2007;117(4):573-576.

14. Nakayama T, Horinouchi H, Asakura K, Ohtsuka T, Izumi Y, Kohno M, et al. Tracheal stenosis due to relapsing polychondritis managed for 16 years with a silicon T-tube covering the entire trachea. Ann Thorac Surg 2011;92(3):1126-1128.

15. Heffner JE. Toward leaner tracheostomy care: first observe, then improve. Respir Care 2009;54(12):1635-1637.