Percutaneous Versus Surgical Tracheostomy: A Randomized Controlled Study With Long-Term Follow-Up

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Crit Care Med. 2006;34(8):2145-2152.
Posted 10/25/2006

Abstract and Introduction

Abstract

Objective: To compare the safety, availability, and long-term sequelae of percutaneous vs. surgical tracheostomy.
Design: Prospective, randomized, controlled study.
Setting: Combined medical/surgical intensive care unit in a tertiary referral hospital.
Patients: Two hundred critically ill mechanically ventilated patients who required tracheostomy.
Interventions: Tracheostomy by either percutaneous tracheostomy or surgical tracheostomy performed in the intensive care unit.
Measurements and Main Results: The primary outcome measure was the aggregate incidence of predefined moderate or severe complications. The secondary outcome measures were the incidence of each of the components of the primary outcome. Long-term follow-up included clinical assessment, flow volume loops, and bronchoscopy. Both groups were well matched for age, gender, admission Acute Physiology and Chronic Health Evaluation II score, period of endotracheal intubation, reason for intubation, and admission diagnosis. There was no statistical difference between groups for the primary outcome. Bleeding requiring surgical intervention occurred in three percutaneous tracheostomy patients and in no surgical tracheostomy patient (p = .2). Postoperative infection (p = .044) and cosmetic sequelae (p = .08) were more common in surgical tracheostomy patients. There was a shorter delay from randomization to percutaneous tracheostomy vs. surgical tracheostomy (p = .006). Long-term follow-up revealed no complications in either group.
Conclusions: Both percutaneous tracheostomies and surgical tracheostomies can be safely performed at the bedside by experienced, skilled practitioners.

Introduction

Tracheostomy is one of the most common procedures undertaken in intensive care. Open surgical tracheostomy (ST) was the only technical approach until the introduction of six different percutaneous methods,[1-6] all relying on the Seldinger technique for insertion, the most common of these being the Ciaglia percutaneous dilational tracheostomy (PT) (personal communication from industry sources).

There is ongoing debate about whether PT is better than ST. Between 1991 and 2002 there were seven proper, randomized, controlled studies of these two methods.[7-13] The seven studies all had insufficient power to show a difference, and none undertook sufficient long term follow-up. Furthermore, only one used a blinded assessment[13] and few studies used objective, defined criteria in assessing complications.

Three meta-analyses have compared ST with percutaneous techniques. Dulguerov et al.'s publication[14] was more like an aggregation analysis than a meta-analysis because it included preliminary reports, case series, and retrospective studies.[15] As argued in an editorial, it also included assessment of four different percutaneous techniques, three of which are known to have a higher complication rate and two of which have virtually disappeared from use due to their high risk.[15] Furthermore, Dulguerov et al. included duplicate counting of complications in the PT group.[15] These authors concluded that PT has a higher incidence of perioperative complications and deaths.

Freeman et al.[16] and Cheng and Lee[17] each published meta-analyses of four to five studies, and both included a study that was not randomized. They both found that PTs were easier to perform and had a lower complication rate. The unresolved controversy prompted us to conduct our study.

We therefore conducted a prospective, randomized, controlled study comparing percutaneous dilational tracheostomy by the Ciaglia technique (PT) and ST. Our hypothesis was that PT would be superior with regard to efficacy, peri- and postoperative complications, and long-term (>12 months) follow-up.

Materials and Methods

Patients

During a 3-yr period, from September 97 to August 2001, all patients in the intensive care unit (ICU) at the Austin Hospital, Melbourne, Australia, who required a tracheostomy were considered for the study. The Hospital Human Research Ethics Committee approved this study. Entry criteria were age ≥16 yrs, separate consents obtained from patient or next of kin for the procedure and the study, and availability of proceduralist to perform either PT or ST. Exclusion criteria were coagulopathy (International Normalized Ratio >2) or platelet count $<40 \times 10^9$/L; anatomical abnormality in the anterior neck involving trachea, vessels, or thyroid; previous tracheostomy scar; or cervical spinal injury that had not been internally fixed.

Tracheostomy Procedure

Once consent was obtained, each patient was randomized by sealed envelope and the proceduralist was informed without delay. All tracheostomies were performed in the ICU. Only intensivists or supervised senior trainees who had completed at least ten PTs performed the PTs, with the Ciaglia Percutaneous Tracheostomy Multiple Dilator Set (Cook Critical Care, Bloomington, IN), using the technique described by Ciaglia and colleagues.[2,18] The Cook kit was cleaned and kept at the bedside in a prominent place for the first 7-10 postoperative days in case of accidental decannulation. Bronchoscopy was performed during the PT at the discretion of the proceduralist.

The STs were carried out in the ICU by one of two thoracic surgeons (SK, SS) or their supervised senior trainees who had completed at least ten STs. Infiltration of the skin with local anesthetic was followed by a 30-mm transverse incision in the skin, meticulous dissection, and ligation and division of any significant vessels or the thyroid isthmus. The endotracheal tube (ETT) cuff was deflated and the ETT was advanced toward the carina while long prolene stay sutures were anchored to the lateral tracheal walls and a midline, vertical incision was made in the anterior tracheal wall. The ETT was then withdrawn above the stoma to enable the insertion of the tracheostomy tube (TT). The surgeon was assisted by a surgical trainee, and no operating room nurses were required.

All patients were anesthetized by an intensivist or senior trainee using an intravenous general anesthetic (fentanyl and propofol). The local anesthetic used in both ST and PT was lignocaine 1% with adrenaline 1:200,000. Patients were ventilated with 100% oxygen, and their arterial blood pressure, electrocardiogram, and oxygen saturation were monitored continuously. An arterial blood gas sample was taken before the procedure and near the end of the procedure, immediately before the insertion of the TT. A postprocedure chest radiograph was viewed to exclude pneumothorax.

Data Collected

The severity of bleeding and infection are defined in Table 1 . Data collected included details as set out in Table 2 and Table 3 . Primary outcome measures are described in data analysis and set out in Table 4 . Patients were followed up before or at hospital discharge and again at a median of 20 months with data collected as set out in Table 5 and Table 6 . Perioperative outcome data were collected by the anesthetist and the ICU nurse, and postoperative data were collected from patient observation by a research nurse blinded to the procedure performed.

The long-term follow-up, including the symptom interview, scar assessment, interpretation of the flow-volume curves, and the bronchoscopies, were conducted by two pulmonologists from the Department of Respiratory and Sleep Medicine who were blinded to the tracheostomy method. The assignment of each patient to each pulmonologist was random (by happenstance) and almost equal.

Maximal flow-volume curves were performed using a computerized pulmonary function testing system that uses a mass flow sensor to measure flow (Sensormedics Vmax 229, Yorba Linda, CA). The patients were tested according to the American Thoracic Society guidelines,[19] in a seated position with a nose clip in place. Where possible, a minimum of three acceptable efforts was obtained.

The flow-volume curves were visually inspected by investigators who were blinded to the patient's details. The curves were classified as displaying no evidence of upper airway dysfunction or as displaying evidence of abnormal flow (limitation, plateau, notching, angulation, saw-toothing, or evidence of upper airway dysfunction) as described previously.[20] Evidence of abnormal flow on the flow-volume curves led to a video fiberoptic bronchoscopy.

Bronchoscopy included functional assessment of the vocal cords and inspection for evidence of tracheal stenosis. The site of tracheostomy was determined in all patients, based on the presence of scar tissue over the anterior wall of the trachea. Then a complete bronchoscopy was undertaken and dynamic maneuvers were performed at the end of the procedure. With the bronchoscope in the upper trachea, patients were instructed to take in a maximal breath and expire as forcefully as possible. A visual assessment was made of the degree of dynamic tracheal collapse.

Data Analysis

The primary outcome measure of this study was the aggregate incidence of significant complications, defined as a) moderate or severe bleeding; b) moderate or severe wound infection at day 3 or day 7; c) pneumothorax; d) accidental decannulation; e) major other operative complication; or f) death caused by the tracheostomy. The secondary outcome measures were the incidence of each of the components of the primary outcome. From the literature,[10, 12] at the study outset, we assumed a 50% incidence of the primary outcome in ST and tested for a 30% relative decrease to 35% with PT. For the study to have an 80% power of detecting this difference, 370 patients would have had to be randomized. At interim analysis of 200 patients, however, we found an incidence of the primary outcome measure of only 14%. We then calculated that we would need to randomize 1,450 patients to detect the hypothesized 30% decrease. As this would have been logistically overwhelming, the study was terminated early.

Data were analyzed using a commercial statistical software package (Statview, Abacus Concepts, Berkeley, CA). Data are presented as means or medians (depending on whether they represent parametric or nonparametric continuous variables) with either sd or interquartile range. Differences between the two groups were analyzed by Student's *t*-test or Mann-Whitney test (when appropriate for nonparametric data) for numerical measure or by chi-square test or, when appropriate, Fisher's exact test, for dichotomous variables.

Data were analyzed on an intention-to-treat principle from the moment that the tracheostomy anesthetic was commenced.

Results

Of the 298 patients requiring tracheostomy, 95 were excluded by the selection criteria and consent was obtained for 203 patients (Fig. 1). One hundred and two patients were randomized to PT; however, two patients deteriorated leading to withdrawal of active treatment, leaving 100 patients in the PT group. One hundred and one patients were randomized to ST; however, one patient was extubated successfully before the procedure could be performed, leaving 100 patients in the ST group.

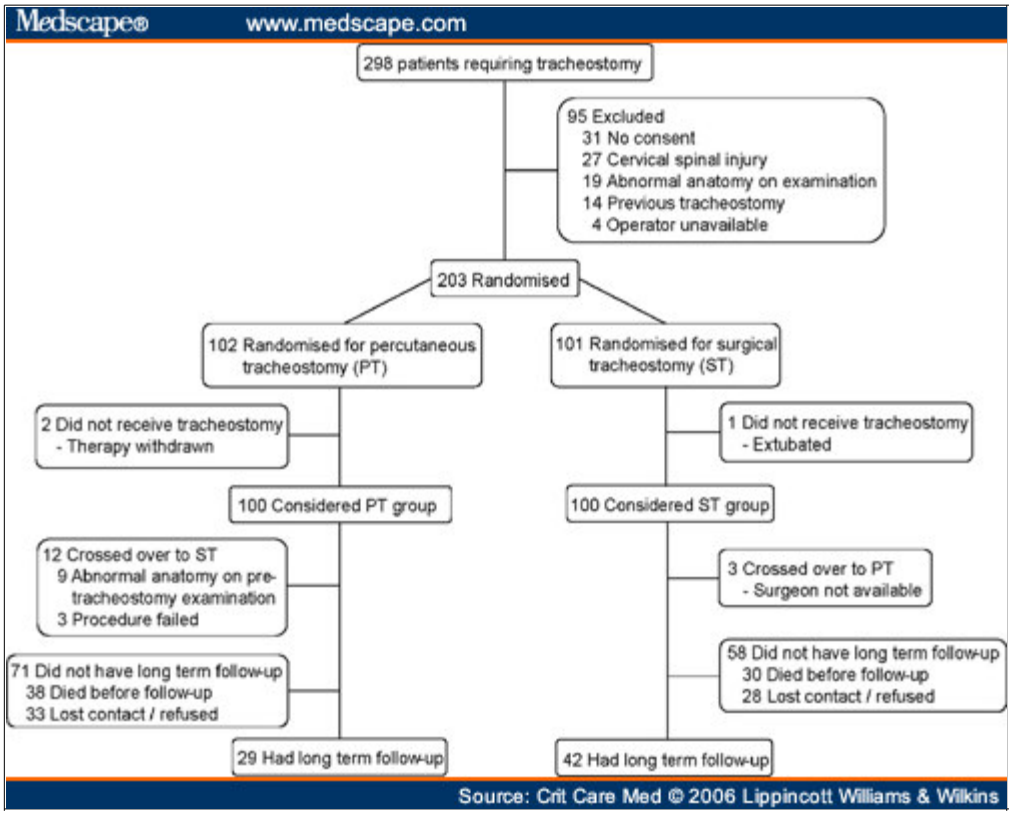


Figure 1.

Patient participation in tracheostomy trial. *PT*, percutaneous tracheostomy; *ST*, surgical tracheostomy.

There were 12 protocol violations. Following randomization to ST, three patients underwent PT when the patients' clinicians did not agree to delay the operation for several days until one of the nominated surgeons would be available to operate. Following randomization to PT, nine patients were then examined by the intended proceduralist and found to meet exclusion criteria and were referred for ST. The reasons were short neck with very low larynx, 4; retrosternal larynx, 2; bull neck, 2; and pulsating vessel anterior to trachea, 1.

The demographic data for patients in both groups are summarized in Table 2 . The patients had a broad spectrum of admission diagnoses as might be expected in a mixed medical/surgical ICU.

There was a significantly shorter time from randomization to procedure in the PT group than the ST group but no significant difference in duration for each procedure (Table 3). There was no difference in safety with respect to oxygenation, but there was a significantly greater number of patients in the ST group with a $Paco_2$ >50 torr.

A larger TT was more likely to be inserted following ST vs. PT (9.0 vs. 8.0 mm, $p < .0001$). A fiberoptic bronchoscope was used in 80 of the PTs.

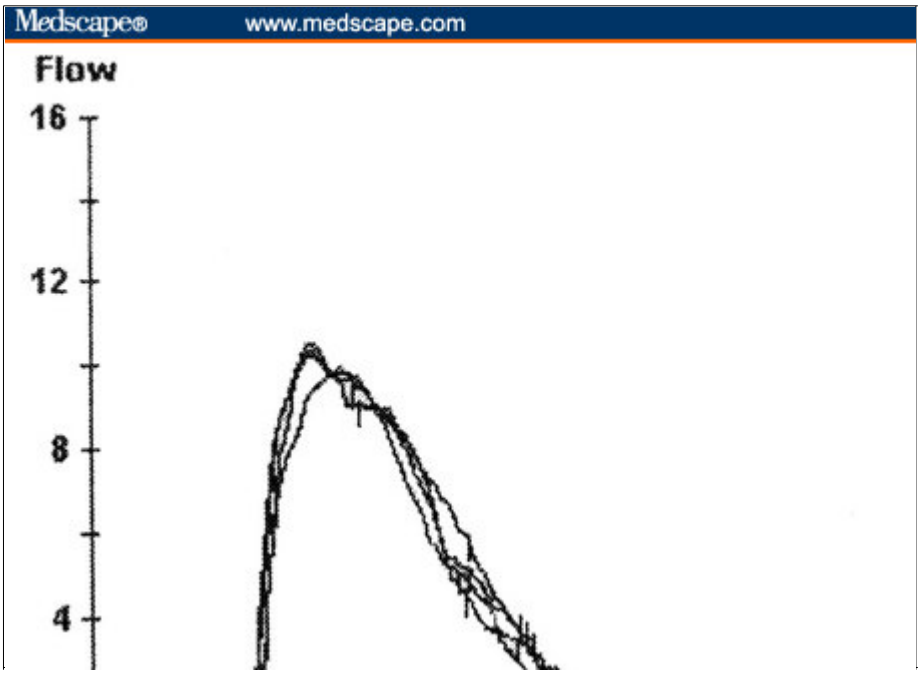
The combined procedural complication rate was 3.5% (Table 4). Perioperative bleeding was minimal in the vast majority of patients, moderate in one patient from each group, and severe in three patients undergoing PT. One was an 84-yr-old with a large thyroid vein punctured by the Seldinger needle, another was a 51-yr-old with a large thyroid isthmus punctured by the Seldinger needle, and the third was a 78-yr-old with significant bleeding from a vein anterior to the trachea. In all three, the bleeding was stemmed with pressure and the procedure was converted to ST. One patient in the PT group developed a pneumothorax, which was treated by insertion of an intercostal tube. One patient in the ST group was accidentally decannulated 10 mins postinsertion. The surgeon inserted a longer, adjustable flange TT. There were no TT cuff punctures or paratracheal insertions. By intention to treat there were five operative complications (5%) in the PT group and two complications (2%) in the ST group.

There was no significant difference between the groups in either the incidence of bleeding in the first 3 postoperative days or the presence of infection on day 3 (Table 4). There was, however, a higher incidence of infection in the ST group compared with the PT group on day 7.

The majority of patients in both groups were decannulated, with a median duration of cannulation of 19 (PT) and 21 days (ST), and discharged from hospital alive (Table 5). Seven percent (PT) and 8% (ST) of patients were discharged with the TT *in situ*, and 15% (PT) and 18% (ST) of the total died with the TT in place. Hospital mortality rate in patients discharged from ICU with a TT in place was 23% (PT) and 26% (ST). There was no difference between the groups for all these outcomes. Importantly, there was no operative or postoperative mortality attributable to the tracheostomy procedures.

Follow-up occurred at a median of 20 months (range 15-40). Death, inability to contact the patient, or patient refusal left only 29 patients in the PT group and 42 patients in the ST group for assessment of long-term sequelae (Fig. 1).

There was an even distribution of the symptoms of dyspnea, stridor, and cough between both groups (Table 6). In the majority of patients with symptoms, interview revealed that the symptoms were present before the ICU admission. All but nine of the patients were able to perform adequate flow-volume maneuvers (Fig. 2). Eight of these patients had sustained significant head injuries and were unable to follow basic instructions, and one had significant pain and was unable to give maximum effort. Four of the remaining 63 patients demonstrated some evidence of flow plateau. None of these patients had symptoms or signs of stridor.



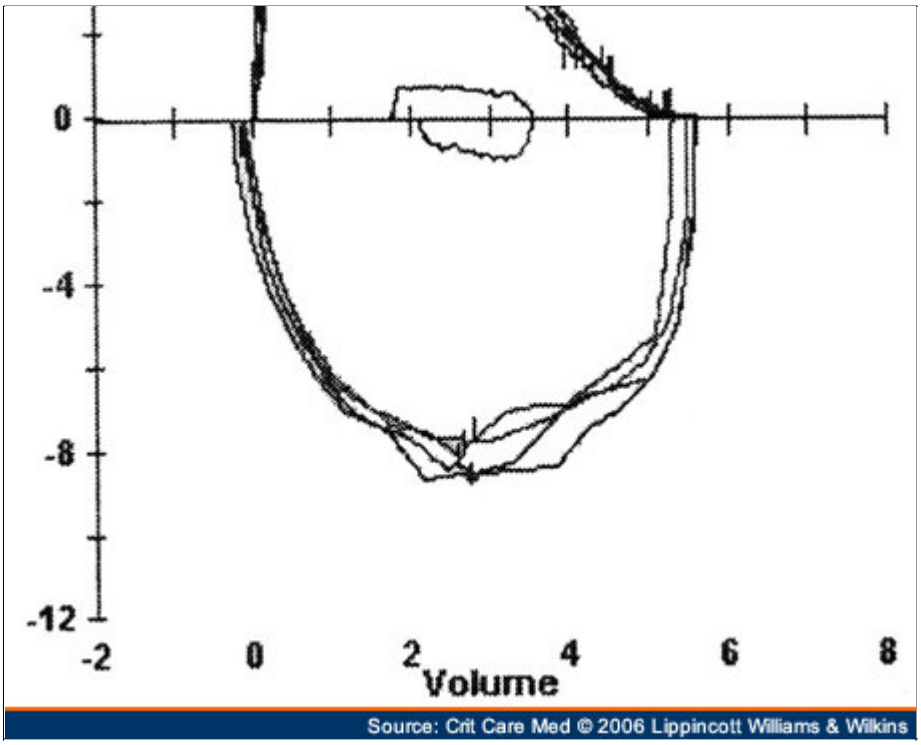


Figure 2.

Normal flow-volume curve.

The flow-volume loops of one ST patient demonstrated flow plateaus in both the inspiratory and expiratory limbs (Fig. 3). At fiberoptic bronchoscopy he was found to have bilateral vocal cord paralysis and no evidence of any tracheal stenosis or dynamic collapse of his airways.

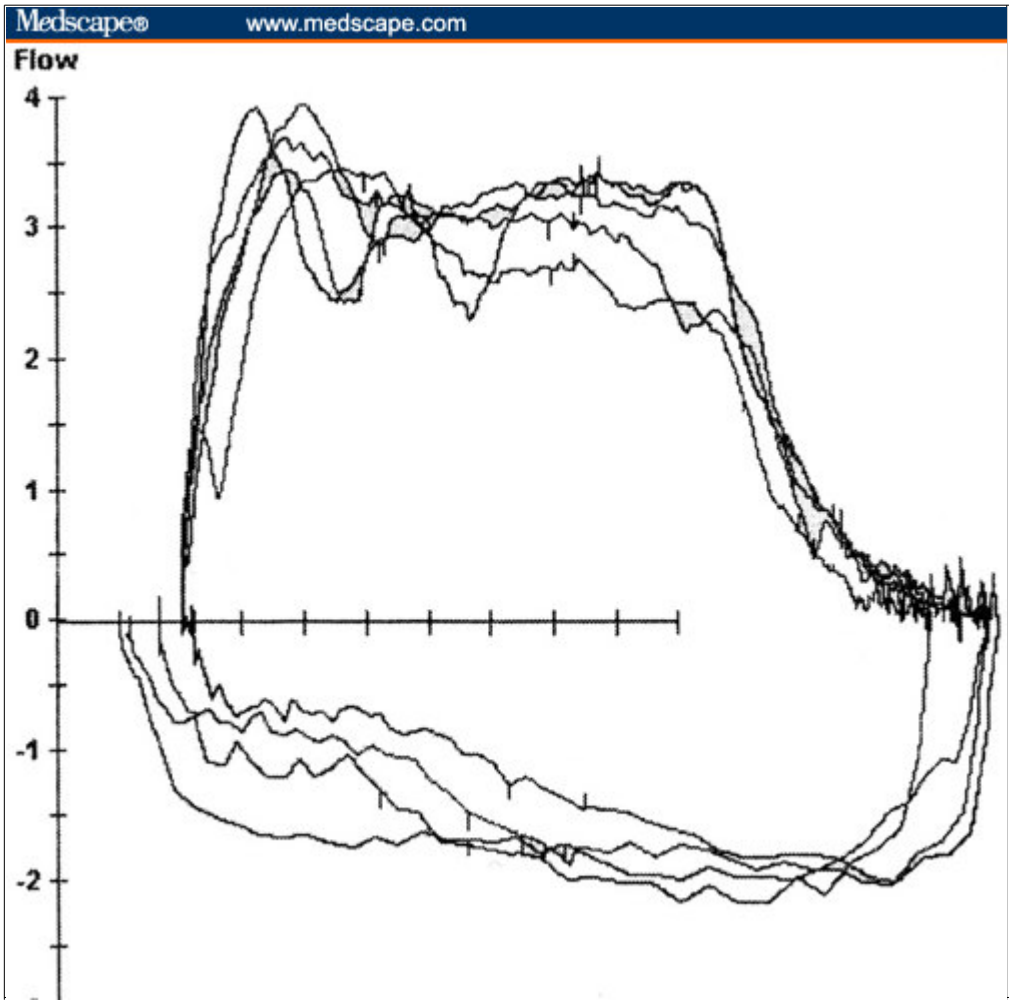


Figure 3.

Patient with bilateral vocal cord paralysis.

The flow-volume curve of a second patient, who was a quadriplegic with head injuries, revealed evidence of plateaus on both the inspiratory and expiratory limbs (Fig. 4). The respiratory scientist performing this test noted that patient effort appeared to be submaximal and bronchoscopy showed no evidence of tracheal stenosis. The final two patients showed evidence of a variable flow plateau on the inspiratory limb and some flow limitation in the expiratory limb, consistent with variable extrathoracic obstruction, but no evidence of fixed obstruction. Bronchoscopy revealed no evidence of tracheal stenosis. No patient from either group demonstrated any evidence of tracheal stenosis.

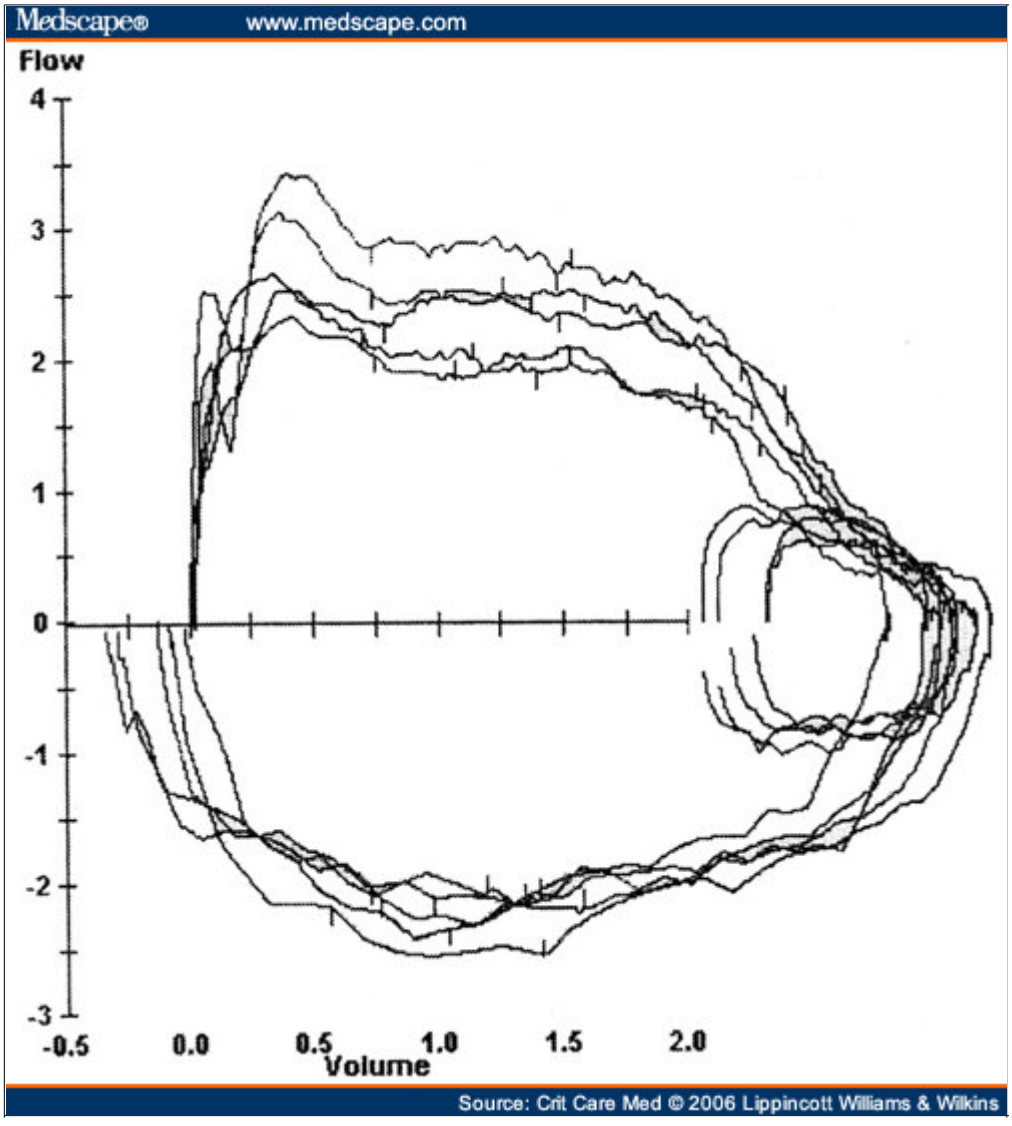


Figure 4.

Patient with quadriplegia and head injuries.

Assessment of the cutaneous scar revealed that the scar length was significantly longer in the ST group (p = .0001) and that there was a trend for the ST scars to be abnormally colored, puckered, hypertrophied, visible, or unsightly (p = .082) (Table 6).

Discussion

We conducted a randomized, controlled trial comparing PT to ST and were unable to detect a difference between the

two groups in the primary outcome measure of total significant perioperative or postoperative complications. An analysis of the secondary outcomes revealed that the procedural complication rate in our study (3.5%) was low. Furthermore, long-term follow-up at 20 months showed no evidence of tracheal stenosis.

The most common procedural complication across all studies, including ours, was hemorrhage. Although definitions of significant hemorrhage varied between studies, the main criterion was the need for extra intervention, including the need to convert to ST[7, 9] or the need for a blood transfusion.[9-11] In all three patients in our study who bled and who were converted from PT to ST, there was an identified cause for the bleeding and the proceduralist was able to secure temporary hemostasis while waiting for the arrival of a suitable surgeon.

Like Friedman et al.,[8] we had one case of pneumothorax in the PT group. By comparison, a patient in Hazard et al.'s[10] ST group sustained a cardiac arrest following a pneumothorax and died. A pneumothorax must always be excluded by a postprocedure chest radiograph. In our ST group, an accidental decannulation was related to the chosen TT being too short for the distance from the skin to the trachea in that patient. Although the situation was rapidly dealt with by replacement with a Portex adjustable flange TT, it is best to anticipate the need for a longer shank TT at the time of the procedure. If the TT only just clicks into place or does not appear to sit well on inspection with the bronchoscope, then a larger or longer TT should be inserted. Accidental decannulation and inability to replace the TT have led to deaths in both STs[8] and PTs.[9]

There were no complications in the 12 protocol violation patients. Unlike other randomized controlled trials, we recorded no complications of paratracheal insertion,[8] cuff puncture[12] or resistance to tube insertion,[7, 12] desaturation,[8] or procedure-related death.[8, 10] One way to improve the safety of PTs is to use bronchoscopy to ensure optimal insertion of the guide wire, thereby minimizing the risk of paratracheal insertion.[11, 21] A second factor is to ensure proper training and supervision of the PT and ST proceduralists to avoid complication rates up to 50%.[12] All our proceduralists are carefully trained and supervised by experienced specialists. In the last 10 yrs, 815 tracheostomies have been performed in the ICU and there have been no deaths due to tracheostomy complications.

Our study also recorded one of the lowest postoperative complication rates, with a 7% incidence of moderate or severe bleeding in the PT group and 5% in the ST group, less than Holdgaard et al.,[12] Hazard et al.,[10] and Friedman et al..[8] Unlike the studies by Hazard et al.[10] and Freeman et al.,[7] none of our patients died from bleeding. Our overall postoperative infection rate was also very low, with 1-5% moderate infection and no severe infection. Similar to studies by Friedman et al.,[8] Hazard et al.,[10] Melloni et al.,[11] and Holdgaard et al.,[12] the infection rate was highest in the ST group. There was also a trend toward a higher infection rate in ST patients at the time of decannulation (Table 5). We drew the same conclusion as Holdgaard et al.[12] that the larger size of the stoma in the ST group, with the propensity of respiratory secretions to pool within the wound, increases the risk of infection.

Our study is significant for four reasons. It is twice the size of the next largest study and used a randomized, controlled methodology. Second, it used blinded assessment of complications when possible and used objective, clearly defined criteria when blinded assessment was not possible. Third, it had very low complication rates and, fourth, was conducted with long-term follow-up using a validated functional assessment.

The patient cohort in this study is typical of a combined medical and surgical ICU with a case mix of postsurgical, trauma and sepsis, and multiple organ failure patients. Our median period of intubation of 6 days is similar to four studies[9-12] but significantly shorter than that of Freeman et al.[7] (12.7-15.6 days) or Friedman et al.[8] (17.2-21.3 days).

The time from randomization to commencement of the tracheostomy was recorded as an objective surrogate for the availability of the procedure. The shorter delay for PT compared with ST was due to the ready availability of an intensivist in comparison with the two thoracic surgeons who were often engaged elsewhere. Nevertheless, the median delays in our study were significantly shorter than the mean delay of 28.5 hrs and 100.4 hrs for PT and ST, respectively, in the only other study that recorded this data.[8] A shorter delay in a tracheostomy has the potential benefit of shortening the period of sedation and the ICU length of stay.

All tracheostomies were performed in the ICU, similar to the study by Massick et al.,[9] whereas the operating room was used for the ST in four studies[7, 8, 10, 11] and for both ST and PT by Holdgaard et al..[12] Performing the tracheostomies in the ICU is more convenient, does not need to fit into the operating room schedule, avoids the risks of transport,[12] and saves significant costs.[7]

There was no significant difference in the duration of the two techniques. Compared with the other randomized controlled trials (mean duration ranged from 4.3 to 20.1 min), we took longer to perform the PT.[7, 8, 10-12] We do not, however, believe that taking a few extra minutes is clinically significant when procedural safety is considered paramount. We deliberately performed the dilation slowly to avoid rapid separation of the anterior tracheal tissues.

We also waited until the guide wire position through the anterior tracheal wall was confirmed by bronchoscopy. There is quite a variation in the literature in the duration of the ST, from 13.5 min [10] to 41.7 min.[7]

Insertion of larger TTs in ST patients was a similar finding in the only other randomized controlled trial that recorded this data (median size 8 inner diameter in PT vs. 8.5 in ST).[12]

Oxygenation in both groups was excellent throughout the procedure. We recorded the $Paco_2$, both before the procedure and at the time of the TT insertion, as there was a concern that patients might become hypercarbic during PT.[22] We found that this was not the case (Table 3). This finding was similar to the report by Byhahn et al.[23] and in contrast to the report by Cantais et al.,[24] who found a significant increased in the $Paco_2$ during both translaryngeal and forceps PTs.

The hospital mortality rate in this group of patients was 26% (PT) and 23% (ST). This is lower than in other studies-Melloni et al.[11] 36%, Hazard et al.[10] 33-54%, Friedman et al.[8] 33-42%, and Freeman et al.[7] 23-45%-but the mortality rate at long-term follow-up had risen to 38% (PT) and 30% (ST). This reflects the severity of the underlying illnesses in patients requiring tracheostomies in ICU.

The follow-up in this study is longer and more extensive than any other study, with no documented, symptomatic airway obstruction or any other lesion attributable to the tracheostomies.

A number of assessment methods have been used in follow-up including clinical assessment,[18, 25] questionnaire,[26] radiographs,[10, 27] and bronchoscopy.[11, 28, 29] The most reliable and objective assessment, however, of a fixed or dynamic extrathoracic airway obstruction is by flow-volume curves. There is often no correlation between symptoms elucidated clinically or by questionnaire and flow-volume curves. Furthermore, radiographs are an unreliable way of quantifying a tracheal obstruction, particularly one that may be dynamic. We studied symptoms and performed flow-volume curves in all follow-up patients and undertook bronchoscopy when appropriate. Law et al.,[30] by bronchoscopy and spirometry, identified two of 41 PT patients to have a stenosis >10%. None of our patients had evidence of stenosis.

Follow-up of the cosmetic appearance of the tracheostomy showed that the ST scars were significantly longer with a trend toward scars that were more visible due to puckering, hypertrophy, or color change. Two of the 42 ST scars were regarded as unsightly.

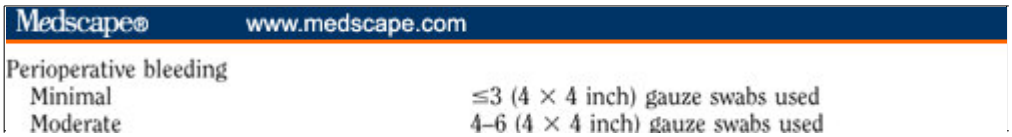
The technique for the ST employed a simple midline incision through two to three tracheal rings. Our surgeons avoid forming an inverted U-flap and suturing the flap to the skin, which is proposed by others including Massick et al., [9] because there is a risk of persistent tracheocutaneous fistula.[31]

This study has some limitations. Similar to other studies, stringent exclusion criteria meant that patients requiring tracheostomies were excluded.[7-12] We believed that it was unsafe to perform a PT on patients with obvious anatomical abnormalities. The included patients were, however, broadly representative of the patients on whom one can safely perform a PT. Several patients crossed over to the other treatment arm; however, the analysis was by intention to treat. Long-term follow-up was restricted to less than half of the original cohort of patients. This is a common problem for all studies involving long-term follow-up, and this study achieved longer follow-up of more patients than any other tracheostomy study. If tracheal stenosis had been detected it may have been impossible to distinguish between preexisting (preintubation) tracheal narrowing and tracheal injury due to intubation, due to tracheostomy, or due to a combination of both. Last, this study had limited power due to the lower than predicted complication rate.

Conclusions

In the largest study undertaken thus far, we found that PTs and STs are both safe when conducted by experienced, skilled practitioners, with no difference in complications being discernable. There is less delay in performing the PT, which has better cosmetic sequelae. Neither technique should be treated lightly; both require training, experience, and an awareness of the potential risks of any medical procedure.[13, 32]

Table 1. Definitions of Bleeding and Infection



Severe	>7 (4 × 4 inch) gauze swabs or further intervention
Postoperative bleeding: in first 3 days	
None	
Minimal	Change of dressing
Moderate	Topical application of adrenaline or Gelfoam
Severe	Suturing or surgical intervention
Postoperative Infection: on day 3, day 7, and postdecannulation	
None	
Minimal	Local inflammation
Moderate	Local cellulitis or pus
Severe	Necrosis or wound breakdown

Table 2. Demographics of Study Patients

	Intention to Treat		
	Percutaneous (n = 100)	Surgical (n = 100)	*p* Value
Age, yrs[a]	67 (50–77)	61 (46–73)	.77
Male	69	68	.99
Diagnosis			)
Cerebrovascular disease	15	16	)
Spinal injury	5	10	)
Other neurological disease	10	7	)
Pneumonia	13	18	)
COAD/asthma	10	9	)
Other respiratory failure	4	2	) .56
Cardiovascular surgery	20	10	)
Out-of-hospital cardiac arrest	4	6	)
Abdominal surgery/sepsis	8	12	)
Trauma	8	6	)
Others	3	4	)
APACHE II score[a]	19 (15–24)	17 (14–22)	.11
Period of intubation, days[a]	6 (4–10)	6 (3–8)	.17
Reasons for intubation[b]			
Primary respiratory failure	50	59	.26
Airway protection	34	32	.77
Multiple-organ failure	18	15	.58
Toileting	5	5	>.99
PT-INR[a]	1.1 (1.0–1.2)	1.1 (1.0–1.2)	.32
APTT, secs[a]	32 (28–36)	33 (30–37)	.078
Platelet count, $\times 10^9$/L[a]	210 (154–329)	218 (157–297)	.85

COAD, chronic obstructive airway disease; APACHE, Acute Physiology and Chronic Health Evaluation; period of intubation, duration of intubation before tracheostomy; PT-INR: prothrombin time-International Normalized Ratio; APTT, activated partial thromboplastin time.

[a]Values expressed as median with interquartile range; [b]some patients had more than one reason.

Table 3. Perioperative Variables

	Intention to Treat		
	Percutaneous (n = 100)	Surgical (n = 100)	*p* Value
Randomization to procedure, hrs[a]	3.8 (2.0–11.2)	6.3 (3.5–8.6)	.006
Anesthesia to procedure, mins[a]	15 (10–20)	13 (10–15)	.008

Duration of procedure, mins[a]	20 (15–30)	17 (15–20)	.58
Lowest Spo_2 during procedure, %[a]	99 (98–100)	99 (98–99)	.003
$Paco_2$ before TT insertion, torr[a]	43 (38–50)	48 (40–54)	.065
Patients with $Paco_2$ >50 before TT insertion, torr	18	32	.024
$Paco_2$ before procedure, torr[a]	50 (44–52)	52 (46–59)	.33
Size of tracheostomy tube, mm[a,b]	8.0 (8.0–9.0)	9.0 (8.0–9.0)	<.0001

Randomization to procedure, time from randomisation to procedure; anesthesia to procedure, time from start of anesthesia to start of procedure; Spo_2, pulse oximetry; TT, tracheostomy tube.
[a]Values expressed as median with interquartile range; [b]internal diameter.

Table 4. Peri- and Postoperative Complications

	Intention to Treat			
	Percutaneous (n = 100)	Surgical (n = 100)	Total (n = 200)	*p* Value
Operative				
Bleeding: operative				
Minimal	96	99	195	
Moderate	1	1	2	)
Severe	3	0	3	) .20
Pneumothorax	1	0	1	)
Accidental decannulation	0	1	1	)
Postoperative				
Bleeding: first 3 days				
Zero	67	64	131	)
Minimal	23	30	53	)
Moderate	4	1	5	) .12
Severe	3	4	7	)
Infection: day 3				
Zero	92	91	183	)
Minimal	3	4	7	) .15
Moderate	1	1	2	)
Severe	0	0	0	)
Infection: day 7				
Zero	90	80	170	)
Minimal	3	9	12	) .044
Moderate	1	5	6	)
Severe	0	0	0	)
Aggregate of significant complications[a]	14	13	27	NS

NS, not significant.
[a]Defined in data analysis.

Table 5. Outcomes at Hospital Discharge

	Intention to Treat		
	Percutaneous (n = 100)	Surgical (n = 100)	*p* Value
Tracheostomy outcome			
Tube removed	78	74	)
Discharged with tracheostomy	7	8	) .80

Died with tracheostomy	15	18	)
Decannulated patients			
Tracheostomy period, days[a]	19 (11–28)	21 (11–27)	.71
Dressing period, days[a]	6 (3–9)	7 (4–11)	.47
Infection when removed			
Zero	57	49	)
Minimal	4	12	) .079
Moderate	3	5	)
Severe	0	0	)
Death in ICU	9	6	.59
Death in hospital	26	23	.74

Tube removed, tracheostomy tube removed in hospital; tracheostomy period, duration tracheostomy tube *in situ*; dressing period: time that dressing was required after tracheostomy removal; ICU, intensive care unit.

[a]Values expressed as median with interquartile range.

Table 6. Long-term Follow-up

	Intention to Treat		
	Percutaneous (n = 29)	Surgical (n = 42)	*p* Value
Dyspnea			
Zero	21	30	)
Minimal	4	7	) .97
Moderate	2 (1)	3 (1)	)
Severe	2	2 (1)	)
Stridor			
Zero	24	37	)
Minimal	5 (3)	3	) .22
Moderate	0	2 (2)	)
Severe	0	0	)
Cough			
Zero	10	22	)
Minimal	11 (1)	15 (5)	) .31
Moderate	5 (1)	3	)
Severe	3	2 (1)	)
Length of scar, cm			
<1	7	2	)
1–2	16	10	) .0001
>2	6	30	)
Color of scar			
Normal	8	4	)
Lighter	16	30	) .18
Darker	5	8	)
Level of scar			
Flat	24	27	)
Puckered	5	13	) .18
Hypertrophied	0	2	)
Appearance of scar			
Barely visible	16	13	)
Visible	13	27	) .082
Unsightly	0	2	)

Numbers in parentheses indicate numbers of patients whose symptoms appear to have developed after tracheostomy.

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Funding Information

No financial support was required for this study.

William Silvester, MD, FRACP, FJFICM, Donna Goldsmith, RN, Shige Uchino, MD, Rinaldo Bellomo, MD, FRACP, FJFICM, Simon Knight, FRACS, Siven Seevanayagam, FRACS, Danny Brazzale, BAppSc, Marcus McMahon, MD, Jon Buckmaster, MD, FANZCA, FJFICM, Graeme K. Hart, MD, FANZCA, FJFICM, Helen Opdam, MD, FRACP, FJFICM, Robert J. Pierce, MD, FRACP, Geoff A. Gutteridge, MD, FANZCA, FJFICM, Austin Hospital, Melbourne, Australia.

Disclosure: The authors have not disclosed any potential conflicts of interest.
