Percutaneous translaryngeal versus surgical tracheostomy: A randomized trial with 1-yr double-blind follow-up*

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Objective: **To compare the outcomes and the short- and long-term complications of percutaneous translaryngeal tracheostomy (TLT) and surgical tracheostomy (ST).**

Design: **Prospective, randomized clinical trial with 1-yr double-blind follow-up.**

Setting: **A general intensive care unit of a university hospital.**

Patients: **A total of 139 consecutive critically ill patients who required a tracheostomy between February 2001 and June 2002 were randomly assigned to receive either ST or TLT.**

Results: **TLTs were performed more rapidly than STs (17 ± 10 mins vs. 22 ± 6 mins, $p = .003$). Early complications were rare in both groups. Major postoperative bleeding was less frequent with TLT (0 [0%] vs. 6 [8%], $p = .03$). Only one case of bleeding (in the ST group) required blood transfusion. Immediately after tracheostomy, six TLT patients (9%) and six patients (8%) in the ST group ($p = .56$) developed culture-confirmed bacteremia with microbes previously isolated from the pharynx or trachea. Group rates for stomal infections and pneumonia after tracheostomy were similar. At 1-yr follow-up, the overall survival rate was 27%, and 14 patients (45% of survivors) still had open tracheostomies. Both groups rated their quality of life as moderately to severely compromised, and the deterioration was strictly related to the presence of tracheostomy. One TLT and two ST survivors ($p = .53$) had clinical signs of tracheal stenosis, and bronchoscopy revealed narrowing of >50%.**

Conclusions: **Compared with ST, the main advantages of TLT are that it is more rapid and associated with less postoperative bleeding. Infectious complications, particularly postoperative bacteremia, and long-term effects (physical and emotional) are similar with the two procedures. (Crit Care Med 2005; 33:1015–1020)**

KEY WORDS: translaryngeal tracheostomy; surgical tracheostomy; randomized trial; complications; bleeding; bacteremia; quality of life

The use of percutaneous tracheostomy (PT) techniques is growing in Europe and the United States. Debate continues on the precise indications for PTs and their possible advantages over conventional surgical tracheostomy (ST). Conflicting conclusions have emerged from two meta-analyses. Dulguerov et al. (1) analyzed findings from 38 studies focusing on ST and 27 others regarding various PT techniques. They found that the latter procedures were associated with higher rates of perioperative complications, deaths, and cardiorespiratory arrests. In contrast, Freeman et al. (2), who reviewed data on a total of 236 patients enrolled in five different prospective, controlled studies, concluded that PTs were generally associated with fewer complications, including bleeding and infections, and better outcomes than ST. They also highlighted the time- and cost-saving aspects of PTs and suggested that they were probably the procedures of choice for most critically ill patients requiring tracheostomies.

To clarify some of these issues, we conducted a randomized, controlled trial comparing STs with those performed using one type of PT procedure, the Fantoni translaryngeal tracheostomy (rarely used in the United States but commonly used in Europe). Our study population consisted of a large consecutive series of patients hospitalized in a general intensive care unit (ICU) in a teaching hospital. Our analysis included short- and long-term complications, the risk of bacteremia and sepsis caused by upper respiratory tract pathogens, and the patient's perceived quality of life (QoL) 1 yr after the tracheostomy procedure.

PATIENTS AND METHODS

Patient Recruitment. The study was conducted in the 18-bed general ICU of the Catholic University Hospital in Rome. The protocol was approved by an *ad hoc* ethics committee, and written informed consent for all study procedures was obtained from all patients or their next of kin.

All patients in the unit requiring tracheostomies between February 1, 2001, and June 30, 2002, were candidates for study enrollment (Table 1). The need for tracheostomy was established by the ICU physician in charge of the patient according to the general indications listed below:

- Verified difficulties in weaning the patient from mechanical ventilation (e.g., patients with chronic obstructive pulmonary disease, other types of preexisting lung disease, or neuropathic or myopathic critical illness and any other patient who could not be weaned after 10 days of assisted ventilation).
- Anticipated need for long-term ventilation (e.g., patients with severe traumatic or post-anoxic brain damage, cerebral infarction, other neurologic disorders, such as spinal cord injury or Guillain-Barre syndrome, and

***See also p. 1159.**

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Table 1. Baseline characteristics of patients undergoing translaryngeal (TLT) and surgical (ST) tracheostomies

	TLT Group n = 67	ST Group n = 72	*p*
Age in yrs, mean (SD)	63 (1)	64 (17)	.54
Male sex, n (%)	41 (61)	42 (57)	.38
SAPS II,[a] mean (SD)	43 (14)	44 (11)	.70
Duration of intubation before tracheostomy, days, mean (SD)	10 (4)	11 (5)	.14
Co-morbid conditions, n (%)			
Hypertension	22 (32)	26 (36)	.77
Diabetes	6 (9)	9 (12)	.59
Chronic obstructive pulmonary disease	4 (6)	7 (10)	.53
Leukemia/lymphoma	3 (4)	2 (3)	.66
Solid tumors	6 (9)	6 (8)	.56
Alcoholism	1 (1)	0 (0)	.47
Kind of admissions, n (%)			
Trauma	16 (24)	22 (30)	.51
Medical	35 (52)	32 (44)	.46
Surgical	16 (24)	18 (25)	.99
Reason for ICU admission, n (%)			
Acute respiratory failure	17 (25)	25 (35)	.35
Neurosurgery	23 (34)	24 (33)	.77
Neurologic (cerebral ischemia and hemorrhage)	11 (16)	7 (10)	.15
Sepsis	7 (10)	5 (7)	.54
Renal failure	0 (0)	2 (3)	.49
Metabolic disorders	3 (4)	2 (3)	.66
Cardiovascular diseases	6 (9)	6 (8)	.99
Hemorrhagic shock	0 (0)	1 (1)	.51

SAPS II, Simplified Acute Physiology Score II; ICU, intensive care unit.
[a]SAPS II was calculated 24 hrs after admission to the ICU (5).

any other patient expected to require mechanical ventilation for >10 days).

Criteria for exclusion from the study were: 1) indications for emergency tracheostomy, 2) age <18 yrs, 3) severe coagulopathy, 4) surgical wounds near the tracheostomy site, 5) previous or preexisting tracheostomy, 6) conditions that compromised adequate visualization of normal anatomic landmarks, and 7) generally accepted contraindications for PT (i.e., inability to extend the neck adequately, significant thyroid gland enlargement, palpable neck vessels that left insufficient space for percutaneous dilational tracheostomy insertion) (3).

Study patients were randomly assigned to receive a standard ST or percutaneous translaryngeal tracheostomy (TLT) using the Fantoni technique (4). Computer-generated random assignments were concealed in sealed envelopes.

Tracheostomy Techniques. Fantoni TLTs (4) were performed at the bedside by two-member teams of ICU physicians, one in charge of airway management and the second performing the tracheostomy. Each team member had completed ≥1 yr of TLT training and had already performed an average of 30 tracheostomies when the study began. This ensured that only experienced clinicians would perform TLTs during the study. Patients were anesthetized with propofol (1.5-mg/kg bolus and 100-$\mu g \cdot kg^{-1} \cdot min^{-1}$ infusion) and sufentanil (0.01 $\mu g \cdot kg^{-1} \cdot min^{-1}$) and paralyzed with atracurium bromide (0.4 mg/kg). Local anesthesia (lidocaine 2%, 5–10 mL) was used in all cases.

Surgical tracheostomies were performed in the operating room by a team of ear, nose, and throat surgeons (all staff doctors). The anesthesia protocol was the same one used for TLT patients.

Data Collection. For each study patient, we recorded demographic characteristics, underlying disease, duration of intubation before tracheostomy, and Simplified Acute Physiology Score calculated 24 hrs after ICU admission (5).

The duration of the tracheostomy procedure was measured from the skin incision/needle insertion to the final placement of the tracheostomy cannula. (These time points were chosen to avoid including transport times in the length of ST procedures.) Electrocardiographic activity and arterial oxygen saturation were monitored continuously (Biox 3700, Ohmeda, Boulder, CO) throughout all TLT and ST procedures, along with heart rate, blood pressure, airway pressure, and body temperature. The same type of monitoring was continued throughout the patient's ICU stay.

All intraoperative complications were recorded, including bleeding, subcutaneous emphysema, episodes of low oxygen saturation, and tube dislocation during TLT. During the patient's postoperative ICU stay, we recorded all episodes of stomal inflammation or infection, stomal bleeding (detailed definitions are provided in Tables 2 and 3), tracheomalacia, bacteremia, sepsis, and pneumonia. To evaluate the risk of bacteremia caused by spread of upper respiratory tract pathogens during tracheostomy, a pharyngeal swab, a sample of tracheal aspirate, and three blood specimens were collected before each tracheostomy procedure and subjected to culture and *in vitro* antibiotic susceptibility studies. Three blood cultures were repeated immediately after the procedure (one every hour), and postoperative bacteremia was diagnosed when two of the latter blood cultures grew microorganisms that were identical at the species level and presented identical *in vitro* antimicrobial susceptibility profiles. The infection was considered to be related to the tracheostomy procedure if the bloodstream isolate was identical to an isolate recovered from preoperative pharyngeal swab or tracheal aspirate. Sepsis was defined as a systemic inflammatory response to an infectious process manifested by tachycardia, tachypnea, hyperthermia or hypothermia, and altered white-cell count; blood-culture positivity was not obligatory (6). All diagnoses of pneumonia were based on bronchoscopic findings with quantitative cultures of bronchoalveolar lavage fluid (7), in accordance with consensus guidelines (8).

Follow-up. One year after the tracheostomy, we attempted to contact all study patients who had been discharged from our hospital. Those who agreed were interviewed using the Short Form 12 Health Survey model questionnaire to rate subjective perceptions of health and QoL (9). Patients were also specifically asked if they had respiratory or phonetic disturbances. The follow-up visit also included a physical examination to identify objective respiratory or speech impairments, incomplete stomal closure, and clinical signs of tracheal stenosis (stridor, cough, or dyspnea at rest or exercise). Patients with the latter symptoms were scheduled for bronchoscopy and laser treatment, if needed. Follow-up examiners and bronchoscopist were blinded to the patient's group origin (ST vs. TLT).

Statistical Analysis. Results are given as mean values ± SD. Demographic and physiologic characteristics for the two groups were compared with the Student's *t*-test for continuous data (separate estimates of variance were used when variance differed significantly) and the Mantel-Haenszel extended chi-square test for categorical data. Fisher's exact test (two-tailed) was used when the expected number of cases per cell was below five.

In the 2 yrs before our study, 32% of the patients in our unit who received STs had experienced bleeding, infections, or both types of complications during perioperative and postoperative periods, which is consistent with literature reports (10, 11). In the same period, the same types of complications had occurred in 12% of our patients who underwent TLTs. The sample size (63 patients) was

Table 2. Complications and mortality rates in patients who underwent translaryngeal (TLT) and surgical (ST) tracheostomies

	TLT Group n = 67	ST Group n = 72	*p*
Duration of procedure in mins, mean (SD)	17 (10)	22 (6)	.003
Complications			
During procedure, n (%)			
Tube dislocation	3 (4)	0 (0)	.10
Subcutaneous emphysema	0 (0)	1 (1)	.52
Bleeding[a]	1 (1)	2 (3)	.99
Major	0 (0)	0 (0)	.99
Minor	1 (1)	2 (3)	.99
Decreased oxygen saturation[b]	2 (3)	2 (3)	.66
After procedure, n (%)			
Stomal complications[c]			
Inflammation	7 (10)	11 (15)	.29
Infection	2 (3)	5 (7)	.26
Severe infection	1 (1)	1 (1)	.72
Bleeding[a]	2 (3)	8 (11)	.06
Major	0 (0)	6 (8)	.03
Minor	2 (3)	2 (3)	.26
Tracheomalacia	1 (1)	1 (1)	.72
Total postprocedure complications[d]	13 (19)	26 (37)	.02
Survivors, n of total (%)			
Discharged from intensive care unit	45 (67)	48 (65)	.80
Discharged from hospital	33 (50)	34 (46)	.46
Alive at 1 yr	19 (28)	18 (24)	.36
Complications at 1-yr follow-up, n (% of survivors)	n = 19	n = 18	
Open stomas	7 (37)	7 (38)	.58
Clinically evident stenosis[e]	1 (5)	2 (11)	.53
Need for stomatoplasty[f]	1 (5)	3 (16)	.48

[a]Bleeding episodes were classified as major if the estimated total blood loss occurring within the 3–4 days postoperatively was ≥150 mL; all other bleeding was considered minor. In two patients of the ST group, major bleedings after the procedure occurred during severe hypertensive crisis, and in another two the platelet count was <30,000 cells/mm^3. [b]Oxygen saturation of <90%. [c]Stomal complications: inflammation—erythema, edema, tenderness, no pus; infection—signs of inflammation + culture-positive pus; severe infection—signs of infection + tissue necrosis. [d]The total number of postprocedure complications observed in each group does not correspond to the number of patients who experienced complications because some patients experienced two or more complications (e.g., one ST patient had both stomal infection and minor stomal bleeding). The numbers in parentheses simply indicate the ratio between the number of post-tracheostomy complications observed and the number of patients in the group. This ratio was significantly higher in the ST group, largely because of the higher rate of major stomal bleeding. [e]Signs of tracheal stenosis: stridor, cough, or dyspnea at rest or on exertion. [f]Three of these four patients also had tracheal stenosis.

chosen to allow detection, with a 95% probability, of a difference between these two postulated complication rates with a power of 80% (12). The SPSS package was used for all analyses (SPSS, Chicago, IL).

RESULTS

During the study period, 1,253 patients were admitted to our general ICU. Endotracheal intubation was never needed in 428 cases, including 250 patients whose acute respiratory failure was successfully managed with noninvasive ventilation. Of the remaining 825 patients, 624 were either extubated or dead a few days after ICU admission. A total of 62 others were excluded from the study as a result of successful late extubation after an initial weaning failure (n = 32), early transfer to another unit (n = 10), refusal to participate in the study (n = 12), or anatomic contraindications for PT (n = 8).

The study population consisted of the remaining 139 patients (82 men, 57 women; mean age, 64 ± 17 yrs) whose baseline characteristics are shown in Table 1. The mean Simplified Acute Physiology Score II at admission was 43 ± 13 points, which is associated with an estimated ICU mortality rate of around 34%. A total of 67 patients were randomly assigned to the TLT group; the other 72 had STs. The two groups were not significantly different in terms of demographic or baseline clinical characteristics, including the pretracheostomy prevalence of infections, pneumonia, and sepsis.

As shown in Figure 1, 61 of the 67 TLT patients (91%) and 59 of the 72 ST patients (82%, $p = .18$) were tracheostomized within 15 days of endotracheal intubation. The other 19 (13% of the total population) had tracheostomies 16–21 days after ICU admission. The length of intubation was not significantly different in the two groups.

Table 2 shows the intraoperative and postoperative complications encountered in the two groups. The duration of the tracheostomy procedure was significantly shorter in the TLT group. Intraoperative bleeding was rare in both groups and never exceeded 150 mL. Major postoperative bleeding (>150 mL) was significantly less frequent in the TLT group. Only one episode of major stomal bleeding required transfusion; it occurred on the first postoperative day in an ST patient, was associated with a hemoglobin reduction of >2 g/dL, and was treated with 1 unit of packed red cells.

Pus from infected stomas grew *Acinetobacter baumannii* in two cases (one ST, one TLT), *Staphylococcus aureus* in three ST cases (including one methicillin-resistant strain [MRSA]), *Pseudomonas aeruginosa* in two cases (one ST, one TLT), *Enterococcus faecium* in one TLT case, and *Candida tropicalis* in one ST case.

Systemic Infectious Complications. Table 3 summarizes the systemic infectious complications encountered in the two groups. Preoperative pharyngeal swab or tracheal aspirate cultures were positive in >70% of those in both groups. The most common isolates were *S. aureus* (21 patients), including seven isolates that were MRSAs; *P. aeruginosa* (19 patients); and *Candida* species (18 patients). Repeat blood cultures drawn during the first 3 hrs after completion of the tracheostomy revealed bacteremia in 12 TLT (18%) and 14 ST (19%) patients ($p = .98$). In 12 patients (six from each group), the blood isolates were identical to those isolated preoperatively from the pharynx or trachea (*P. aeruginosa* [n = 2], *Proteus mirabilis* [n = 1], MRSA [n = 2], and *Streptococcus pneumoniae* [n = 1] in the TLT group and *P. aeruginosa* [n = 3], *Enterococcus faecalis* [n = 1], MRSA [n = 1], and *Staphylococcus epidermidis* [n = 1] in the ST group). The only cases of severe sepsis seen during the study occurred in eight patients from this subgroup: causative organisms were *P.*

Table 3. Systemic infectious complications after translaryngeal (TLT) and surgical (ST) tracheostomies

No. of Patients with	TLT Group n = 67	ST Group n = 72	*p*
Antibiotic therapy before the tracheostomy[a]	46 (68)	51 (71)	.92
Preoperative PS and TA culture negativity and negative preoperative and postoperative blood cultures	14 (21)	19 (26)	.57
Preoperative PS or TA culture positivity and negative preoperative and postoperative blood cultures	41 (61)	39 (54)	.50
Postoperative bacteremia unrelated to preoperative PS or TA culture positivity[b]	6 (9)	8 (11)	.88
Postoperative bacteremia related to preoperative PS or TA culture positivity[c]	6 (9)	6 (8)	.56
Postoperative pneumonia[d]	11 (16)	9 (12)	.31

PS, pharyngeal swab; TA, tracheal aspirate.

[a]The number of infectious complications and bacteremia after tracheostomy was not different between patients who received antibiotics and those who did not, irrespective of the study group. The average time of antibiotic administration before tracheostomy was similar in the two groups. [b]Bacteremia diagnosed within the first three postoperative hours and caused by organisms not found in preoperative PS or TA cultures. [c]Bacteremia diagnosed within the first three postoperative hours and caused by organisms found in preoperative PS or TA cultures (see "METHODS" for details). Eight patients in this category (four of six (67%) in each group) developed severe sepsis. [d]Recurrence of an infection that had been eradicated before tracheostomy (two in each group) or occurrence of a new infection; the incidence of pneumonia in our intensive care unit usually ranges between 10% and 15%.

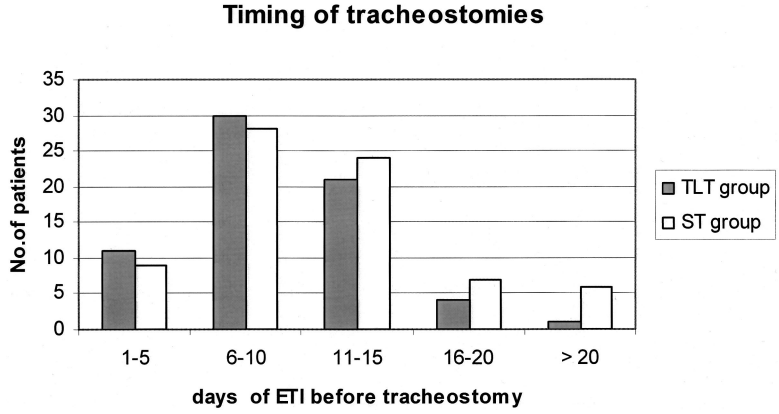

Figure 1. All study patients were intubated on the day of intensive care unit admission, and the majority of tracheostomies were performed after 6–15 days of intubation. The 20 patients who were tracheostomized earlier all had substantial neurologic or neurosurgical disease. Those whose procedures were performed after >15 days of intubation had been subjected to several weaning trials with transient success. *TLT*, translaryngeal tracheostomy; *ST*, surgical tracheostomy; *ETI*, endotracheal intubation.

aeruginosa (one TLT, three ST), MRSA (one TLT, one ST), *E. faecalis* (one ST), or *P. mirabilis* (one TLT). None of the cases of sepsis or simple bacteremia were fatal. The group rates of postoperative pneumonia were not significantly different. These infections occurred 8 ± 5 days after the tracheostomy, and none of the causative organisms (nine *S. aureus*, including five MRSAs; nine *P. aeruginosa*; and two *A. baumannii*) had been found in the same patient's pharynx or trachea.

ICU stays (29 ± 19 days in the TLT group and 27 ± 17 days in the ST group, $p = .52$) and hospital and ICU mortality rates (Table 2) were similar for the two groups. All survivors were discharged from the hospital with open tracheostomies.

Follow-up. One year after the tracheostomy procedure, we attempted to contact each of the 67 patients (33 TLT patients, 34 ST patients) who had survived the hospitalization associated with our study. Thirty had died at home (n = 12) or in another hospital (n = 18). Four others were alive but could not be contacted, and two were contacted but refused to participate in the follow-up evaluation.

A total of 31 patients (18 TLT patients, 13 ST patients) were interviewed and examined. The results of the follow-up physical examinations are summarized in Table 2. In all three patients (one TLT patient, two ST patients) with clinical signs of tracheal stenosis, subsequent bronchoscopy revealed granulomas that reduced the tracheal diameter by >50%. Full patency was later restored with argon laser treatment. Three of these patients and a fourth with no signs of stenosis required stomatoplasty.

Five of the 13 TLT respondents (38%) and six of the 18 from the ST group (33%) reported subjective phonetic or respiratory problems ($p = .53$) described as mild or moderate. As shown in Table 4, there were no significant intergroup differences in QoL reflected by Short Form 12 Health Survey scores. Well over half of the interviewed survivors of both groups rated their physical health as moderately or severely compromised, and emotional health ratings were even lower. As shown in Figure 2, QoL ratings for patients with open stomas were significantly lower than those of the patients whose stomas had been closed ($p < .005$).

DISCUSSION

Over the last decade, the popularity of TLT and other PT techniques has increased dramatically (1, 2, 13). The efficacy and safety of these procedures in critically ill patients requiring prolonged mechanical ventilation have been compared with those of ST in several previous studies, including nine prospective, randomized, controlled trials (14–22) like our own. The populations examined (24 to 100 patients/study) were considerably smaller than the one we analyzed. Our study is also novel in its focus on a single percutaneous technique, TLT, which was not considered at all in most of the previous trials. Furthermore, although two groups (14, 15) provided follow-up data on complications encountered, respectively, up to 3 and 6 months after tracheostomy, we also analyzed the longer-term (1 yr) effects of TLT and ST in terms of both general health and QoL. Finally, we specifically evaluated the relative risks of postoperative bacteremia and sepsis related to the two techniques.

When comparing PT with ST, each technique should be compared individually (23), as we did. Unfortunately, the paucity of data concerning the Fantoni PT obliged a comparison with techniques

Table 4. Short Form 12 Health Survey scores for survivors of translaryngeal (TLT) and surgical (ST) tracheostomy 1 yr after tracheostomy

	TLT Group 19 Survivors	ST Group 18 Survivors	*p*
No. of respondents (% of survivors)	18 (94)	13 (72)	.08
Physical health subscore,[a] mean (SD)	12 (5)	16 (5)	.09
Emotional health subscore,[b] mean (SD)	11 (3)	12 (4)	.27
Total score,[c] mean (SD)	23 (8)	28 (9)	.10

[a]Possible subscore range, 6–20; [b]possible subscore range, 6–27; [c]sum of physical and emotional subscores (possible range, 12–47)—the higher the score, the better the person's health and functioning.

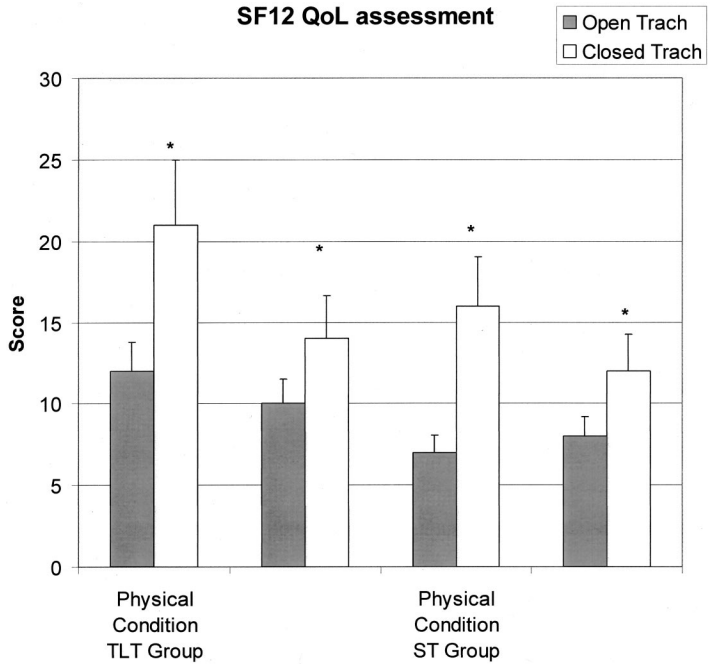

Figure 2. Quality of life as a function of tracheostomy (*Trach*) status (open vs. closed) in translaryngeal tracheostomy (*TLT*) and surgical tracheostomy (*ST*) survivors. The 14 patients whose tracheostomies were still open at the 1-yr follow-up (seven patients per group) had physical and emotional subscores on the Short Form 12 Health Survey (*SF12 QoL*) that were significantly lower (*$p < .005$) than those of the 17 patients (11 in the TLT group) whose tracheostomies were closed.

whose nuances with respect to performance and complication rates were slightly different, affecting, in part, our discussion.

Collectively, our findings indicate that both TLT and ST are safe procedures with low rates of intraoperative and perioperative complications. Our experience confirms the validity of TLT and its low risk for bleeding (24, 25). Like Holdgaard et al. (21), who compared Ciaglia's PTs with ST, we found that major postoperative bleeding was significantly more common with ST, but even in this group, the bleeding rate was only 8%. Others, however, have reported slightly higher rates of minor bleeding with percutaneous procedures (13% vs. 11% in ST) (18). The meta-analysis by Freeman et al. (2) that prevalently examined Ciaglia's and Grigg's PTs showed that PTs are generally associated with lower rates of stomal bleeding, infection, and postoperative complications than ST.

Like others (26), we encountered very few stomal infections after TLT (3 of 67 patients, 4.5%), and although these events were more frequent in ST patients (6 of 72 patients, 8.3%), the difference was nonsignificant. In two previous studies, however, ST was associated with strikingly higher stomal infection rates, ranging from 33% (19) to 63% (21). This difference may be due, at least in part, to the criteria used to define infection because all of our reported infections were confirmed by cultures of the tracheostomy stoma.

The rates of perioperative bacteremia and sepsis have never been systematically investigated in previous studies. Mazzon et al. (26) suggested that PTs, and TLT in particular, carry a higher risk of systemic infection caused by organisms colonizing the oropharynx or trachea before the procedure, but this finding was not confirmed in our study. Preoperative cultures revealed signs of upper respiratory tract colonization/infection in similarly high percentages of patients from each group, but only 12 of these 106 patients (11%) subsequently developed tracheostomy-related bacteremia, and the frequency of these events was almost identical in the two groups. However, in four cases from each group, tracheostomy-related bacteremia resulted in severe sepsis (promptly controlled in all cases).

The ICU and hospital mortality rates documented in this study were fully consistent with the patients' Simplified Acute Physiology Score II evaluations and unrelated to the tracheostomy technique used. At 1-yr follow-up, 27% of the study population was still alive, and only around one third of the interviewed survivors rated their QoL as acceptable or good. Negative ratings were closely related to the persistence of open stomas (documented in almost 40% of TLT and ST respondents).

There were very few cases of clinically manifested tracheal stenosis in either group. Unfortunately, clinical symptoms are unlikely unless the tracheal caliber is reduced by >50% (27). Considering the QoL of our patients, we thought that global bronchoscopic evaluations or other exams that implied the transfer of the patient from home could not be justified, but this obviously means that other patients may have had milder asymptomatic forms of stenosis. The number of cases documented is too low to allow any hypotheses regarding causative factors.

Another limit of our investigation is the absence of a systematic cost-effectiveness analysis. As other authors have noted, bedside procedures like TLT can eliminate many of the delays, risks, and inconveniences associated with operating room procedures (15, 28). Our experience confirms that percutaneous tracheostomies require less time than STs (16). The average time savings, 5–10 mins, was statistically significant ($p = .003$), but we agree with others (2) that its clinical im-

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plications are probably limited. However, at least in our institution, the fact that operating room facilities and personnel were not necessary certainly reduced patient charges and risks for intrahospital transport and may sway the balance to performing bedside tracheostomies.

In conclusion, our experience indicates that, on the whole, TLT and ST are equally safe and effective approaches to long-term or complicated airway management in the critically ill. Survival rates in both groups were low, as predicted by initial Simplified Acute Physiology Score II, but the tracheostomy technique used had no significant effect on most of the short- and long-term variables we measured, including QoL 1 yr after tracheostomy. Apart from certain practical benefits shared with other bedside tracheostomy techniques, the main advantage of TLT over ST is a somewhat lower bleeding rate. We found no evidence that TLT increases the risk of bacteremia caused by the spread of upper respiratory tract microbes. Our findings indicate that, in the absence of specific indications for one procedure or the other, the choice between TLT and ST should be based primarily on operator preference and experience and the clinical characteristics of each case.

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