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Percutaneous *Versus* Surgical Tracheostomy

A Double-Blind Randomized Trial

Claudine Gysin, MD,* Pavel Dulguerov, MD,* Jean-Philippe Guyot, MD,* Thomas V. Perneger, MD, PhD,‡ Blanca Abajo, RN,† and Jean-Claude Chevrolet, MD†

*From the *Department of Otolaryngology—Head and Neck Surgery; †Medical Intensive Care, Department of Internal Medicine; and ‡Institute of Social and Preventive Medicine, Geneva University Hospital, Geneva, Switzerland*

Objective
To compare surgical (SgT) and percutaneous (PcT) tracheostomies.

Background
Percutaneous tracheostomy has been said to provide numerous advantages over classical SgT.

Methods
A prospective randomized trial with a double-blind evaluation was used to compare SgT and PcT. SgT and PcT were performed according to established techniques (n = 70). The procedure was performed at the bedside in the intensive care unit in 21 cases (30%). The outcome measures were divided into procedure-related variables, perioperative complications, and postoperative complications. The procedure-related variables (location, duration, and difficulty) were evaluated by the surgeon. The perioperative and postoperative complications were divided into serious, intermediate, and minor. Perioperative and early postoperative (14 days) complications were evaluated daily by an intensive care unit nurse blinded to the technique used. Long-term postoperative complications were evaluated 3 months after decannulation by a surgeon blinded to the surgical technique.

Results
There were no major complications in either group. Most variables studied were not statistically different between the PcT and SgT groups. The only variables to reach statistical significance were the size of the incision (smaller with PcT, $p < 0.0001$), minor perioperative complications (greater with PcT, $p = 0.02$), and difficult cannula changes (greater with PcT; $p < 0.05$). Among nonsignificant differences, difficult procedures and false passages were more frequent with PcT, whereas long-term unesthetic scars were more frequent with SgT.

Conclusions
Both techniques are associated with a low rate of serious or intermediate complications when performed by experienced surgeons. There were more minor perioperative complications with PcT and more minor long-term complications with SgT.

Surgical tracheostomy (SgT) is a time-established procedure. Percutaneous tracheostomy (PcT), first described by Shelden in 1957,[1] gained popularity after the description of the progressive dilatation technique and the availability of a commercial set.[2] PcT has been said to have many advantages over SgT: a smaller skin incision and less dissection and tissue trauma, and therefore fewer wound complications such as hemorrhage and infection.[2–15] Long-term complications, such as tracheal stenosis or scar problems, have also been reported less frequently.[3–7,9,10,12–20] Finally, PcT is proposed as a bedside procedure that can be performed by every physician, with less assistance and less material.[2–9,11–17,19–25] This was supposed to diminish the cost of the intervention.[3,5,6,11,13,15,18,20,22,24–26]

When comparisons between PcT and SgT studies are drawn, the SgT publications cited are usually those published in the 1960s and 1970s.[3,12,14,18,27–36] When the comparison between the two techniques is made with studies conducted during the same period, the advantages of PcT are less obvious.[37] In the rare randomized trials comparing SgT and PcT,[6,12,38] the evaluation was not performed in a blinded fashion. Therefore, we conducted a prospective

The first two authors contributed equally to the design and conduct of this study, and to the data analysis and writing of this article.

Correspondence: Pavel Dulguerov, MD, Division of Head and Neck Surgery, Geneva University Hospital, 24, rue Micheli-du-Crest, Geneva, 1205, Switzerland.

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randomized double-blind study comparing the two techniques of tracheostomy.

METHODS

We conducted a prospective randomized trial with double-blind evaluation to compare PcT with SgT. From May 1995 to December 1997, all patients older than 18 years, hospitalized at the Geneva University Hospital, who underwent an elective tracheostomy were included in this study. Patients who had had a tracheostomy in the past or those with previous tracheal pathology were excluded. The study was approved by the hospital ethics committee. The patients (or for unconscious patients their families) gave their informed consent. The age, sex, diagnosis, previous intubations, reasons for tracheostomy, and drugs used were recorded.

The choice of tracheostomy technique was randomized using a computer-generated random numbers table. The procedure was done either in the operating room or at the bedside in the intensive care unit. All patients were intubated during the procedure, which was performed under general anesthesia.

The technique used for SgT was as follows: the skin was opened horizontally 2 cm above the sternal notch. The platysma muscle was sectioned horizontally and the strap muscles were separated at the level of the midline raphe. The thyroid gland was visualized and retracted. After careful hemostasis, an inferior tracheal flap was made according to Björk[39] at the level of the second or third tracheal ring. This flap was then sutured to the skin. A cannula was inserted and sutured to the skin.

For PcT, the technique used was close to that described by Ciaglia et al,[2] using the Cook set (Cook Inc., Bloomington, IN). In Ciaglia's technique, a vertical cutaneous incision is made below the cricoid cartilage, a mosquito clamp is used to spread the tissue in the midline, and the trachea is palpated through the wound. A trocard needle connected to a water-filled syringe is inserted in the trachea, just below the cricoid cartilage. Air is aspirated to verify the position of the needle. A metallic guide wire is passed into the trachea, and dilatation tubes are used until a sufficient diameter is created to insert a cannula. The cannula is then inserted and sutured to the skin. We modified Ciaglia's technique, first by using a horizontal skin incision to have the same postoperative status as with SgT. The incision was carried only through the skin and subcutaneous fascia, without direct visualization of the trachea, before the needle puncture. Also, the trachea was opened at the level of the second or third tracheal ring and not below the cricoid cartilage. Finally, we performed the intervention under tracheoscopic control, as previously described.[22] All tracheostomies were performed or supervised by one of the first two authors (CG, PD), both of whom have extensive experience with this procedure.

A standardized questionnaire was used to evaluate intraoperative variables. The morphology of the neck (normal, large, short) and thyroid gland (normal or enlarged), the size of the cutaneous incision, the duration of the procedure, the difficulty of the procedure, and intraoperative complications were recorded. The duration of surgery was timed starting with the skin opening and ending when the cannula was inserted. The surgeon subjectively evaluated the difficulty of surgery and the intraoperative bleeding on a scale of 0 to 2. Perioperative complications, such as death, cardiorespiratory arrest, aspiration, pneumothorax, pneumomediastinum, laryngeal lesion, posterior tracheal wall lesion, subcutaneous emphysema, and difficult cannula insertion, were recorded.

Postoperative evaluation was performed daily during the first week and then on the 14th day by the same intensive care unit nurse (BA), who was blinded to the tracheostomy technique used. Local status and complications from tracheostomy were assessed through a standardized questionnaire: death, pneumothorax, pneumomediastinum, aspiration, subcutaneous emphysema, hemorrhage, wound infection, and general infection were recorded.

Long-term evaluation was done 3 months after decannulation by the same physician (JPG), who was also blinded to the tracheostomy technique used. Patients were questioned about subjective dyspnea, dysphonia, or unesthetic scar. The physician evaluated the scar, using criteria such as color, level, and mobility. A flexible nasofibroscope was used to perform an indirect laryngoscopy and was passed, when possible, through the vocal cords to evaluate the trachea.

Complications were categorized as previously described.[37] Perioperative complications covered the actual procedure and the following 48 hours. Postoperative complications included the remaining follow-up, up to the long-term evaluation. For each group, complications were classified as serious, intermediate, or minor.[37]

The enrollment and follow-up of patients is shown in Figure 1, following the CONSORT statement guidelines.[40]

Categorical data were compared using the Fisher exact test, whereas continuous data were analyzed using the two-sided Mann-Whitney test (exact p value, based on 10,000 Monte Carlo replications).

RESULTS

From May 1995 to December 1997, 70 patients were included in the study, 35 in each group (see Fig. 1). The characteristics of the patients in both groups were similar (Table 1).

Thirty-six patients had a head and neck cancer. Among them, 30 underwent a tracheostomy during the operation for resection of their tumor, whereas 6 had a tracheostomy because of upper airway obstruction or aspiration. Thirty-four patients were recruited from the intensive care unit. The underlying disease was neurologic (n =

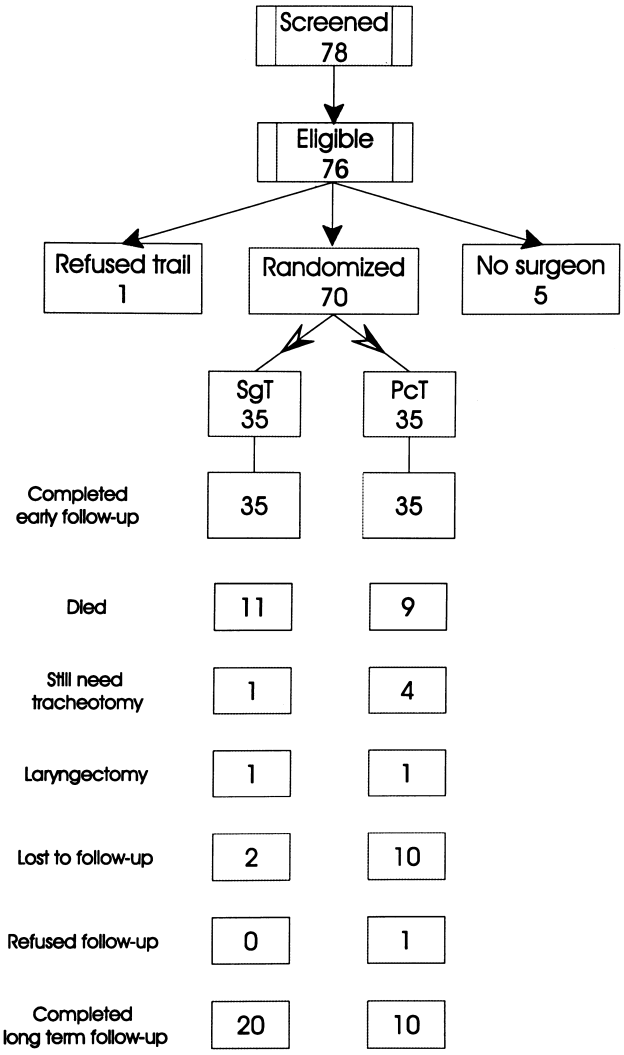

Figure 1. Enrollment, randomization, and follow-up of trial patients.

16), trauma (n = 9), cardiorespiratory (n =6), or gastrointestinal (n = 2). One patient had a laryngeal sarcoidosis. In this group, tracheostomy was performed in 22 patients for prolonged mechanical ventilation, in 7 patients for aspiration, and in 5 patients for upper airway obstruction.

Table 1. PATIENT CHARACTERISTICS

Characteristic	SgT	PcT	p Values
Number of patients	35	35	
Mean age (years) ± SD	56 ± 13.8	55 ± 15.4	
Sex ratio	3.5	3.5	
Duration of intubation (days) ± SD	4.9 ± 7.5	8.3 ± 12.4	
ICU patients	14	20	
ICU tracheostomy	13	8	
Abnormal neck	10	5	
Enlarged thyroid	2	0	
Skin incision size (cm)	3.7 ± 1.7	2 ± 0.6	<0.0001
Duration of surgery (minutes)	15.8 ± 5.5	18.2 ± 11.2	0.84
Difficulty of surgery (0–2)	0.17 ± 0.4	0.57 ± 0.5	0.012
Bleeding (0–2)	0.1 ± 0.3	0.3 ± 0.4	0.11

Table 2. PERIOPERATIVE COMPLICATIONS

Complication	SgT	PcT	Fisher Exact Test
Serious	**0 (0%)**	**0 (0%)**	**—**
Death	0	0	—
Cardiopulmonary arrest	0	0	—
Pneumothorax	0	0	—
Pneumomediastinum	0	0	—
Intermediate	**0 (0%)**	**1 (2.9%)**	**1.0**
Desaturation/Hypotension	0	0	—
Posterior tracheal wall lesion	0	0	—
Cannula misplacement	0	0	—
Switch to surgical technique	—	1	NA
Aspiration	0	0	—
Minor	**4 (11.4%)**	**13 (37.1%)**	**0.024**
Hemorrhage	0	0	—
Difficult tube placement	2	9	0.045
False passage	2	4	0.67
Subcutaneous emphysema	0	0	—
Total	4 (11.4%)	14 (40%)	0.013

Perioperative Complications

There were no serious perioperative complications (Table 2). One intermediate perioperative complication was noted: the conversion of one PcT into a SgT because of difficult insertion of dilatation tubes.

Seventeen minor perioperative complications (24%) occurred in 13 patients (18%). Minor perioperative complications were significantly more frequent with PcT (n = 13) than with SgT (n = 4; p = 0.02). These problems were immediately recognized and did not result in any long-term complications.

The incidence of perioperative complications was 11% in the SgT group and 40% in the PcT group (p = 0.013). The incidence of serious and intermediate perioperative complications was 0% in SgT group and 3% in PcT, representing 7% of the perioperative complications in this group. In other words, most of the perioperative complications were minor.

Postoperative Complications

Cannula obstruction, the only serious postoperative complication that occurred, was observed in 1 PcT patient with no untoward consequences (Table 3). Seven intermediate postoperative complications were observed: one case of pneumonia in the SgT group, and six difficult cannula changes during the first week (1 SgT and 5 PcT), also without further complications.

There were 14 minor postoperative complications (20%), seven in each group. All hemorrhages were controlled by

Table 3. EARLY POSTOPERATIVE COMPLICATIONS

Complication	SgT	PcT	Fisher Exact Test
Serious	**0 (0%)**	**1 (2.9%)**	**1.0**
Death	0	0	—
Tracheoesophageal fistula	0	0	—
Mediastinitis	0	0	—
Sepsis	0	0	—
Hemorrhage: intratracheal	0	0	—
Pneumothorax	0	0	—
Cannula obstruction	0	1	1.0
Cannula displacement	0	0	—
Tracheal stenosis	0	0	—
Intermediate	**1 (2.8%)**	**6 (17.1%)**	**0.11**
Pneumonia	0	1	1.0
Atelectasis	0	0	—
Aspiration	0	0	—
Difficult cannula change	1	5	0.2
Minor	**7 (20%)**	**7 (20%)**	**1.0**
Hemorrhage: external	4	4	1.0
Wound infection	3	3	1.0
Tracheitis	0	0	—
Total	8 (22.8%)	14 (40%)	0.20

local compression, without a need for additional surgical procedures or blood transfusion. Wound infections were all treated by local antibiotics with favorable resolution.

The cumulative incidence of early postoperative complications was 23% in the SgT group and 40% in the PcT group ($p = 0.20$). Only 12.5% of the SgT postoperative complications were serious or intermediate, whereas 50% of the PcT postoperative complications were serious or intermediate.

Long-term evaluation was completed in 30 patients (20 SgT and 10 PcT; Table 4). Twenty patients (11 SgT and 9 PcT) died of their underlying disease, 5 (1 SgT and 4 PcT) still needed their tracheostomy, and 2 (1 SgT and 1 PcT) had a total laryngectomy due to recurrence of their cancer; 12 (2 SgT and 10 PcT) were lost to follow-up and 1 (PcT) refused the long-term evaluation.

Although in most patients the tracheostomy wound closed within a week of decannulation, three patients had a delayed closure of the wound, two in the SgT group and one in the PcT group (delays: 10, 12, and 21 days). In one patient, the tracheostomy cannula was removed after 18 months, and surgical closure of the wound was performed under local anesthesia. The second patient had been treated with radiotherapy 1 year before the tracheostomy, and the third one had a postoperative local infection.

None of the patients had dysphonia or dyspnea. The scar was considered unesthetic in 8 of 20 (40%) patients from the SgT group and 2 of 10 (20%) patients from the PcT group. In six patients this resulted from color changes; in four patients it resulted from a level difference with the surrounding skin. One patient in the SgT group found her scar unesthetic and asked for surgical repair. Laryngotracheoscopic evaluation revealed a partial anterior loss of one tracheal ring in one patient from the SgT group and either small irregularities or mucosal hyperemia at the level of the third tracheal ring in four patients (3 SgT and 1 PcT). No tracheal stenosis was observed.

Overall, 35 postoperative complications, 18 in the SgT group and 17 in the PcT group, occurred in 25 patients. Seven patients (4 SgT and 3 PcT) had more than one complication. The total incidence of postoperative complications was 51% in the SgT group and 49% in the PcT group. The incidence of serious and intermediate postoperative complications was 3% for the SgT group and 20% for the PcT group. Again, most postoperative complications were minor.

No difference was observed in terms of complications between patients from the intensive care unit or patients with a head and neck cancer. Half of the perioperative complications and 10 of the 35 postoperative complications occurred in the intensive care unit group.

DISCUSSION

Our results show no important differences between the two techniques of tracheostomy, when the choice of technique is randomized and the evaluation conducted in a double-blind fashion. Both types of tracheostomy were performed at the bedside in the intensive care unit, avoiding the transportation problems of patients with endotracheal tubes and several catheters.[41,42]

The two groups were similar in terms of age, underlying disease, indication for tracheostomy, and duration of intubation before tracheostomy. The duration of surgery was similar in both groups. Among the presumed advantages of PcT, the size of incision was the only one to reach statistical significance.

There were no serious perioperative complications. The only problems encountered during surgery resulted from difficult tube placement, which was responsible for a false passage in four patients and a conversion from PcT to SgT

Table 4. LONG-TERM POSTOPERATIVE COMPLICATIONS

Complication	SgT	PcT	Fisher Exact Test
Tracheal stenosis	0	0	—
Tracheal cartilage lesion	1	0	1.0
Delayed cutaneous closure	2	1	1.0
Keloid	0	0	—
Unesthetic scar	8	2	0.42
Total	11 (55%)	3 (30%)	0.26

Number of patients evaluated: 30 (20 SgT, 10 PcT).

in one patient. False passages were immediately recognized by tracheoscopic control and corrected. Therefore, although some authors conclude that tracheoscopic control is not necessary,[25,43] we, like others,[20,22,24,43] strongly advocate its use to avoid serious complications.

This one conversion in technique occurred early in the study and can be attributed to insufficient experience, despite prior training with the procedure. Before starting this study, PcT was practiced first on cadavers and then performed in the operating room with patients who were ventilated with a rigid bronchoscope and the tracheoscopy image seen on a video screen. We think that this is a safe way of learning the procedure and strongly recommend it to PcT novices. After this, tracheoscopy with a flexible bronchoscope, either at the bedside or in the operating room, is recommended. Despite this training, PcT was evaluated as more difficult by the surgeons, probably because most of procedure is performed without direct visualization. Nevertheless, the scores of this subjective evaluation remained low for both techniques, and therefore they can be considered safe. The perceived degree of difficulty with the procedure may decrease with further surgical experience. The issue of the learning curve with the procedure has been previously discussed.[7,12,17,18]

In terms of postoperative complications, an important point to emphasize is the difficulties encountered in changing the cannula during the first 7 postoperative days with the PcT technique. No problems were encountered after 1 week; therefore, changing the cannula should be avoided during the first 7 days, and the appropriate cannula should be placed at the time of surgery. This complication results from the tight fit of the pretracheal conduit around the cannula with PcT. If insufficient time is allowed for fibrosis to consolidate this conduit, the pretracheal tissues tend to collapse and close off the opening almost immediately. With SgT, this problem is less common because of the size of the pretracheal conduit created by the intraoperative dissection and the use of a Björk tracheal flap technique that fixes the trachea to the neck skin. Because of these difficulties, already reported by others,[15,21,23,25] a new set has been recently marketed (Weinmann tracheostomy exchange set; Cook Inc.). In a study published by Van Heerden et al,[23] cannula change was impossible in one patient, who had to be reintubated. In the case of head and neck surgery or facial trauma, reintubation can be difficult or even impossible. In these situations, PcT should probably be avoided.

Hemorrhages and wound infections all responded to local treatment. Although some studies have reported fewer hemorrhages and wound infections with PcT,[6,7,12] there was no difference between the two groups in our study. Delayed cutaneous wound closure was another minor complication in three patients, again with no difference between the two groups.

The only long-term complications resulted from the wound scar and were more common in the SgT than in the PcT group. We did not pay special attention to the wound closure after the ablation of the cannula. The time to closure and the esthetic aspect of the scar could probably have been improved with better local care. The scar was considered unesthetic more often because of its level relative to the surrounding skin. Because scar maturation continues for >6 months, final evaluation at 12 months might give different results. In the literature, the scar after PcT has been described as "more aesthetic,"[4,5,18,20,23,44] with no criteria given. We used the criteria offered by Fischler et al[43] in the only well-conducted study on the long-term effects of PcT. This aspect has been neglected in SgT studies. Laryngotracheoscopy of our decannulated patients did not reveal any significant tracheal lesion or stenosis. As previously reported, tracheal rings are probably broken during PcT,[45] although without apparent problems.[15,18,20]

At first glance, the incidence of complications appears to be high in our study: a 26% rate of perioperative complications and a 50% rate of postoperative complications. However, closer examination of our results reveals that no serious perioperative complications and only one serious postoperative complication occurred. In addition, the intermediate complications, notwithstanding difficult cannula changes, were also rare. Difficult cannula changes can be easily prevented, and none of the observed complications had any consequences for the patients. Therefore, most of complications were minor and subjective: 94% of perioperative complications and 77% of postoperative complications were minor. Nevertheless, the higher incidence of perioperative complications in the PcT group resulted in a significant difference when compared with the SgT group. In short, both techniques are associated with a low morbidity rate.

As we previously discussed,[37] minor complications are subjective and do not result in significant consequences, and their incidence is largely dependent on the diligence with which they are sought. Perioperative difficult tube placement, postoperative external hemorrhage and wound infection, and unesthetic scars are good examples of these subjective and probably incidental complications. It is likely that the prospective nature of our study, with rigorous daily evaluation, was responsible for the high overall incidence of reported complications. For example, the appearance of the scar has not been considered a potential complication in SgT studies and is usually not even mentioned in PcT studies.

Advocates of PcT report low rates of complications and use older SgT studies, with high complication rates, for comparison. Once the bias resulting from historical trend is eliminated, the complication rates associated with SgT appear to be similar to those of PcT.[37] Other sources of bias in PcT studies include patient selection—namely the exclusion of obese patients, those with a short or large neck or an enlarged thyroid, and those with a coagulopathy. With such a selection of favorable cases, it is not surprising that PcT can be considered a quick and easy technique, with few complications. In our study, no patient was excluded before

randomization other than previously tracheotomized patients, and the incidence of complications was higher with PcT.

Despite the high incidence of complications with both techniques, we see both techniques as safe. This does not mean that tracheostomy is a trivial procedure; indeed, proper training cannot be overemphasized. We certainly agree with the adage "there is no simple surgery," because despite the authors' extensive prior experience with both tracheostomy techniques, the complication rates are high. PcT has its indications, especially for patients in the intensive care unit. For patients undergoing a major head and neck intervention, this procedure has no specific advantages. Therefore, the final choice of technique belongs to the physician performing the procedure.

The obvious limitation of our study is its small sample size and hence its limited power. However, this sample size was sufficient to demonstrate a significant difference in perioperative minor complications, favoring ScT. As for severe and intermediate complications, these appear to be so rare, regardless of tracheostomy technique, that a prohibitively large trial would be necessary to demonstrate a difference. Because we have no reason to believe that a substantial difference in the rates of severe or intermediate complications even exists, conducting such a trial is probably unwarranted.

A second shortcoming is the presence of a larger dropout in the PcT population and hence a smaller number of PcT patients with long-term evaluation. This reflects mainly the referral pattern of our institution and especially of the intensive care unit. Although the difference between PcT[20] and SgT[14] performed on intensive care unit patients is not statistically significant, the higher loss to follow-up in the intensive care unit population could be a possible explanation.

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