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LARYNGOLOGY

Results of vocal rehabilitation using tracheoesophageal voice prosthesis after total laryngectomy and their predictive factors

Alexandre Bozec · Gilles Poissonnet · Emmanuel Chamorey · François Demard · José Santini · Frédéric Peyrade · Cécile Ortholan · Karen Benezery · Juliette Thariat · Anne Sudaka · Katia Anselme · Brigitte Adrey · Paul Giacchero · Olivier Dassonville

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Abstract The aims of this retrospective study were to evaluate prosthetic voice restoration by tracheoesophageal puncture (TEP) in laryngectomized patients and to identify clinical factors correlated with functional outcomes. Between 2000 and 2008, 103 patients who underwent total laryngectomy or pharyngolaryngectomy (TPL) were included in our study. Functional outcomes were recorded 6 months postoperatively, and results were scored from 0 to 2 for oral diet and speech intelligibility. Lifetime of voice prosthesis and early and late complications were recorded. The impact of several clinical factors on functional outcomes, prosthetic valve lifetime and complications was assessed in univariate analysis. A total of 87 patients (84%) underwent TEP and speech valve placement (79 primary and 8 secondary punctures). Hypopharyngeal tumors ($P = 0.005$), circular TPL ($P = 0.003$) and use of a pectoralis major myocutaneous flap ($P = 0.0003$) were significantly associated with secondary TEP. Successful voice rehabilitation was obtained by 77 of 82 evaluable patients (82%). A high level of comorbidity (ASA score ≥ 3; $P = 0.003$) was correlated to speech rehabilitation failure. The median device lifetimes were 7.6 and 3.7 months for Provox I and II speech valves, respectively. Minor leakage around the valve occurred in 26% of the patients. Late complications occurred in 14 patients (16%) including: severe enlargement of the fistula ($n = 3$), prosthesis displacement ($n = 7$) and granulation tissue-formation ($n = 4$). In conclusion the use of voice prosthesis showed a high success rate of vocal rehabilitation with an acceptable complication rate.

Keywords Total laryngectomy · Tracheoesophageal puncture · Voice prosthesis

A. Bozec (✉) · G. Poissonnet · F. Demard · J. Santini · K. Anselme · O. Dassonville
Département de Chirurgie, Institut Universitaire de la Face et du Cou, Centre Antoine Lacassagne, 33 avenue de Valombrose, 06189 Nice, France
e-mail: alexandre.bozec@nice.fnclcc.fr

E. Chamorey
Département de Statistiques Médicales, Centre Antoine Lacassagne, 33 avenue de Valombrose, 06189 Nice, France

F. Peyrade
Département d'Oncologie Médicale, Centre Antoine Lacassagne, 33 avenue de Valombrose, 06189 Nice, France

C. Ortholan · K. Benezery · J. Thariat
Département de Radiothérapie, Centre Antoine Lacassagne, 33 avenue de Valombrose, 06189 Nice, France

A. Sudaka
Département d'Anatomie Pathologique, Centre Antoine Lacassagne, 33 avenue de Valombrose, 06189 Nice, France

B. Adrey · P. Giacchero
Département de phoniatrie, Service d'Oto-Rhino-Laryngologie, Centre Hospitalier Universitaire, Hôpital Pasteur, 30 voie romaine, 06000 Nice, France

Introduction

With the development of organ preservation trials including induction chemotherapy and concurrent chemoradiotherapy, total laryngectomy (TL) or pharyngolaryngectomy (TPL) are increasingly used as salvage procedures after failure of conservative treatments [1, 2]. However, TL and TPL are still common surgical procedures for patients with pharyngeal or laryngeal squamous cell carcinoma (SCC) and are associated with major consequences, such as loss of

normal voice, swallowing problems, loss of nasal function, altered smell and taste, poor cough, lung function changes, tracheostomal complications, and lifelong functional and psychological consequences [3, 4]. Functional rehabilitation of laryngectomized patients has become a crucial issue in recent decades with the increasing interest in patients' quality of life [3, 4]. A lot of progress has been made over the past 30 years, particularly in the area of voice rehabilitation with the advent and development of tracheoesophageal speech using voice prosthesis. The advantages of these devices are numerous and include immediate voice production, high success rates, and possibility of sustained speech with a more fluent quality than with esophageal speech. Consequently, in many centres, tracheoesophageal puncture (TEP) with voice prosthesis placement has replaced esophageal speech as the gold standard for voice rehabilitation [5, 6].

The aims of this study were to assess functional outcomes and short and long-term complications of TEP in laryngectomized patients and to determine their potential predictive factors.

Patients and methods

Between April 1, 2000, and March 31, 2008, 103 patients (95 men and 8 women) who underwent TL or TPL at our institution were included in this retrospective study. Their mean age was 65.4 ± 10.6 years (range 45–90 years). Comorbidity of patients, determined by the ASA-score, was obtained from the preoperative records and was distributed as follows: I = 2, II = 48, III = 51 and IV = 2. The indications for TL or TPL were primary (i.e. previously untreated) laryngeal or pharyngeal squamous cell carcinoma ($n = 47$), recurrent laryngeal or pharyngeal squamous cell carcinoma ($n = 46$), persistent and severe aspirations after partial laryngectomy ($n = 4$), pharyngolaryngeal radionecrosis ($n = 4$), cricoid chondrosarcoma ($n = 1$), and laryngeal metastasis of uterine leiomyosarcoma ($n = 1$). Patients with a previously untreated pharyngeal or laryngeal squamous cell carcinoma were staged according to the 2002 American Joint Committee on Cancer (AJCC) staging system. The pharyngeal defect was repaired by a direct mucosal suture for small defects or by using a pectoralis major myocutaneous flap for more extensive non-circular defects. In cases of circular TPL, pharyngeal reconstruction was done using a tubulized radial forearm free flap. A pectoralis major muscular flap was used to cover the pharyngeal suture line, or the tubulized radial forearm free flap in previously irradiated patients. The main clinical and treatment characteristics of the patients are listed in Tables 1 and 2.

Table 1 Clinical characteristics of the 103 patients

Characteristics	Number of patients	Percent
Sex		
Male	95	92
Female	8	8
Age (years)		
<70	67	65
≥70	36	35
ASA score		
<3	50	49
≥3	53	51
Tumor site[a]		
Larynx	62	67
Hypopharynx	31	33
T stage[b]		
T2	4	8
T3	14	30
T4	29	62
N stage[b]		
N0	28	60
N1	3	6
N2 (a, b or c)	14	30
N3	2	4

[a] Only for the 93 patients who underwent total laryngectomy or pharyngolaryngectomy for primary or recurrent squamous cell carcinoma

[b] Only for the 47 patients who underwent total laryngectomy or pharyngolaryngectomy for primary squamous cell carcinoma

Functional outcomes were recorded 6 months postoperatively for patients who were still alive and disease-free or at the last follow-up visit prior to recurrence or death for patients who presented a relapse of the tumor or died before the sixth post-operative month.

To determine objective functional outcomes, we developed a standardized physical examination form inspired by a study by Hidalgo and colleagues and by the Harrison-Robillard-Shultz TEP rating scale [7, 8]. The results were scored from 0 to 2, as follows:
oral diet:

- 2: swallowing is nearly normal or slightly impaired, diet slightly restricted, difficulties encountered with certain solid foods,
- 1: swallowing is moderately impaired, restricted diet, soft or semi-liquid diet,
- 0: swallowing is severely impaired or impossible, requiring maintenance of a feeding tube,

speech intelligibility:

- 2: voice easily produced, good occlusion and intelligibility,

Table 2 Treatment characteristics of the 103 patients

Characteristics	Number of patients ($n = 103$)	Percent
Type of surgery		
Total laryngectomy	66	64
Total non-circular pharyngolaryngectomy	16	16
Total circular pharyngolaryngectomy	21	20
Reconstruction		
Absent	58	56
Pectoralis major muscle or myocutaneous flap	24	23
Fasciocutaneous radial forearm free flap	7	7
Pectoralis major muscle or myocutaneous flap and fasciocutaneous radial forearm free flap	14	14
Neck dissection		
Absent	28	27
Unilateral	14	14
Bilateral	61	59
Radiotherapy		
Absent	21	20
Preoperative	30	29
Postoperative	39	38
Pre- and postoperative	13	13
Chemotherapy		
Induction chemotherapy	20	19
Concomitant to preoperative radiotherapy	11	11
Concomitant to postoperative radiotherapy	18	17

- 1: voice moderately strained or moderately breathy, patients obliged to repeat themselves but remain intelligible,
- 0: voice too strained or too breathy to permit functional use in conversation, patients most often unintelligible.

We also recorded the following data for all patients: lifetime of the first prosthetic valve (Provox I), mean lifetime of the subsequent prosthetic valves (Provox II), number of valve replacements (anterograde replacement with Provox II prosthetic valve insertion when possible), complications of the first prosthetic valve insertion, complications of prosthetic valve replacements, long-term complications of TEP and speech valves and their management.

The impact of the following factors, age, gender, comorbidity, preoperative or postoperative radiotherapy, tumor site, type of surgery, use of a pectoralis major muscular or myocutaneous flap, on functional outcomes (oral diet, speech intelligibility), long-term complications of TEP and lifetime of prosthetic valves was assessed in univariate analysis. Statistical analyses were performed by chi-squared tests confirmed by Fisher's exact tests for qualitative variables and by Student tests for quantitative variables. All statistical tests were performed with the R.1.7.1. software program for Windows, with a significance threshold of 5%.

Results

Tracheoesophageal puncture for voice rehabilitation

A TEP with prosthetic valve insertion (Provox I) for speech rehabilitation was performed in 87 of the 103 patients (84%). It was a primary (at the time of the TL or TPL) TEP for 79 patients (91%). It was a secondary procedure for 8 patients (9%) with a mean delay after TL or TPL of 4.4 ± 2.7 months. Indications for secondary TEP were extensive surgical resections in the tracheoesophageal area including resection of the cervical esophagus and extended resection of the trachea, which both led to a large dissection of the tracheoesophageal space (4 cases of circular TPL, 3 cases of non-circular TPL and pharyngeal reconstruction with a pectoralis major myocutaneous flap, 1 case of TL with resection of 6 tracheal rings). Among the 16 patients who could not undergo speech valve placement by TEP, 4 patients suffered from severe neurological or psychological impairments and 2 patients lived in countries where the management of tracheoesophageal speech valves was not possible. The remaining ten patients had not undergone primary TEP and were not eligible for secondary puncture because of rapid tumor recurrence ($n = 9$) or pharyngeal stenosis ($n = 1$). In univariate analysis, the absence of speech valve placement by TEP was significantly associated with circular TPL or use of a pectoralis major myocutaneous flap ($P = 0.005$ and $P = 0.008$, respectively). Secondary TEP (rather than primary TEP) was significantly more frequent in cases of hypopharyngeal tumors (in comparison with laryngeal tumors), circular TPL or use of a pectoralis major myocutaneous flap ($P = 0.005$, $P = 0.003$ and $P = 0.0003$, respectively).

Functional results

Oral diet was evaluable in 99 patients (4 patients died in the 2 postoperative months: 1 myocardial infarction, 1 massive pulmonary embolism, 1 pneumonia and 1 death of indeterminate origin). Six months after surgery, oral diet was normal or slightly impaired in 70 patients. Oral intake was severely altered or impossible (enteral nutrition through a feeding tube) in 14 patients (see Table 3). Among them, 6 patients presented a tumor recurrence in the 6 postoperative months, 4 patients developed a pharyngeal stenosis (2 circular TPL and 2 non-circular TPL) and 2 patients

Table 3 Functional outcomes 6 months after surgery

Outcomes	Scores		
	0	1	2
Oral diet			
Number of patients[a]	14	15	70
Percentage	14	15	71
Speech intelligibility			
Number of patients[b]	15	19	48
Percentage	18	23	59

[a] Functional results of 99 evaluable patients

[b] Functional results of 82 evaluable patients among the 87 patients with speech valve insertion by tracheoesophageal puncture

Table 4 Potential explicatory factors of speech rehabilitation failure

Potential explicatory factors	Number of patients ($n = 15$)
Neurological and/or psychological impairment	3
Bad compliance and lack of motivation for speech reeducation	3
Poor respiratory function with incoercible cough and expectoration when using speech valve	2
Local tumor recurrence in the 3 postoperative months	2
Death not associated with tumor recurrence in the 3 postoperative months	2
Repeated granulation and obstruction of the tracheoesophageal fistula posterior aspect	2
Extensive mandibular radionecrosis with complete trismus	1

suffered from extensive radionecrosis (1 mandibular osteoradionecrosis and 1 cervical soft-tissue radionecrosis). In univariate analysis, the following clinical parameters were identified as significant predictors of poor functional outcome for oral diet: circular TPL ($P < 0.0001$); hypopharyngeal tumor ($P < 0.0001$) and use of a pectoralis major myocutaneous flap ($P = 0.001$).

Among the 16 patients who did not undergo TEP, two patients lived abroad and were not evaluable for speech. The remaining patients could not use an alternative speech technique for the reasons mentioned previously (see "Tracheoesophageal puncture for speech rehabilitation"). Eighty-two of the 87 patients with speech valve insertion by TEP were evaluable for speech (4 deaths in the 2 postoperative months and 1 postoperative speech valve ablation for tracheal necrosis). Sixty-seven of them were able to speak with their speech valve and were intelligible in conversation (functional score of 1 or 2, see Table 3), giving a success rate for voice restoration by TEP of 82%. The voice restoration success rates were 81% (14 failures among 74 evaluable patients) for primary puncture and 88% (1 failure among 8 evaluable patients) for secondary puncture. Fifteen patients could not use their speech valve efficiently (i.e. speech restoration failure, functional score = 0). In these patients, a number of factors could explain the failure of speech rehabilitation and are listed in Table 4. In univariate analysis, high level of comorbidity (ASA score ≥ 3; $P = 0.003$) was the only clinical parameter identified as a significant predictor of poor functional outcome for speech intelligibility. A heat and moisture exchanger (HME) device was used by 51 patients. A Provox Free-Hands HME valve allowing "hands-free speech" was used by 16 patients.

Complications of tracheoesophageal puncture and speech valves

Early complications of TEP creation occurred in three cases. Peristomal necrosis associated with necrosis of the fistula wall appeared in two patients, after primary TEP, on postoperative days 12 and 14, requiring re-intervention with removal of speech valve, ablation of necrosed tissue and closure of tracheoesophageal fistula. In 1 of these 2 patients, a secondary TEP was successfully performed 2 months later. A speech valve displacement with esophageal migration of the prosthesis and closure of the tracheal aspect of the fistula occurred in 1 patient 8 days after a secondary TEP and required a new puncture under general anesthesia with insertion of a longer valve (10 mm for the second valve vs. 8 mm for the first valve). Therefore, early complications rates were 2.5% (2/79) for primary TEP and 12.5% (1/8) for secondary punctures.

The median device lifetimes were 7.6 months (from 1.2 to 39.5 months) for the first prosthetic valves (Provox I) and 3.7 months (from 1.7 to 29.4 months) for the subsequent prosthetic valves (Provox II). Complications of prosthetic valve change occurred in two patients with an aspiration of the valve into the airway requiring bronchoscopy to extract the prosthesis. Thus, the prosthetic valve change complications rate was 0.5% (2 complications out of 376 changes). One patient requiring multiple speech valve changes for leakage through the valve lumen (median lifetime of Provox II prostheses = 1.9 months for this patient) underwent insertion of Provox Acti-Valve prostheses with an obvious reduction in the frequency of prosthetic valve changes (median lifetime of Provox Acti-Valve prostheses = 6 months for this patient). In univariate analysis, female gender ($P = 0.02$), circular TPL ($P = 0.006$), hypopharyngeal tumor ($P = 0.02$) and use of a pectoralis major myocutaneous flap ($P = 0.03$) were associated with a lower Provox 2 prosthetic valves lifetime.

Minor leakage around the speech valve managed by reducing the size of the prosthesis and/or by collagen

injections around the tracheoesophageal fistula occurred in 23 patients (26% of the 87 patients with tracheoesophageal speech valve). Fourteen of these patients required multiple collagen injections around the speech prosthesis with a mean number of 2.6 injections per patient. Severe leakage around the speech valve caused by a major enlargement of the tracheoesophageal fistula appeared in three patients. Two of them required ablation of the prosthesis and surgical closure of the fistula. For the third patient, after ablation of the prosthetic valve, an adequate tracheoesophageal fistula contraction was spontaneously obtained after 1-month allowing insertion of a new prosthesis. Displacement of the prosthetic valve with closure of the posterior aspect of the fistula resulting in voice failure and requiring re-puncture under general anesthesia occurred in seven patients. In one of them, the prosthetic valve was definitively removed because of failure of speech rehabilitation. Granulation tissue formation around the valve requiring laser pulverisation under local anesthesia appeared in four patients. Thus, excepting minor leakages around and/or through the speech valve, late complications occurred in 14 patients, giving a late complications rate of 16%. There was no clinical factor identified as a significant predictor of late complications.

Discussion

Tracheoesophageal puncture for voice rehabilitation

In our series, 84% of the patients underwent TEP with a large majority of primary punctures (91%). Like many authors, we recommend a primary rather than a secondary puncture because greater exposure and access at the time of original surgery preclude the likelihood of major complications in the visceral compartment such as esophageal perforation and mediastinitis [5, 6, 9]. Primary puncture allows earlier speech rehabilitation. Furthermore, most papers demonstrate that the success rate with primary puncture is similar or higher than with secondary puncture [10, 11]. Previous radiotherapy to the head and neck is not a contraindication to primary TEP. Nevertheless, in our experience, secondary puncture should be preferred in cases of large surgical resection of the cervical esophagus and/or trachea, particularly in previously irradiated patients, because of the risk of peristomal and fistula wall necroses [10, 11]. This explains why, in our series, secondary TEP was significantly more frequent in cases of hypopharyngeal tumors which are generally more aggressive than laryngeal tumors, and following circular TPL or extensive TPL associated with pectoralis major myocutaneous flap reconstruction than following standard TPL or TL. Tumor recurrence which had precluded secondary TEP for nine patients and neuropsychological impairments which had made four patients ineligible for voice rehabilitation by speech prosthesis were, in our series, the leading causes of absence of voice rehabilitation.

Functional results

As usually reported in clinical studies of laryngectomized patients, deglutition and oral diet were satisfactory in our series with 86% of patients recovering autonomous oral intake [12, 13]. It was not surprising that hypopharyngeal tumors, circular TPL and extensive TPL with pectoralis major myocutaneous flap reconstruction were correlated to poor functional outcomes for oral diet. Circular TPL and TPL with large pharyngeal defect require reconstruction of the hypopharynx, and sometimes of the cervical esophagus, and are commonly associated with more deglutition difficulties than standard TPL or TL with direct closure of the hypopharynx [14]. After circular TPL, free-flap reconstruction of the hypopharynx and the cervical esophagus is accomplished by means of a jejunum free flap or tubulized fasciocutaneous free flaps, such as radial forearm or anterolateral thigh. For us, as for numerous authors, tubulized fasciocutaneous flaps are now the first choice flap in this indication with better functional results for voice rehabilitation and lower complication rates at the donor site than jejunal flap. With an adequate suture of the inferior part of the flap to the remaining cervical esophagus, the risk of stenosis, which was the main problem of hypopharyngeal reconstruction with fasciocutaneous flaps, is acceptable and comparable to the risk of stenosis obtained using a jejunal flap [15, 16].

The success rate of prosthetic voice restoration in our series was 82% which appeared very satisfactory and similar to previously reported results [5, 6, 11]. A number of clinical factors could explain the failure of speech rehabilitation. They include neurological or psychological impairments, lack of motivation, recurrent disease, granulation, and obstruction of the fistula. These factors of failure have also been well established by other authors [5, 11]. As several of them could be identified in the preoperative period, it seems particularly judicious to evaluate seriously the neurological and psychological status of the patients, as well as their motivation for speech rehabilitation before surgery. In a recent study, Boscolo-Rizzo et al. [6] showed an equivalent success rate of 82% for speech rehabilitation by TEP. As reported in this study, we have found a tendency toward higher success rates with secondary puncture. These findings, although not statistically significant, contrast with most published results on speech rehabilitation TEP which have demonstrated a tendency toward higher success rates with primary puncture. A possible explanation could be a selection bias since patients who underwent secondary

puncture were selected more accurately (adequate evaluation of the neurological and psychological status of the patient, endoscopic and radiological explorations of the pharyngoesophageal tract, good patient motivation, etc.).

We found no significant correlation between the success rate of speech rehabilitation and patient age, gender, radiotherapy, tumor site and type of surgery (circular or non-circular TPL, use of a pectoralis major muscular or myocutaneous flap). Nevertheless, the success rate of speech rehabilitation was significantly lower in patients with a high comorbidity level. A reduced vital lung capacity, neurological disabilities affecting hand coordination, decreased motivation and willingness to learn, chronic asthenia and dyspnea, which are more frequent in patients with severe comorbidities, could be the possible causes of unsuccessful vocal rehabilitation.

Beside voice restoration, pulmonary rehabilitation is also of vital importance to every laryngectomized patient. As often as possible, we use heat and moisture exchanger (HME) devices which can restore some of the lost normal nasal conditioning functions (warming, moisturizing and filtering of the air). Furthermore, by increasing the airflow resistance of the stoma, pulmonary physiology is also improved. The consistent use of these devices appears to have a positive effect on pulmonary function and problems (cough, expectoration, etc.) [17, 18]. In addition, the valved Provox HME can improve stomal occlusion and increase the quality of voice restoration. In our study, 16 patients wore a Provox FreeHands HME automatic tracheostoma valve system that allows hands-free speech. One of the most frequent problems with this device is the fixation of the valve to the stoma which generally requires the use of different types of adhesive and base plates, cannulas and/or tracheostoma buttons. In order to avoid deep tracheostoma and to improve adhesion of the base plates to the skin, we systematically perform sections of the sternocleidomastoid muscle anterior insertions at the time of initial surgery. In a recent study, Lorentz and colleagues also reported difficulties for patients using Provox FreeHands HME in securing the valve to the skin. Nevertheless, they concluded that this device allows hands-free speech with excellent compliance and good voice rehabilitation [19].

Complications of tracheoesophageal puncture and speech valves

Early complications of TEP creation were rare in this series, particularly for primary puncture with a complication rate of only 2.5%. Peristomal necrosis and necrosis of the fistula wall resulting in prosthesis displacement and creation of a large oesotracheal fistula occurred in two cases in our study after primary puncture. This type of complication can be difficult to manage and often requires re-intervention. This occurs more frequently in previously irradiated patients undergoing extensive TPL. Secondary puncture should be considered in this type of patient [9, 10]. In our study, patients experiencing secondary puncture also exhibited an acceptable complication rate without major complications in the visceral compartment of the neck, such as esophageal perforation resulting in severe infection processes (mediastinitis, cervical cellulitis, septicemia, etc.) that have been reported in up to 7.8% of secondary punctures [9].

The median device lifetime was longer for the first prosthetic valves (median Provox I lifetime = 7.6 months) than for all subsequent prosthetic valves (median Provox II lifetime = 3.7 months). For most authors, the median Provox II device lifetime varies from 3 to 6 months, which is consistent with our results [9]. Leakage of fluids through the valve is the most common problem related to maintenance of the TEP and is also the commonest indication for replacing any voice prostheses. Valve incompetence is generally caused by *Candida albicans* deposits on the silicon material and is the most important factor determining the life of the voice prostheses [9]. Negative pressure in the esophagus during the deglutition process is also recognized as a factor of leakage through the valve lumen. This phenomenon which causes the flap valve to be sucked open is commonly associated with multiple speech valve replacements. In order to manage this problem of esophageal negative pressure, magnets have been used to maintain closure of the valve mechanism and prevent leakage. The recently developed Provox Acti-Valve includes a new valve mechanism using Candida-resistant fluoroplastic (Teflon-like) material for the valve and valve seat and magnets to generate an active closing force, thus preventing inadvertent opening of the valve during swallowing or deep inhalation. As illustrated for one patient in our study, this innovative voice prosthesis offers a solution for patients requiring very frequent voice prosthesis replacements [20].

Interestingly, in our study, extensive TPL with large hypopharyngeal defect requiring free flap or pedicled myocutaneous flap reconstruction were associated with a shorter Provox 2 prosthetic valve lifetime. This phenomenon could be explained by decreased pharyngeal motility with more stasis of food residue around the prosthetic valve resulting in more Candida colonization around the silicone. In a recent large study on prosthetic speech valves, Op de Coul et al. [5] found that radiotherapy and young age were correlated to a lower speech valve lifetime. However, they reported no relationship between type of surgery (with or without hypopharyngeal reconstruction) and voice prosthesis lifetime. Anterograde replacement of the Provox 2 prosthetic valve is a very safe technique with a complication rate of only 0.5% in our study. To alleviate the risk of the valve being aspirated into the airway, it is essential to check

carefully that the prosthesis has been correctly placed in the tracheoesophageal fistula by pulling the valve slightly with hemostatic forceps before the end of the procedure.

Progressive enlargement of the tracheoesophageal fistula resulting in salivary leakage around the prosthesis and aspirations is one of the most common problems with speech valves, occurring in 7–42% of patients [9]. In our study, 26% of the patients with a tracheoesophageal speech valve suffered minor leakage around the prosthesis. These patients were easily managed by downsizing the prosthesis, where necessary, and/or by collagen injections around the fistula. Injections of collagen derivatives or other absorbable or non-absorbable materials (autologous fat, hyaluronic acid, Bioplastique, etc.) into the fistula edges are easy, safe and well-tolerated procedures which can be performed without general anesthesia [9, 21, 22]. They are often not sufficient in cases of severe enlargement of the tracheoesophageal fistula, resulting in major leakage around the valve (3 patients in our series). This last complication is generally associated with atrophy of the fistula wall and can be very difficult to manage. The traditional management of an enlarged fistula has been to remove the valve to allow the fistula to contract spontaneously. The resulting salivary leakage through the fistula requires hospital admission and use of a cuffed tracheal cannula to prevent aspirations during several days. A Foley catheter can be inserted into the fistula to feed the patient [9]. As illustrated by one case in our series (after 1 month), a new prosthetic valve can be inserted when adequate shrinkage of the fistula is obtained. In some cases with satisfactory local conditions (large stoma, good trophicity of the tracheoesophageal wall), a submucosal purse-string suture can be effective [23]. Persistent and incoercible leakage around the valve may necessitate definitive ablation of the prosthetic valve with surgical closure of the tracheoesophageal fistula, particularly in patients with unsuccessful vocal rehabilitation. Surgical closure of the fistula, most often in previously irradiated patients, can be a difficult procedure with possible severe local complications such as tracheal or peritracheostomial tissue necroses. Classically, this meticulous surgical procedure consists in separation of the tracheoesophageal party wall, a 2-layer closure of the esophagus and a 1-layer closure of the trachea, with or without graft interposition [24].

In our study, displacement of the prosthetic valve with partial or complete closure of the posterior aspect of the fistula occurred in seven patients. This complication results in voice failure and requires retrograde prosthesis replacement under general anesthesia and, sometimes, re-puncture [9]. A possible explanation for this phenomenon is shortness of the valve resulting in invagination in the tracheoesophageal wall. Granulation tissue formation around the valve is a common complication of prosthetic valves which can also occur when the valve is too short. Nitrate cauterization or laser pulverization of the granulations is often necessary before adequate replacement of the prosthetic valve.

Conclusion

The results of our study demonstrate that surgical voice restoration with prosthetic valve by TEP can provide a high rate of successful voice rehabilitation in most laryngectomized patients. The contraindications of this technique must be known and respected in order to avoid severe complications or unsuccessful voice restoration. As our experience with voice rehabilitation by TEP increases, the management of its complications is being more and more clearly defined. In most cases, these complications can be managed easily using conservative procedures. Finally, the benefits of this voice rehabilitation technique in terms of communication in the alaryngeal patient greatly outweigh the risks associated with the procedure.

Conflict of interest statement The authors have no conflict of interest to declare.

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