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Voice

Post-laryngectomy voice rehabilitation with voice prosthesis: 15 years experience of the ENT Clinic of University of Catania. Retrospective data analysis and literature review

Riabilitazione vocale post laringectomia con voce protesica: 15 anni di esperienza della Clinica Otorinolaringoiatrica dell'Università di Catania. Analisi retrospettiva dei dati e revisione della letteratura

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SUMMARY

This study reports our 15-year experience, in Sicily, with the use of voice prostheses, analysing the different variables that have influenced the success or failure of speech rehabilitation. The retrospective clinical analysis was carried out by reviewing the clinical histories of 95 patients with laryngeal cancer, in whom a voice prosthesis had been placed by trachea-oesophageal puncture between 1998 and 2013. Age, type of tumour, type of surgery, use of prior radiation therapy, type of puncture, prosthesis used and its duration, number of replacements, complications and causes for prosthetic success or failure were analysed. The results showed a mean of Harrison-Robillard-Schultz (HRS) TEP rating scale of 11.8 in primary TEP and 12.6 in secondary TEP (P =0.613). PORT did not affect overall rehabilitation success. In these patients, the mean HRS rating scale was 11.2, with long-term success of 85% (P =0.582). In patients over 70 years old, long-term success was 82.5%, with 78% in primary and 86% in secondary TEP, the mean HRS was 11.2 in primary and 12 in secondary TEP (P =0.648). In total, long-term success was 87.5%, with 84% in primary and 91% in secondary TEP. The results obtained by retrospective analysis of 15 years of prosthetic rehabilitation in the Sicilian territory highlighted standard rehabilitation, in terms of intra and postoperative complications, fistula related pathology and overall success.

KEY WORDS: Laryngectomy • Alaryngeal voice • Tracheoesophageal puncture • Vocal prosthesis • PORT

RIASSUNTO

L'obiettivo dello studio è stato quello di riportare 15 anni di esperienza, nel territorio Siciliano, con l'utilizzo della voce protesica (VP), analizzando le differenti variabili che hanno influenzato il successo o il fallimento riabilitativo vocale. L'analisi clinica retrospettiva è stata condotta revisionando le storie cliniche di 95 pazienti affetti da carcinoma laringeo, nei quali una protesi vocale era stata posizionata a mezzo di una puntura tracheoesofagea tra il 1998 e il 2013. Età, tipologia neoplastica, tipo di chirurgia, utilizzo di radioterapia, complicanze e cause di successo o fallimento protesico riabilitativo erano analizzate. I risultati hanno mostrato una Harrison-Robillard-Schultz (HRS) TEP rating scale media di 11,8 in TEP primaria e di 12,6 in TEP secondaria (P =0,613). PORT non ha influito sul successo riabilitativo globale. In questi pazienti l'HRS media è stata di 11.2 in primaria e 12 in TEP secondaria (P =0,648). Complessivamente, il successo a lungo termine è stato 87,5%, con 84% in primaria e 91% in TEP secondaria. I risultati ottenuti dall'analisi retrospettiva su 15 anni di attività protesico riabilitativa condotta nel territorio siciliano hanno evidenziato un elevato standard riabilitativo, in termini di complicanze intra e postoperatorie, patologia fistolo correlata e successo riabilitativo globale.

PAROLE CHIAVE: *Laringectomia • Voce alaringea • Puntura tracheoesofagea • Protesi vocale • Radioterapia postoperatoria*

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Introduction

Voice rehabilitation is commonly achieved by oesophageal speech, an artificial larynx, or the creation of a trachea-oesophageal fistula with insertion of vocal prosthesis. As is known, the advantages of prosthetic speech are immediate phonation, simple training, longer phonation time, greater volume and better intelligibility. The disadvantages of trachea-oesophageal speech include finger utilisation required to occlude the tracheostoma, dependence on the physician for change of prosthesis and a second intervention if the patient is undergoing a secondary insertion [1].

Since the introduction of the trachea-oesophageal puncture (TEP) method coupled with insertion of voice prosthesis (VP) by Singer and Blom in 1980, the success of restoring vocal communication in laryngectomies has improved significantly. At the beginning caution was indicated, however trachea-oesophageal speech (TES) soon became widely accepted. Nowadays, the method is generally recognised as a routine procedure for speech restoration after laryngectomy [2].

Technological advancements have been such that today the indwelling prostheses are designed to meet the criteria of low airflow resistance, optimal retention in the trachea-oesophageal party wall, prolonged device lifetime, simple maintenance by patient and comfortable outpatient replacement.

Indwelling low-resistance voice prostheses have become the valves of choice in patients with TEP, reporting success rates from 40 to 90% with excellent voice quality [3 4 5 6].

In Sicily, trachea-oesophageal voice rehabilitation has improved significantly only during last decade. This finding is justified mainly by steady progress of care towards patients with laryngectomies, who until a few years ago, made use of electrolarynx almost exclusively for voice recovery, significantly limiting both psychosocial and working aspects.

This geographical area, marked until recently by a large negligence of the population, especially in more rural areas, towards neoplastic risk factors and the possibility of early diagnosis for conservative or reconstructive surgery, is characterised by a high number of laryngectomees, whose tracheo-oesophageal speech recovery occurred only in the last 15 years.

This effort, however, has been wide spread in our area, placing for over a decade the gold standard rehabilitation over other vocal rehabilitative methods.

The objective of this study is to report our 15-year experience, in Sicily, with the use of voice prostheses following total laryngectomy, analysing the variables that have influenced the success or failure of speech rehabilitation.

Materials and methods

In a tertiary care centre, ENT Clinic of the Department of Medical Sciences, Surgical and Advanced Technologies, University of Catania, a retrospective study was carried out by examining the clinical outcomes of 15 years of experience (1998-2013) in trachea-oesophageal voice rehabilitation, during which period 95 patients with laryngeal cancer were subjected to TEP with vocal prosthesis.

The following variables were analysed: age, type of tumour, type of surgery, use of prior radiation therapy, type of puncture, prosthesis used and its duration, number of replacements, complications and causes for prosthetic success or failure.

In particular, 95 subjects were included, 78 males and 17 females with a mean age at the time of intervention of 61 years (range 42-80).

The indications for total laryngectomy (TL) or total pharyngolaryngectomy (TPL) were primary laryngeal squamous cell carcinoma (n = 57), pharyngeal squamous cell carcinoma (n = 8), recurrent laryngeal or pharyngeal squamous cell carcinoma (n = 27), persistent and severe aspirations after partial laryngectomy (n = 2) and adenoid cystic carcinoma (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. Patients whose surgical margins were involved by tumour, with perineural invasion, extralaryngeal extension, neck metastasis or extracapsular extension of metastasis were subjected to adjuvant radiation or chemoradiation.

Considering disease control: 58 patients underwent TL and neck dissection (ND), 13 patients underwent TL, 14 patients underwent TL and ND and postoperative radiotherapy (PORT) and 10 patients underwent TL and partial hypopharyngectomy with pharyngoesophageal reconstruction and ND and PORT, the latter in 3 cases (Tab. I).

In particular, a phonatory fistula between trachea and oesophagus with prosthesis positioning by means of a primary puncture (primary TEP) was carried out in 43 cases and a secondary puncture (secondary TEP) was performed in 52 cases (Tab. I); all TEPs were performed after appropriate assessment of motivations, local oncological conditions, comorbidities and psychic and physical fitness, both local and systemic.

Procedures for primary and secondary TEP were carried out according to those described by other authors [5 7 8]. All patients were rehabilitated with indwelling Provox voice prostheses (Atos Medical AB, Hörby, Sweden). The local institutional review board approved the study protocol and informed consent was obtained from the patients.

In all patients, a surgical refinement was performed at the time of TL for prevention of hypertonicity of the neoglottis, microstoma or deep stoma and pseudo-vallecula formation. In particular, a short cricopharyngeal myotomy

Table I. Study group.

Surgery group	Number of patients	Primary TEP	Secondary TEP
TL	13	9	4
TL+ND	58	30	28
TL+ND+PORT	14	4	10
TPL+ND	7	0	7
TPL+ND+PORT	3	0	3
TOTAL	95	43	52

TL = Total laryngectomy; TPL = Total laryngectomy + partial hypopharyngectomy; ND = Neck dissection; PORT = Postoperative radiotherapy

and tracheostoma construction was performed by suturing the skin flap as far back as possible to the lateral-posterior tracheal cartilage and sectioning of the sternal head of the sternocleidomastoid muscles, and pharyngeal reconstruction by closure in T-shape and constrictor muscle closure across the midline and to the base of the tongue muscles.
In secondary TEP, presurgical evaluation of pharyngoesophageal segment (PES) tonicity was carried out by an insufflation test as described by Blom et al [9]. Swallowing videofluoroscopy was performed to rule out hypertonicity or spasm of the PES. Patients with hypertonicity or spasm of the PES did not undergo voice prosthesis insertion and were excluded from the examination group. In 15-years experience of prosthetic rehabilitation, this finding was fortunately infrequent, involving <5% of patients annually submitted to TL.
We also excluded patients who presented cancer recurrence or metastases at the time of evaluation or a new primary head and/or neck tumour.
The results were obtained analysing complications and problems during and after surgery, the long-term overall success, which was evaluated no sooner than one year after surgical procedures, according to the parameters *use, quality* and *care* as they are stated by the Harrison-Robillard-Schultz (HRS) TEP rating scale [10]. A total overall score ≥11 was established as the cut-off for successful voice prosthesis rehabilitation. Because the Provox voice prosthesis was not to be self-removed and inserted by most patients, the maximum reachable score of subscale parameter *care* in these patients was only 4 instead of 5 points.
The rate of speech restoration was analysed using a non-parametric Mann-Whitney's-test, which was used to assess differences between categories. In all cases, P values <0.05 were considered statistically significant.

Results

The rate of postoperative laryngectomy complications was 13%, and the most common were pharyngocutaneous fistulas in 90% of cases, followed by bleeding in 5% and medical complications in another 5%. The presence of postoperative complications did not have an overall significant impact on failure of TEP (*P*=0.716).
Primary trachea-oesophageal punctures with immediate insertion of the vocal prosthesis at the time of total laryngectomy were performed in 43 patients. In this group, no major complications during or after surgery were observed. However, in seven cases, instability of tracheostomy diameter was seen that prevented cannula removal and needed adequate management a fenestrated LaryTube use, making counselling for trachea-oesophageal voice learning particularly difficult and mildly reducing vocal intelligibility. In four other cases, a reduction of vocal intelligibility with strained voice was observed, unsuitable for functional use during conversation caused by a residual hypertonicity of the PE segment (Tab. II).

Table II. Intra and postoperative problems.

Group	Major Surgical Complications	Hypertonicity of PES	Tracheostome Instability
Primary TEP	0	4	7
Secondary TEP	3	1	0
TOTAL	3	5	7
Overall percentage	3.1%	5.2%	7.3%

PES=Pharyngo-oesophageal segment; TEP=Tracheo-oesophageal puncture-

In 52 cases, who underwent secondary TEP, the mean interval between laryngectomy and prosthesis implant was 22.2 months, with a range of 6.3 to 38.1 months. In this group, two cases of TEP tract infection were recorded with cellulitis of soft perifistula tissue that made it necessary to immediately remove the prosthesis; specific antibiotic therapy was started that led to the subsequent healing of trachea-oesophageal tissue. Moreover, another case of mediastinitis was observed due to a small lesion of the posterior wall of the oesophagus during rigid esophagoscopy. In secondary TEP, only one patient had an unsatisfactory voice prosthesis (Tab. III).
Moreover, in this group, 10 cases were subjected to a partial hypopharyngectomy with pharyngoesophageal reconstruction. In these patients, 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 the same patients, TEP was performed less than 8 months after reconstruction only in patients free of complications and major comorbid diseases. No intraoperative and/or postoperative complications were observed, nor problems of vocal intelligibility, and there were no differences in TEP complications between the standard TL and the reconstructed TL group (*P*=0.782)
Prosthetic replacement is generally performed in the absence of prosthetic or fistula related disease in 75% of cases. In such circumstances, the substitution occurred, on average, not later than the fifth month, mainly to reduce the risk of fistula related disease. The anterograde procedure was used in 90% of cases. All patients performed regular cleaning of the valve including oral antifungal drops at least twice a week.
The reason for this was that prosthetic replacement was necessary before the specified intervals, involving 25%

Table III. Fistula related pathology.

TEP	TE Granuloma	Periprosthetic Leakage	Fistula Migration	Overall Percentage
Primary TEP	4	4	1	5.2%
Secondary TEP	7	3	2	12.6%
TOTAL	11	7	3	22%

TEP=Tracheo-oesophageal puncture; TE Granuloma= Tracheo-oesophageal granuloma.

of patients mainly due to abnormal colonisation of mycobacterial biofilms with leakage through the prosthesis. We report, hereinafter, the median device lives of different types of indwelling voice prosthesis used in 15 years of prosthetic clinical practice, considering that, in view of the significant longer device life of the first prosthesis, some authors suggest to not include the first device in calculation of the mean and/or median device life of indwelling voice prostheses [11].

The median device lifetimes were 150 days (from 120 to 180 days) for the first generation of prosthetic valves (Provox I - 95 patients) and 125 days (from 95 to 155 days) for the second generation of prosthetic valves (Provox II - 73 patients) and 140 days (from 125 to 165 days) for the third generation (Provox Vega - 22 patients). In patients with PORT, the mean device lifetime was generally shorter, often due to major early fungal colonisation, but this difference was not significant (*P=0.*573). In such cases, the replacement procedure was observed following the above cited criterion.

Regarding fistula-related pathologies, this occurred in 22% of cases. Tracheo-oesophageal granuloma was most frequently observed and occurred in 11 patients (12%) (Fig. 1); periprosthetic leakage occurred in 7 patients (7%) (Fig. 2), severe atrophy of the fistula party wall was recorded in two cases presenting persistent and incoercible leakage and fistula migration was seen in 3 patients (3%) (Fig. 3).

The surgical closure of the fistula was recorded in 8 cases. The main causes leading to the closure were: five patients for ineffective voice production (four in primary and one in secondary TEP), one case due to progressive downward fistula migration and another two patients due to giant tracheoesophageal granuloma, which necessitated the closure of the fistula and surgical removal of the granuloma. In these latter two patients, a new fistula in secondary technique was repackaged after six months.

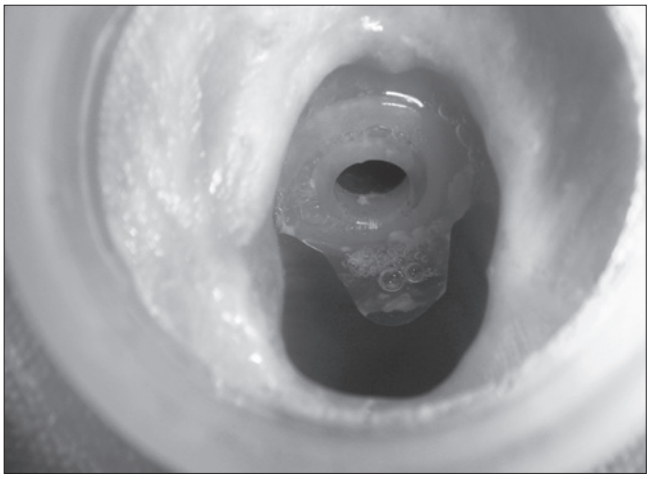

Fig. 2. Periprosthetic leakage.

As far as long-term success is concerned, the parameters taken into consideration were *use*, *quality* and *care* as stated by the HRS TEP Rating Scale [10]. The mean HRS rating scale was 11.8 in patients with primary TEP and 12.6 in patients with secondary TEP (*P*=0.613). PORT did not affect overall rehabilitation success. The mean HRS rating scale of patients who underwent PORT was 11.2 points, with long-term success of 85% (*P*=0.582). In patients over 70 years old, the long-term success was 82.5%, with 78% in primary TEP and 86% in secondary TEP. The

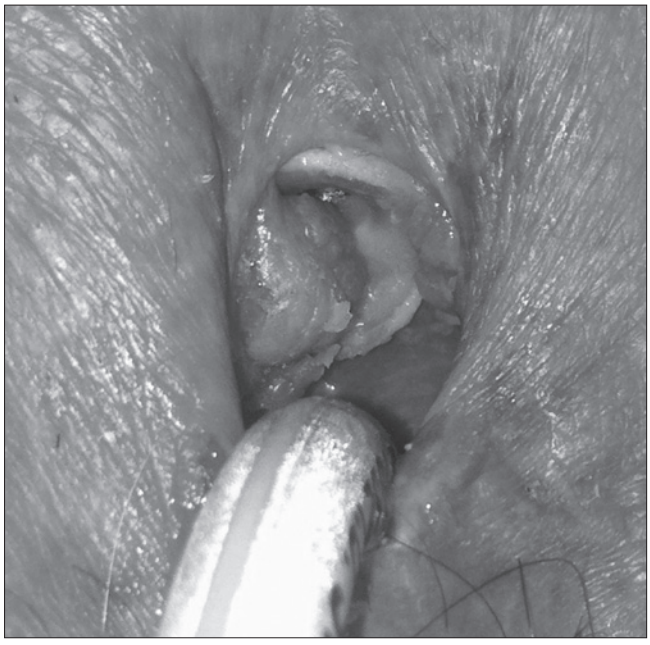

Fig. 1. Tracheoesophageal granuloma.

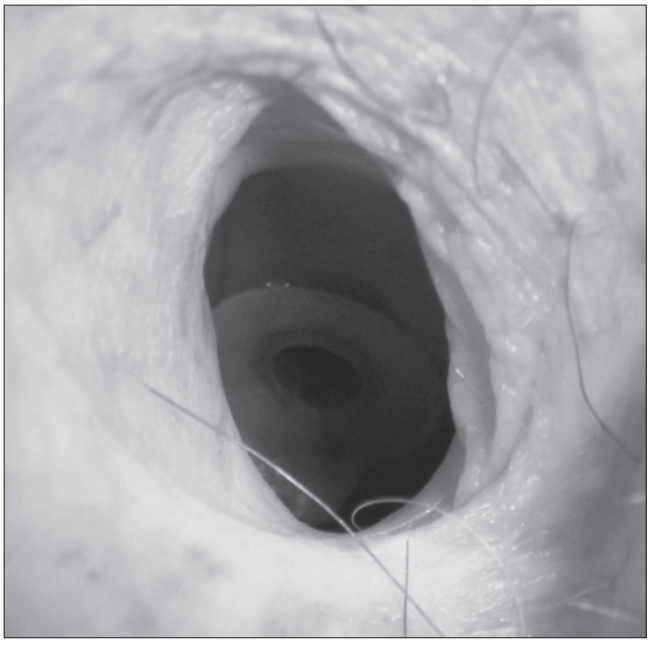

Fig. 3. Fistula migration.

mean HRS rating scale was 11.2 in patients with primary TEP and 12 in patients with secondary TEP (*P*=0.648) (Tab. IV). In total, long-term success (HRS overall score ≥11) was 87.5%, with 84% in primary TEP and 91% in secondary TEP (Tab. V).

Table V. Long-term success.

Group	Without PORT (n=81)	With PORT (n=14)	Elderly (n=40)
Primary TEP	84%	83%	78%
Secondary TEP	91%	87%	86%
TOTAL	87.5%	85%	82.5%

TEP=Tracheo-oesophageal puncture; PORT= Postoperative radiotherapy.

Discussion

Progress in voice rehabilitation following TL over the last 30 years has made an enormous difference in the concept of management of laryngeal cancers. As is well known, there are currently several options available for these patients and the choice varies from patient to patient.

Data concerning the tracheoesophageal overall success rehabilitation in Sicilians in patients over 70 years were registered in a recent retrospective study, which assessed advantages and drawbacks of this method of vocal recovery in 40 subjects, underwent a primary puncture in 18 cases and a secondary puncture in 22 cases. The results from these patients were compared with data obtained from a group of 39 patients, less than 70 years of age, which thus represented the control group. The results showed the absence of a statistically significant difference in incidence of complications, during and after surgery (p>0.9) as well as the overall success ratio of prosthesis implants between the two groups (p>0.7) [12]. In this context, the ability of the larynx of the elderly to functional recovery after partial laryngectomy is widely known [13].

TEP can be performed primarily or secondarily. This approach provides serviceable and satisfactory vocal function after laryngectomy in the vast majority of patients, with an overall success rate that ranges between 80% and 92% [3 4 14].

Essentially, the benefits of primary TEP consist in avoiding a second procedure and immediate good voice restoration with a remarkable psychological boost to patients. According to the literature, intra- and/or postoperative complications may occur during a secondary puncture with an incidence varying from 15 to 25%, and include para-oesophageal abscess cellulitis, aspiration of the prosthesis, enlarged fistula, oesophageal perforation, oesophageal stenosis, death from aspiration pneumonia, fracture of the cervical spine, osteomyelitis, subcutaneous emphysema, and wound infection [15-17].

Our series showed a much lower rate of complications than sometimes reported in the literature. The surgical problems and immediate postoperative complications that we encountered were rarely serious and unusual only in 2.5% of cases (*P*=0.695). The routine use of prophylactic broad-spectrum antibiotics was a regular practice, especially in potentially high-risk patients. This would include diabetic patients, those with severe chronic obstructive lung disease, malnourished individuals and immunosuppressed patients.

A retrospective multicentre study, conducted to record the complications of trachea-oesophageal voice restoration involving 95 patients, found complications that ranged from mild to severe, and included problems with predictive values obtained during insufflation, fistula retention, TEF angulation shifts, fungal colonisation of the prosthesis, valve retention problems, difficulty with digital occlusion, pressure necrosis, post radiation necrosis, dysphagia, phonatory gagging, emesis, gastric distention, pouching, stenosis, infection, hypertrophy, shunt insufficiency, persistent spasm, myotomy, inadvertent fistula closure and aspiration of the prosthesis [18].

With few exceptions [19 20], primary and secondary TEP have been shown to be equally successful in voice rehabilitation with reported success rates of 65-85% and 69-83%, respectively [5 21-23]. This range can depend on the criteria used to select candidates to TEP and on the method to assess the success of post-TEP voice. Brown et al. found that patients with TEP described a high degree of satisfaction with no difference between patients undergoing primary or secondary TEP [24].

Based on our experience, the overall success was almost the same in the two methods, but we preferred to use secondary insertion of vocal prosthesis, and mainly to test the real motivations of the patient to trachea-oesophageal

Table IV. HRS score*.

Group	HRS <11	HRS >11	HRS mean without PORT	HRS mean with PORT	HRS mean Elderly pt
Primary TEP (n)	11	32	11.8	11	11.2
Secondary TEP (n)	6	46	12.6	11.4	12
TOTAL (n)	17	78	12.2	11.2	11.6
p value	-	-	0.613	0.582	0.648

HRS = Harrison-Robillard-Schultz; TEP = Tracheo-oesophageal puncture.

**In accord with TEP Rating Scale[8].*

voice and his/her decisions toward a more acceptable vocal recovery, assessing accurately the pattern of response of the pharyngo-oesophageal segment (PE segment), predictive of a good and satisfactory voice quality.
As is known, the characteristics of the trachea-oesophageal voice production are determined by aerodynamic factors of the prosthesis, but primarily by the characteristics of the PE segment.
In terms of clinical management of the vocal valve, the time between the placement of the prosthesis and the first replacement varies between 3 and 6 months (mean 4.5 months). During the learning curve of both the patient and the medical services, visits to the hospital are more frequent; however, at present, the replacement procedure is so simple and the mean duration of the vocal prosthesis practically eliminates the burden for these patients.
The replacement of the prosthesis is not complicated, especially with improved devices for trans-tracheostomal application and retrograde method, which requires only local anaesthesia. The retrograde means with guide wire was considered uncomfortable in 80%, in our series, for the following reasons: gagging, coughing, pain and/or anticipatory anxiety. The data for the anterograde method were much more favourable.
In the majority of the patients leakage through the prosthesis was the reason for valve replacement (75%), which was mostly secondary to myco-bacterial biofilm colonisation of the prosthetic valve, despite regular cleaning of the prosthesis with the appropriate original brushes and antimitotic solution for the prevention.
In spite of how traditionally performed in the past, prosthetic management should include a process of replacement no longer performed in necessity but programmatically to reduce the risk of the onset of fistula related problems. In addition to traditional data, reported by Op de Coul et al. [6] (89 days), de Carpentier et al. [25] (137 days), and Laccourreye et al. [26] (216 days) on the median device lifetime, variables in relation to the case series and to the type of prosthesis, we report our data in relation to the prosthetic generation: 125 days for first, 140 days for second and 165 days for third generation.
Fistula related pathologies were seen in 22% of cases in our series. In agreement with some authors, we believe that gastro-oesophageal reflux and its treatment currently is a central and determining role in the onset of the two main fistula related diseases, namely leakage around the prosthesis and trachea-oesophageal granulomas, which represent the causes that may lead to potential rehabilitation failure [27-30].
Recently, Lorenz KJ et al. reported data on the correlation between severity of reflux and trachea-oesophageal fistula problems before and after anti-reflux therapy with proton pump inhibitors (PPI), performing a simple biopsy from the region of the fistula and a subsequent molecular examination [31].
In this context, a retrospective study recorded the therapeutic outcomes in patients with trachea-oesophageal granulations, unsatisfactory vocal results and frequent prosthesis replacement, within a 3-month period, due to abnormal biofilm development, using a therapeutic protocol characterised by full-dose PPI treatment given twice daily for 2 months and a maintenance-dose PPI treatment for 1 month, with the addition of alginate at the maximum dose three times daily for 3 months and correct diet indications. The introduction of a specific therapeutic protocol improved the quality of prosthesis (QoP) in 22 of the 43 patients [32].
In our series, the rate of fistula enlargement and periprosthetic leakage was 7%, comparable with what is reported in the literature, about 10% [33 34]. Some authors, however, associate this problem with a number of risk factors, including radiotherapy, malnourishment, diabetes, smoking, oesophageal stricture, hypothyroidism, VP diameter, timing of TEP placement and flap reconstruction [34]. According to other authors, the increasing use of radiotherapy as a primary treatment modality for laryngeal cancers and the subsequent challenge of salvage surgery may contribute to an increasing incidence of this problem [33 34].
In our series, these patients, after failure with aggressive anti-reflux treatment (2/7), were generally managed by downsizing the prosthesis, and/or by permanent augmentation of the party wall with a non-degradable collagen or Bioplastique® (silicone product) injected around the fistula, with long-term success in all cases.
The effect of radiotherapy on VP restoration remains controversial. Radiation therapy may cause lack of wound healing because of tissue necrosis, scar formation, and vascular impairment and may deteriorate the pliability of the pharyngo-oesophageal mucosa [36-41], but considering long-term speech success, no significant influence of postoperative radiotherapy and primary or secondary VP rehabilitation was found on speech quality; in this context, many retrospective studies have reported the absence of consequences on quality of voice or complication rates [4 5 37]. In addition, a report suggested that neck dissection in conjunction with postoperative radiotherapy does not adversely affect short-term speech success in VP rehabilitation patients [38].
In our series, no data were found to support the influence of prior radiation therapy on the rate of surgical complications, voice problems, or HRS score. Instead, we believe that voice prosthesis patients who have undergone radiotherapy may be particularly sensitive to the reflux effect without the protective and neutralising action of saliva. This phenomenon seems to play a significant role in the development of fistula pathology, in which its incidence and relapsing character can drastically reduce therapeutic control of reflux for successful voice recovery in patients.
In this context, a recent study has analysed the association of radiotherapy (PORT) with gastro-oesophageal re-

flux as a determinant of fistula-related pathology in voice prosthesis patients. The authors observed a higher rate of failure of speech rehabilitation in laryngectomy patients with gastro-oesophageal reflux: this occurred when there was a history of postoperative radiotherapy (45%) or not (17%) (P<0.05), although all patients were treated with PPIs. The results seem to confirm the importance of the association between PORT and gastro-oesophageal reflux in fistula-related problems [39].

Elving et al. reported that radiation on the primary tumour site with a dose ≥60 Gy was correlated with a limited lifetime of voice prosthesis [11]. Voice failure after prolonged speech therapy may be due either to fistula or prosthesis related complications or may be due to poor patient motivation. In our series, trachea-oesophageal voice failure was recorded in 6% of cases. In these subjects, surgical closure of the fistula was performed. The causes were essentially fistula-related pathologies with persistent leakage around the prosthesis (2%), giant trachea-oesophageal granuloma (2%) and downward fistula migration (1%). Only one patient with persistent poor vocal quality preferred prosthesis removal.

In the surgical procedure of closure there is no standard reconstructive procedure and a tailored approach is always required. It was performed by separating the trachea-oesophageal party wall, 2-layer closure of the oesophagus and 1-layer closure of the trachea with the use of a fascia graft interposition to reinforce the oesophageal and tracheal suture lines. No failure was recorded.

The overall success was 87.5%, 84% in primary TEP and 91% in secondary TEP, which appeared to be very satisfactory and similar to previously reported results, which show comparable overall success rates [36-40].

Conclusions

Tracheo-oesophageal speech using VP has revolutionised vocal rehabilitation following TL and, today, must be considered as the gold standard for voice rehabilitation in Sicily. This data have demonstrated the benefits of a focused therapeutic protocol from time of cancer diagnosis to recovery time of trachea-oesophageal voice. Retrospective analysis of 15 years of prosthetic rehabilitation in the Sicilian territory highlighted standard rehabilitation almost identical to those found in the recent literature in terms of intra-and postoperative complications, fistula-related pathologies and overall success.

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