

Original Research Article

Voice rehabilitation with phonatory prosthesis after total laryngectomy and pharyngolaryngectomy: comparison of functional outcomes between primary and secondary puncture

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ABSTRACT

Background: Tracheoesophageal puncture (TEP) with voice prosthesis (VP) placement is considered the standard for vocal rehabilitation after total laryngectomy (TL). This study aimed to compare the success rate of primary and secondary TEP and to evaluate the impact of clinical factors on functional outcome.

Methods: A retrospective medical chart review was conducted in patients who underwent TL or pharyngolaryngectomy (PLT) and TEP. Variables collected included age, gender, comorbidities, tumor location and stage, extension of surgical resection, reconstruction, neck dissection, radiation therapy, salvage surgery, device lifetime, postoperative complications and successful voice restoration.

Results: A total of 186 patients were enrolled in this study, 164 patients (88.2%) underwent primary TEP and 22 (11.8%) secondary TEP. Successful voice rehabilitation was achieved in 76.9% of patients and there was no difference between primary and secondary TEP groups (76.2% vs. 81.8%, $p=0.76$). A poorer voice restoration outcome was found in patients who underwent radiation therapy ($p=0.01$) or salvage surgery ($p=0.03$). Adjuvant radiation was the only independent prognostic factor for functional success (OR=4.7, IC 95%= 1.4-15.9, $p=0.04$). VP related complications occurred in 65.7% of patients, with higher incidence in secondary TEP group (90.9% vs. 67.7%, $p=0.03$). Overall device lifetime was similar between primary and secondary groups (9.2 vs. 8.7 months, $p=0.89$).

Conclusions: Voice rehabilitation outcome was similar with primary and secondary TEP. However, TEP related complications were more common in secondary procedures. Primary TEP allows earlier voice restoration, avoiding a second surgical intervention. Functional success rate was poorer for patients who underwent radiation therapy.

Keywords: Voice rehabilitation, Tracheoesophageal puncture, Voice prosthesis, Outcome

INTRODUCTION

Loss of natural voice is a major disable consequence of TL and PL.¹⁻³ Voice rehabilitation is commonly achieved by esophageal speech, artificial larynx and tracheoesophageal voice restoration.⁴⁻¹⁰ Tracheoesophageal speech is obtained by a one-way valved VP inserted in a surgically created TEP.^{8,11} Fistula can be performed as a primary procedure at the time of TL/PL (primary TEP) or in a late stage (secondary

TEP).^{7,12} Tracheoesophageal speech has become the method of choice for speech restoration in patients undergoing TL, providing longer phonation time, better intelligibility and fluency compared with esophageal speech or electronic larynx.^{1-3, 6-10, 12,13}

There is a wide range of reported results in literature, with successful voice restoration after TEP commonly ranging from 40 to 90%.^{2,7,9} Primary TEP achieves a success rate of 65 to 85% and secondary TEP of 69 to 83%.¹⁴ Both primary and secondary TEP are safe and

effective procedures.^{7,15,16} Primary TEP avoids a second surgery and allows earlier voice restoration.^{1,17} However, it is associated with an increased risk of stoma and surgical related complications (fistula, fluid leakage, stenosis and local infection) compared to secondary procedures, in which a better tracheostoma maturation occurs.^{1,17,18} Secondary TEP is recommended in patients who present high risk for postoperative complications such as fistula formation or wound breakdown.³ In patients undergoing salvage surgery or in patients who received radiation therapy, there is an increased risk of postoperative complications due to poor wound healing.³

Several factors may influence the outcome of TEP speech, including adjuvant therapy, extension of surgery and timing of surgery (primary vs. salvage).¹⁰ There is an ongoing controversy about the most appropriate time to perform a TEP regarding success rate and associated complications.^{7,10,17,18} This study aimed to analyze voice outcome and complications after primary and secondary TEP and to evaluate the impact of selected clinical variables on voice restoration.

METHODS

Study design

This study was designed as a retrospective medical chart review of patients who underwent TL or PL and PTE with VP insertion, between January 1998 and December 2017. All patients received a Provox voice prosthesis (Atos Medical, Malmö, Sweden). Patients with a follow-up period inferior to 6 months and those with incomplete medical records were excluded from the study.

Variables

In the present study, collected data included the following variables: patient age and gender, tumor site, staging, extension of surgery and reconstruction, radiotherapy treatments and timing of TEP (primary vs. secondary). Moreover, total number of prosthesis used, device lifetime, postoperative complications and functional speech outcome were evaluated. Patient comorbidities were assessed with the ASA-score. Patients were staged according to the 2010 American joint committee on cancer (AJCC) staging system. TEP or VP-related complications included leakage through or around the prosthesis, granulation tissue, dislodgement of the prosthesis and spontaneous closure of TEP. Surgical-related complications included a large and deep tracheostomy hole, cutaneous infection, pharyngocutaneous fistula and pharyngoesophageal stricture.⁸ Device lifetime was measured from VP insertion to date of removal.

Tracheoesophageal puncture

Before surgery patients were informed about available a laryngeal speech options and were evaluated by a multidisciplinary team which included a surgeon and a

speech therapist. Patients with poor motivation and those with a poor vital lung capacity and/or neurological comorbidities with handling problems were not considered candidates for TEP.² Timing of TEP was dependent on the extension of planned resection and/or reconstruction, radiotherapy complications and surgeon's preference.¹⁹ Prior treatment history, functional and social ability to comply with necessary rehabilitation were also considered.³ Patients were proposed to secondary TEP after insufflation test to evaluate pharyngoesophageal segment tonicity. Those with hypertonicity or spasm of pharyngoesophageal segment did not underwent secondary TEP.

Primary and secondary TEP were performed under general anesthesia according to techniques described in literature.^{13,19,20} In selected cases, cricopharyngeal myotomy was performed. Indwelling voice prostheses (Atos Medical, Sweden-Provox®, Provox Vega® and Provox 2®) were used in all patients. Voice prosthesis were immediately inserted after tracheoesophageal puncture. All patients received rehabilitation training by a speech therapist. Functional status and complications were assessed during control visits. Patients who received primary TEP were instructed to speak ten days after the procedure, whereas those who underwent secondary TEP were encouraged to speak the day after the surgical procedure.

Outcome

The main endpoint was to obtain a functional tracheoesophageal speech, which was determined by reviewing the speech therapist and surgeon's follow-up reports. Patients who use TEP as the primary source of communication, with adequate intelligibility were considered to have a successful functional outcome.³ The secondary outcome was the complication rate, either prosthesis- or surgical related.

Statistical analysis

Patients were divided in two groups according to timing of TEP: primary TEP group included patients who underwent TEP with VP insertion at the time of TL or PLT and secondary TEP group was composed by patients who underwent TEP in other surgical procedure. Chi-square test and the Fischer's exact test, with a 95% confidence interval, were used to compare categorical variables. We assessed the influence of selected factors (age, gender, comorbidities, radiation therapy, tumor location, timing of surgery) on functional outcome (successful rehabilitation), on TEP-related complications and device lifetime. Multivariate logistic regression analysis with forward stepwise likelihood ratio method was performed to obtain independent prognostic factors for functional success and to access their relative importance. Statistical analysis was performed using Statistical Package for the social sciences® (version 24.0,

SPSS®). Statistical significance was accepted at p value of <0.05.

RESULTS

Patient characteristics

A total of 186 patients were enrolled in this study, of whom 179 (96.2%) were male and 7 (3.8%) females. Median (range) age of patients at time of TEP was 62.7 (30-92) years. Study population characteristics are described on Table 1. Indications for surgery consisted of laryngeal carcinoma in 155 (83.3%) and hypopharyngeal carcinoma in 31 (16.7%) patients. Surgical procedure included TL in 141 (75.8%) and PLT in 45 (24.2%) patients with primary closure of the defect being achieved in 97.8% of the cases. All patients underwent neck dissection. Most patients had history of radiation therapy (n=146; 78.5%). Primary radiotherapy was performed in 5 (2.7%) patients, who underwent salvage surgery. Postoperative radiation was used in 141 (75.8%) patients. Of these, 68 (48.2%) underwent adjuvant RT and 73 (51.8%) chemoradiotherapy (CRT).

Tracheoesophageal puncture: primary vs. secondary groups

Among the 186 patients, 164 (88.2%) underwent primary voice restoration and 22 (11.8%) secondary TEP. Median time from surgery until secondary TEP was 1.1 years (range 0.6-11 years). The groups did not differ significantly regarding sex (p=0.194), age (p=0.241), tumor location (p=0.417), stage (p=0.262), type of surgery (p=0.864), use of radiation therapy (p=0.267) and comorbidities (p=0.237) (Table 2). Overall, successful voice rehabilitation was achieved by 76.9% of patients. Voice restoration rate was similar between primary TEP and secondary TEP (76.2% vs. 81.8%, p=0.789).

Surgical-related complications occurred in 36 patients (19.4%). Pharyngoesophageal stenosis (n=10) was the most commonly observed complication, followed by a large or deep tracheostomy hole (n=9) (Table 3).

TEP and/or VP related complications occurred in 121 (65.1%) patients and were more common after secondary TEP procedure compared to primary TEP (90.9% vs. 67.7%, p=0.025). Leakage was the most common complication (60.2%). Comparison between groups

revealed higher incidence of leakage in secondary TEP (90.9 vs. 56.1%, p=0.002). Patients who underwent previous radiation therapy before TEP had a higher incidence of leakage (83.3 vs. 57.7%, p=0.035). There were no other factors statistically associated to fluid leakage (Table 4). Trans prosthetic leakage occurred in 79 (42.5%) and periprosthetic leakage in 72 patients (38.7%). Granulation tissue appearance (6.5%) and VP extrusion (12.9%) were also observed. While incidence of trans prosthetic leakage was similar between groups (p=0.22), periprosthetic leakage was more common in secondary TEP group (63.6 vs. 35.4%, p=0.018) (Table 4).

Mean postoperative follow up time was of 40.6±33 (range 1-204) months. A total of 586 VP were used for voice restoration during the study period. The total number of prosthesis was comparable between groups (3.1 vs. 3.9, p=0.1). Overall mean device lifetime was 10.15±9.4 months (range 1-42 months), with no significant differences between primary and secondary TEP groups (9.2 vs. 10.5, respectively, p=0.134). First VP had an average lifetime of 11.6 months (1-52). Primary TEP group presented a longer first device lifetime when compared to secondary TEP group (12.4 vs. 6.7, months p=0.002).

An analysis was conducted to evaluate the influence of selected variables on device lifetime. We found no impact of extension of surgery (p=0.905), radiation therapy (p=0.885), age (p=0.254), timing of TEP (p=0.134) and comorbidities (p=0.276) as shown in the Table 5.

Assessing clinical predictors of successful voice rehabilitation

12 patients required revision surgery, which represents 9% of the study population and 26% of patients who had recurrence of nasal polyposis. The influence of prognostic factors on revision surgery after FESS are described in table 3. An analysis was performed to evaluate prognostic factors to undergo revision surgery. Revision surgery was related to asthma (p=0.01), AERD (p=0.002), Lund-Kennedy (p=0.001) and Lund-Mackay score (p=0.001). Multivariate analysis found a higher Lindholdt score (score 5-6) (OR=4.05, CI 95%: 1.91-8.01, p=0.001) as the only independent predictor of revision surgery.

Table 1: Descriptive characteristics of study population.

Characteristics	Total (n=186)
Gender N (%)	
Male	179 (96.2)
Female	7 (3.8)
Age, mean (±SD) (years)	62.7 ± 9.8 (39-86)
<60	72 (38.7)
≥60	114 (61.3)

Continued.

Characteristics	Total (n=186)
Comorbidity N (%)	
ASA ≤3	124 (66.7)
ASA >3	62 (33.3)
Tumor site, N (%)	
Larynx	155 (83.3)
Hypopharynx	31 (16.7)
Staging, N (%)	
≤III	105 (56.5)
IV	81 (43.5)
Surgical resection, N (%)	
Total laryngectomy	141 (75.8)
Pharyngolaryngectomy	45 (24.2)
Reconstruction, N (%)	
No (primary closure)	182 (97.8)
PM Flap	4 (2.2)
Salvage surgery, N (%)	
Yes	6 (3.2)
No	180 (96.8)
Neck dissection, N (%)	
Functional	154 (82.8)
Radical	32 (17.2)
Radiation therapy, N (%)	
Yes	146 (78.5)
Preoperative	5 (2.7)
Postoperative	141 (75.8)
Complementary treatment, N (%)	
No	40 (21.5)
RT	73 (39.2)
CTRT	73 (39.2)
Tracheoesophageal puncture, N (%)	
Primary	164 (88.2)
Secondary	22 (11.8)
Successful PTE	143 (76.9)

Table 2: Baseline characteristics of primary and secondary TEP groups.

Variables	Primary TEP (n=164) N (%)	Secondary TEP (n=22) N (%)	P value
Gender (male)	159 (97)	20 (90.9)	0.194
Age (≥60 years)	98 (59.8)	16 (72.7)	0.351
Comorbidity (ASA >3)	56 (34.1)	6 (27.3)	0.521
Tumor site (larynx)	138 (84.1)	17 (77.3)	0.417
Staging (IV)	74 (45.1)	7 (31.8)	0.237
Surgical resection (TL)	124 (75.6)	47 (77.3)	0.864
Salvage surgery (Yes)	5 (3)	1 (4.5)	0.535
Radiation therapy (Yes)	131 (79.9)	15 (68.2)	0.210

Table 3: Outcome analysis: primary vs. secondary groups.

Variables	Total (n=186) N (%)	Primary TEP (n=164) N (%)	Secondary TEP (n=22) N (%)	P value
Success rate	143 (76.9)	125 (76.2)	18 (81.8)	0.789
Complications				
Surgical complications	36 (19.4)	33 (20.1)	3 (13.6)	0.577
TEP/VP complications	121 (65.1)	111 (67.7)	20 (90.9)	0.025
Leakage	112 (60.2)	92 (56.1)	20 (90.9)	0.002
Transprosthetic	79 (42.5)	67 (40.9)	12 (54.5)	0.222
Periprosthetic	72 (38.7)	58 (35.4)	14 (63.6)	0.01
Granulation tissue	12 (6.5)	11 (6.7)	1 (4.5)	0.573
Extrusion	24 (12.9)	23 (14.1)	1 (4.5)	0.863

Continued.

Variables	Total (n=186)	Primary TEP (n=164)	Secondary TEP (n=22)	P value
Device lifetime				0.453
First prosthesis	11.6±7.8	12.4±7.8	6.7±5.6	0.002
Subsequent	8.5±7.4	8.2±6.9	10.7±9.5	0.134
Number of prosthesis (mean)	3.2±2.5	3.1±2.4	3.9±2.8	0.103

Abbreviations: TEP, Tracheoesophageal puncture; VP, Voice Prosthesis; Y, Years. Statistically significant parameters are highlighted on bold (p<0.05).

Table 4: Complications related to tracheoesophageal puncture and voice prosthesis.

Variables	Leakage (n=108)	P value	Periprosthetic leakage (n=72)	P value	Trans prosthetic leakage (n=72)	P value
Age (year), mean ± SD						
<60	40 (55.6)	0.302	22 (30.6)	0.07	31 (43.7)	0.89
≥60	72 (63.2)		50 (43.4)		48 (42.1)	
Surgical resection						
TL	85 (60.3)	0.973	54 (38.3)	0.838	61 (43.3)	0.732
PLT	27 (60)		18 (40)		18 (40)	
Salvage surgery						
Yes	2 (33.3)	0.218	0 (0)	0.083	2 (33.3)	0.645
No	110 (66.1)		72 (40)		77 (42.8)	
Radiation therapy						
Yes	84 (57.5)	0.779	56 (38.4)	0.850	55 (37.7)	0.587
No	24 (60.0)		16 (40)		17 (42.5)	
Preoperative RT						
Yes	16 (84.2)	0.035	11 (57.9)	0.134	9 (47.4)	0.325
No	92 (55.1)		62 (36.5)		63 (37.7)	
Postoperative RT						
Yes	86 (61.0)	0.701	56 (39.7)	0.726	60 (42.6)	0.969
No	26 (57.8)		16 (35.6)		19 (42.5)	
Timing of TEP						
Primary	20 (90.9)	0.002	58 (35.4)	0.018	12 (54.5)	0.255
Secondary	92 (56.1)		14 (63.6)		67 (40.9)	

Statistically significant parameters are highlighted on bold (p<0.05).

Table 5: Device lifetime duration analysis.

Variables	Overall	P value	First prosthesis	P value	Subsequent prosthesis	P value
Surgery						
LT	10.4±9.9	0.605	11.1±7.9	0.143	8.5±7.7	0.905
PLT	9.5±7.8		13.3±7.5		8.4±6.3	
ASA						
≤3	10.3±8.9	0.713	11.5±7.8	0.914	8.9±7.7	0.276
>3	9.8±10.4		11.7±7.9		7.6±6.9	
Salvage surgery						
Yes	9.9±9.4	0.139	11.6±7.1	0.914	8.3±7.0	0.05
No	15.7±10.4		10.1±7.8		14.7±6.1	
Radiation therapy						
Yes	9.95±9.3	0.603	12.3±7.1	0.039	8.4± 6.9	0.985
No	10.9±10.2		9.1±9.6		8.6±9.1	
TEP						
Primary	9.2±7.3	0.896	12.4±7.8	0.002	8.2±6.9	0.134
Secondary	10.5±7.7		6.7±6.5		10.7±10.5	

Statistically significant parameters are highlighted on bold (p<0.05).

Table 6: Univariate and multivariate analysis successful TEP.

Variables	Univariate analysis			Multivariate analysis		
	Successful (n=143) Counts (%)	Unsuccessful (n=53) Counts (%)	P	OR	CI (95%)	P
Age (Y), mean ± SD	63.3±9.9	60.7±8.8	0.133			
<60	52 (72.2)	20 (27.8)				
≥60	91 (79.8)	23 (20.2)	0.284			
Gender, n (%)						
Male	137 (76.5)	42 (23.5)				
Female	6 (85.7)	1 (14.3)	0.490			
Comorbidity						
ASA ≤3	92 (74.2)	32 (25.8)				
ASA >3	51 (82.3)	11 (17.7)	0.270			
Tumor site						
Larynx	122 (78.7)	33 (21.3)				
Hypopharynx	21 (67.7)	10 (32.3)	0.242			
Staging						
≤III	81 (77.1)	24 (22.9)				
IV	62 (76.5)	19 (23.5)	0.923			
Surgical resection						
Total laryngectomy	112 (79.4)	29 (20.6)				
Pharyngolaryngectomy	31 (68.9)	14 (31.1)	0.158			
Reconstruction						
No (primary closure)	141 (77.9)	40 (22.1)				
PM flap	2 (50)	2 (50)	0.222			
Salvage surgery						
Yes	2 (33.3)	4 (66.7)				
No	141 (78.3)	39 (21.7)	0.026	5.8	1.02-32.9	0.05
Neck dissection						
Functional	121 (78.6)	33 (21.4)				
Radical	22 (68.8)	10 (31.3)	0.252			
Radiation therapy						
Yes	106 (72.6)	40 (27.4)				
No	37 (92.5)	3 (7.5)	0.010	4.3	1.3-14.7	0.02
Timing of TEP						
Primary	125 (76.2)	39 (23.8)				
Secondary	18 (81.8)	4 (18.2)	0.788			

Statistically significant parameters are highlighted on bold (p<0.05)

DISCUSSION

Voice restoration following total laryngectomy influences long-term quality of life in patients without larynx.¹³ Communication is commonly achieved by esophageal speech, artificial larynx or by tracheoesophageal fistula with voice prosthesis insertion.²¹ TEP was introduced in 1980 and is considered the most effective method of a laryngeal speech rehabilitation.^{1,2,10} The advantages of prosthetic speech over other available methods include a more natural sounding voice, a longer phonatory time, superior voice quality, better intelligibility and improved success rate. In this study we compared the results of primary and secondary TEP regarding the success rate of voice restoration, voice prosthesis lifetime and complications. Moreover, we intended to assess clinical predictors to obtain successful speech rehabilitation.

Speech rehabilitation outcome

In the present study, overall voice restoration rate after TEP was 76.9%, a result in accordance with other authors who reported successful TEP speech ranging from 50 to 90%.^{2,5,8,21,22} Successful voice restoration rate was similar between primary and secondary TEP groups (76.2 vs. 81.8%, p=0.79). Most studies in literature also found no differences regarding voice outcomes between primary (65-85%) and secondary TEP procedures (69-83%).^{2,3,7,9,10,13,17,20}

Tracheoesophageal speech was first described as a secondary procedure, however it has been performed safely as a primary procedure.¹⁹ Advantages of primary TEP include the avoidance of a second surgical procedure and the earlier voice restoration which has a positive

psychological effect.^{2,9} Patient motivation is important in the acquisition and maintenance of TEP speech.¹⁴ Some studies found a tendency towards better results with primary TEP.^{3,14,16,18} The authors suggest that the earlier rehabilitation of patients with primary TEP induces a greater motivation for TEP speech.¹⁴ Better results with primary TEP can also be attributed to increased pharyngoesophageal plasticity.¹² This contrasts with secondary TEP, which may present a deficient plasticity of PES musculature, due to the absence of airway protection in a laryngeal patients.¹ Furthermore, patients without primary TEP, usually develop other a laryngeal voice, such as pharyngeal phonation, which difficult acquisition of secondary TEP speech.^{13,14}

In the present study there was a tendency towards better results in secondary TEP group. Other authors found similar results.^{2,9,23} Boscolo et al reported an overall success rate of 81.7%, with no significant differences between primary and secondary procedures 80 vs. 88.9%.² A selection bias can explain the higher success rate in secondary TEP: patients were selected based on esophageal insufflation test and motivation.² Bozec et al reported similar results, with an overall success rate for voice restoration of 82%.²³ The authors reported 81% of success for primary TEP and 88% for secondary TEP.²³

Previous studies have shown that both procedures are equally effective.¹⁸ However, in our center most patients underwent primary TEP (88.2%), which allows earlier speech rehabilitation.²³ Secondary TEP is advocated in cases of large resection of cervical esophagus and/or trachea, mainly in previous irradiated patients, due to a risk of peristomal and fistula wall necrosis.²³ Secondary TEP is preferred for patients with higher risk of wound complications, in order to allow longer time for healing before creating a tracheoesophageal fistula.⁷

Complications

Voice prosthesis replacement is one of the few limitations of TEP speech.²⁴ The most commonly described cause of device failure is fluid leakage through the prosthesis.²⁵ Recurrent replacements are uncomfortable, increasing excessive healthcare burden and decreasing patient motivation.²⁶

In the present study, the overall rate of voice prosthesis and/or tracheoesophageal complications was 65%. Our results are in agreement with previous studies, which report complication rate ranging from 15 to 72%.²⁷ Our results evidenced that secondary TEP presented higher rate of complications compared to primary TEP (90.9 vs. 67.7%, $p=0.02$). This contrasts with most of literature which report primary and secondary TEP as equally effective and safe with no differences in complication rate between groups.^{2,3,7,11,13,17,18,28} Other studies report higher complications rate in primary TEP. Gitomer et al reported a high rate of direct complications, either in primary (64.6%) and secondary (60.9%).⁸

Most common complications were fluid leakage through and around the prosthesis, development of granulation tissue and displacement of the prosthesis.⁵ Fluid leakage through the prosthesis was the most common indication for replacing VP (54.5%), in accordance to other studies.^{9, 23} Functional impairment of the speech valve is usually associated to *Candida albicans* colonization.⁵ Negative esophageal pressure during swallowing also contributes to this problem.²³ In most cases this complication was corrected by prosthesis replacement.¹ Incidence of periprosthetic leakage is reported between 7 and 70% and occurs due to progressive enlargement of the fistula and can be effectively managed by prosthesis downsizing.^{6, 23} This complication was found in 38.7% in our sample, which is in accordance with several previous studies.²⁹ Other fistula-related complications included granulation tissue and scarring, which can promote dislodgment of the VP. Hypertrophic granulation tissue occurred in 6.5% of our patients and was treated conservatively by cauterization with silver nitrate or excision.²⁹

TEP enlargement can be a serious complication that results in fluid leakage around the prosthesis and can cause aspiration pneumonia.³⁰ There is an ongoing debate about the factors associated with periprosthetic leakage. We found an increased incidence of periprosthetic leakage in secondary TEP compared to primary TEP group (63.6 vs. 35.4%, $p=0.01$). Previous studies reported comparable postoperative VP related complications between primary and secondary TEP. Lorenz et al in a review of the literature, reported higher risk in secondary TEP and the authors relate the increased risk with the healing problems induced by postoperative RT.²⁹ However, some studies did not correlate the timing of TEP with the occurrence of leakage around the prosthesis.¹⁰

The influence of RT on periprosthetic leakage presents controversial results in the literature.³⁰ RT induces fibrosis of TEP region and vascular rarefaction, which have a negative impact on healing and can cause enlargement of TEP.³⁰ Several authors found an increased risk of periprosthetic leakage in irradiated patients. Kummer et al found that previous radiation increased the risk of shunt-related complications such as leakage around the prosthesis (1.51; $p=0.046$) and widening of the shunt (2.32; $p=0.014$).³¹ Hutcheson et al reported that the higher incidence of periprosthetic leakage in patients who received RT ($p=0.039$) was not observed in those patients who received intensity modulated RT.³⁰ However other authors did not found an association between RT and periprosthetic leakage.^{28,32} Lorenz et al in a review of the literature suggested that RT alone is not associated with an increased risk of fistula enlargement, but there is a tendency towards higher risk in patients who underwent preoperative RT and higher RT dose.²⁹ Our results showed a tendency towards higher periprosthetic leakage in patients who underwent radiation therapy before TEP (57.9 vs. 36.5%, $p=0.134$).

Device lifetime

Device lifetime is a limiting factor of TEP speech restoration due to its influence on patient satisfaction and health care costs.¹¹ Primary TEP group presented a longer first prosthesis lifetime (12.4 vs. 6.7 months, $p=0.002$). This can be explained by complementary RT in most cases following surgery. RT can be a limiting factor in the postoperative period following primary TEP. Due to a higher incidence of mucositis, a deterioration on voice quality can occur.³³ No manipulation of prosthesis is advised until resolution of acute radiation reaction.

Device lifetime in our study was similar to other studies, which report a mean device lifetime between 2 and 14 months.^{5,11,21,34,35} Bozec et al reported a median device lifetime of 7.6 months (ranging from 1.2 to 39.5 months). Several factors have been proposed to justify the disparity between studies, although the majority had a device lifetime between 4 and 6 months.²⁴ Possible factors which may account for a longer device lifetime could be related to a better monitoring and prosthesis care by the patient, the speech therapist and the surgeon along the follow-up period.²⁴

We found a tendency towards lower subsequent device lifetime in primary TEP compared to secondary TEP group (8.2 vs. 10.7 months, respectively; $p=0.134$). Previous studies described similar results, with mean primary and secondary VP lifetime of 4.2 months and 9.1 months, respectively.¹³ Careful selection of patients, regular control visits and VP care have been suggested to increase lifetime of VP.³⁵ The total number of prosthesis was comparable between groups (3.1 vs. 3.9, $p=0.103$).

The influence of radiation therapy on voice prosthesis lifetime has been previously analyzed. Xerostomia induced by RT can decrease device lifetime due to a reduction in antibacterial and antifungal salivary properties.³⁴ There is a local disturbance in microflora of the pharyngoesophageal segment, due to a reduction in salivary mucin, which induces a colonization by *Candida* species.³³ In our study mean prosthesis device lifetime in patients who underwent RT was comparable to the group of patients who were not submitted to RT (8.6 vs. 8.4 months, $p=0.885$). Guttman et al found similar results, without association of VP lifetime and radiation therapy or patient age.¹³ An association between radiotherapy dose ≥ 60 Gy and a reduced device lifetime was previously identified.³³ Radiation therapy has negative effects on salivary gland tissue, with a consequent hyposalivation and altered composition of saliva.³³ This alters PES microflora increasing the susceptibility to *candida* spp. colonization.²⁶

Factors associated with a successful voice restoration with TEP

Radiotherapy is recurrently identified as a poor prognostic factor for voice restoration.¹⁸ However, the effect of radiotherapy remains controversial.⁹ Radiation

therapy has a negative impact on wound healing due to tissue necrosis, vascular impairment and scar tissue formation.⁹ In the present study, radiation therapy was a negative prognostic factor to obtain a successful voice restoration with TEP. Several studies found no significant effect of prior radiation therapy on success rate.^{2,14} Some authors reported better voice outcome in primary TEP without postoperative RT compared to patients who underwent postsurgical radiation treatment.³² Carpentier et al reported that radiotherapy decreased the rate of successful voice restoration.³⁶ RT can compromise healing process and affect the functional outcome of TEP.¹⁷ On the other hand, several studies did not find relation between radiotherapy and the success of TEP speech, suggesting that TEP after RT is a safe and effective method of voice restoration.^{2,8,10,13,14,18,28}

There is an increased number of patients undergoing salvage surgery, after organ preservation treatment.³ Salvage TL is associated with a higher risk of local complications and functional morbidities when compared to primary surgery.³ Evaluation of factors related to speech outcomes after TEP revealed that patients who underwent salvage surgery had poor voice outcome compared to primary surgery (33.3 vs. 78.3%, $p=0.03$). Although salvage surgery was not an independent predictive factor of TEP voice failure, it should be considered in the selection of TEP candidates. Some authors suggested that reduction in success rate of TEP speech is attributed to the increased number of PLT and salvage TL.³ However our results showed a similar success rate with primary and salvage treatment, in agreement with other studies.³

Patients with higher comorbidity level ($ASA \geq 3$) presented poor functional prognosis.²³ Reduced vital lung capacity, decreased motivation, chronic asthenia and dyspnea can contribute to this finding.²³ Neurological impairment, reduced motivation, recurrent disease and fistula obstruction are other factors that can be related with a failure of TEP speech rehabilitation.²³ A sufficient pulmonary reserve is important to achieve a successful TEP speech, which requires high driving pressures.³⁷

Limitations

Our study has some limitations. This is a retrospective study based on medical charts with a potential information bias. Some additional limitations include the lack of an objective measure of speech outcome and the selection bias that may have occurred in the process of choosing the candidacy for TEP and the timing to perform the procedure (primary vs. secondary). Future studies should include an objective measure of voice outcome.

CONCLUSION

Voice restoration with TEP after total laryngectomy and pharyngolaryngectomy presents a high success rate. Our results suggest that primary and secondary TEP are

equally effective and safe. However, TEP related complications were more common in secondary procedures, mainly periprosthetic leakage. Primary TEP allows earlier voice restoration, avoiding a second surgical intervention and it was the preferred timing to perform TEP. Functional success rate was poorer for patients who underwent radiation therapy. Although salvage surgery was not an independent predictive factor to obtain a functional voice, it should be considered in the selection of TEP candidates.

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