

Voice rehabilitation with voice prosthesis post-laryngectomy: IPO-LFG ENT department expertise

Original Article

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Abstract

Objectives: To determine and compare, retrospectively, the success rate of speech rehabilitation with voice prosthesis (VP) according to the age, radiotherapy (RT) status and total laryngectomy (TL) type: primary or salvage.

Study design: By reviewing post-laryngectomy patients with voice prosthesis insertion between 2016-2022. Surgical and prosthesis complications, first prosthesis replacement and number of replacements per year were analysed.

Material and Methods: Statistical analysis used t-student when there was normal distribution and Mann-Whitney when the group didn't show normal distribution. P values <0.05 were considered statistically significant.

Results: In the groups age and type of TL, there was an absence of statistically significant difference in every variable. The post-RT group had, paradoxically, less prosthesis complications (p=0,036).

Conclusion: Data had demonstrated that the benefits of a voice prosthesis protocol should not have age, salvage surgery and RT as restrictive factors.

Keywords: speech rehabilitation; voice prosthesis; total laryngectomy

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Introduction

In 2020, a total of 529 new cases of malignant laryngeal tumors and 412 of hypopharyngeal tumors were reported in Portugal¹. Despite the development of organ-sparing therapeutic modalities, total laryngectomy (TL) is still the therapy of choice for both primary and salvage treatment of advanced tumors of the larynx and hypopharynx. Moreover, TL restores both speech and swallowing in disease-free patients with a non-functioning larynx. With the continued use of TL for

the treatment of tumors of the larynx and hypopharynx, it is essential to optimize post-laryngectomy function. Although the perioperative results have improved substantially since the first laryngectomy was performed in 1873, attributable in part to the advances in antibiotic therapy and asepsis, the ablative aspects of the procedure have barely changed². TL not only results in loss of vocal function, but also loss of nasal function, ineffective coughing, difficulty in swallowing, changes in lung function, complications of tracheostomy, as well as inherent functional and psychological complications³. Of all the losses associated with the procedure, vocal rehabilitation has shown the greatest progress in recent decades, considerably improving the quality of life of the rehabilitated patients³.

With the introduction of the tracheoesophageal puncture (TEP) technique and insertion of a voice prosthesis (VP) by Singer and Blom in 1979, a third alternative for vocal rehabilitation was established, after the esophageal voice and artificial larynx (electrolarynx). The advantages of the tracheoesophageal voice are immediate phonation, simple training, longer phonation time, higher volume, and better intelligibility⁴. This method of vocal rehabilitation quickly became accepted and implemented globally and is the gold standard nowadays.

The objectives of this study were to report the recent experience of the Otorhinolaryngology Service of the IPO-LFG in vocal rehabilitation with VP and to retrospectively analyze the variables that influence the success or failure of this type of rehabilitation.

Materials and Methods

The clinical records of patients who underwent TL for a malignant laryngeal tumor with the insertion of a VP at the IPO-LFG during the 5 years between 2016 and 2020 were analyzed. Cases with primary hypopharyngeal tumors who underwent combined pharyngectomy were excluded. TEP with VP insertion were performed primarily in the same operative time as TL, under appropriate local oncological conditions

and physical comorbidities. In order to prevent hypertonicity of the pharyngoesophageal segment, a cricopharyngeal myotomy was performed prior to the insertion. Patients' demographic and clinical data, as well as disease-specific data were collected, including sex, age, primary tumor location, histological type, and clinical tumor staging (using the TNM system of the 8th edition of the AJCC). Patients were divided into groups according to the main variables analyzed in this study. For the age variable, they were divided into <70 and ≥70 years age-groups at the time of surgery. For the surgical indication, they were divided into primary and salvage TL groups. For the radiotherapy status (RT), patients were grouped into with and without adjuvant RT. The main outcomes evaluated were surgical complications, prosthesis-related complications, time (months) until the first replacement, and number of prostheses used per year. Statistical analysis was performed using the Student's t-test when the data had a normal distribution and the Mann-Whitney test when the data did not have a normal distribution. Statistical significance was set at $p < 0.05$. The analysis was based on a review of the relevant literature.

Results

Between January 2016 and December 2022, 108 patients underwent TP with TEP for a laryngeal tumor, of which 98 were men and 10 women. The mean age was 64.6 ± 9.1 years, and 66.7% patients were younger than 70 years. The histological diagnosis was squamous cell carcinoma in 95.4% of the patients. A total of 93 patients underwent TL as primary treatment, while 15 underwent salvage TL. Fourteen patients had no prior adjuvant RT, while 80 patients underwent adjuvant RT. The summary of the demographic and clinical characteristics of the patients is displayed in Tables 1 and 2. The rate of complications after laryngectomy was 15.2%, with pharyngocutaneous fistula being the most common, in 11.5% of the patients (75% of all complications). The mean time until the first VP replacement was

13±10.1 months and the mean number of VP per year was 1.9±1.2. The first prosthesis, the one placed intraoperatively, had a longer duration, while the replacement prostheses

were more frequently changed, mostly due to incontinence. The rate of VP-related complications was 32.3%, with granuloma being the most frequent, in five patients, which led to closure of TEP in 19.2% patients. Of the total 108 patients included in the study, only 105 had data on the presence (or not) of surgical complications; data on possible VP-related complications were obtained for only 99 patients. A summary of the surgical complications, characterization of prosthesis replacement, and prosthesis-related complications that led to the failure of vocal rehabilitation are shown in Tables 3, 4, and 5, respectively. With regard to the comparison between age-groups (<70 and ≥70 years), there were no significant differences in surgical complications (p=1.000), prosthesis-related complications (p=0.366), first prosthesis replacement (p=0.366), or number of prostheses per year (p=0.199) between the two

Table 1
Demographic characteristics of the patients

Characteristic	n	%
Sex		
Male	98	90,7
Female	10	9,3
Age (years)		
Minimum	46	88
Maximum	64,6	(9,1)
Age group		
< 70 anos	72	66,7
≥ 70 anos	36	33,3

Table 2
Clinical characteristics of the patients

Characteristic	n	%
Type of tumor		
SCC	103	95,4
Other	5	4,6
Primary treatment		
TL	17	15,7
TL + RT	55	50,9
TL + CRT	21	19,4
Treatment of recurrence		
TL	4	3,7
CRT	6	5,6
Partial laryngectomy	5	4,6
Laryngectomy		
TL	28	25,9
TL + RT	58	53,7
TL + CRT	22	20,4
Radiotherapy		
Without prior or adjuvant RT	14	13,0
Adjuvant RT	80	74,1
Prior RT	12	11,1
Prior and adjuvant RT	2	1,9

Table 3
Surgical complications

Surgical complications n=105	n	%
No complications	89	84,8
Pharyngocutaneous fistula	12	11,5
Tracheostoma stenosis	1	1,0
Tracheostoma fistula	1	1,0
Spondylodiscitis	1	1,0
Lymphatic fistula	1	1,0

Table 4
Characterization of prosthesis replacement

Characteristic	n	%
First replacement (months)		
Minimum-maximum	1	59
Mean (Standard deviation)	13,0	10,1
Mean prostheses per year		
Minimum-maximum	0,25	5,30
Mean (Standard deviation)	1,9	1,2

Table 5
Complications leading to failure of voice rehabilitation

Complications related to the prostheses n= 99	n	%
No complications	67	67,7
Complications without closure	13	13,1
Complications leading to TEP closure	19	19,2
Closure		
Granuloma	5	
Mobilization	1	
TEP in lung	2	
Wide TE fistula	7	
Esophageal stenosis	3	
Wide Tracheostoma	2	

Abbreviations: TEP, tracheoesophageal puncture; TE, tracheoesophageal

groups. The characteristics according to the age-group are summarized in Tables 6, 7, and 8. For the variable of therapeutic indication, no significant differences were observed in the number of surgical complications ($p=0.492$), mean time to the first prosthesis replacement ($p=0.934$), number of prostheses per year ($p=0.275$), or complications related to the prostheses ($p=1.000$) between the primary and salvage TL groups. The characteristics according to the therapeutic indication are summarized in Tables 9, 10, and 11.

For the variable RT, three groups were compared according to the RT status: no previous or adjuvant RRT ($n=14$), adjuvant RT ($n=80$), and previous RT ($n=12$). The fourth group that underwent previous and adjuvant RT ($n=2$) was excluded from the comparison.

Table 6
Surgical complications according to age

Age	n	Without complications		Pharyngocutaneous fistula		Tracheostoma stenosis		Tracheostoma fistula		Spondylodiscitis		Lymphatic fistula		$\chi^2_{(6)}$	p-value
		n	%	n	%	n	%	n	%	n	%	n	%		
<70 years	71	59	83,1	8	11,2	1	1,4	1	1,4	1	1,4	1	1,4	2,166	1,000
≥ 70 years	34	30	88,2	4	11,8	0	0,0	0	0,0	0	0,0	0	0,0		
Total	105	89	84,8	12	11,5	1	1,0	1	1,0	1	1,0	1	1,0		

Table 7
First replacement of prosthesis and number of prostheses per year

Prosthesis	Age	N	Mean	SD	t	p-value
First replacement (months)	<70 years	60	13,43	11,71	0,703	0,484
	≥ 70 years	27	12,15	5,33		
Prostheses per year	<70 years	58	1,76	1,18	-1,291a	0,199
	≥ 70 years	22	2,13	1,31		

Table 8
Complications related to prostheses according to age

Age	n	Prosthesis complications				$\chi^2_{(1)}$	p-value
		Without		With			
		n	%	n	%		
<70 years	66	46	69,7	20	30,3	0,818	0,366
≥ 70 years	33	20	60,6	13	39,4		
Total	99	66	66,7	33	33,3		

Table 9
Therapeutic indication-related surgical complications

Treatment	n	Without complications		Pharyngocutaneous fistula		Tracheostoma stenosis		Tracheostoma fistula		Spondylodiscitis		Lymphatic fistula		X ² (6)	p-value
		n	%	n	%	n	%	n	%	n	%	n	%		
Primary	91	77	84,6	11	12,1	1	1,1	0	0,0	1	1,1	1	1,1	7,738	0,492
Recurrence	14	12	85,7	1	7,1	0	0,0	1	7,1	0	0,0	0	0,0		
Total	105	89	84,8	12	11,5	1	1,0	1	1,0	1	1,0	1	1,0		

Table 10
Replacement of first prosthesis and number of prostheses per year according to the therapeutic indication

Prosthesis	Treatment	N	Mean	SD	t	p-value
First replacement (months)	Primary	75	13,11	10,34	-0,086 ^a	0,934
	Recurrence	12	12,58	9,24		
Prostheses per year	Primary	69	1,78	1,15	-1,144	0,275
	Recurrence	11	2,35	1,58		

aZ statistic and non-parametric Mann-Whitney p-value.
Abbreviation: SD, standard deviation.

Table 11
Complications of prostheses related to the therapeutic indication

Treatment	n	Prosthesis complications				X ² (1)	p-value
		Without		With			
		n	%	n	%		
Primary	85	57	67,1	28	32,9	0,042	1,000
Recurrence	14	9	64,3	5	37,5		
Total	99	66	66,7	33	33,3		

Table 12
Surgical complications according to the radiotherapy status

RT Group	n	Surgical complications				X ² (2)	p-value
		No		Yes			
		n	%	n	%		
Without RT	14	11	78,6	3	21,4	0,692	0,738
Adjuvant RT	78	66	84,6	12	15,4		
Prior RT	11	9	81,8	2	18,2		
Total	103	86	83,5	17	16,5		

There were no differences in the rate of surgical complications (p=0.738), time to first prosthesis replacement (p=0.267), or number of prostheses per year (p=0.119) among the three groups. Regarding prosthesis-

related complications, the results revealed a statistically significant association between the type of RT and presence of prosthesis-related complications (p=0.036), and cases without RT were more likely to develop future

Table 13
Replacement of first prosthesis and number of prostheses per year according to the radiotherapy status

Prosthesis	RT Group	N	Mean	SD	F	p-value
Replacement time of first prosthesis	Without RT	14	9,36	5,15	2,638 ¹	0,267
	Adjuvant RT	64	13,88	10,80		
	Prior RT	8	13,38	11,39		
Prostheses per year	Without RT	10	2,20	1,16	2,187	0,119
	Adjuvant RT	62	1,73	1,14		
	Prior RT	7	2,64	1,82		

¹ Kruskal-Wallis statistic and non-parametric p-value.
Abbreviations: RT, radiotherapy; SD, standard deviation.

Table 14
Future prostheses-related complications according to the radiotherapy status

RT Group	n	Future complications				X ² (2)	p-value	Adjusted residuals
		No		Yes				
	n	n	%	n	%			
Without RT	13	5	38,5	8	61,5¹	6,499	0,036	⁽¹⁾ 2,3 - Without RT *Yes
Adjuvant RT	74	54	73,0²	20	27,0			⁽²⁾ 2,4 - Adjuvant RT *No
Prior RT	11	6	54,5	5	45,5			
Total	98	65	66,3	33	33,7			

prosthesis-related complications (AdjRes =2.3) than those who underwent RT. In addition, cases that underwent adjuvant RT tended more frequently to have no prosthesis-related complications (AdjRes=2.4), compared to those who underwent previous RT or no RT. The characteristics according to the RT status are summarized in Tables 12, 13, and 14.

Discussion

This study presents an overview of patients who underwent TL with insertion of VP due to a malignant tumor of the larynx or hypopharynx in a Portuguese cancer center. The most prevalent surgical complication in all comparative groups was the pharyngocutaneous fistula, which considerably increased the morbidity, length of hospital stay, delayed the start of adjuvant RT, and predisposed to lesions of large cervical vessels and substantial discomfort. The incidence of pharyngocutaneous fistula observed in this study is concurrent with

that in the literature, which reportedly varies between 3 and 65%. Its main prognostic factor is the advanced stage of the tumour⁵.

With regard to primary (at the same surgical time as laryngectomy) or secondary placement (at a different surgical time as the laryngectomy), primary insertion is the protocol at our cancer center because of the following advantages: there is an immediate restoration of vocal function (which is an important psychological gain) and the success rate is similar to that of secondary placement according to previous studies^{6,7}. Consequently, the number of secondary prostheses was only four out of 108 in the present study, and this variable was not compared. Regarding the clinical follow-up and rehabilitation of patients, the frequency of hospital visits tends to increase, with the variation in the characteristics of the pharyngo-esophageal segment being the main determinant factor, which in turn is influenced by the patient's weight variations. The variations in the

conformation of this segment invariably cause the prosthesis to become incontinent, leading to prosthesis replacement by the attending physician. For the variable age, patients over 70 years of age did not demonstrate significant differences in the analyzed outcomes in the present study, which is in agreement with the findings in the literature⁸. On comparing patients according to the surgical indication, no significant differences were found between patients with primary and salvage TL for any of the analyzed outcomes.

The effect of RT on vocal rehabilitation with VP remains controversial. RT may cause a delay in the healing of the surgical wound and, consequently, healing of the TEP due to tissue necrosis, scar formation, and vascular damage that may cause deterioration of the mucosa of the pharyngoesophageal segment⁹. In the present study, there were no significant differences in the rate of surgical complications, time until the first replacement, and number of prostheses per year. However, paradoxically, the group without RT showed a lower rate of complications related to the prosthesis and, therefore, greater success in vocal rehabilitation. According to the literature¹⁰ and results of the present study, RT at doses higher than 60 Gy may damage both the mucosal segment and, specifically, the prosthetic silicone material. Other factors may explain this paradoxical result, including the increasingly reported influence of the gastro-esophageal reflux¹¹. According to a previous study, patients undergoing adjuvant RT become particularly sensitive to the direct effect of the gastro-esophageal reflux, and therefore tended to get treatment earlier¹¹. The authors observed a higher failure rate in patients with gastro-esophageal reflux, regardless of the RT status.

The success of vocal rehabilitation can be compromised by numerous surgical and prosthesis-related factors, as well as by the patient's poor motivation. For the same reason, if the patient does not use the tracheoesophageal voice, it is an indication for closure of the puncture. The success rate

in the present case series was 76.9%. The limitations of this study are its retrospective design, lack of variables for analysis, and lack of measurement of voice quality among the patients studied.

Conclusion

During the treatment of malignant tumors of the larynx, in addition to considering the oncological outcome, the patient's quality of life, namely social integration and communication should also be considered. The restoration of voice is currently the main goal of rehabilitation after TL. The tracheoesophageal voice through a VP has revolutionized vocal rehabilitation since its inception. This study demonstrates the experience of an oncology center and how a therapeutic protocol can benefit and maximize the success rate of vocal rehabilitation. The results demonstrate that advanced age, salvage surgery, and adjuvant RT should not be restrictive factors for this type of rehabilitation.

Conflicts of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

Data Confidentiality

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

Protection of humans and animals

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

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Availability of scientific data

There are no datasets available, publicly related to this work.

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