



USAGE AND LONG-TERM COMPLICATIONS OF VOICE PROSTHESIS IN PATIENTS WITH TOTAL LARYNGECTOMY – OUR APPROACH TO PERIPROSTHETIC LEAKAGE

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Summary

Aim: To determine success in use of voice prosthesis, prosthesis lifetime and long-term complications after total laryngectomy with primary tracheoesophageal puncture and to describe our approach to periprosthetic leakage.

Introduction: Voice restoration after total laryngectomy is usually performed by placing a silicone voice prosthesis in an artificially formed tracheoesophageal fistula.

Methods: We performed a retrospective study on 187 laryngectomies with primary tracheoesophageal puncture in the 15-year period, treated in our hospital.

Results: In the group of patients with more than 1 year follow up, 87.8% of patients had successful voice restoration. Average prosthesis lifetime was 8 months. Long-term complications developed in 17.5% of patients. Periprosthetic leakage was the most common. We were able to successfully resolve long-term complications in 19/24 patients and they continued to use their vocal prostheses.

Conclusion: The primary placement of the voice prosthesis is successful and safe way to restore a voice after a total laryngectomy. Complications are commonly treatable in an outpatient clinic or with minor surgery.

KEYWORDS: *total laryngectomy, voice prosthesis, periprosthetic leakage*

INTRODUCTION

Primary prosthetic voice restoration at the time of surgery is the standard of care in patients treated with total laryngectomy for advanced laryngeal or hypopharyngeal cancer(1). Traheoesophageal puncture (TEP) can be performed at initial surgery (primary TEP) or after initial surgery (secondary TEP). Primary TEP is considered a safe and efficient approach for voice rehabilitation(2,3). According to some authors secondary

TEP should be preferred when there is a higher risk of pharyngocutaneous fistula(4,5).

Although TEP with voice prosthesis placement has improved voice rehabilitation, the procedure may be associated with complications both at the time of placement and later(6). The incidence of complications is higher for patients who required salvage total laryngectomy after chemoradiotherapy or radiotherapy than in patients initially treated surgically(7).

There are several types of prostheses available worldwide. Two types are the most widely used, and both of them are used in Croatia as well: Provox prosthesis – I, II and the VEGA (Atos Medical, Hörby, Sweden) and the Blom-Singer prosthesis (Inhealth Technologies, Carpinteria,

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CA, USA). Successful voice restoration is achieved in 75-85% of patients(8,9). Different prostheses comparisons did not identify a best prosthesis, but patients have personal preferences(10).

Voice prosthesis is a one way valve, preventing entrance of fluids from esophagus to trachea, and allowing airflow from trachea to esophagus. One of the major drawbacks of voice prostheses is limited device lifetime. Expected prosthesis lifetime is 3 to 9 months. Due to the deterioration of the silicone material by biofilm formation, prostheses either leak or increase airflow resistance(11). Valve failure can interfere with respiration, swallowing and speech. Internal prosthetic leakage may result in aspiration pneumonia and dehydration, and repeated valve replacement may lead to either tracheoesophageal fistula stenosis or insufficiency(12). Prevention and control of biofilm formation are crucial for the lifespan of the prosthesis(13).

The other frequent problem in patients with voice prosthesis is periprosthetic leakage. It develops in up to 30% of patients(14-16). Depending on the severity of fistula enlargement, treatment ranges from conservative approaches to invasive procedures(14-16).

PATIENTS AND METHODS

This is a retrospective study that included patients surgically treated from 2005 to 2019 at University Hospital for Tumors. Data was collected from our database. All patients who received total laryngectomy with primary TEP for advanced laryngeal or hypopharyngeal cancer were included. Patients lost from follow-up within first year after surgery were excluded.

The demographic data, use of voice prosthesis, prosthesis lifetime and long-term complications were collected and analyzed.

This is a single institution experience. During 15 year-period 10 ENT surgeons were educated to perform TEP, replace prosthesis and take care of complications. In cases of major periprosthetic leakage at least two trained ENT surgeons are involved in selection of appropriate treatment.

Prosthesis was routinely replaced when leakage through the prosthesis or acquired inability to speak were found.

Periprosthetic leakage was classified as minor or major. Leakage was considered *minor* in

cases when it was resolved in one outpatient visit. Leakage was considered *major* and a long-term complication when it could not be resolved in one outpatient visit.

Minor periprosthetic leakage is assessed and appropriate procedure performed:

- a) inappropriate prosthesis size - replacing prosthesis with appropriate size prosthesis (usually downsizing)
- b) minor fistula widening - replacing prosthesis with custom prosthesis (large esophageal or tracheal flange, or both)
- c) minor granulation tissue – excision of granulation tissue and replacing prosthesis with appropriate size prosthesis (usually downsizing)

Supportive measure is oral protein pump inhibitor therapy during 1-2 weeks.

In cases of major periprosthetic leakage, conservative approach is implemented first:

- 1) prosthesis removal and nasogastric tube placement
- 2) in cases of excessive granulation tissue – cutting off or silver nitrate cautery
- 3) daily monitoring of fistula size – when adequate diameter reduction is observed - placing appropriate size prosthesis or custom prosthesis

In cases of unsuccessful conservative treatment:

- a) persistent granulation - CO₂ laser ablation and placing appropriate size prosthesis
- b) fistula widening -multiple layers suture of tracheoesophageal fistula
- c) fistula closure - secondary TEP

Major periprosthetic leakage is treated during short hospital stay. CO₂ laser ablation and secondary TEP are performed under short intravenous anesthesia. Multiple layers suture of tracheoesophageal fistula can be done in short intravenous anesthesia or local anesthesia. Supportive measures include parenteral protein pump inhibitor therapy during hospital stay and sometimes antibiotic therapy. Protein pump inhibitor therapy is continued orally for 1-2 months.

We used descriptive statistical methods.

RESULTS

In the 15-year period a total number of 187 laryngectomies with primary TEP were performed. The results are presented in Table 1.

Table 1.

Data summary.

			TOTAL
FOLLOW UP	>12 months	<12 months	187
	156 (83.4%)	31 (16.6%)	
VOICE RESTORATION	SUCCESSFUL	UNSUCCESSFUL	156
	137 (87.8%)	19 (12.2%)	
LONG-TERM COMPLICATIONS	WITHOUT	WITH	137
	113 (82.5%)	24 (17.5%)	

Table 2.

Causes and treatment of major periprosthetic leakage. All patients were initially treated conservatively, and surgical treatment was done only if conservative treatment was not successful.

CAUSE OF PERIPROSTHETIC LEAKAGE	CONSERVATIVE TREATMENT			SURGICAL TREATMENT		
	NUMBER OF PATIENTS		RATE OF SUCCESS	NUMBER OF PATIENTS		RATE OF SUCCESS
GRANULATIONS	11	EXCISION + PROSTHESIS REMOVAL AND NG TUBE	6/11	5	CO2 LASER	4/5
WIDE FISTULA	6	PROSTHESIS REMOVAL AND NG TUBE	3/6	3	MULTIPLE LAYERS SUTURE +/- SECONDARY TEP	2/3
MISSING PROSTHESIS	4	PATENT FISTULA - PROSTHESIS PLACEMENT	2/4	2	CLOSED FISTULA - SECONDARY TEP	2/2
TOTAL	21		11/21	10		8/10

During the first year 31 (16.6%) patients were lost from follow-up.

In the group of 156 (83.4%) patients average follow up was 55 (12-174) months. The mean age was 62.2 (42-84) years. There were 138 (88.5%) male and 18 (11.5%) female patients.

In this group of patients 137 (87.8%) were successful in using the prostheses, and 19 (12.2%) never achieved voice restoration. In the group of patients who never achieved voice restoration all patients were males.

Further analysis was performed in the group of 137 patients who were successfully using voice prostheses. During the study period 1192 prostheses (in total) were replaced according to indications described. The average prosthesis lifetime was 8 months.

In 113 (82.5%) patients the use of voice prosthesis went without any complications. Long-term complications were observed in 24 (17.5%) patients.

Periprosthetic leakage developed in 21 patients (Table 2). According to clinical records excessive granulation tissue around the prosthesis was described in 13 patients, a wide fistula in 4 patients and 4 patients came after noticing a missing prosthesis. All patients were initially treated conservatively. CO₂ laser ablation was performed in 5 patients. Minor surgery (multiple layers suture of tracheoesophageal fistula) was performed in 3 patients. Secondary TEP was performed in 3 patients. Two (2/21) patients from this group stopped using the prosthesis.

Two patients developed a second primary tumor and after a second surgery (1 and 6 years after the first surgery) stopped using the prosthesis.

One patient developed fibrosis of the tracheoesophageal fistula and stopped using the prosthesis after 9 years.

Overall, we were able to successfully resolve long-term complications in 19 (19/24) patients and they continued to use their vocal prostheses.

DISCUSSION

Voice rehabilitation after total laryngectomy is achieved by primary TEP and voice prosthesis placement in majority of cases.

Demographic data in our study show that majority of patients are males between 60 and 70 years of age what is similar to series described in literature(14-16).

According to the literature successful voice restoration is achieved in 75-95% of patients(8, 9,15). In our series it was almost 88%.

Prosthesis lifetime was 8 months which is near to the upper limit of expected prosthesis lifetime - 3 to 9 months(15).

Periprosthetic leakage is clinically recognized as a significant complication of tracheoesophageal voice restoration, however there is no consensus regarding the frequency of its occurrence, risk factors or management(14). It is considered as a long-term complication with mean time to fistula enlargement estimated between 20 and 40 months(14).

Periprosthetic leakage develops in up to 30% of patients(14-16). We have found long-term complications in 17.5% of patients, and majority (21/24) was periprosthetic leakage.

Periprosthetic leakage can be clinically presented in several ways. In our study patients were presented with excessive granulation tissue formation around prosthesis or with widening of the fistula or they were complaining of missing the prosthesis. In the latter group fistula can be patent or not. Based on clinicians finding the individual treatment is selected. A variety in presentation implies that single approach is not successful for all patients. At the moment, there is no sufficient data to determine an evidence-based algorithmic model of management(14).

Conservative treatments applied include: adjusting prosthesis length, removing granulation tissue, use of customized prosthesis with a large esophageal and/or tracheal flange and removal of the prosthesis with placement of a nasogastric tube. In patients without prosthesis and with patent fistula, placement of prosthesis can be done in outpatient setting.

Periprosthetic leakage may occur as the result of improper length of the prosthesis in the absence of TEP enlargement(14). Op de Coul et al. reported 57% success rate of prosthesis downsiz-

ing(17). Several authors reported 80-100% success rates of customized prostheses(16). Removal of the prosthesis with placement of a nasogastric tube is widely accepted approach. Reduction of the fistula diameter is expected after 7 to 14 days. Reported success of this approach is about 50%, and it can lead to a complete closure of the fistula(16). Other methods described are tissue augmentation, botulinum toxin injections, anti-reflux medications and proton pump inhibitors(16,18).

In a small proportion of patients revision surgery is indicated. Indications include several unsuccessful attempts to resolve the problem or very wide fistula at follow-up visit. In our series minor revision surgery included removing granulation tissue with CO₂ laser, multiple layers suture of tracheoesophageal fistula or secondary TEP.

The literature shows that cautery silver nitrate, electrocautery and CO₂ LASER are used to treat granulation tissue around the prosthesis(19). Multiple layers suture is technique described in small series with success rates of 50-70%(16). Following the closure of a tracheoesophageal fistula, a secondary TEP can be performed and a new voice prosthesis can be inserted after 3–4 months. Other described techniques include purse-string suture, interposition of local or distant flap(16).

In our series we were able to successfully resolve long-term complications in 19/24 patients and they continued to use their vocal prostheses. The majority of patients with periprosthetic leakage can be managed with minimally or moderately invasive procedures.

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Sažetak

UPOTREBA I ODGOĐENE KOMPLIKACIJE NAKON UGRADNJE GOVORNE PROTEZE
KOD LARINGEKTOMIRANIH BOLESNIKA - NAŠ PRISTUP RJEŠAVANJU CURENJA UZ PROTEZU

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Cilj rada je analizirati uspješnost korištenja govornih proteza, životni vijek proteza kao i odgođene komplikacije kod primarne ugradnje govorne proteze nakon totalne laringektomije kao i opisati naš pristup rješavanju curenja uz protezu.

Uvod: Govorna rehabilitacija nakon totalne laringektomije se najčešće postiže ugradnjom silikonske govorne proteze u umjetno formiranu treheoezofagealnu fistulu.

Metode: retrospektivno smo analizirali 187 bolesnika koji su u 15-godišnjem periodu liječeni u našoj bolnici te kod kojih je učinjena primarna ugradnja govorne proteze nakon totalne laringektomije.

Rezultati: U grupi bolesnika koji su postoperativno praćeni više od godine dana, 87,7% je zadovoljavajuće govorno rehabilitirano. Prosječno trajanje govorne proteze je bilo 8 mjeseci. Odgođene komplikacije je razvilo 17,5% bolesnika. Najčešća komplikacija je bila curenje uz govornu protezu. Uspješno smo riješili odgođene komplikacije kod 19 od 24 bolesnika koji su se nakon toga nastavili služiti govornom protezom.

Zaključak: Primarna ugradnja govorne proteze je uspješan i siguran način postizanja govorne rehabilitacije nakon totalne laringektomije. Komplikacije nakon postupka je najčešće moguće riješiti već prilikom ambulantnog pregleda ili manjim kirurškim zahvatima.

KLJUČNE RIJEČI: *totalna laringektomija, govorna proteza, curenje uz govornu protezu*