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ORIGINAL ARTICLE

Postlaryngectomy vocal rehabilitation in Albania

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Summary

Purpose: *To assess short and midterm results with consistent use of indwelling voice prostheses (Provox 1 and Provox 2 valves) for vocal rehabilitation after total laryngectomy.*

Methods: *From May 2008 to June 2010 106 patients (104 men, 2 women, median age 62.32 years) with total laryngectomy underwent vocal prosthesis insertion and replacement procedures as needed. Patients were prosthesized primarily or secondarily and follow-up was performed monthly.*

Results: *Median patient-device follow-up was 279 days (range 184-995). Leakage through the prosthesis, mainly caused by Candida deposits on the valve, was the most common cause of failure of the Provox valves.*

Conclusion: *Compared to other European countries, like the Netherlands (100 days) and France (150 days) Albania has the longest device half life. This relatively long prosthesis' lifetime in our country is perhaps related with the use of spicy food (a common custom in our country), and the use of antifungal and antiacid agents.*

Key words: laryngeal cancer, provox prosthesis, total laryngectomy, voice device

Introduction

The concept of a simply created tracheo-oesophageal fistula by puncture of the back wall of the upper trachea into the upper oesophagus was a landmark in surgical voice rehabilitation and goes back to 1927 where there are reports of a patient who had deliberately punctured the back wall of the trachea by passing a heated ice pick through the tracheostoma. The first tracheo-oesophageal prosthesis was a silicone oesophagus with a "duck bill" valve sitting in the upper oesophagus. Voice was obtained by diverting the air through this from the upper trachea following occlusion of the tracheostoma by the patient, again setting up vibrations in the pharyngo-esophageal segment. Later developments included the use of indwelling devices which are put in usually at the time of laryngectomy or in a smaller number of patients as a secondary procedure, the earliest of which was the Groningen valve and more recently the Provox.

Total laryngectomy is a surgical intervention that mutilates the patient physically and socially, by depriving him from a very important physiological function, speech. Unfortunately, in Albania, up to May 2008 there was no strategy for vocal rehabilitation after total laryngectomy. This often led patients refusing surgical intervention and sometimes choosing having treatment abroad, which ended up in much higher treatment costs. In totally laryngectomized patients psychological disorders are noted which in some cases lead to suicide. A very small number of patients was able to acquire esophageal speech. In May 2008, Albania was the second country in the Balkans, after Greece, to apply the technique of indwelling voice prosthesis through tracheoesophageal puncture. The commonly used device in Albania is indwelling, low resistance Provox voice prosthesis.

Unfortunately in Albania there is a lack of speech therapy specialists, so the rehabilitation process is performed by the surgeon. On the contrary, there are excellent rehabilitation results in all patients, each one of them starting talking within 3 minutes after removing the nasogastric tube [1]. These results of almost immediate total speech rehabilitation surprised all our surgical team, including patients with poor intelligibilities, taking into consideration that patients had undergone only 4-5 minutes of training [1,2].

In our hospital, in secondary insertion of a voice

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device, although no myotomy of cricopharyngeus muscles was performed during total laryngectomy, voice rehabilitation was achieved in all patients.

Approximately all (96.2%) of our patients reported fair to good intelligibility both in face-to-face conversations and in speaking on the phone. The only maintenance required from the patient is the daily brush-cleaning of the device. The indwelling voice prosthesis is not a permanent implant, but requires periodic replacement (after 1 year on average).

The most frequent indication for replacement of any voice device is incompetence of the valve, mainly because of *Candida* overgrowth, causing leakage of fluids through the prosthesis [3]. The replacement method for the original Provox voice prosthesis consists in the anterograde, directly through the tracheostoma, insertion of a special applicator that places the prosthesis in the tracheoesophageal fistula. This is achieved through the Provox tool set, which consists of the inserter and a loading tube with 5 different shaft lengths. This procedure is performed under local anesthesia.

Methods

From May 2008 through December 2010 106 patients (104 males, 2 females; median age 62.3 years, range 44-76) underwent vocal rehabilitation with the indwelling voice device Provox 2 (ATOS Medical AB, Horby, Sweden). Primary and secondary prostheses were 86 and 10, respectively. Patients underwent prosthesis during total laryngectomy, or at a secondary time (months after the intervention). Both procedures were realized under total anesthesia. Patients were trained to use the indwelling voice prosthesis starting immediately after removing the nasogastric tube. Minimum follow-up was 7 months after the insertion. All patients underwent preoperative or postoperative locoregional radiotherapy and all were treated with anti-candida (Nystatin orally) and anti-reflux (Nexium orally) medications to prevent *Candida* overgrowth.

After discharge from hospital, patients were checked up every 3 months and extra check up visits were performed at the patients' request or health conditions.

The periodical check up visit included inspection of stomal condition, effects of radiotherapy, device' technical condition, speech quality and patient satisfaction.

Patient satisfaction with the device was measured through a special questionnaire filled in the waiting room; this questionnaire included questions about speech quality in general, effortless speech, phone communication, social communication, social life in general, and time spent to take care about the prosthesis.

In case of a patient presenting with device malfunction or indication for device replacement (fistula or leakage), he was advised for immediate change of the prosthesis. All cases but 2 gave the consent and the replacement procedure was performed in the doctor's office (Table 1).

The Provox 2 voice prosthesis is available with shaft lengths of 4.5, 6, 8, 10, and 12.5 mm. The prosthesis shaft lengths used in our

Table 1. Prosthesis replacement in 26 patients

Pros date	*Repl ind*	*Repl date*	*Repl ind*	*Repl date*	*Repl ind*	*Repl date*
02.05.08	Lk around	07.11.08				
05.05.08	Lk around	26.12.08	Centre repl	14.11.10		
07.05.08	Lk through	27.11.08				
09.05.08	Lk around	24.09.09	Lk through	07.09.10		
27.06.08	Lk around	22.10.09				
09.07.08	Lk around	14.09.09	Infection around	12.10.10		
09.09.08	Lk around	28.12.09	Swallow prosth	No repl		
22.09.08	Lk through	15.11.09	Lk through	09.11.10		
20.10.08	Lk around	22.06.09	Lk through	20.08.10		
29.10.09	Lk around	01.06.09				
21.11.08	Lk through	10.12.09	Lk through	26.10.10		
24.11.08	Lk around	13.02.10				
26.11.08	Lk around	22.09.09	Centre repl	23.06.10	Lk around	No repl
01.12.08	Lk through	27.07.09	Lk through	15.04.10		
01.04.09	Lk around	09.02.10				
22.04.09	Lk through	11.12.09	Lk through	20.06.10	Lk around	20.12.10
06.05.09	Lk around	28.02.10				
27.05.09	Lk around	29.04.10	Infection around	02.12.10		
19.06.09	Lk around	06.05.10	Swallow prosth	23.12.10		
10.07.09	Lk through	06.07.10				
15.07.09	Lk through	16.09.10				
29.07.09	Lk around	02.11.10				
11.08.09	Lk through	15.02.10				
20.08.09	Lk around	20.05.10				
07.09.09	Lk around	14.01.10				
16.09.09	Lk around	02.03.10				

Pros date: prosthetization date, Repl ind: replacement indication, Repl date: replacement date, Lk around: leakage around, Lk through: leakage through, Centre repl: centre replacement, Prosth: prosthesis, No repl: no replacement

patients were: 66 patients with 8 mm shaft, 12 with 6 mm, 26 with 10 mm, and 2 patients with 12.5 mm. Compared with the original Provox 1 voice prosthesis, the Provox 2 has slightly thinner flanges (esophageal flange 1.5 mm instead of 1.6 mm, and tracheal flange 1.3 mm instead of 1.6 mm) and the junctions between the shaft and the flanges are more curved [4]. The esophageal flange is thus more rigid than the tracheal flange, therefore diminishing the chance of inadvertent dislodgment into the trachea. These adaptations have been made to optimize the device for anterograde insertion. In addition to this, Provox 2 has a tapered tracheal flange for increasing flexibility, figures on the tracheal flange for length identification *in situ*, and an enhanced valve construction [5].

Results

Patients' and medical staff' experience

The patients' and medical staff' judgment of the primary and secondary insertion procedure was rated on a 5-point scale (from comfortable to very uncomfortable; Table 2). This took into consideration the insertion procedure itself as well as the 10-day rehabilitation period of the surgical procedure in patients with primary prosthetization and total laryngectomy. In primary insertions vocal rehabilitation started on the 14th day (4 days after removing the nasogastric tube). In secondary insertions the vocal rehabilitation started the next day after the prosthetization procedure. Since this procedure was introduced for the first time in Albania, the medical staff at first encountered technical difficulties. For example, in one patient the prosthesis was inserted laterally, and this required the replacement and centered insertion of the prosthesis after a 6-month period.

Table 2. Results of medical staff experience on replacement procedure and patient comfort

Comfort	*Patients*		*Medical staff*	
	Primary	*Secondary*	*Primary*	*Secondary*
	N (%)	*N (%)*	*N (%)*	*N (%)*
Comfortable	30 (70)	90 (90)	33 (77)	3 (30)
Not uncomfortable	6 (14)		1 (2)	
A little uncomfortable	2 (5)		3 (7)	
Quite uncomfortable	5 (11)		6 (14)	7 (70)
Very uncomfortable		1 (10)		

The prosthesis was kept in place for 55768 days, with a mean patient prosthetization period of 526 days. Leakage through the prosthesis, mainly caused by *Candida* deposits on the valve, was the most common cause of failure of the Provox valve (Figure 1). Other reasons for replacement of the prosthesis were leakage around the prosthesis or specific fistula problems, such as infection, granulation formation, and hypertrophic scaring. From 106 patients with primary insertion 20 (18.8%) required prosthesis replacement. In this group 28 replacements were carried out and the causes were leakage around (14 patients, 50%), leakage through (10 patients, 35.7%), infection around the prosthesis (2 patients, 7.1%), and centre replacement (2 patients, 7.1%; Figure 2). Prosthesis half life in these patients was 255 days.

From 20 patients with secondary insertion 6 (30%) required prosthesis replacement because of leakage through (4 patients), and leakage around (2 patients) it. Prosthesis half life device in these patients was 205 days. Ten patients had locoregional cancer recurrences (6 peristomal, 2 local, 2 nodal), and 2 patients died of other causes (one of acute myocardial infarction 634 days after insertion of prosthesis, and the other one of pulmonary edema 582 days after prosthetization). The half life of the device in our patients was as follows: 16 patients (15.1%) over 2 years (mean of 833 days), 38 (36.8%) over 1 year (mean 553 days), and 52 (49.1%)

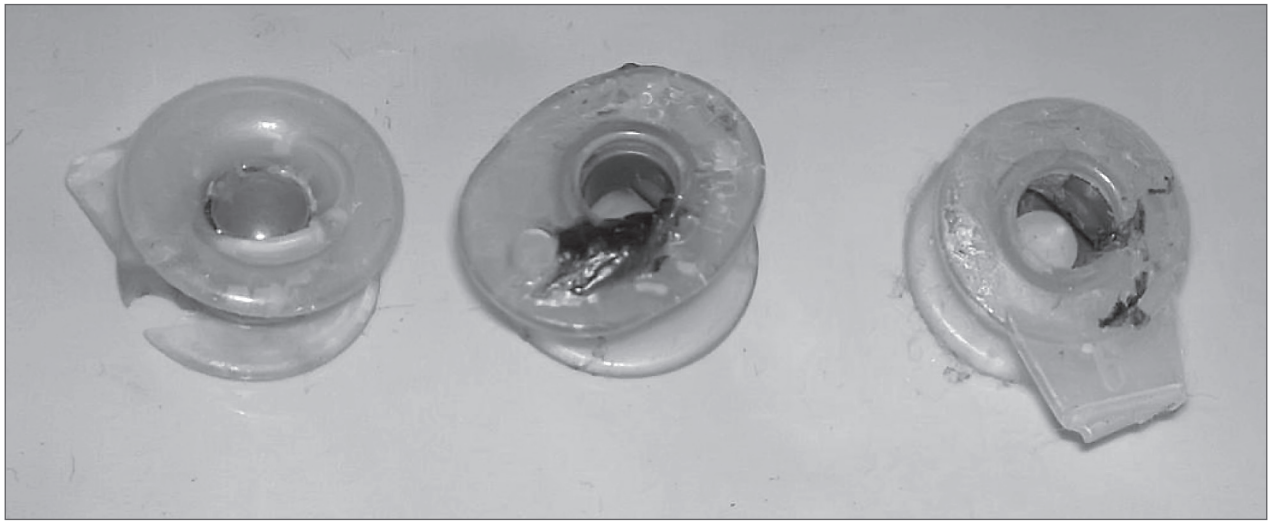

Figure 1. Candida overgrowth.

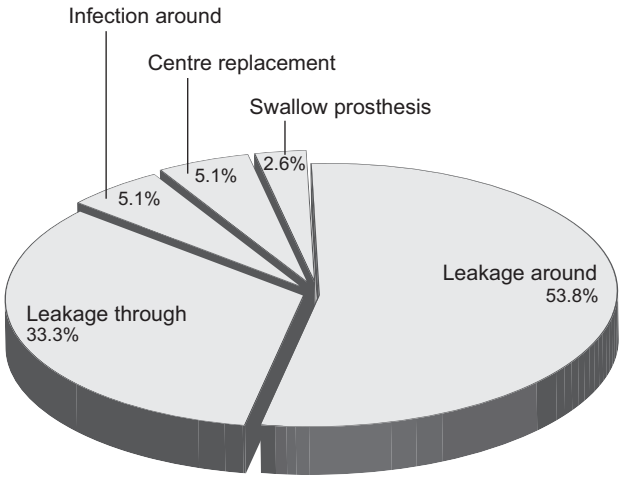

Figure 2. Causes of prosthesis failure.

less than a year, but the follow up in this group was mostly less than a year (patients prosthesized in the last year of the study). Adverse effects were minimal; only 1 patient didn't tolerate the prosthesis, 1 patient was unable to speak and in one patient the prosthesis was not inserted in the centre of the tracheoesophageal membrane. Although the vocal rehabilitation procedure was new in Albania, accompanied with lack of experience and lack of speech therapist, the quality of speech in all prosthesized patients was excellent. Vocal rehabilitation and speech training were undertaken by the surgeon.

Discussion

For many years vocal rehabilitation in Albania for patients with laryngectomy has been a real challenge for medical staff, because some patients refused the treatment or chose to be treated abroad, increasing the therapeutic costs. This prospective study, the first of its kind in our country, aimed at overviewing the method of prosthesis implantation, their numbers, prosthesis' life, the comfort of the patients and medical staff with the replacement procedure, and patient satisfaction with speech performance [2,5-7]. Prosthesis replacement procedure was performed by surgeons and residents, but not by nurses because of lack of experience. The replacement was performed retrogradely in cases of lower positioned prosthesis, deeply positioned fistulae, or difficult narrow tracheal stoma [7]. Correct positioning of voice prosthesis is usually confirmed by rotating and pulling the prosthesis. In all cases of first-time prosthetization (primary or secondary) the procedure was performed under general anesthesia. Anterograde replacement procedure was performed in all cases under local anesthesia (xylocaine 10%). From the patient point of view, this anterograde procedure clearly diminished and/or prevented uncomfortable side effects, such as coughing, gagging, pain and anticipation anxiety. The obstacle encountered in some patients in the pharyngeal-esophageal segment in primary and secondary retrograde prosthesis insertion was not present in later anterograde replacement.

During radiotherapy, some patients complained for loss of voice quality and painful speech. Some authors suggest that radiotherapy accelerates failure of the primary valve, but not of subsequent valves. In our study we didn't have any patient with radiotherapy-induced valve failure or anticipated replacement (this may be related to the intensive follow-up of patients during radiotherapy and oral use/prosthesis cleaning with antifungal agents). Today it is widely accepted that antifungal treatment can improve or increase prosthesis' life [8-11].

Because the prosthesis lies in a humid environment for a long time we recommended to all our patients either oral antifungal therapy or cleaning the prosthesis daily with the brush and antifungal solutions. We also advised our patients not to use beer (favors Candidiasis), and to use more spicy food in order to disfavor fungal colonies (as in countries with spicy diets prosthesis life is much longer, about 2.5 years). Our patients with total laryngectomy were also advised to use antireflux agents, raising the question on the effects of this treatment in prosthesis lifetime.

Because of the lack of evidence, although some authors recommend the use of antifungal agents in patients using an indwelling device [12-15], their effect on valve life is not yet clear, and can lead to overmedication.

The average life of a Provox 2 prosthesis in our study was 255 days. Compared to other European countries, like the Netherlands (104 days) and France (150 days), Albania has the longest device life.

This study does not offer yet enough data to support whether the cause of this increase in lifetime are antifungal agents and diet or it is related to other factors. This topic will be the object of another prospective study which will compare valve lifetime of a group under antifungal treatment with that of a control group without such treatment.

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