Lomg-Term Results with Consistent Use of Indwelling Voice Prosthesis in Albania

Healthcare

Keywords: Device lifetime, indications for replacement (device or fistula related), adverse events, and voice quality.

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Abstract

Objective: To assess long term results with use of indwelling voice prosthesis (Provox) for vocal rehabilitation after total laryngectomy in Albania.

Design: Retrospective clinical analysis

Patients: One hundred four patients (101 men and 3 women) from May 2008, through April 2014.

Interventions: Standard wide-field total laryngectomy (89 patients), or total laryngectomy and circumferential pharyngeal resection (15 patients), and 44 prosthesis replacements. Prostheses remained in situ during 121080 days.

Results: Median patient-device follow- up was 38.7 months. Mean actuarial device lifetime for all indications for replacement was 807.2 days. Main indications for replacement were device related, ie, leakage through the prosthesis (41.3%) or fistula related, ie, leakage around the prosthesis (33.3%), and hypertrophy and/or infection of the fistula (4.2%). Adverse events occurred in 12.5% of all replacements mostly solvable by a shrinkage period of 7 days, adequate sizing and/or antibiotic treatment. Significant clinical factors for increased device life time were no radiotherapy and age older than 70 years ($p<02$). Success rate with respect to voice quality (ie, fair to excellent rating) was 83.2%.

Conclusion: The consistent use of indwelling voice prosthesis shows a high success rate of prosthetic vocal rehabilitation, in terms of the percentage of long-term users (90.9%), and a fair to excellent voice quality (83.2% of patients).

Introduction

Since Billroth in 1873 in Vienna performed the first laryngectomy for cancer, the loss of normal voice had been considered the predominating problem after this procedure for more than 100 years. Only after Singer and Blom[1] introduced their first voice prosthesis in 1980, initiating prosthetic tracheoesophageal voice, better and more consistent results, with respect to vocal rehabilitation of these patients have been achieved. Of the 3 rehabilitation methods, ie, tracheoesophageal, esophageal, and electrolaryngeal voice, the first method is considered the most successful mode of restoring communication after a total laryngectomy[1-5]. The use of various prostheses has become widely accepted in recent years.

In our country vocal rehabilitation after total laryngectomy has certainly been a great challenge for ENT doctors, and in many cases the patients refused surgical intervention due to the lack of voice. In 2008 we began in our country the vocal rehabilitation process with Provox voice prosthesis (Atos Medical, Horby, Sweden). This voice prosthesis was designed to meet the criteria of low airflow resistance, optimal retention in the tracheoesophageal party wall, prolonged device lifetime, simple patient maintenance, and comfortable outpatient replacement[6].

In this study we assess the clinical experience in our service during the May 2008 - April 2014 with consistent use of indwelling voice prostheses for vocal rehabilitation after total laryngectomy. We analyze long

term results, with special attention to the importance of adequate management of the adverse events inevitably encountered with every prosthetic rehabilitation method.

Material and Methods

Patients: The study period is May 2008 - April 2014, with prosthetization period between period prosthetic May 2008 - December 2013. During this time there was a total of 130 patients who underwent total laryngectomy and vocal rehabilitation with indwelling voice prosthesis. The prosthesis of choice was Provox 2. Among 130 patients, 26 dropped out of the study for the reasons listed below: deaths short after prosthetization, prosthesis intolerance, and local recurrence which made vocal rehabilitation impossible. The basis of this retrospective study is the tracking and follow-up of 104 patients and 150 events performed during the rehabilitation process in Albania. The study included 101 (97.1%) males and 3 females (2.9%). Minimum age of patients was 38 years and a maximum of 76 years (mean, 60.3 years). Indications for total laryngectomy were laryngeal carcinoma in 89 patients (85.6%) and 15 patients with pharyngolaryngeal carcinoma (14.4%). 8 of 104 patients (7.7%) have made preoperative radiotherapy followed by total laryngectomy due to local recurrence. The remaining 96 patients (92.3%) have performed post-radiotherapy at a dose 60 Gy. Pre or post operative radiotherapy was never considered as a contraindication for primary or secondary tracheo-esophageal puncture (TEP). Of 130 patients initially part of the study, 26 dropped out of the study, and 22 of them died of the following reasons: 1 acute miocardial infarction, 4 died of other non oncologic causes, 3 remote metastases, and 18 local relapses.

Surgery: Type of surgery that was chosen was total laryngectomy in patients with laryngeal cancer and laryngectomy with pharyngeal resection for patients with laryngopharyngeal cancer. Vocal rehabilitation in all patients was achieved by Provox 2 prosthesis. Primary TEP technique was performed in 92 (88.5%) patients, and the secondary TEP with retrograde valve placement in 12 patients (11.5%). The chosen surgical procedure to avoid pharyngoesophageal segment tonicity during total laryngectomy was the myotomy of crycopharyngeus muscle, applied in all patients with primary TEP. In patients with secondary TEP the tonicity of the crycopharyngeus muscle was corrected by local injection of lydocaine, injection of Botuline toxin was never applied in our patients. 2 patients with secondary TEP have shown signs of hyper tonicity with pain, for this reason these patients were excluded of the study group.

Voice prostheses: Since vocal rehabilitation procedures in Albania started later in comparison with other countries of Western Europe, prostheses used in our service have been of last generation, Provox 2 Voice Prosthesis. For every valve replacement we have recorded patients' indications for replacement, technical problems, prosthesis size, fistula related problems, macroscopic signs of candida overgrowth, medical treatment, and voice quality. Indications for replacement of prostheses were associated to the fistula and the device. Device-related indications were leakage through the valve, and prosthesis blockage that leads to high air resistance during speech. Fistula-related indications include leakage around the prosthesis, inappropriate valve size, fistula infection or hypertrophy. In the fistula-related replacement category were also included cases when the prosthesis was extracted for definitive fistula closure, this has happened in 2 cases in which patients could not afford financially the long term vocal rehabilitation costs.

Voice Quality

Evaluation of voice quality was done, during all replacement procedures or follow-up visit, using a five point score: 5 points for excellent, 4 points for good, 3 points for fair, 2 points for poor and 1 pt for no voice. "Excellent" and "good" stand for fluent and comprehensive speech in all social conditions, the excellent evaluation was used only when the patient's voice is very similar to his pre-surgery voice. "Fair" was used for a voice of lesser quality then "good" that can still be used as the main communication tool. "Poor" was used for a

not so acceptable voice that was not useful as the main communication tool. To make possible the use of voice quality in a multivariable statistical analysis a variable was designed, Measurement of Voice Quality (MVQ), which is calculated with each patient's individual average during all the study. Mean values were rounded (excellent >4.5; good 3.5-44, ecc.).

Statistical Methods

The main objective of the statistical analysis was the investigation of the relation between patients, different treatment-related factors, and prostheses lifetime. Study's data were collected and recorded during all follow-up visits and adverse events management procedures, then the collected data were analyzed using the "student's test"[7]. Prosthesis replacement was required for causes related to the prostheses and the fistula. Prostheses lifetimes not ended at the end of the study period were not censored from the study. Prostheses lifetime varies from 85 to 2082 days. Collected data was analyzed using the "student's test", to calculate information on patients' sex and age, myotomy (yes/no), type of surgery (larynx/laryngopharyng), radiotherapy (pre/post op), and characteristics of Provox2.

Results

This retrospective study consists initially of 130 patients, (Table 1) of which 26 were dropped out of the final study course. During the study period between 2008 – 2014, all the patients were prosthesized with Provox 2 indwelling voice prosthesis. There were 2 periods without voice prosthesis, ie prosthesis were taken out and not replaced leading to fistula definitive closure (fistula closed in 4 weeks). Finally there were 150 periods with Provox prosthesis in situ, at the end of which the existing voice prosthesis was replaced by a new device, or was still in situ at the end of the follow-up. Of the 130 initial patients 26 dropped out of the study because of death without prosthesis problems 5 (19.2%), problems with prosthesis toleration 3 (11.5%), and the remaining 18 had local recurrences (69.3%). 104 patients in total completed the study course. The median follow-up of the 104 patients in the observation period was 1164.2 (38.7 months). All 104 patients were alive at the end of the follow up (May 2014), 102 (98.1%) were still using Provox 2 prosthesis. In total, the series consists of 121080 days with an indwelling voice prosthesis in situ.

Charactristic	**Finding**
Patients (N=104)	
Male, No (%)	101 (97.1)
Female, No (%)	3 (2.9)
Age range (Mean)	38-76 (60.3)
Indication for laryngectomy, No (%)	
Laryngeal carcinoma	89(85.6)
Laryngopharyngeal carcinoma	15(14.4)
Treatment, No (%)	
Total laryngectomy	89(85.6)
Total laryngectomy and circumferential pharyngeal resection	15(14.4)
Radiation before total laryngectomy	8 (7.7)
Postoperative laryngectomy	96 (92.3)
Vocal rehabilitation, No (%)	
Primary tracheoesophageal puncture	92(88.5)
Secondary tracheoesophageal puncture	12(11.5)

Primary tonicity control, PE segment	
Myotomy	92(88.5)
Secondary tonicity control, PE segment	
Lydocaine	12(11.5)
No. of periods	
With Provox prostheses	150
Without Provox prostheses	2
Follow-up	
Days with Provox Prostheses in situ	121080
Patients alive with voice prosthesis in situ	104

Table 1: Clinical data 2008-2014

22 patients needed several prostheses replacement during the study period with a mean of 1.44 (replacement range, 1-6). Two particular patient needed 6 prosthesis during the period study, 4 patient needed 5 prosthesis, and 15 patients with only one replacement (2 prosthesis during the study period). The mean actuarial device lifetime during the complete period was 807.2 days. Figura 1 shows mean device lifetime per patient for all replacement indications.

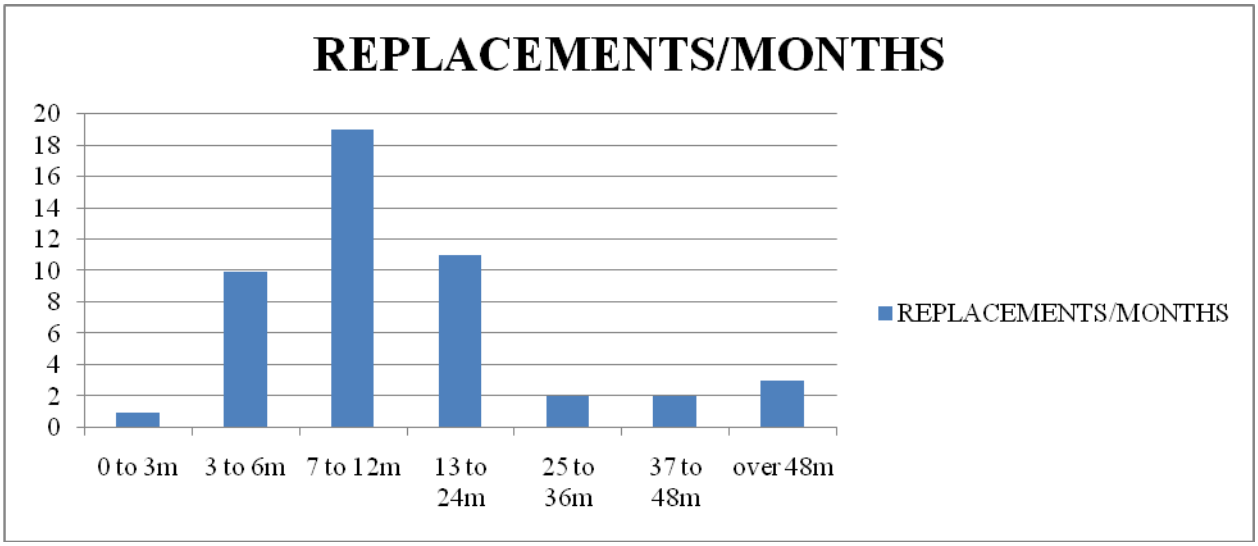


Figure 1: Mean device lifetime per patient for all replacement indications

Figure 2 gives an overview of the different indications for replacement of the 48 voice prosthesis used in the study period for Provox 2. At the end of the follow-up 102 prosthesis were still in use, 46 prosthesis were replaced. There appeared to be no difference in replacement indications of the first (primarily) inserted prosthesis vs that of the following device, ie device- and fistula-related indication occurred at the same frequencies in the first indwelling voice prosthesis.

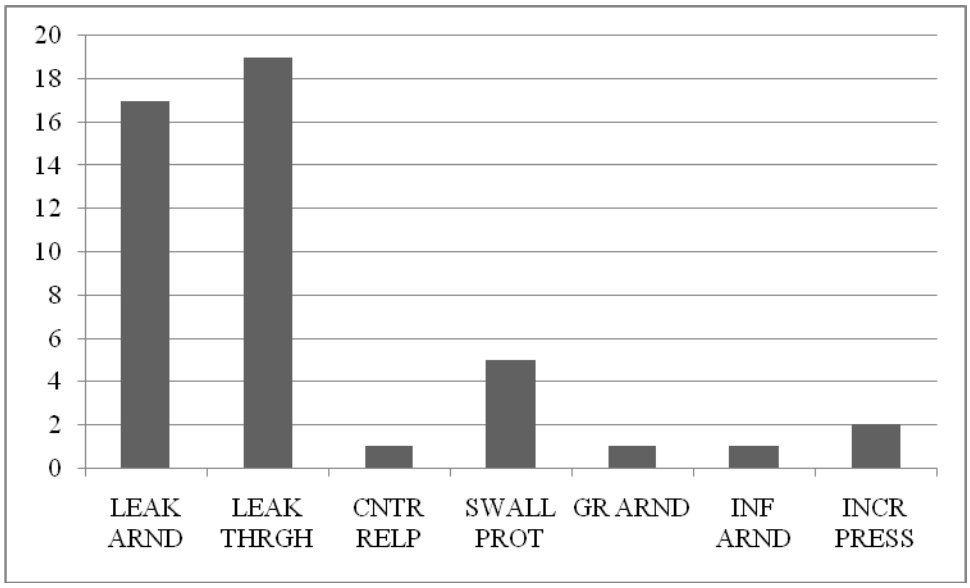


Figure 2: Indications for replacement

Device- related indications for replacement

The main reason for replacement was leakage of fluids through the prostheses 19 (41.3%). Improper closer of the valve occurred due to Candida deposits on the device. Increased pressure, another device related was less frequently observed, in 2 (4.3%). Theoretically radiotherapy (pre- and post-operative) is negatively associated with time to device-related problems, but all patients in our study group underwent radiotherapy treatment. No significant difference in prostheses lifetime was noted between pre-operative and post-operative radiotherapy group. Age appeared to have no significant correlation with device lifetime. Other factors like sex, tumor type, and stage of disease were not significantly associated with time to device related problems.

Fistula – related indications for replacement

Replacement was required for leakage around the prostheses in 16 (33.3%) patients. Downsizing solved this problem in 14 patients (87.5%). Leakage around the prostheses not solvable by simple downsizing was observed in 2 (12.5%) patients, this adverse event treated mostly with short-term removal of the prosthesis to allow for spontaneous shrinkage of the fistula tract. The median duration of removal of the voice prosthesis was 7 days, this period solved the problem in both patients[8]. A less frequent fistula-related reason for replacement was inaccurate sizing, observed in one patient (2.1%). In this case the patient came back to the clinic because the prosthesis felt uncomfortable, which was solvable by upsizing the device. Hypertrophic scaring (granulation tissue) or infection of TE fistula as indication for replacement were observed in 2 (4.2%) patients, one for hypertrophic scaring and one for infection of TE fistula. These adverse events were solved by upsizing the prosthesis, treatment with antibiotics and resection of granulation tissue with radiofrequency scaple. In the patient with granulation formed around the prosthesis there were needed two radiofrequency procedures (6 months apart) because of granulation recurrences. The last category of adverse events was spontaneous loss of the device, which occurred in 5 times (10.4%) in 5 patients. There were no cases of aspiration, and in none of these cases did device loss result in medical complications. There were no other indications for prostheses replacement.

Sizing of the voice prostheses

In 27 occasions (58.7%) the size of the replacing prosthesis was the same as the one removed. A device one size shorter was inserted on 16 (34.7%), and one size longer in 3 occasions (6.6%).

Voice- quality assessment

Voice quality assessment was available for all 104 patients, allowing calculations of MVQ (Measurement of Voice Quality). In 67 of 104 patients (64.4%) the MVQ score was Excellent; in 20 patients (19.2%) the MVQ score was Good; in 8 patients (7.7%) the MVQ score was Fair; in 5 patients (4.8%) the MVQ score was Poor; and in the remaining 4 patients (3.9%) the MVQ score was no Voice. Owing to the small numbers, the voice results in patients who underwent Lidocaine injection in secondary TEP were not analyzed separately. The improved ratings after the treatment are included in their overall MVQ score. According to the current literature the MVQ was related to patients age; in our study we concluded that patients >70years had a lower MVQ score (3) than patients aged 60 – 70 years old (4)($p<0.01$). The MVQ score sex, radiotherapy, and tonicity control procedure showed no significant relation with the MVQ score.

Comments

High success rate of vocal rehabilitation in Albania with indwelling voice prosthesis has raised some adverse events. We used the term "prosthesis related complications", which included more or less the same indications as our fistula-related adverse events, such as granulation hypertrophy, widening of the fistula, leakage around the prosthesis, and the loss of voice prosthesis. Hence, we classified the results in device and fistula-related indications for replacement, and decided to discuss them in the same order.

Device-related indications

Leakage through the prosthesis was the reason for replacement in 41.3% patients and was most likely to be associated with Candida deposits on the valve, as has been reported by many others[9,10,11,12]. Although it was not documented, we have observed some improved device lifetimes in individual cases by prescribing antifungal agents such as Nystatine and Fluconazole as described by others [13,14]. No significant difference in prostheses lifetime was noted between pre-operative and post-operative radiotherapy group. Compared to other countries, and mainly the Netherlands (one of the leading countries in voice rehabilitation lifetime studies), the results of our study, in Albania, show a much extended prostheses lifetime. We attribute this to two factor; the first one is related to post-prosthetization medical treatment we antifungal therapy, and the second one is related to local-Albanian and recommended dietary reasons (patients were recommended a spicy diet composed onion, garlic, pepper and other spicy food)[15,16]. This ended up in an impressive extension of prostheses lifetime, 32 (30.1%) patients had a prosthesis lifetime of over 4 years. Candida deposits on the valve, when noted, were documented by high resolution photography.

Candida overgrowth

Fistula-related indications and adverse events

Concerning the fistula-related indications leading to replacement, leakage around the prosthesis appeared to be the second replacements cause (33.3% of all replacement's indications). The few studies mentioning this issue, report this problem between 7 – 27% of replacements[11,17,18,19,20]. Leakage around the device, as a replacement indication, was not seen more frequently in the first prostheses inserted during surgery. It could be assumed that the immediate insertion of an indwelling device during the TEP procedure, as is the custom in many European clinics for the past 20 years[21,22], would lead to more frequent replacements due to widening of the fistula, which itself leads to leakage around the fistula. In our experience, simple downsizing of the voice prosthesis was the solution in the most of the leakage around cases. Therefore, it's important, never to replace the voice prosthesis automatically with one of the same size, but to check the proper length first, avoiding the piston effect of too long prosthesis. In our experience, downsizing should not be done rapidly, and should not exceed more than 1 shaft length, to prevent too much pressure on the tissues. Removal of the prosthesis to allow the fistula to shrink was reported in some studies but an indication of how long the fistula should be left alone or whether to close the tract was not given[23]. One shrinking period (median, 7 days) was sufficient in most of our cases; recurrence of this problem was not seen.

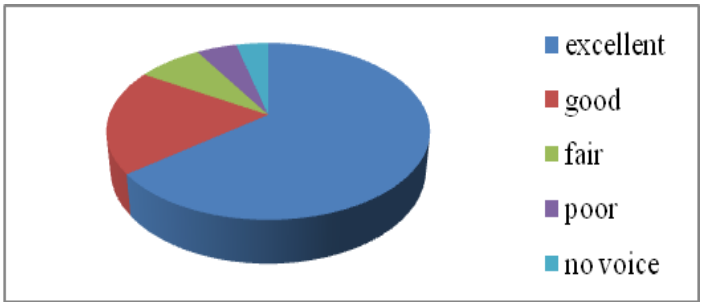
During the shrinking period the patient needs a nasal feeding tube, sometimes, a cuffed tracheal tube. In our study fistula secondary closure without suturing occurred in approximately 3 weeks. In one case the fistula was closed by submucosal purse-string suture around the TE fistula tract. This is a relatively simple procedure, using an no traumatic Vicryl 3.0 suture under local anesthesia and providing an instant solution which avoids nasogastric tube feeding and use of a canula. Hypertrophic tissue, scarring, and infection of the TE fistula was seen in 1.9% of the patients. In two cases with granulation tissue, the treatment was by excision of the granulation by radiofrequency, and the recurrence in one of these cases happened after 6 months but responded very well to the second radiofrequency procedure. In our study there was found only one case of infection around the TE fistula, the problem was addressed and solved by 2 weeks of antibiotic therapy. Once the TE fistula had the tendency to granulate or retract into the mucosa during regular follow-up visits, or when the patient complained about higher pressure during speech as a result of esophageal-mucosal swelling, we upsized the prosthesis to prevent actual granulation formation or infection. Accurate sizing and an adequate approach to infection problems with the use of antibiotics or antifungal medication can prevent many adverse events. One of the problems discussed in the recent years is the existence of gastro esophageal reflux disease in patients undergoing laryngectomy[24]. Although there seems to be a relation to postoperative wound healing problems, there is at present no clear evidence that gastro esophageal reflux disease has an influence prosthesis or fistula-related device lifetime. Still, the practice in our clinic is to treat patients with anti-reflux treatment until the nasogastric tube is taken of, in order to prevent the reflux induced by the nasogastric tube itself.

Device lifetime

As discussed before, there are many influencing factors in the assessment of the device lifetime of voice prostheses. However interpretation of the results can be difficult, as device lifetimes have not always been calculated in a consistent manner. It's probably more realistic to report on median survival times. In our study the mean value is 807.2 days, notably much higher than values reported by other studies (range 148-311 days) and nearly 10 times more than lifetime studies reported in the Nederland (89 days)[11,25,26]. The increased valve lifetime is related with the use of spicy foods by our patients, the advice to avoid beer consumption which favors Candida overgrowth, use of anti reflux, antifungal and antibiotic medical treatment. Considering the extended prosthesis lifetime in Albania (median of one replacement in over 2 years), the issue of reimbursement should be taken into account, as for now Albanian patients cover the treatment costs by themselves.

Voice quality

Tracheoesophageal speech is considered the first method of communication in patients who have undergone total laryngectomy, and far superior to esophageal voice. Subsequently, the rating of voice quality is of less concern in these patients and is still somewhat difficult to quantify. The voice quality assessment used in our clinic is simple but consistent. Voice quality assessment was available for all 104 patients, allowing calculations of MVQ (Measurement of Voice Quality). In 67 of 104 patients (64.4%) the MVQ score was Excellent; in 20 patients (19.2%) the MVQ score was Good; in 8 patients (7.7%) the MVQ score was Fair; in 5 patients (4.8%) the MVQ score was Poor; and in the remaining 4 patients (3.9%) the MVQ score was no Voice. According to some authors, extended surgery total laryngectomy vs. laryngectomy combined with partial pharyngectomy, influence the voice quality. We subscribe to the explanation that the preservation of the hypopharynx, which means a larger vibrating mucosa segment, results in a better voice. In our study, there were 15 patients who underwent laryngectomy combined with pharyngectomy, and in none of the cases the voice quality was compromised. In addition to this, we noticed that in some patient it was possible for them to speak excellently without blocking the outer valve with the finger (HME Cassette, Heat and Moisture Exchange).



Conclusions

The results of our 5 years follow-up study demonstrate that the consistent application of indwelling voice prostheses such as the Provox system can result in a high percentage of successful vocal rehabilitation. In ratting success, it is important differentiate between device-related indications for replacements and replacements due to fistula adverse events, and to evaluate possible influencing factors. By an intensive and consequent multidisciplinary approach to problems, most of the inevitable adverse events can be solve adequately, minimizing the discomfort for patients who have undergone laryngectomy and used indwelling voice prostheses.

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