Analysis of Factors Affecting the Longevity of Voice Prosthesis Following Total Laryngectomy with a Review of Literature

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Abstract Tracheoesophageal voice puncture (TEP) coupled with the use of voice prosthesis has been considered as the gold standard for speech rehabilitation in patients of advanced laryngeal/hypopharyngeal carcinomas, who have undergone a total laryngectomy with or without partial pharyngectomy. Although prosthetic voice rehabilitation is commonly practiced worldwide including India, there is a paucity of published Indian data, more so in the current era of organ conservation. This study included 60 laryngectomized patients with a prosthetic voice rehabilitation at a tertiary cancer center in South India between January 1, 2010 and December 31, 2013. Among the 60 patients, the primary site of cancer was the larynx in 43 patients and hypopharynx in the remaining 17. All patients had undergone a primary TEP insertion, 55 in the upfront setting and five in the salvage (post-radiation/chemo-radiation) setting. The ability to retain a successful tracheoesophageal speech on follow-up (median 15.5 months) in our series was around 82%. The mean device life of voice prosthesis in our patient cohort was 16 months. There was surprisingly no significant difference in the prosthesis device life on correlation with age, co-morbidities, habitat, literacy status, pre-operative tracheostomy, setting of surgery, and the extent of surgery. Our series has successfully demonstrated the safety and feasibility of using primary TEP coupled with the use of voice prosthesis for voice rehabilitation in properly selected and motivated patients of advanced laryngeal and

hypopharyngeal carcinomas across all clinical settings. A mean device life of 16 months makes prosthetic voice rehabilitation, an attractive as well as a financially viable option for patients in a resource constrained setting.

Keywords Voice prosthesis · Tracheoesophageal voice puncture · Total laryngectomy · Carcinoma larynx · Carcinoma hypopharynx · Voice rehabilitation

Introduction

Total laryngectomy with or without partial pharyngectomy is a procedure of choice in moderately advanced carcinoma of the larynx/hypopharynx in primary setting. With the advent of effective organ preservation protocols like chemo-radiation, the role of total laryngectomy has steadily declined over the years. Despite these trends, a sizable number of patients have to undergo a laryngectomy as a result of failure of organ preservation protocols of due to primary advanced disease. The surgical procedure of total laryngectomy significantly alters the speech mechanics. For a normal speech, three basic elements are considered necessary, i.e., a power source, a sound source, and a sound modifier. For individuals with an intact larynx, the air from the lung is the power source, the larynx is the sound source, and the vocal tract is the sound modifier. During the performance of a total laryngectomy, the sound source (larynx) is removed and the power source (lungs) is disconnected from the sound modifiers (pharyngo-esophageal segment). Over the years tracheoesophageal voice puncture (TEP) coupled with the use of voice prosthesis has become the gold standard for speech rehabilitation in patients who have received total laryngectomy [1–10]. Although prosthetic voice rehabilitation is commonly practiced in major centers worldwide, there is sparse published Indian data in literature.

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We share our experience of voice rehabilitation with primary TEP coupled with the use of voice prosthesis in tertiary cancer care center in South India with an emphasis on the voice prosthesis device life in the era of organ conservation.

Material and Methods

Sixty consecutive patients with laryngeal and hypopharyngeal cancer treated with total laryngectomy with or without partial pharyngectomy and primary TEP coupled with the use of voice prosthesis for voice rehabilitation in tertiary cancer center between 2010 and 2013 formed our study cohort. Data pertaining to the patient's demography, pre-operative tracheostomy, setting of surgery (primary or salvage), extent of surgery, concomitant neck dissection, life of prosthesis, complications associated with prosthesis, and follow-up data were abstracted and analyzed.

Post-laryngectomy prior to the creation of the neo-pharynx, the Provox® I/II voice prosthesis (Atos Medical AB, Hörby, Sweden) was inserted. The patients who underwent upfront surgery received adjuvant radiation/chemoradiation as per standard guidelines. The patients were followed up 1–2 monthly for the first year and 3 monthly for the second year and six monthly from the third year onwards. All patients received pre-operative counseling and instructions on post-operative hygiene and maintenance of prosthesis by a dedicated speech therapist. More recently, we have shifted to the routine use of Provox Vega prosthesis. The success of TEP was measured as consistency of using voice prosthesis as primary mode of communication and the duration of device life and failure was recorded in months.

Results

In 43 of the 60 patients, the primary site of cancer was in the larynx, while 17 patients had their primary in the hypopharynx. Barring one patient of sarcoma of the larynx, all the patients were histologically proven squamous cell carcinomas. The mean age of our cohort was 56 years (mean 31–73 years). There was a significant male preponderance (56 male and four female patients), of which 41 patients (68%) had at least secondary level of education. Twenty-two [36.6%] patients had undergone a pre-operative tracheostomy. All patients had undergone a primary TEP insertion, 55 in the upfront setting and five in the salvage (post-radiation/chemoradiation) setting. The tumor stage distribution was mentioned in Table 1. The voice prosthesis has to be removed in two patients within a month following surgery, both of whom had to undergo re surgery, one for a secondary hemorrhage and the other for a spinal stabilization due to an unrelated event of vertebral collapse.

Forty-three patients received adjuvant radiation therapy, while four patients received adjuvant chemo-radiation. Seven patients were planned for adjuvant radiotherapy, but the same could not be administered either due to patient refusal or defaulting for treatment (including the patient who developed cervical vertebral collapse post-operatively and was not advised radiation due to delay after spine stabilization). Ten (16.6%) patients recurred loco-regionally, and two (3.3%) had distant metastasis on follow-up. The follow-up ranged from 1 to 50 months with median follow-up of 15.5 months. The mean life of prosthesis was 16 months with a range of 1–42 months. The ability to retain a successful trachea-esophageal speech in our series was 82%. Eleven patients (18%) were unable to maintain a prosthetic voice at the time of analysis (Table 2). Patients who continued to maintain their prosthetic voice after device replacements were not considered as failures of voice rehabilitation.

There was *no significant difference* in the prosthesis device life on correlation with age, co-morbidities, habitat, literacy status, pre-operative tracheostomy, setting of surgery, and the extent of surgery as depicted in Table 3.

Discussion

The history of voice rehabilitation following a total laryngectomy is in fact as long as the history of laryngectomy itself. Ever since the introduction of the TEP coupled with the use of voice prosthesis by Singer and Blom in 1980, the success of restoring vocal communication following laryngectomies has improved significantly.

The voice rehabilitation options include both surgical as well as nonsurgical methods; the nonsurgical methods include the electrolarynx, pneumatic artificial larynx, and esophageal speech while the surgical methods primarily includes TEP using voice prosthesis [1]. The multitude of methods which have been adopted over the years illustrates the difficulty of finding an optimal method of reestablishing verbal communication. The choice of voice rehabilitation is made keeping in mind the patient's communicative needs, physical and mental status, personal preferences and also based on the inputs from

Table 1 Stage distribution

Stage distribution	Number	Adjuvant treatment
Bulky T3 tumors who were aspiration/prior tracheostomy	17	PORT: 13 Could not be given: 4
T4a tumors	37	PORT+CT-4 PORT- 30 Could not be given-3
Salvage setting	5	No further therapy
Sarcoma larynx	1	PORT

Table 2 Status of voice prosthesis at the time of analysis

Status of voice prosthesis	Numbers
Patients continuing to use the voice prosthesis WITHOUT any replacement	37
Patients continuing to use prosthesis WITH replacement	12
Patients in whom the prosthesis had to be REMOVED/extruded necessitating TEP site closed (prosthetic voice failure)	11

the surgeon and the speech language pathologist. Specific tissues pertaining to a voice prosthesis include details pertaining to the length of voice prosthesis, expense, diameter, type of retention collar, method of insertion, need for follow-up care, and the patient's ability to care for the prosthesis. For the past several decades, a voice prosthetic device has become the gold standard of voice rehabilitation for a majority of the laryngectomy patients, with the exception of the odd patient who has acquired good esophageal speech or for whom an external device is the only practical method of voice production [1–10].

The core principle of prosthetic voice rehabilitation is to use the lung-powered air for speech and to prevent the aspiration of ingested food material. To achieve this, the head and neck surgeon creates a fistula through the party wall that divides the trachea from the esophagus for insertion of a voice prosthesis either at the time of the total laryngectomy (primary TEP) or at a later time (secondary TEP). The voice prosthetic

device has a one-way valve, which prevents aspiration and to allow passage of air from lung into the esophagus, which causes mucosal vibrations in the pharyngoesophageal segment and produces sound. This sound subsequently is further processed to intelligible speech in the oropharyngeal tract. The initial voice prosthesis was designed as ex-dwelling devices to be exclusively cared for by the patients, indwelling devices and the hands-free devices that need less dexterity on the part of the patient and can be cleaned in situ were subsequently developed followed by low-pressure devices.

In tracheoesophageal speech, the entire tidal volume of expired air (500 ml) is available which is significantly more than the 40–70 ml of air that is available for an esophageal speech, thus making the lung powered the speech louder, sustained, more fluent in quality, better intelligibility, and more closer to normal laryngeal speech. This is also objectively reflected as the better voice parameters, i.e., fundamental frequency, shimmer, jitter, words per minute, and better

Table 3 Life span of Prosthesis correlating with variables

		No of patients	Life of prosthesis			<i>p value</i>
			< 6 months	6–12 months	>12 months	
Age	< 40 years	2	0	2	0	0.32
	40–60 years	36	3	9	24	
	> 60 years	22	4	8	10	
Habitat	Rural	33	5	11	17	0.93
	Urban	27	2	8	17	
Literacy	Illiterate	10	1	6	3	0.29
	Primary	9	2	4	3	
	Middle	12	2	2	8	
	Secondary	23	2	7	14	
	Graduate	6	0	0	6	
Co-morbids	None	35	6	12	17	0.69
	One comorbid	20	1	5	14	
	> 1 comorbid	5	0	2	3	
Pre-op tracheostomy	Not done	38	13.9	25	61.1	0.86
	Done	22	0	45.5	54.5	
Setting	Primary	55	7.4	33.3	59.3	0.47
	Salvage	5	25	25	50	
Extent of primary surgery	Laryngectomy alone	43	7.1	33.3	59.6	0.81
	With partial pharyngectomy	17	12.5	33.3	56.3	
Therapeutic neck dissection	Done	26	9.1	30.3	60.6	0.89
	Not done	34	8	36	56	
	Not received	7				

maximum phonation time for the lung-powered speech. Voice rehabilitation after laryngectomy has in fact been revolutionized by use of TEP with voice prosthesis; many studies over the years have in fact reported its superiority to esophageal speech/electrolarynx speech [1–10].

A few studies have suggested that immediate rehabilitation with primary TEP and earlier voice restoration provide a positive psychological impact, a tendency towards better voice outcome and improved short-term quality of life [9] although many studies have shown both primary and secondary TEP to have identical success rates in voice rehabilitation [3]. The success rate of achieving a tracheoesophageal voice following total laryngectomy varies across the published studies between 70 and up to 95% in motivated long-term users, with a vast majority (88%) achieving a fair-to-excellent voice quality.

A major limitation of voice prosthesis is its finite life span necessitating replacements [10–12]. The reasons for device/voice failure can be attributed either due to TE puncture or prosthesis-related complications/problems or due to poor understanding or motivation of the patient. The device failure and the need for replacements impede communication and can potentially create enormous psychosocial and financial burdens to the patient. It is prudent to mention that apart from a proper patient selection, a meticulous technique of insertion, proper maintenance of the puncture site, and selection of adequately fitting prosthesis are additional key determinants of the device life. Different prostheses have different life spans, and the normal wear and tear of the valve will eventually cause leakage through the valve. New generation voice prostheses have a good life span of several months and need replacement in outpatient setting [13] and less than 3% require general anesthesia for change of prosthesis.

It was initially believed that xerostomia following radiation may decrease prosthesis life span as it decreases the antibacterial and antifungal salivary peptides. A few studies including our study have found no difference in prosthesis life span with or without adjuvant radiation [14]; however, another study showed that radiotherapy doses to the primary tumor exceeding 60 Gray significantly shortened the mean voice prosthetic lifetime per patient [15]. In addition, yet another series further suggested that the addition of neck dissection along with post-operative radiotherapy does not affect short-term speech outcomes [16]. The addition of therapeutic neck dissection and adjuvant therapy did not affect the device life in our series as well. The mean prosthesis device life for laryngectomy patients who did not receive adjuvant radiation was not statistically different from those who received adjuvant treatment (19.28 months versus 16.87 months, $p = 0.30$).

The common reasons of prosthesis replacement usually are fungal colonization, incompetent valve leading to endoprosthetic leak, widening of TEP leading to periprosthetic leak, prosthesis displacement, aspiration, granuloma formation, and stenosis of tracheostoma [17, 18].

Candida biofilm formation on the prosthetic surface can lead to deterioration of prosthesis, loosening and leakage requiring replacement. Antifungal agents have been advocated to tackle this problem and help prolong the life span of the prostheses [19, 20]. However, the long-term use of antimicrobial and antifungal agents can potentially induce the development of resistant strains and hence needs to use with caution. It has further been suggested that the use of biosurfactants, probiotics, and targeted decontamination regimens may also help in preventing the microbial biofilm formation [20]. The use of anti-reflux therapy has been attempted to increase the life of the voice prosthesis [21–23].

Most of the studies on the association of dairy products and probiotics in increasing prosthesis lifespan had a finding of reduction in the growth of *Candida albicans* which produce enzymes, which can degrade the silicon biomaterial [24]. The traditional Indian-based diets of curd and buttermilk have been shown to prevent the candida colonization and improve prosthesis lifespan [25]. The longevity of the prosthesis in our cohort of patients could be partly attributed to this. This benefit is postulated due to the presence of *Streptococcus thermophilus* and *Lactobacillus* in the yoghurt [26]. Fluoroplastic material in the prosthesis valve which seems insusceptible to destruction by *Candida* species has been tied in an attempt to improve durability of voice prostheses [27].

Approximately one fourth of all patients with voice prostheses develop periprosthetic leaks within the first few years of deployment. TEP leaks were in fact the most common cause of prosthesis replacement in our study as well. An enlarged TEP site can cause a periprosthetic leak; this may be related to the use of a wide-diameter valve in a thin party wall [28]. Depending on the severity of fistula, the management options ranges from conservative to invasive approaches. Collagen, autologous fat injection, injection of hyaluronic acid, use of a silastic wafer or a purse string suture can potentially help improve the seal around the prosthesis and prevent leakage [29, 30]. Insertion of small bore nasogastric tube can be used to allow shrinkage of fistula in the interim period which is followed by a subsequent prosthesis reinsertion.

A periprosthetic leak can also be caused by a too long prosthesis which moves like a piston in the TEP site, which can be corrected by downsizing the valve. An endoprosthetic leak usually demands a prosthesis replacement. Occasionally granulation tissue can form around the prosthesis at the TEP site as a result of trauma or chronic irritation to the mucosa, which can be easily cauterized or excised as was done in two of our patients. It is paramount to rule out the possibility of a tumor recurrence during the management of prosthetic leaks.

Occasionally extrusion of the voice prosthesis can occur during cleaning or following a bout of severe coughing. Failure to immediately replace the voice prosthesis may result in a stenosis of the puncture site necessitating a dilatation and reinsertion. In cases of severe stenosis, a surgical correction

may be required if a spontaneous closure does not occur. Bronchial aspiration is a potentially life-threatening complication, which has been reported to occur in about 0.75–13% of patients. We had one patient who presented with aspiration of voice prosthesis into tracheobronchial tree which needed emergency bronchoscopic removal [31].

An important cause of voice failure is hypertonicity of the PE segment. An inadequately performed cricopharyngeal myotomy is an important cause of increased tonicity of the PE segment. The use of *botulinum toxin* to relieve constrictor hypertonicity has become the preferred method of management. A cricopharyngeal myotomy is generally reserved for circumstances in which the botulinum toxin injection has been ineffective in relieving the hypertonicity. Conversely, hypotonicity of the PE segment as a result of the loss or absence of muscular tone or when the PE lumen is large results in a weak and breathy voice. The outcome of surgical attempts to correct this problem has been varied; the use of prosthesis with a higher-resistance duckbill valve may be attempted. We did not observe any case of altered PE segment tonicity in our cohort of patients.

The prosthesis device life can also vary across regions due to number of reasons, including diet, patient preference, reimbursement and voice expectations, and tolerance of periods of minor leakage prior to replacement. The life of the voice prosthesis has been reported to be anywhere between 2 and 14 months based on the different group of patients, devices, and regions studied [10, 32–46] (Table 4).

In a very recent retrospective observational study of 390 laryngectomized patients, the authors reported a prosthesis device life much lower durability (mean 61 days) than historically reported which they attribute to the intensification of treatment regimens in an era of organ preservation which eventually complicates the TEP management [12].

The much longer prosthesis device life has been reported in studies from Africa, Portugal, and also from the Indian sub-continent. Cornu et al. who reported device life of 303 days in a South African patient population describe this phenomenon as patients taking “a more conservative approach” and this may have contributed to longer mean device life [32]. In a review by Sara Cruz et al. in Portugal, mean device life were 1–74 months for primary prosthesis and 1–24 months for secondary prosthesis [33]. Two Indian studies reported mean prosthesis longevity of 18 and 15 months, respectively [25, 44]. The mean life of our prosthesis was 16 months (1–42 months), which is similar to the experience of the other published Indian series (Table 4).

Interestingly, none of the factors analyzed in our cohort were significant determinants of the life of the prosthesis. We can therefore conclude that a primary TEP should be considered safe and feasible in properly selected and motivated patients of advanced laryngeal and hypopharyngeal carcinomas across all the clinical settings. Another interesting observation in our series is the fact that a majority of our patients

Table 4 Prosthesis lifespan as determined by various authors

Authors (number of patients)	Prosthesis type	Mean device life in months (range)
Cornu [32] (<i>n</i> = 128)	Provox I	10
Hilgers [34] (<i>n</i> = 79)	Provox I	7.8 (0.2–24)
de Carpentier JP [35] (<i>n</i> = 39)	Provox	4.5 (1.0–12)
Laccourreye O [36] (<i>n</i> = 37)	Provox	10.3
Heaton [37] (<i>n</i> = 40)	Provox II	4.1 (1.0–21)
Ackerstaff [38] (<i>n</i> = 292)	Provox I	4.2 (0.3–19.4)
Graville [39] (<i>n</i> = 30)	Provox II	4.9 (0.5–11)
Op de Coul [40] (<i>n</i> = 318)	Provox I	5.4
Schafer [41] (<i>n</i> = 58)	Provox I	224
	Provox II	94
	Bloom Singer	107
Free [42]	Provox II	2.8 (0.3–12.4)
Lequeux T [43] (<i>n</i> = 38)	Provox I	10
	Provox II	5
Ramalingam [44] (<i>n</i> = 41)	Provox I	15
Chaturvedi [25] (<i>n</i> = 60)	Provox II	18 (1.0–87)
Yenigun [45] (<i>n</i> = 28)	Provox	17.1 (1.0–36)
Serra A [46] (<i>n</i> = 43)	Provox I	5
	Provox II	4.1
	Provox Vega	4.6
Thylur DS [10] (<i>n</i> = 21)	Provox	3.5
	Provox Vega	2.17
Lewin [12] (<i>n</i> = 390)	Provox	2 (1.2–2.3)
Our series (<i>n</i> = 60)	Provox I/II	16 (1–42)

were reluctant for replacement of prosthesis for wear and tear and even in the presence of minor leaks. This tolerant approach may have contributed to the longer median device life in our cohort. However, the reasons for the wide variations of the device lives across the various published studies worldwide need to be investigated.

Conclusion

Our series has successfully demonstrated the safety and feasibility of using primary TEP coupled with the use of voice prosthesis for voice rehabilitation in properly selected and motivated patients of advanced laryngeal and hypopharyngeal carcinomas across all the clinical settings. Voice rehabilitation is a continuous ongoing process, not just about prosthesis and hence, careful attention must be directed towards the integrity of the pharyngoesophageal segment, voice prosthesis selection and insertion, and equally importantly troubleshooting. Meticulous adherence to the above principles can potentially increase the device life and make the prosthetic voice rehabilitation a safe, effective, and a financially viable option. Further objective assessments of voice outcomes, including prosthesis

longevity are necessary to counsel patients and engage them in shared decision-making process regarding the voice rehabilitation options following laryngectomy and these issues incidentally are potential avenues for further research.

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