Tracheo-esophageal Puncture (TEP) for Voice Rehabilitation in Laryngectomised Patients Blom-singer® Vs Provox® Prosthesis : Our Experience

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Abstract

Background: Stage III and IV cancers of larynx and hypopharynx often require total laryngectomy which leaves the patient with severe communication handicap. In such laryngectomised patients tracheo-esophageal puncture is the best way for voice rehabilitation using either Blom-Singer® prosthesis or Provox® indwelling valve.

Methods: A prospective comparative study of Blom-Singer® prosthesis and Provox® indwelling valves placed in Tracheo-esophageal Punctures (TEP) for voice rehabilitation following total laryngectomy was carried out at the Tata Memorial Hospital, Mumbai and Malignant Diseases Treatment Centre of Armed Forces, to assess their efficacy. This report comprises of our experience in 41 (39 males and two females) laryngectomees who underwent TEP of which 15 patients were fitted with low pressure Blom-Singer® prostheses and 26 with Provox® indwelling prostheses.

Results: Prostheses related problems like granuloma formation, leakage, candidal growth over the valves and prosthetic decay were significantly less in the patients fitted with Provox® prosthesis. Dislodgement of prosthesis with closure of the tract or persistent fistula formation and creation of false passage, while reinsertion were problems encountered in the Blom-Singer group. After three months, speech assessment revealed a better quality of voice production and patient compliance in maintaining the prosthesis in the case of Provox® indwelling valve.

Conclusion: In Indian scenario where illiteracy amongst the patients hinders in maintenance of Blom-Singer® prosthesis, Provox® indwelling valve is an appropriate choice for voice rehabilitation.

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Key Words: Tracheo-esophageal puncture (TEP); Blom-Singer® prosthesis; Provox® Valve

Introduction

Cancers of the endolarynx and pyriform fossa comprise about 8- 9% of all Head and Neck cancers. Stage III or IV cases require total laryngectomy and postoperative radiation therapy, in most patients [1]. With prevailing low literacy rates in India, total laryngectomy and loss of speech leaves the patients severely handicapped in communication, which has psychological, social and economic impact. Rapid and effective voice restoration is critical for the quality of life in these patients.

Historically, esophageal voice has been the method of choice for alaryngeal speech. In this method, air is injected or inhaled into the cervical esophagus and immediately expelled, setting the apposing mucosal surfaces of the pharyngo-esophageal (P-E) segment into vibration. This method usually takes many months to learn with intense speech therapy and the acquisition rate for good esophageal voice is disappointing (around

30%). The electro-larynx devices produce an electronic speech when held against the vocal tract below the mandible, by converting the vibrations into electronic sound. The mechanical monotonous voice so produced is not preferred by many, apart from the prohibitive cost for majority of our patients.

In 1980, Singer and Blom [2] revolutionized vocal rehabilitation by introducing Tracheo-esophageal puncture (TEP) and valved silicone prostheses, which produced successful voice. It gained universal acceptance because of its simplicity, reproducibility and high rate of success. In this method, under endoscopic guidance, a puncture is placed through the centre of the membranous trachea into the esophagus, about 8mm below the superior margin of tracheostoma i.e. on posterior tracheal wall which is readily visible and allows easy introduction of a removable silicone valve. This unidirectional tubular prosthesis effectively prevents stenosis of the puncture, protects the airway during deglutition and allows

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pulmonary air to be diverted across the tracheo-esophageal puncture for voice production.

Over the years, different modifications to the original Blom-Singer duckbill voice prosthesis have taken place. In 1988, Provox [3] indwelling prosthesis was developed at the Department of Otolaryngology of the Netherlands Cancer Institute. We have used Blom-Singer low pressure prosthesis and Provox prostheses in our patients with the aim of evaluating their efficacy in terms of successful vocal rehabilitation.

Material and Methods

Fifteen patients who underwent total laryngectomy from 1996 to 1997 with or without partial pharyngectomy and primary closure with primary TEP at Tata Memorial Hospital (TMH), Mumbai were included in this study. Twenty six patients who underwent total laryngectomy from 1998 to 2003 with or without partial pharyngectomy and primary/secondary TEP at Malignant Diseases Treatment Centre (MDTC) of Command Hospital, Pune were also included in this study. There were 41 (39 males and two females) patients in our study. All patients had stage III/IV disease of which 24 patients had laryngeal and 17 pyriform fossa cancers. Salvage surgery for radiation failure was done in four patients. Postoperative radiation therapy was given to 35 patients. Mean age was 48 years (range 25 to 68 years). Of the 41 patients 30 underwent primary TEP (15 at TMH, Mumbai and 15 at MDTC, Pune). Blom-Singer low-pressure prosthesis was fitted in 20 patients (Group 1) and Provox valve in 21 patients (Group II). In 15 patients pharyngeal neurectomy and in 24 crico-pharyngeal myotomy was done during total laryngectomy to reduce the hypertonicity of the Pharyngo-esophageal (P-E) segment. Two patients, who were referred from other institutions for TEP, did not have pharyngeal neurectomy or crico-pharyngeal myotomy done. Assessment of speech following insertion of prosthesis was done after three months on a scoring scale of 0-3 (Table 1). The score given for failure of development of speech was 0; development of speech but short sentences only (<5 words in one breath) was given a score of 1, development of speech with long sentences i.e. 10 or more words, had a score of 2, fluency of speech with good quality had a score of 3. All patients received adequate speech therapy (three weeks) for development of TEP speech.

Results

There was no post-operative mortality. Prosthesis related complications in Group 1 patients were, leak around the

prosthesis in five (25%) cases, granuloma formation around prosthesis in three (15%), dislodgment of prosthesis and persistent tracheo-esophageal fistula in two (10%), creation of false passage while re-insertion of prosthesis by the patient in one (5%), candida growth in 10 (50%) and an early decay of prosthesis (i.e. within 3 months of TEP) (Fig 1) due to poor maintenance in five (25%) cases (Table 2). In the patients with Provox valve system (Group II), the only problem encountered was leak through or around the prosthesis in 18 (85.7%) due to candida growth on the outer aspect of the prosthesis i.e. tracheo-stomal part in six patients and on the inner aspect of the valve i.e. in oesophageal pharyngeal part in 12 patients, which was demonstrated endoscopically. In all patients successful treatment with application of antifungal lotion on stomal part of the prosthesis and oral antifungal

Fig. 1 : A-shows Blom Singer prosthesis in situ, B-shows Blom Singer prosthesis on left and provox valve on right, C-shows early decay of Blom Singer prosthesis due to improper care and fungal infection, D-shows Blom Singer prosthesis in false track

Table 2

Complications of different prostheses (n=41)

Type of prosthesis	Complications	Number of cases (%)
Blom-Singer (n=20)		
Immediate	Haematoma	1(5)
	Wound infection	2(10)
Delayed	Leak around prosthesis	5(25)
	Granuloma around prosthesis	3(15)
	Dislodgement of prosthesis & persistent T-E fistula	2(10)
	False passage creation while re-insertion by the patient	1(5)
	Candida growth	10(50)
	Early decay of < 3 months prosthesis i.e. due to poor maintenance	2(10)
Provox (n=21)		
	Temp leak through prosthesis due to candida growth	18(85.7)

Table 1

Speech assessment score

Proficiency of speech	Speech score
Failure of development of speech	0
Development of speech but short sentences only <5 words	1
Development of speech with long sentences	2
Fluency of speech with good quality	3

Table 3**Speech assessment with different prostheses (n=41)**

Type of prosthesis	Speech score			
	0 (%)	1 (%)	2 (%)	3 (%)
Blom-Singer prosthesis (n=20)	1 (5)	5 (25)	14 (70)	0
Provox valve (n=21)	0	0	6 (28.6)	15 (71.4)

solution was carried out and the leaks subsided. During follow-up of about 6 to 18 months, no other complications were noticed. The average life of the Blom-Singer removable prostheses was 3 months and 15 months for the Provox indwelling prostheses.

Speech assessment after three months of fitting Blom-Singer prosthesis (20 patients) showed a speech score of 0 in one (5%) patient, 1 in five (20%) patients and 2 in fourteen (70%) patients. The speech score in patients fitted with Provox valve was found to be 2 in six (28.6%) patients and 3 in fifteen (71.4%) patients (Table 3).

Discussion

Total laryngectomy creates a major communication problem, which can result in disruption of the patient's normal pattern of social interaction [4]. It is for this reason that voice rehabilitation of laryngectomised patients has been the focus of research. Surgical approaches to voice restoration have undergone an evolution over the past two decades. In contrast to the wide range of success rates reported on voice rehabilitation with esophageal speech (between 14% and 76%), results of prosthetic voice rehabilitation are strikingly uniform, achieving a success rates of 80% or higher [3]. A small minority of esophageal speakers have an adequate voice, whereas the majority of prosthetic speakers do well. With respect to voice quality, pitch, loudness, intelligibility, rate of speaking, visual presentation during speech, extraneous speaking noise and overall communicative effectiveness, tracheo-esophageal speech appears to be superior to esophageal voice [5]. Therefore prosthetic voice rehabilitation of laryngectomised patients is the method of choice.

Many prostheses for voice rehabilitation, such as the Blom-Singer prostheses, the Panje buttons, the Gronningen button and the Provox prostheses are available. The major difference between the Blom-Singer and Panje devices, on one hand and the Gronningen and Provox prostheses on the other, is the role of the patient in prosthesis replacement. The Blom-Singer and Panje devices need to be taken out by the patient himself for cleaning and re-insertion thereafter, whereas the Gronningen and Provox valves are indwelling and need not be taken out for cleaning. The latter feature ensures better patient compliance and maintenance and is

probably the reason for the absence of certain complications such as dislodgement of prosthesis or creation of false passage. The complications with the Blom-Singer prostheses in our series were higher than those of the Provox valve, because most of our patients were from rural backgrounds with low literacy rates. In spite of training for the maintenance of the prosthesis, they did not do so, as they were afraid of taking out the prosthesis and re-insertion, leading to candida growth, early decay of prosthesis and its malfunction. However, patients fitted with the Provox valve found it easier to maintain the valve by cleaning with the brush provided. The granuloma formation around the Blom-Singer prosthesis occurs due to ill-fitting prosthesis. The failure of voice production in one case in our series where Blom-Singer prosthesis was used could possibly be attributed to lack of cricopharyngeal myotomy/pharyngeal neurectomy.

In vitro and in vivo aerodynamic characteristics study has shown that the Provox prostheses have favourable air flow characteristics [6]. This explains the good quality and effortless speech observed in patients fitted with Provox valve vis-à-vis those with Blom-Singer prostheses. Another factor which could be the reason for production of good quality speech in Provox prostheses is the internal diameter of the shaft which is 5mm as compared to 3.5 mm internal diameter of Blom-Singer prosthesis (16Fr), which helps in greater amount of air flow across the device for speech production. Yamada H et al [7], assessed the performance of Provox voice rehabilitation in 15 patients fitted with Provox and found that 13 patients developed very good speech with maximum phonation time of more than 10 minutes. In one patient the prosthesis was removed due to stomal stenosis and in another there was failure in development of speech due to oesophageal stenosis. Cornu AS et al [8], published their experience with Provox in 104 patients and showed that mean device life was 303 days. Voice quality was assessed subjectively in 104 patients and objectively in 26 patients. Subjectively, 77 of 104 patients had a good voice, and objectively 22 of 26 patients had good voice intelligibility. Op de Coul BM et al [9], in their study of assessment of long-term results of Provox in a large series of 318 patients and 2700 prosthesis replacement at Netherlands Cancer Institute, Amsterdam, showed that the consistent use of indwelling voice prostheses shows a high success rate of prosthetic vocal rehabilitation, in terms of the percentage of long-term users (95%), and of a fair to excellent voice quality (88% of patients). Tisch M et al [10], carried out quality of life survey on 52 patients who underwent total laryngectomy, using EORTC questionnaire. They found that as many as 52.8% expressed themselves satisfied

with their current life, which is perhaps attributable to the successful rehabilitation of their voice.

The life of a Provox valve is comparatively longer than that of a Blom-Singer prosthesis [3], though the Blom-Singer prosthesis is less expensive. In the long run, the Provox valve is more cost-effective. Lequeux T et al [11], in their study of survival life time of Provox found that the mean survival period was 303 days. Schafer P et al [12], assessed survival time of 378 Provox-1, Provox-2 and Blom-Singer Voice Prosthesis provided to 58 patients and found that average survival lifetime of the prosthesis was 224 days for Provox-1, 96 for Provox-2 and 107 for Blom-Singer respectively. The survival time of Provox-1 prosthesis is significantly longer.

Hilgers et al [13], developed voice prosthesis with a new valve mechanism, applying candida resistant fluoroplastic (Teflon-like) material for the valve and valve seat. Magnets have been used to generate an active closing force, preventing inadvertent opening of the valve during swallowing or deep inhalation. The life span of the prosthesis has also increased significantly i.e. 14-fold increase on an average (range 3-39 fold); $p < 0.001$. This new voice prosthesis, the Provox Acti Valve, represents a solution for patients who have the problem of requiring very frequent voice prosthesis replacements due to excessive candida growth and/or inadvertent opening of the valve by swallowing.

We conclude that although the cost of the Provox valve is an hindrance, it is superior to the Blom-Singer prosthesis because of low complications rate, longer life of the prosthesis and better compliance in patients.

Conflicts of Interest

None identified

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