Long-term Performance of Indwelling Tracheoesophageal Speaking Valves in Chinese Patients Undergoing Laryngectomy

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Objectives: To assess the use of indwelling tracheoesophageal speaking valves in Chinese patients undergoing laryngectomy, to identify the clinicopathologic factors for favorable outcome, and to evaluate the factors that determine prosthesis lifetime.

Design: Retrospective review.

Setting: Tertiary care institution.

Patients: Sixty consecutive patients with total laryngectomy were included. All had indwelling tracheoesophageal speaking valves for voice restoration.

Intervention: Anterograde replacement of voice prosthesis in case of failure of functional speech production or leakage of saliva.

Main Outcome Measures: Incidence of successful tracheoesophageal speech rehabilitation for daily communication, influence of different clinicopathologic factors on the outcome, and prosthesis lifetime and its relationship to different clinicopathologic factors.

Results: The success rate of speech rehabilitation was 78%. Age younger than 60 years was the only clinicopathologic factor associated with successful speech rehabilitation ($P = .04$, Fisher exact test). The median device lifetime was 8.2 months. Both age of 60 years or older and the use of subsequent prosthetic valves were identified as risk factors for valve failure on univariate analysis ($n = 192$; log-rank test; $P = .02$ and $P = .03$, respectively), with age of 60 years or older as the only risk factor that reduced the device lifetime in the Cox proportional hazards model ($P = .03$; relative hazard ratio, 1.5; 95% confidence interval, 1.1-2.4).

Conclusions: Our success rate in using indwelling tracheoesophageal speaking valves was comparable to that reported in the Western literature. The median device lifetime of 8.2 months was satisfactory. Patient age was found to be a significant predictor of successful tracheoesophageal speech rehabilitation, with age of 60 years or more adversely affecting device lifetime.


In the mid-20th century, a few reconstructive methods were proposed to achieve a pulmonary-supported alaryngeal voice following total laryngectomy. In 1978, Singer and Blom described the method of tracheoesophageal puncture (TEP) and used the silicone prosthetic valved device as a voice prosthesis. This has become the standard for voice reconstruction in alaryngeal patients. The advantage of TEP speech over esophageal and electrolarynx speech is that the lungs are once more acting as a driving source for the voice. Thus, patients can achieve louder speech with longer sustained phonation.

Tracheoesophageal puncture appears to be a simple operative technique for alaryngeal voice restoration, but otolaryngologists and head and neck surgeons have also recognized that prosthetic valves might develop complications that pose a challenging management problem. Successful speech rehabilitation depends on seamless collaboration between speech pathologists and physicians. Possession of sufficient knowledge, training, and accrued experience in speech rehabilitation contributes to successful outcome.

To date, all published scientific evidence that describes the experience of using indwelling prosthetic valves for alaryngeal speech rehabilitation has been gained from white patients. For Asian alaryngeal patients, the success of acquiring a useful indwelling prosthetic voice with
Sixty consecutive Chinese patients who underwent total laryngectomy between 1999 and 2004 were included in the study. They all underwent the insertion of tracheoesophageal speaking valves for voice restoration. Fifty-eight patients had primary TEP during tumor extirpation, and only 2 patients had secondary TEP for voice restoration. The demographic factors are given in Table 1. There were 56 men (93%) and 4 women (7%). Their ages ranged from 40 to 92 years (mean, 65.8 years). The primary diseases were laryngeal carcinoma in 41 patients (68%), hypopharyngeal carcinoma in 16 (27%), oropharyngeal carcinoma in 2 patients (3%), and carcinoma of the tongue base in 1 patient (2%). According to the American Joint Committee on Cancer/Union Internationale Contre le Cancer staging system, there were 4 patients (7%) with stage I disease, 4 (7%) with stage II disease, 21 (35%) with stage III disease, and 31 (52%) with stage IV disease. The tumor statuses were T1 in 6 patients (10%), T2 in 8 patients (13%), T3 in 25 patients (42%), and T4 in 21 patients (35%), whereas the nodal statuses were N0 in 36 patients (60%), N1 in 4 patients (7%), N2 in 17 patients (28%), and N3 in 3 patients (5%). None of the patients had any distant metastasis.

Preoperative radiotherapy for definitive treatment was given in 22 patients (37%), whereas 36 patients (60%) received postoperative irradiation. Two patients had surgery only as the definitive treatment without any radiotherapy.

Patients with laryngeal or hypopharyngeal carcinoma, either too advanced for radiotherapy or recurrent after irradiation, were treated by total laryngectomy based on our institutional protocol and patients’ consent. Patients with extensive carcinoma of the tongue base or oropharynx underwent total laryngectomy together with primary tumor extirpation to achieve safe oncologic clearance.

For the 43 patients who underwent total laryngectomy, with or without partial pharyngectomy, the TEP was constructed following completion of tumor extirpation. To obviate the problem of pharyngoesophageal spasm, cricopharyngeal myotomy was performed for all 43 patients. In the other 14 patients with more extensive pharyngeal resection for tumor eradication, the pharynx was reconstructed with a pectoralis major myocutaneous flap as an onlay patch. In the remaining 3 patients with circumferential pharyngectomy, the pharynx was reconstructed with a free jejunal graft to restore the neopharyngeal conduit. The voice prosthesis was inserted through the esophageal remnant. Among the 60 patients, 26 patients underwent simultaneous radical neck dissection, and 1 had deltopectoralis flap coverage for a neck defect after removal of neck skin for oncologic purposes.

When the patients developed prosthesis-related complications, such as prosthetic valve leakage or failure of functional speech production resulting from valve blockage, the defective prosthetic valves were removed by pulling the device out of the tracheoesophageal fistula, and an interstage replacement of the voice prosthesis was performed in the same session. A total of 203 prosthetic valves were used for these 60 patients during this period. The prostheses used in this study included 192 Provox II prostheses (Atos Medical AB, Horby, Sweden) (95%) and 7 indwelling Blom-Singer prostheses (Inhealth Technologies, Carpinteria, Calif) (3%). The other 4 prosthetic valves (2%) were 3 non-indwelling Duckbill prostheses (Bivona Medical Technologies, Inc, Gary, Ind) and 1 VoiceMaster prosthesis (Entermed International Ltd, Woerden, the Netherlands). Closure of tracheoesophageal fistula due to various reasons, including persistent tracheoesophageal fistula leakage or prosthesis extrusion, was recorded.

For all users of TEP speaking valves, the quality of tracheoesophageal speech was retrospectively assessed by otorhinolaryngologists and speech pathologists. Tracheoesophageal speech was regarded as functionally successful if patients could produce fluent and intelligible Cantonese, and it was used as the chief mode of communication during face-to-face interview and telephone conversation. Information from the initial endoscopic reports, the findings of the imaging studies (ultrasonography, computed tomography, and magnetic resonance imaging), the operation records, and the pathology reports were used to assess the tumor site and tumor staging. The correlation between successful speech rehabilitation with different clinicopathologic factors (age, tumor site, tumor staging, extent of surgical resection, reconstruction, neck dissection, and radiotherapy) were analyzed using the χ² test or Fisher exact test.

Prosthetic valve life duration curves were estimated with the Kaplan-Meier method and compared with the log-rank test. In the calculations of the lifetime of the prosthetic valves, the period between the date of insertion and the date of removal of the voice prosthesis was used. The prosthesis was replaced when the prosthetic valve failed to aid the production of functional speech or there was leakage through the valve. Only the indwelling prosthetic valves were used for device lifetime analysis. The 3 non-indwelling Duckbill prosthetic valves were excluded. A Cox proportional hazards model, using a forward variable selection technique (entry, P<.05; removal, P>.10), was used to identify the independently predictive variables of prosthetic valve failure. All statistical analysis was performed using SPSS statistical software, version 12.0 (SPSS Inc, Chicago, Ill).
The median follow-up time among the 60 patients was 29 months (range, 2-60 months). Eighteen patients (30%) died of locoregional failure or distant metastasis. The mean disease-free survival time was 45.6 months (95% confidence interval, 40.1-51.0 months).

Forty-seven patients (78%) achieved success of TEP speech rehabilitation when assessed within 1 month after operation. The success rate was 77% (33 of 43 patients) in the group with total laryngectomy and direct pharyngeal closure, 79% (11 of 14 patients) for those with pectoralis major flap reconstruction, and 100% (3 of 3 patients) in the group with free jejunal repair. Among patients who had unsuccessful TEP speech, a physical cause could be identified in 8 patients: chronic obstructive pulmonary disease and ineffective respiratory support in 2 patients, tracheostomal stenosis in 2 patients, a large tracheostoma that led to incompetent digital occlusion in another 2 patients, and poor general conditions and impaired hand-eye coordination in the remaining 2 patients. In the other 5 patients, no obvious physical cause was identified to account for the failure. Seven of the 13 patients who failed TEP speech used an alternative method for speech rehabilitation, including an electrolarynx in 6 patients and a pneumatic speaking valve in 1 patient. In the remaining 6 patients, all modalities of speech rehabilitation failed, and these patients relied on writing as the sole method of communication.

Among the 47 patients who had successful tracheoesophageal speech immediately after surgery, 8 patients developed delayed problems. These problems included persistent tracheoesophageal fistula leakage in 3 patients and frequent prosthetic valve changes in 1 patient, all of whom subsequently had their tracheoesophageal fistula closed surgically. Extrusion of prosthetic valves that led to spontaneous closure of tracheoesophageal fistula occurred in 2 patients. Both of these patients had subsequent puncture of the tracheoesophageal fistula and reinsetion of the prosthesis. Parastomal tumor recurrence developed in 2 patients, which led to the removal of voice prosthesis.

The outcome of TEP speech rehabilitation is given in Table 2. The success rate of tracheoesophageal vocal restoration was significantly higher in patients younger than 60 years (P = .04; Fisher exact test). No significant difference in the success rate was detected in relation to primary disease (P > .99; Fisher exact test), primary resection (P > .99; Fisher exact test), reconstruction (P = .74; Fisher exact test), neck dissection (P = .39; χ² test), and radiotherapy before or after surgery (P = .18; Fisher's exact test). Comparison among different types of indwelling voice prostheses was not performed because most voice prostheses used were the Provox II and the number of other indwelling prosthetic valves was too small for evaluation.

The median device lifetime for the entire group of successful indwelling prosthetic speech rehabilitation was 8.2 months. The median device lifetime was 9.2 months for patients younger than 60 years and 6.5 months for patients 60 years or older. There was a significant difference between these 2 groups of patients (P = .02; log-rank test). The median device lifetimes were significantly different between the first prosthetic valves and all subsequent prosthetic valves (P = .03; log-rank test). The first prosthetic valves had a median device lifetime of 9.0 months, which was longer than subsequent prosthetic valves, with a median device lifetime of 6.5 months. No significant difference in device lifetime was associated with the primary disease (P = .75; log-rank test), primary resection (P = .55; log-rank test), reconstruction (P = .53; log-rank test), neck dissection (P = .14; log-rank test), and radiotherapy before or after surgery (P = .80; log-rank test). Ap-

### Table 2. Clinicopathologic Factors and Functional Outcome of Tracheoesophageal Puncture Speech Rehabilitation

<table>
<thead>
<tr>
<th>Factor</th>
<th>No. (%) of Patients</th>
<th>Speech Outcome</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;60</td>
<td>19 (32)</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>⩾60</td>
<td>41 (68)</td>
<td>29</td>
<td>12</td>
</tr>
<tr>
<td>Primary carcinoma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Larynx</td>
<td>41 (68)</td>
<td>31</td>
<td>9</td>
</tr>
<tr>
<td>Hypopharynx</td>
<td>16 (27)</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Resection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TL only</td>
<td>39 (65)</td>
<td>30</td>
<td>9</td>
</tr>
<tr>
<td>TL, PP/CP, and tongue base resection</td>
<td>21 (35)</td>
<td>17</td>
<td>4</td>
</tr>
<tr>
<td>Reconstruction</td>
<td></td>
<td></td>
<td>.74</td>
</tr>
<tr>
<td>Yes</td>
<td>43 (72)</td>
<td>33</td>
<td>10</td>
</tr>
<tr>
<td>No</td>
<td>17 (28)</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Neck dissection</td>
<td></td>
<td></td>
<td>.18</td>
</tr>
<tr>
<td>Yes</td>
<td>26 (43)</td>
<td>19</td>
<td>7</td>
</tr>
<tr>
<td>No</td>
<td>34 (57)</td>
<td>28</td>
<td>6</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>21 (35)</td>
<td>18</td>
<td>3</td>
</tr>
<tr>
<td>Postoperative</td>
<td>37 (62)</td>
<td>27</td>
<td>10</td>
</tr>
</tbody>
</table>

Abbreviations: CP, circumferential pharyngectomy; PP, partial pharyngectomy; TEP, tracheoesophageal puncture; TL, total laryngectomy.

*All P values were determined using the Fisher exact test, with the exception of that for neck dissection, which was determined using the χ² test.
plying the Cox proportional hazards model, age of 60 years or older was identified as the only significant predictor of prosthetic valve failure (P = .03; relative hazard ratio, 1.5; 95% confidence interval, 1.1-2.4).

**COMMENT**

Although total laryngectomy is effective in removing the primary carcinoma, the subsequent inability of verbal communication has a profound impact on the quality of life and psychosocial aspect of a patient. Since the introduction of TEP by Singer and Blom, many rapid reestablishment of an acceptable voice with prosthetic valves can be accomplished in contrast to other methods of vocal rehabilitation, such as electrolarynx and esophageal speech. Although a handheld electrolarynx can provide most patients undergoing laryngectomy with an adequate voice, the mechanical quality of the voice and the necessity for manual operation limit its communicative effectiveness. Although esophageal speech is hazard-free, the driving force is weak and only a small percentage of patients undergoing laryngectomy can successfully achieve this communication technique; even when successful, many of them are not comparable to preoperative communication parameters. Tracheoesophageal puncture speech with pulmonary support provides patients with a louder voice, a longer phonation period, and better intelligibility. It also has greater tonal variation than the electrolarynx, which is important in the Chinese tonal language (eg, Cantonese).

To date, to our knowledge no studies have reported on indwelling prosthetic valves for vocal rehabilitation after total laryngectomy in the tonal language population. Our overall success rate of 78% with the TEP speech was in accordance with most other reports. Of particular note is that TEP speech could be achieved with 77% to 100% success in our patients with laryngeal and hypopharyngeal carcinoma, necessitating pectoralis major myocutaneous flap reconstruction and free jejunal graft repair following tumor extirpation. It was found that the neopharynx served well both as a resonating box for speech production and as a conduit for food passage. In 1994, Omori et al reported stroboscopic evidence of undulating regular movements observed in the neoglottis. Another report on 46 patients undergoing laryngectomy with their pharynx either repaired primarily or reconstructed with myocutaneous pectoralis major flap, free radial forearm flap, or gastric pull-up also showed successful recordings of neoglottic vibration obtained by high-speed digital imaging in 44 patients. Parise et al reported successful vocal rehabilitation with primary puncture in a patient with total pharyngolaryngoesophagectomy and transposed colon reconstruction.

Our previous study showed that 79 (52%) of 153 patients acquired functional Cantonese tracheoesophageal speech using a nonindwelling Duckbill prosthetic valve after total laryngectomy for voice rehabilitation. In the present study, the success rate of vocal rehabilitation with indwelling prosthetic valves was higher than our previous study. The non-indwelling device has to be changed and cleansed regularly by the patient, whereas the indwelling prosthetic valve is self-retaining. The latter is also easier to maintain by the patient and has a wider lumen; thus, air can travel through this low-resistance voice prosthesis with ease. All of these factors contribute to a high success rate.

We found that age younger than 60 years was associated with a higher success rate of TEP speech rehabilitation. The relatively poor dexterity and hand-eye coordination in elderly patients and the reduced vital capacity of lung function probably contributed to the limited use of TEP speech in the older age group. Hilgers and Balm found that age had no effect on the intelligibility achieved, and in the group older than 80 years, 92% of patients had a good or fair voice. However, an important phonatory characteristic of the Chinese dialects is their tonal variation. The Cantonese language is made up of 6 contrastive tones according to the different pattern of variation of the fundamental frequency within a single word. The 6 Cantonese tones are T1 (high level), T2 (high rising), T3 (midlevel), T4 (low falling), T5 (low rising), and T6 (low level). Each tone possesses a unique meaning, although the word is segmentally identical. For example, the word ma can mean “mother,” “measles,” a question intonation, “grandmother,” “horse,” or “reprimand,” depending on the tone produced. Therefore, correct production of tone is crucial for effective verbal communication when using the Chinese dialects. Gandour et al reported difficulties in controlling lexical tone among native Thai patients who underwent laryngectomy. The present study showed that patients younger than 60 years could vary their tone more efficiently and thus produce better tonal language. The age of 60 years was selected as the optimal cutoff point after examining several different values. The relative hazard of valve failure was greatest in this age group, and it represented a clinically relevant value. Although the success rate of prosthetic valve rehabilitation can be increased by patient selection (ie, not to include those elderly patients with impaired hand-eye coordination, poor motivation, and chronic obstructive pulmonary disease), we still do not consider chronological age to be the only factor. Since assessment of learning capacity can be subtle, we consider that age is not a contraindication for TEP speech rehabilitation and is still worthwhile to offer freely to elderly patients without any significant physical disabilities and at the same time accept a lower than optimal success rate.

In our present study, satisfactory use of prosthetic valves had no relationship with the modality of resection and reconstruction, including pectoralis major myocutaneous flap and free jejunal repair. Mendelson et al found that the subjective and objective speech intelligibility, acceptability, and intonation scores were higher in the laryngectomy group with primary closure compared with the laryngopharyngeal group with free jejunal flap. In the case of a circumferential pharyngectomy defect of the hypopharynx, we still advocate free jejunal flap as our reconstructive method of choice and use the tubed pectoralis major flap repair when a free jejunal flap is not applicable. We observed successful vocal rehabilitation without excessive “wet” voice in all 3 patients...
in whom a circumferential pharyngectomy defect was reconstructed with a free jejunal graft.

Our overall median indwelling prosthetic device lifetime of 8.2 months is longer than those reported in other series. Forty-eight percent of patients had a valve that survived longer than 6 months in our series. This may be a result of differences in dietary habits, body build, genetic factors, and the prevalence of gastroesophageal reflux disease. Wong and Wong\(^\text{17}\) stated that the incidence of esophageal motility disorder is low in the Chinese population compared with the Western population. In theory, the food in the esophagus should be propelled efficiently to the stomach without much residue left behind when the esophageal motility is functioning properly. Therefore, less stasis of food residue around the prosthetic valves with less candida colonizing around the silicone material may lead to longer device lifetime.

Five (10%) of the 47 patients who had immediate success of TEP speech rehabilitation developed fistula-related complications subsequently. Three patients needed surgical closure of TEP and thus switched to other modalities of speech rehabilitation. Two of them with spontaneous fistula closure after prosthesis extrusion received subsequent puncture and reinsertion of speaking valves. We found that an age of 60 years or older was associated with a shorter device lifetime on both univariate and multivariate analyses. This finding is probably due to poor dexterity and motivation in using and cleansing the prosthetic valves. We also found that the first prosthetic valves last longer than all other subsequent prosthetic valves on the univariate analysis. However, the study by de Carpentier et al\(^\text{18}\) showed that the device lifetime of the first valve was adversely affected by previous radiotherapy. This was suggested to be related to poor healing of the tracheoesophageal fistula in the tissues compromised by radiotherapy. We speculate that the different results of our study may be due to a different definition of valve failure. In that study, valve failure was defined as salivary leakage through or around the valve or the inability to produce effective speech using the valve, necessitating valve replacement.\(^\text{18}\) Our definition of valve failure was mechanical dysfunction of the prosthetic valve leading either to leakage through the valve or failure to produce effective, intelligible speech. Although we also identified that subsequent prostheses had shorter device lifetime on univariate analysis, this observation was refuted by the Cox regression analysis. We speculate that when patients age, their dexterity deteriorates and thus they encounter difficulties in cleansing and maintaining the prosthetic valves.

Our success rate of 78% in TEP speech rehabilitation with indwelling prosthetic valves was comparable to the success rates reported in the literature. The median device lifetime of 8.2 months was also satisfactory. Patient age was found to be a significant predictor of successful TEP speech rehabilitation and device lifetime; age of 60 years or older shortened the lifetime of the prostheses. Therefore, in Chinese laryngeal patients, careful screening of elderly patients is essential for a satisfactory outcome of TEP rehabilitation.

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