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Outcomes and Adverse Events of Enlarged Tracheoesophageal Puncture after Total Laryngectomy

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Abstract

Objective—Enlargement of the tracheoesophageal puncture (TEP) results in aspiration around the voice prosthesis (VP) and may lead to pneumonia. The primary objective was to summarize control of leakage around the VP after conservative management of enlarged TEP.

Study Design—Retrospective cohort study.

Methods—This 5-year cohort included 194 patients who underwent total laryngectomy ($\pm$ pharyngectomy) and TEP at the University of Texas MD Anderson Cancer Center. Control of leakage around the VP was analyzed at last follow-up after enlarged TEP. Adverse events were compared in patients with and without enlarged TEP.

Results—The incidence of enlarged TEP was 18.6% (36/194, 95% CI: 13.0%-24.1%). Conservative methods commonly attempted in lieu of complete TEP closure included placement of an enlarged-flange VP (34/36, 94%), temporary VP removal (14/36, 39%), and TEP-site injection (8/36, 22%). At last follow-up, conservative methods controlled leakage around the VP in 81% (29/36) of patients. Only 2 patients required complete TEP closure due to persistent leakage after enlarged TEP. Unresolved leakage was more common in patients with recurrent cancer after laryngectomy ($p=0.081$) and irregular TEP contour ($p=0.003$). Relative to controls without TEP enlargement, patients with enlarged TEP had 3-fold higher risk of pneumonia (RR: 3.4, 95% CI: 1.9-6.2) and aspiration of the prosthesis (RR: 3.3, 95% CI: 0.8-14.1).

Conclusions—Although the rate of enlarged TEP is relatively low, the complication significantly elevates risk of pneumonia. Prosthetic leakage related to TEP enlargement can often be managed conservatively to avoid complete closure of the TEP.

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tracheoesophageal puncture; total laryngectomy; enlarged tracheoesophageal puncture; risk factors

INTRODUCTION

Tracheoesophageal puncture (TEP) is considered the gold-standard for alaryngeal voice restoration after total laryngectomy. Tracheoesophageal (TE) voice restoration has been widely adopted over the last three decades because it provides superior voice outcomes relative to other modes of alaryngeal communication.¹⁻⁴ However, TEP is not without risk as it requires creation of a controlled TE fistula. Enlargement of the TE fistula is a major complication of surgical prosthetic voice restoration that, among other consequences, results in aspiration around the voice prosthesis (VP). Recurrent aspiration of saliva, liquids, and/or foods around the VP likely increases the risk of pneumonia. Enlarged TEP may also result in dislodgment of the VP and possible tracheal aspiration of the prosthesis. Although associations between enlarged TEP and these adverse events have been suggested, a recent systematic review found little published data on the consequences of enlarged TEP.⁵

Therapeutic interventions for enlarged TEP aim to eliminate leakage around the voice prosthesis. Therapeutic interventions can be conceptualized in two categories: 1) complete TEP site closure, and 2) conservative management. Complete closure of the TEP may be accomplished surgically or non-surgically and is typically reported in less than 20% of cases.⁶⁻¹² Complete closure of the TEP eliminates leakage, but also precludes the ability to communicate using TE voice. For this reason, a variety of conservative treatment methods have been proposed as an alternative to complete TEP closure in an effort to eliminate leakage around the voice prosthesis but maintain functional TE voice. Our published systematic review⁵ found that most conservative methods are non-surgical and include temporary removal^{9, 13-16} or modification of the prosthesis,^{17, 18} TEP-site injection,^{7, 11, 15, 19-23} and cautery.^{6, 10, 13} Placement of a surgical purse-string suture around the TEP has also been reported as a conservative method aimed at facilitating stenosis of the TEP.^{7, 8, 14} Current literature suggests that a variety of treatments are used in clinical practice, and that conservative methods often provide only transient relief of leakage around the VP.⁵ For this reason, studies that seek to evaluate management of enlarged puncture must consider long-term outcomes. The primary objective of this study was to evaluate control of leakage around the VP in patients with enlarged TEP at last follow-up after conservative treatment. We also sought to describe the time to complication, physical characteristics of enlarged TEP, functional outcomes, and adverse event rates.

METHODS

Study Design and Inclusion/Exclusion Criteria

A retrospective cohort study was conducted. All patients who underwent TEP for voice restoration after total laryngectomy at The University of Texas MD Anderson Cancer Center (MDACC) between May, 2003 and December, 2008 were eligible for inclusion in the study.

Patients whose surgical resection and/or TEP were performed at an outside institution and those with less than 3-months follow-up post-TEP were excluded. Two hundred thirty-seven eligible patients were identified by a search of the MD Anderson Cancer Center TEP Tracking Database. Forty-three patients were excluded, 25 whose resection and/or TEP was performed at an outside facility, 17 who had less than 3-months follow-up, and 1 whose voice prosthesis was placed in a persistent postoperative fistula rather than a surgically created TE fistula. Therefore, 194 patients were included in this analysis. Institutional review board approval and a waiver of informed consent were obtained.

Institutional TEP Management

Both primary and secondary TEP are performed at MDACC. A red rubber catheter (12-14-French) is used to stent the TEP in the immediate postoperative setting. A VP is first placed 7-10 days postoperatively after primary TEP and 3-5 days postoperatively after secondary TEP. Standard practice is to dilate the TE tract to 18-French and insert a 16- or 17-French prosthesis on the date of initial prosthetic fitting. A variety of indwelling and non-indwelling TE voice prostheses are used within the institution (InHealth Technologies, Carpinteria, CA; Atos Medical, Hörby, Sweden).

Data Collection

Data sources for this study included the MDACC TEP Tracking Database and retrospective review of the electronic medical record. Prosthetic variables and leakage patterns were captured prospectively in the TEP Tracking Database. An enlarged TEP was defined by leakage around the VP unresponsive to standard prosthetic management. This included leakage around the VP that was not resolved by replacement of a standard prosthesis or downsizing the length of the VP, or that required placement of a VP with an enlarged flange. Leakage patterns were observed by direct visualization of the TEP during liquid swallows and were prospectively documented and recorded by the speech pathologist in the TEP Tracking Database and medical record. Diagnosis and outcomes of enlarged TEP were confirmed by two reviewers (KAH, JSL). Conservative management was defined as any surgical or non-surgical intervention used to eliminate leakage around the voice prosthesis without complete closure of the TEP. These included, but were not limited to, temporary removal or modification of the prosthesis, TEP-site injection, TEP-site cautery, and thickening liquids. Complete closure of the TEP site was also recorded. Surgical closure was accomplished by a local mucosal advancement flap or pedicled pectoralis major myocutaneous flap reconstruction. Non-surgical closure was accomplished by removal of the VP or stenting catheter to allow for spontaneous closure of the TEP. Complete closure of the TEP site (surgical or non-surgical) was not considered a conservative management technique. Leakage outcomes were assessed at last follow-up, prior to complete TEP closure, if applicable. Two leakage outcomes were assessed: 1) control of leakage around the VP using conservative treatment methods, and 2) the ability to return to use of a standard voice prosthesis without leakage around the VP. A standard VP was defined as one that did not have an enlarged esophageal or tracheal flange.

Time to enlarged TEP was calculated from the date of the TEP procedure to date of enlargement. Physical characteristics of the enlarged TEP were also recorded and included:

length of the TE tract as measured by length of the VP, visible irregularity in TEP site contour or shape (e.g., oblong or divot), and TEP site granulation tissue. Functional outcomes were recorded as use of the TEP for primary communication prior to and after enlarged TEP, and the need for enteral feeding due to leakage around the VP after enlarged TEP. Adverse events were defined as postoperative pneumonia confirmed radiographically (>1 month post-laryngectomy), VP dislodgement, and aspiration of the VP. Adverse events were recorded for all patients with and without enlarged TEP. Postoperative stricture confirmed by endoscopic or fluoroscopic examination; and a diagnosis of locoregional recurrence, distant metastatic carcinoma, or new primary cancer after total laryngectomy were also captured. These 2 postoperative variables have been found to significantly relate to enlarged TEP and were considered as possible correlates of leakage outcomes.²⁴

Statistical Methods

Descriptive statistics were calculated to summarize time to presentation, physical characteristics, leakage outcomes, functional outcomes, and adverse events related to enlarged TEP. Statistical associations between the 2 categorical leakage outcomes and physical characteristics of enlarged TEP, time to enlarged TEP, postoperative stricture, and recurrent cancer after laryngectomy were analyzed using Fisher's exact test. Unadjusted relative risk (RR) ratios and 95% confidence intervals were estimated for adverse events including pneumonia, VP dislodgement, and tracheal aspiration of the VP in patients with enlarged TEP relative to TEP controls without enlargement. Statistical significance was considered α -level 0.05. Statistical analyses were performed using the STATA data analysis statistical software, version 10.0 (StataCorp LP, College Station, TX).

RESULTS

Population Characteristics

Thirty-six of 194 patients developed an enlarged TEP during the study period with an incidence of 18.6% (95% CI: 13.0%-24.1%). Table I summarizes demographic, disease, and treatment characteristics of the population. A detailed description of this cohort has been described previously.²⁴ Among the 36 patients who developed an enlarged TEP, 50% were diagnosed with locoregional recurrence (8/36, 22%), distant metastatic disease (8/36, 22%), or new primary cancer (2/36, 6%) after laryngectomy. Only 2 of these patients developed enlarged TEP related to local recurrence near the TEP site. Fifty percent (18/36) were living disease-free at last follow-up, 17% (6/36) were living with disease, 28% (10/36) were dead of disease, and 6% (2/36) died of other causes. Mean length of follow-up was 31 months (sd: 20, range: 3-72) post-TEP, and 16 months (sd: 15, range: 1-55) after TEP enlargement.

Diagnostic Variables

Enlarged TEP was diagnosed a median of 318 days after TEP (range 1 to 1,653 days). Overall, 58% (21/36) were diagnosed within 1 year of TEP, and 42% (15/36) more than 1 year post-TEP. All enlarged TEPs were diagnosed after radiotherapy, a median of 19.2 months after the completion of radiotherapy (range: 2 days to 16.2 years). Time to TEP enlargement and physical characteristics of the enlarged TEP are summarized in Table II.

Methods of Conservative Management of Leakage Related to Enlarged TEP

Conservative treatments attempted in lieu of complete closure of the TEP are described in Table III. Conservative treatments were attempted in all but 1 patient whose prosthesis was removed to allow the TEP site to close completely after developing an enlarged TEP in the immediate postoperative setting. Conservative management was not attempted for this patient due to altered mental status that precluded successful TE voice restoration.

Initial Method of Conservative Management—The initial method of conservative management attempted for each patient is summarized in Table III. Placement of a VP with an enlarged flange was the initial conservative method attempted in most patients (89%, 32/36). Catheter placement was the initial conservative treatment method attempted in only 2 patients as it proved unsuccessful in both. One patient used thickened liquids as the initial conservative treatment attempt while awaiting esophageal dilation.

Summary of All Conservative Methods—All conservative treatment methods attempted to address leakage around the VP during the review period are listed in Table 3. Overall, placement of a voice prosthesis with an enlarged tracheal and/or esophageal flange was the most commonly attempted conservative treatment method (34/36, 94%). Custom enlarged-flange prostheses were placed in 86% of patients (31/36), and VPs with a standard commercially-available enlarged esophageal flange were placed in 67% (24/36) of patients. Eleven patients (11/31, 36%) required a single custom prosthesis, 14 (45%) required 2 to 4 custom prostheses, and 6 (19%) required 5 or more custom prostheses during the study period.

Temporary removal of the voice prosthesis was attempted in 14 patients (39%), with placement of a smaller diameter catheter attempted in 8 of these patients, open TE tract stenosis attempted in 1 patient, and both open TE tract stenosis and catheter placement attempted in the remaining 5 patients. All patients were made NPO for open TE tract stenosis. Temporary prosthesis removal ranged from a few hours to 39 days. TEP site injection using Radiesse (BioForm Medical, Inc., San Mateo, CA, USA) or Cymetra (LifeCell Corporation, Branchburg, NJ, USA) was attempted in 8 patients (22%), half of whom required repeat injections (range: 1 to 3 injections) due to recurrent leakage. Thickened liquids were also used temporarily in 33% of patients (12/36), typically in combination with placement of an enlarged-flange prosthesis. Ultimately, a variety of conservative treatment methods were attempted for most patients (23/36, 64%). The success of each independent treatment method could not be rated because most patients were treated using more than one method, and conservative methods were often used in conjunction with one another. Only 12 patients (33%) were managed using a single method of conservative treatment; these 12 cases were managed exclusively using enlarged-flange prostheses.

Leakage Outcomes after Enlarged TEP

At last follow-up, leakage around the voice prosthesis was resolved using a single conservative treatment method in 12 patients (33%) and using a combination of conservative treatment methods in 17 patients (47%). Leakage around the prosthesis persisted despite conservative treatment attempts in 6 (17%) patients. Among these 6, one underwent surgical

pectoralis flap closure of the TEP site, and the remaining 5 who had developed locoregional recurrence or metastatic cancer remained gastrostomy dependent at last follow-up due to chronic leakage. Thirteen patients (36%) were able to resume use of a standard voice prosthesis without recurrent leakage around the VP after successful conservative management of enlarged TEP.

Complete TEP Closure

Overall, 7 patients had complete TEP closure at last follow-up. Only 2 patients underwent intentional complete TEP closure (1 surgical, 1 non-surgical) due to persistent leakage around the VP after enlarged TEP. The TEP site was closed for other reasons subsequent to successful management of leakage around the VP in the remaining 5 patients. Unintentional closure due to accidental dislodgement occurred in 1 of the 5 patients, and intentional closure was undertaken in the remaining 4 due to intractable leakage through the prosthesis, granulation tissue, and TE speech failure.

Clinical Correlates of Leakage Outcomes

Table IV describes leakage outcomes at last follow-up after enlarged TEP stratified by physical appearance of the enlarged TEP, time to enlargement, disease status, and stricture. Patients who required intentional TEP site closure due to leakage around the prosthesis and those in whom leakage was not controlled using conservative treatment methods were classified as unresolved. Unresolved leakage around the prosthesis at last follow-up was significantly more common in the presence of a visible divot or irregular contour of the TEP site ($p=0.003$). Leakage was also less successfully controlled in patients who developed locoregional recurrence, metastatic disease, or second primary cancer after laryngectomy. At last follow-up, leakage around the prosthesis was eliminated with conservative methods in 94% (17/18) of patients who remained disease-free compared with 67% (12/18) of patients with recurrent cancer ($p = 0.081$). Similarly, 61% (11/18) of patients who remained disease free were able to resume use of a standard voice prosthesis after successful conservative management compared with only 11% (2/18) of patients who had developed recurrent cancer ($p=0.005$). Both of the patients who experienced TEP enlargement due to local recurrence near the TEP site had unresolved leakage and required gastrostomy placement. Postoperative stricture was not significantly associated with control of leakage around the VP ($p=0.163$) or the ability to resume use of a standard prosthesis ($p=0.825$).

Communication Outcomes

Use of the TEP as the primary mode of communication was recorded before and after enlarged TEP. Among the 24 patients who used TE voice as their primary mode of communication before the TEP enlarged, 20 (83%) continued functional TE communication after leakage around the VP was controlled using conservative management. Two of 3 patients whose TEP enlarged in the immediate postoperative setting went on to achieve successful TE voice after conservative management of enlarged TEP. Temporary cessation of TE voice was required in 7 patients (from 3 days to 1 month) until leakage was successfully managed, and permanent cessation of TE voice in 2 terminal patients who required placement of a custom dummy prosthesis at the end of life.

Feeding Tube Outcomes

Four patients required prolonged use of postoperative feeding tubes due to leakage around the VP, and 5 had temporary feeding tubes placed (4 to 31 days). Eight additional patients required feeding tubes for leakage that remained in use at last follow-up; 5 remained in use because of persistent leakage in patients with recurrent or metastatic disease, and 3 due to persistent dysphagia despite successful management of leakage. Feeding tubes were not required in 53% (19/36) of patients with enlarged TEP.

Adverse Events Associated with Enlarged TEP

Adverse events including pneumonia, VP dislodgement, and aspiration of the VP were compared in patients with (36/194) and without (158/194) enlarged TEP. Pneumonia was significantly more common in patients who experienced enlarged TEP ($p < 0.001$). The incidence of pneumonia after enlarged TEP was 39% (14/36) compared with 11% (18/158) in patients who did not experience enlarged TEP (RR: 3.4, 95% CI: 1.9-6.2). Seventeen percent of patients with enlarged TEP experienced recurrent pneumonias. Dislodgement of the VP was also significantly more common in patients with enlarged TEP (44%, 16/36) compared with patients who did not experience enlarged TEP (26%, 41/158, RR: 1.7, 95% CI: 1.1-2.7). Four patients experienced dislodgement of their standard VP closely preceding onset of leakage around the prosthesis (1 day to 7 weeks). Risk of tracheal aspiration was 3-fold higher in patients with enlarged TEP (3/36, 8% versus 4/158, 3%, RR = 3.3, 95% CI: 0.8-14.1).

DISCUSSION

The results of this 5-year cohort study indicate that, in most cases, leakage around the prosthesis due to an enlarged TEP can be managed without complete closure of the TEP site. Conservative treatment methods controlled leakage around the voice prosthesis in 81% of patients with enlarged TEP in this study; only 2 patients (6%) required complete TEP closure due to enlargement. These results compare favorably to outcomes (67% - 86% success) previously reported by other investigators who have employed an assortment of conservative treatment methods.⁷⁻¹⁰ In addition, our experience using a number of treatment alternatives in this broad cohort of patients may be more generalizable to clinical practice than reports that focus on a single treatment method.

It was difficult to ascertain and compare the independent effect of conservative treatments because a majority of patients (64%) were managed with multiple, complimentary methods that in some cases were also used concurrently. For instance, it was not uncommon for patients to be fit with an enlarged-flange prosthesis and concomitantly receive TEP site injections or use thickened liquids to help stop leakage. Furthermore, several patients were effectively managed for long periods of time using a single conservative method, but additional conservative treatments became necessary months or years later due to progressive or recurrent leakage. These findings highlight the need for careful surveillance and consideration of various treatments to achieve long-term control of leakage around the VP in patients with enlarged TEP.

Prosthetic modification plays an integral role in the management of enlarged TEP at our institution. The addition of an enlarged silicone collar to the esophageal and/or tracheal end of the VP is used to prevent leakage by creating a seal over the enlarged fistula. Enlarged-flange prostheses have been commercially available since 1996 and have also been custom fabricated in our institution for over a decade. Placement of an enlarged-flange VP was the initial method attempted in most patients and was sufficient as the exclusive method of managing leakage in one third of patients with enlarged TEP. Early in the cohort, we attempted to facilitate stenosis of the TEP around smaller catheters as the initial method of conservative treatment. This proved largely unsuccessful and led to progressive enlargement in some cases. Hence, temporary placement of a small-gauge catheter is no longer selected as the first choice to manage an enlarged TEP. Instead, placement of an enlarged-flange VP is favored as it has the ability to immediately alleviate leakage, allows for continued TE voice, and is easily coupled with other conservative treatments as needed. Although custom prostheses are primarily available in specialty tertiary care centers, access to enlarged-flange prostheses through commercial vendors facilitates management of enlarged TEP for clinicians in a variety of settings.^{25, 26}

Two clinical variables, recurrent cancer after laryngectomy and visible irregularity of the enlarged TEP, may help to identify patients who are less likely to respond favorably to conservative management of an enlarged TEP. All cases of unresolved leakage after conservative management occurred in patients with locoregional recurrence or metastatic cancer. The reason for this requires further assessment, and we speculate that management of leakage is challenged by the unstable medical status of the patient related to carcinogenesis and systemic treatments. Similarly, it is difficult to achieve surface coverage of the enlarged TEP in the presence of a divot or irregular TEP contour. As such, it was not surprising that unresolved leakage was significantly more common when the enlarged TEP was visibly irregular in shape or contour ($p = 0.003$). Finally, although stricture has been shown to significantly increase the risk of developing an enlarged TEP,²⁴ these data suggest that stricture does not preclude effective management of leakage related to enlarged TEP.

A unique objective of this analysis was to quantify functional consequences and adverse events associated with enlarged TEP. Although most patients with enlarged TEP (83%) maintained functional TE voice after conservative management of leakage around the prosthesis, temporary or permanent cessation of TE voice occurred as a consequence of enlarged TEP in 25% of patients. TE voice cessation occurred in some cases when a catheter was placed to temporarily stent the TEP and in others when digital pressure against a compromised TEP site was ill-advised. Negative functional effects also included enteral feeding required at least temporarily to prevent leakage in half of patients with enlarged TEP. Notably, TEP enlargement also increased the risk of adverse health outcomes. A statistically significant 3-fold increased risk of pneumonia was observed in patients with enlarged TEP and, although rare in the total cohort, tracheal aspiration of the voice prosthesis was 3 times more likely in patients with enlarged TEP. These data confirm that enlarged TEP is associated with significant health problems but also suggest a potential unfavorable effect on quality of life due to cessation of TE voice and enteral feeding requirements incurred as a consequence of enlarged TEP, particularly in patients with progressive cancer.

CONCLUSIONS

These data clearly establish enlarged TEP as a serious postsurgical complication that significantly increases the risk of pneumonia. Our results suggest that complete TEP closure may be avoided in most cases by using conservative methods to control leakage related to TEP enlargement. However, successful conservative management requires multidisciplinary collaboration of expert clinicians with access to a variety of treatments and specialty products. The results of this study also promote a hierarchical approach to conservative management that commonly begins with placement of an enlarged-flange VP. Patients with recurrent cancer after laryngectomy remain challenging to manage effectively, and appear most functionally impacted by enlarged TEP. Uncontrolled leakage in these cases caused further restrictions to communication and oral intake at the end of life, with significant quality of life implications. Prospective data are needed to confirm our findings and to determine best practices for management of enlarged puncture.

REFERENCES

1. Williams SE, Watson JB. Speaking proficiency variations according to method of alaryngeal voicing. *Laryngoscope*. 1987; 97:737–739. [PubMed: 3586817]
2. Debruyne F, Delaere P, Wouters J, Uwents P. Acoustic analysis of tracheo-oesophageal versus oesophageal speech. *J Laryngol Otol*. 1994; 108:325–328. [PubMed: 8182320]
3. Max L, Steurs W, de Bruyn W. Vocal capacities in esophageal and tracheoesophageal speakers. *Laryngoscope*. 1996; 106:93–96. [PubMed: 8544636]
4. Ward EC, Koh SK, Frisby J, Hodge R. Differential modes of alaryngeal communication and long-term voice outcomes following pharyngolaryngectomy and laryngectomy. *Folia Phoniatr Logop*. 2003; 55:39–49. [PubMed: 12566765]
5. Hutcheson KA, Lewin JS, Sturgis EM, Kapadia A, Risser J. Enlarged Tracheoesophageal Puncture After Total Laryngectomy: A Systematic Review and Meta-Analysis. *Head Neck*. [Epub ahead of press].
6. Singer MI, Blom ED. An endoscopic technique for restoration of voice after laryngectomy. *Ann Otol Rhinol Laryngol*. 1980; 89:529–533. [PubMed: 7458140]
7. Op de Coul BM, Hilgers FJ, Balm AJ, et al. A decade of postlaryngectomy vocal rehabilitation in 318 patients: a single Institution's experience with consistent application of provox indwelling voice prostheses. *Arch Otolaryngol Head Neck Surg*. 2000; 126:1320–1328. [PubMed: 11074828]
8. Jacobs K, Delaere PR, Vander Poorten VL. Submucosal purse-string suture as a treatment of leakage around the indwelling voice prosthesis. *Head Neck*. 2008; 30:485–491. [PubMed: 17979112]
9. Hilgers FJ, Balm AJ, Hilgers FJ, Balm AJ. Long-term results of vocal rehabilitation after total laryngectomy with the low-resistance, indwelling Provox voice prosthesis system. *Clinical Otolaryngology & Allied Sciences*. 1993; 18:517–523. [PubMed: 8877233]
10. Singer MI, Blom ED, Hamaker RC. Further experience with voice restoration after total laryngectomy. *Ann Otol Rhinol Laryngol*. 1981; 90:498–502. [PubMed: 7305208]
11. Perie S, Ming X, Dewolf E, et al. Autologous fat injection to treat leakage around tracheoesophageal puncture. *Am J Otolaryngol*. 2002; 23:345–350. [PubMed: 12430126]
12. Garth RJ, McRae A, Rhys Evans PH, Garth RJ, McRae A, Rhys Evans PH. Tracheoesophageal puncture: a review of problems and complications. *J Laryngol Otol*. 1991; 105:750–754. [PubMed: 1919346]
13. Andrews JC, Mickel RA, Hanson DG, et al. Major complications following tracheoesophageal puncture for voice rehabilitation. *Laryngoscope*. 1987; 97:562–567. [PubMed: 3573901]
14. Cornu AS, Vlantis AC, Elliott H, et al. Voice rehabilitation after laryngectomy with the Provox voice prosthesis in South Africa. *J Laryngol Otol*. 2003; 117:56–59. [PubMed: 12590857]

15. Ferrer Ramirez MJ, Guallart Domenech F, Brotons Durban S, et al. Surgical voice restoration after total laryngectomy: long-term results. *Eur Arch Otorhinolaryngol.* 2001; 258:463–466. [PubMed: 11769993]
16. de Carpentier JP, Ryder WD, Saeed SR, et al. Survival times of Provox valves. *J Laryngol Otol.* 1996; 110:37–42. [PubMed: 8745779]
17. Kress P, Schafer P, Schwerdtfeger FP, Kress P, Schafer P, Schwerdtfeger FP. [The custom-fit voice prosthesis, for treatment of periprosthetic leakage after tracheoesophageal voice restoration]. *Laryngorhinootologie.* 2006; 85:496–500. [PubMed: 16586287]
18. Blom, ED.; Singer, MI.; Hamaker, RC., editors. *Tracheoesophageal voice restoration for total laryngectomy.* 1 ed. Singular Publishing Group, Inc.; 1998.
19. Trussart C, Lawson G, Remacle M, Trussart C, Lawson G, Remacle M. Voice prostheses: long-term follow-up retrospective study (three- to sixteen-year follow-up of 22 patients). *Rev Laryngol Otol Rhinol (Bord).* 2003; 124:299–304. [PubMed: 15144025]
20. Lorincz BB, Lichtenberger G, Bihari A, et al. Therapy of periprosthetic leakage with tissue augmentation using Bioplastique around the implanted voice prosthesis. *Eur Arch Otorhinolaryngol.* 2005; 262:32–34. [PubMed: 14986020]
21. Margolin G, Masucci G, Kuylensstierna R, et al. Leakage around voice prosthesis in laryngectomees: treatment with local GM-CSF. *Head Neck.* 2001; 23:1006–1010. [PubMed: 11754506]
22. Seshamani M, Ruiz C, Kasper Schwartz S, et al. Cymetra injections to treat leakage around a tracheoesophageal puncture. *ORL J Otorhinolaryngol Relat Spec.* 2006; 68:146–148. [PubMed: 16449823]
23. Recher G, Pesavento G, Cristoferi V, et al. Italian experience of voice restoration after laryngectomy with tracheoesophageal puncture. *Ann Otol Rhinol Laryngol.* 1991; 100:206–210. [PubMed: 2006820]
24. Hutcheson, KA. Multivariable analysis of risk factors for enlarged tracheoesophageal puncture after total laryngectomy. The University of Texas School of Public Health; Houston, TX: 2010.
25. Blom-Singer Rapid Response: Special Order Voice Prosthesis Program. InHealth Technologies; Carpinteria, CA: 2009.
26. Provox XtraFlange: Problemsolver - A tool to treat leakage around the voice prosthesis. Atos Medical AB; Horby, Sweden: 2009.

Table I

Population Characteristics

	Total No. (%)	Enlarged TEP No. (%)
Sex		
Male	162 (83.5%)	28 (77.8%)
Female	32 (16.5%)	8 (22.2%)
Age		
<50 years	27 (13.9%)	4 (11.1%)
50-59 years	58 (29.9%)	13 (36.1%)
60-69 years	62 (32.0%)	11 (30.6%)
70 years	47 (24.2%)	8 (22.2%)
Smoking Status		
Never	24 (12.4%)	2 (5.6%)
Former	77 (40.0%)	15 (41.7%)
Current	93 (47.9%)	19 (52.8%)
Tumor Site		
Glottic/subglottic	102 (52.6%)	14 (38.9%)
Supraglottic	56 (28.9%)	11 (30.6%)
Hypopharynx	21 (10.8%)	7 (19.4%)
Other	15 (7.7%)	4 (11.1%)
T classification		
T2	9 (4.6%)	2 (5.6%)
T3	19 (9.8%)	3 (8.3%)
T4	57 (29.4%)	13 (36.1%)
TX or missing	5 (2.6%)	0 (0.0%)
Recurrent	104 (53.6%)	18 (50.0%)
N classification		
N0	41 (21.1%)	3 (8.3%)
N1	12 (6.2%)	3 (8.3%)
N2	32 (16.5%)	12 (33.3%)
N3	2 (1.0%)	0 (0.0%)
NX or missing	3 (1.5%)	0 (0.0%)
Recurrent	104 (53.6%)	18 (50.0%)
Type of Surgery		
TL	147 (75.8%)	24 (66.7%)
TL + partial pharyngectomy	26 (13.4%)	5 (13.9%)
TLP	21 (10.8%)	7 (19.4%)
Type of Reconstruction		
None	143 (73.7%)	23 (63.9%)
Patch	28 (14.4%)	6 (16.7%)
Circumferential	23 (11.9%)	7 (19.4%)
Timing TEP		

	Total No. (%)	Enlarged TEP No. (%)
Primary	119 (61.3%)	18 (50.0%)
Secondary	75 (38.7%)	18 (50.0%)
Radiotherapy		
None	17 (8.8%)	0 (0.0%)
Preoperative	114 (58.8%)	19 (52.8%)
Postoperative	63 (32.5%)	17 (47.2%)
Postoperative Stricture		
No	160 (82.5%)	23 (63.9%)
Yes	34 (17.5%)	13 (36.1%)
Total	194	36

Abbreviations: TL, total laryngectomy; TLP, total laryngopharyngectomy

Table II**Time to Enlargement and Physical Characteristics of Enlarged TEP**

	No. (%)
Time to TEP enlargement	
<6 mos. post-TEP	13 (36.1%)
6-12 mos. post-TEP	8 (22.2%)
>12 mos. post-TEP	15 (41.7%)
TE tract length *	
<6mm	5 (13.9%)
6mm	31 (86.1%)
Appearance of enlarged TEP [†]	
Circumferential enlargement	22 (61.1%)
Irregular TEP	14 (38.9%)
Granulation	
No	25 (69.4%)
Yes	11 (30.6%)
Total	36

Abbreviations: TEP, tracheoesophageal puncture; VP, voice prosthesis

* Based on length of VP

[†] Appearance of TEP was rated based on visual exam; irregularity included visible divot and/or irregular, noncircular shape or contour of the TEP.

Table III**Conservative Treatments Attempted to Control Leakage around the Voice Prosthesis after Enlarged TEP**

Treatment	Initial Method[*] No. Pts (%)	All Methods[†] No. Pts (%)
VP with Enlarged Flange	32 (88.9)	34 (94.4)
Custom enlarged-flange	11 (30.6)	31 (86.1)
Commercially available enlarged-flange	21 (58.3)	24 (66.7)
Temporary removal of VP (open TE tract)	0 (0.0)	6 (16.7)
Downsizing around catheter	2 (5.6)	13 (36.1)
TEP Injection	0 (0.0)	8 (22.2)
Thickening liquid	1 (2.8)	12 (33.3)
Esophageal Dilation	0 (0.0)	7 (19.4)
NPO	0 (0.0)	14 (38.9)
Multiple conservative treatments attempted	N/A	23 (63.9)

^{*} Initial method attempted to address leakage around the VP.

[†] Attempted at any point during the review period. NOTE: Treatments are not mutually exclusive.

Table IV

Clinical Correlates of Leakage Outcomes after Enlarged TEP

	Prosthetic Leakage Outcomes [*]					
	Resolved		Unresolved	<i>p</i>	Standard Voice Prosthesis [§]	<i>p</i>
	Single Approach	Combined Approach				
Appearance of enlarged TEP						
Not irregular	11 (50.0%)	10 (45.5%)	1 (4.6%)		8 (36.4%)	
Irregular TEP [‡]	1 (7.1%)	7 (50.0%)	6 (42.9%)	0.003	5 (35.7%)	1.000
Time to Enlargement						
<6 mos. post-TEP	4 (30.8%)	5 (38.5%)	4 (30.8%)		4 (30.8%)	
6-12 mos. post-TEP	2 (25.0%)	4 (50.0%)	2 (25.0%)		6 (75.0%)	
>12 mos. post-TEP	6 (40.0%)	8 (53.3%)	1 (6.7%)	0.565	3 (20.0%)	0.037
Recurrent Cancer after TL [‡]						
No	6 (33.3%)	11 (61.1%)	1 (5.6%)		11 (61.1%)	
Yes	6 (33.3%)	6 (33.3%)	6 (33.3%)	0.081	2 (11.1%)	0.005
Stricture						
No	9 (39.1%)	8 (34.8%)	6 (26.1%)		8 (34.7%)	
Yes	3 (23.1%)	9 (69.2%)	1 (7.7%)	0.163	5 (38.5%)	0.825
Total	12 (33.3%)	17 (47.2%)	7 (19.4%)		13 (36.1%)	

Abbreviations: TEP, tracheoesophageal puncture; TL, total laryngectomy

^{*} Outcomes rated at last follow-up, prior to complete TEP closure, if applicable[†] Includes visible divot and/or irregular TEP shape or contour[‡] Includes locoregional recurrence, distant metastasis, or new primary cancer diagnosed after TL[§] Resumed use of standard voice prosthesis after conservative management