

## Clinical Evidence Series

### Primary versus Secondary Puncture

# Clinical Evidence Series

## Primary vs. Secondary Puncture

- Comparison of primary vs. secondary TEP
- Primary puncture and pharyngocutaneous fistula

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## Preface

This document contains a bibliography and summaries of selected publications relating to Primary versus Secondary Tracheoesophageal Puncture (TEP). The document is part of a growing, and regularly updated collection of documents, the Atos Medical Clinical Evidence Series, covering various clinical topics related to Atos Medical's areas of expertise. The topics are chosen based on questions that we receive from patients and healthcare professionals using our products.

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## Introduction

During a total laryngectomy, the entire voice box is removed. The trachea is bent forward and sutured to the anterior neck, ending in a tracheostoma. The remainder of the pharynx is closed to restore the digestive tract. The three main methods of voice rehabilitation available to the laryngectomized patient are the use of an electrolarynx (EL), esophageal speech (ES), and tracheoesophageal (TE) speech using a voice prosthesis<sup>1</sup>, see Figure 1.



Figure 1. Schematic drawings of the three main methods of voice rehabilitation following total laryngectomy: esophageal speech (left), speech using an electrolarynx (middle), and tracheoesophageal speech using a voice prosthesis and heat and moisture exchanger with finger occlusion.

Speaking mode



Hands-free



The three techniques present their advantages and disadvantages. ES is a difficult to learn technique but low cost and does not require additional surgical intervention. EL speech is easy to learn and requires no additional surgical procedures but presents major disadvantages due to the mechanical sound of the produced voice and cost of equipment. Over the past decades, TE speech has become the gold standard for voice rehabilitation after Total Laryngectomy and is nowadays the most commonly used method in the developed countries<sup>2,3</sup>. TE speech is technically easier to learn with a superior vocal quality, superior voice quality, shorter rehabilitation time, and a higher success rate (>80%)<sup>1,4-6</sup> but cost of the prosthesis limits its availability for low-income patients and in developing countries<sup>7</sup>.

Tracheoesophageal puncture (TEP) can either be performed at the time of laryngectomy, primary TEP, or as a separate procedure at a later stage, secondary TEP, with both techniques presenting advantages and disadvantages. At the moment, consensus is lacking on when to perform primary or secondary TEP, usually based on institution or clinician preference, expertise, and capacity<sup>8</sup>.

Generally, the reasons preventing widespread use of TES are surgical complications (early complication), long-term voice prosthesis/fistula problems (late complications), cost of the device and burden on the clinicians<sup>9</sup>. This document presents clinical evidence on success rates and complications surrounding TEP. By doing this, we hope to dispel myths surrounding the topic, helping physicians make an informed decision on when a primary or secondary TEP might be preferred, but most importantly, to consider TES as the best voice rehabilitation option after total laryngectomy

## Comparison of primary and secondary puncture

Complication rates for primary and secondary procedures are similar<sup>9-17</sup>, even in geriatric patients<sup>18</sup>. Studies have shown that postoperative radiotherapy do not increase the complication rates<sup>9, 19-22</sup>. However, the most serious observed complications seem to occur after secondary puncture due to restricted access to the puncture site<sup>23</sup>.

An increased risk for pharyngocutaneous fistulae is reported for primary TEP compared to secondary TEP after delayed VP fitting in patients who have undergone chemoradiation<sup>24</sup>, although this finding has been contradicted in other studies (see section 'Primary puncture and Pharyngocutaneous fistulae'). One study showed that older patients with more complications, that received primary TEP, are more likely to suffer from aphonia<sup>25</sup> whereas one study showed that enlarged tracheoesophageal puncture/leakage around rates do not significantly differ between primary and secondary puncture procedures<sup>23</sup>.

Benefits reported for primary puncture are early voice restoration with positive psychological impact<sup>20, 22, 24, 26-28</sup>, eliminating the need for a second surgical procedure<sup>15, 20, 22, 24, 28, 29</sup>, ease of determining the length of the voice prosthesis needed<sup>14, 26</sup>, increased device life of the voice prosthesis<sup>14</sup>, decrease of surgical time<sup>30</sup> and equal or greater likelihood of successful voice restoration<sup>12, 15-18, 23, 27-29, 31, 32</sup>.

Generally, primary puncture is preferred, especially in cases without previous radiotherapy when postlaryngectomy radiation is expected<sup>16</sup>. However, one study reported a significantly shorter average prosthesis lifetime after primary TEP than after secondary TEP<sup>29</sup>. Secondary puncture is recommended when the proximal esophagus has been dissected from the trachea<sup>18, 19</sup>.

### Articles included in this section

The publications listed below concern the publications regarding the comparison of primary and secondary puncture that are referenced above. Clicking the link while holding the *Ctrl*-key will take you directly to the summary you are interested in. See Appendix 1 – Publications with abstracts for "Comparison of primary versus secondary puncture" for publication list with abstracts.

- Parrilla, C., et al., A one-year time frame for voice prosthesis management. What should the physician expect? Is it an overrated job? *Acta Otorhinolaryngol Ital*, 2020. 40(4): p. 270-276.
- Thavarool et al. Tracheo Esophageal Prosthesis Insertion Under Endoscopic Guidance and Local Anaesthesia- Feasibility and Outcome. *Indian J Otolaryngol Head Neck Surg* 2022 Vol. 74 Issue 1 Pages 39-44
- Iype, E.M., et al., Voice Rehabilitation After Laryngectomy: A Regional Cancer Centre Experience and Review of Literature. *Indian J Otolaryngol Head Neck Surg*, 2020. 72(4): p. 518-523.
- Luu et al. Primary versus secondary tracheoesophageal puncture for voice rehabilitation in laryngectomy patients: A systematic review. *Clin Otolaryngol*. 2018 May 16.
- Panwar A et al. Impact of Primary Tracheoesophageal Puncture on Outcomes after Total Laryngectomy. *Otolaryngology Head and Neck Surgery* Aug 2017.
- Barauna Neto JC et al. Comparison between primary and secondary tracheoesophageal puncture prosthesis – a systematic review. *ORL J*. 2017 Jul 29;79(4):222-229.
- Balm et al. The indwelling voice prosthesis for speech rehabilitation after total laryngectomy: a safe approach. *Otolaryngol Pol*. 2011 Nov-Dec;65(6):402-9.
- Mastronikolis et al. Voice restoration after total laryngectomy using provox 2 (generation II) prosthesis. *Eur Rev Med Pharmacol Sci*. 2008 Sep-Oct;12(5):327-30.
- Kummer et al. [Prosthetic voice rehabilitation after laryngectomy. Failures and complications after previous radiation therapy]. [Article in German] *NO*. 2006 Apr;54(4):315-22.
- Cocuzza et al. Post laryngectomy speech rehabilitation outcome in elderly patients. *Eur Arch Otorhinolaryngol*. 2013 May;270(6):1879-84.
- Lewin et al. Device life of the tracheoesophageal voice prosthesis revisited. *JAMA Otolaryngol Head Neck Surg*. 2017;143(1):65-71.
- Cheng et al. Outcomes of primary and secondary tracheoesophageal puncture: a 16-year retrospective analysis. *Ear Nose Throat J*. 2006 Apr;85(4):262, 264-7.
- Chone et al. Speech rehabilitation after total laryngectomy: long-term results with indwelling voice prosthesis Blom-Singer. *Braz J Otorhinolaryngol*. 2005 Jul-Aug;71(4):504-9.
- Kao et al. The outcome and techniques of primary and secondary tracheoesophageal puncture. *Arch Otolaryngol Head Neck Surg*. 1994 Mar;120(3):301-7
- Hutcheson et al. Enlarged tracheoesophageal puncture after total laryngectomy: a systematic review and meta-analysis. *Head Neck*. 2011 Jan;33(1):20-30.
- Emerick et al. Primary versus secondary tracheoesophageal puncture in salvage total laryngectomy following chemoradiation. *Otolaryngol Head Neck Surg*. 2009 Mar;140(3):386-90.
- Peres Borges Dos Santos, N., et al., Associated Factors With the Prosthetic Vocal Rehabilitation Outcome in Older Patients (Over 70 Years). *J Voice*, 2021.
- Guttman et al. Post-laryngectomy voice rehabilitation: comparison of primary and secondary tracheoesophageal puncture. *IMAJ* 2013 Sept; 15:565-567.
- Sinclair et al. Primary versus delayed tracheoesophageal puncture for laryngopharyngectomy with free flap reconstruction. *Laryngoscope*. 2011 Jul;121(7):1436-40.
- Boscolo-Rizzo et al. Long-term results with tracheoesophageal voice prosthesis: primary versus secondary TEP. *Eur Arch Otorhinolaryngol*. 2008 Jan;265(1):73-7.
- Moon et al. Changing trends of speech outcomes after total laryngectomy in the 21st century: a single-center study. *Laryngoscope*. 2014 Nov; 124:2508-2512.
- Gitomer et al. Influence of timing, radiation, and reconstruction on complications and speech outcomes with tracheoesophageal puncture. *Head Neck*. 2016 Dec; 38(12):1765-1771.
- Scherl, C., et al., Secondary Tracheoesophageal Puncture After Laryngectomy Increases Complications With Shunt and Voice Prosthesis. *Laryngoscope*, 2020.
- Malik et al. Surgical complications of tracheo-oesophageal puncture and speech valves. *Curr Opin Otolaryngol Head Neck Surg*. 2007 Apr;15(2):117-22.

## Primary puncture and pharyngocutaneous fistulae

Pharyngocutaneous fistula is the most serious common complication after laryngectomy<sup>33</sup>. The incidence reported in literature varies widely, ranging from 2.6% to 65.5%<sup>34</sup>. A retrospective study of both primary and secondary TEP patients (n=95) demonstrated pharyngocutaneous fistula to be the most common postoperative laryngectomy complication (90% of the complications)<sup>35</sup>.

However, the evidence on associations between the timing of TE puncture and development of a pharyngocutaneous fistula is contradictory<sup>33</sup>. Primary TEP has not been associated with the development of pharyngocutaneous fistulae in three large series of patients<sup>36-38</sup>, and two smaller studies<sup>39, 40</sup>. In two smaller series of patients undergoing salvage surgery after chemoradiation, primary puncture was associated with an increased risk for pharyngocutaneous fistulae<sup>24, 41</sup>. In a recent study, secondary TEP and no TEP were identified as significant factors predictive for pharyngocutaneous fistulae compared to primary TEP while early oral intake did not influence the PCF rate<sup>34</sup>.

Several factors may play a role in the development of PCF, such as time interval between pre-operative (chemo) radiotherapy<sup>33, 34, 36, 39</sup>, performance of selective or radical neck dissection<sup>34, 36</sup>, previous tracheotomy<sup>34</sup>, BMI<18<sup>34</sup> and comorbidities<sup>40</sup>.

Overall, pharyngocutaneous fistula remains an unpredictable complication<sup>33, 34, 38</sup>.

### Articles included in this section:

The publications listed below concern the publications regarding primary puncture and pharyngocutaneous fistulae that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in. See Appendix 2 – Publications with abstracts for “Primary puncture and pharyngocutaneous fistulae” for publication list with abstracts.

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# Appendix 1 – Publications with abstracts for “Comparison of primary versus secondary puncture”

## Thavarool et al., 2022

### Title

Tracheo Esophageal Prosthesis Insertion Under Endoscopic Guidance and Local Anaesthesia- Feasibility and Outcome

### Authors

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### Journal and year of publication

Indian J Otolaryngol Head Neck Surg

### Type of publication

Retrospective review

### Introduction

Voice rehabilitation after laryngectomy is by tracheo esophageal puncture (TEP) and prosthesis insertion. Secondary TEP is very difficult due to neck fibrosis. Puncture under local anaesthesia with endoscopy guidance is a feasible option.

### Subjects and Methods

Retrospective review of all laryngectomy patients from March 2009 till March 2019 was done and the methods of voice rehabilitation were assessed. The patients undergoing the procedure were classified according to the timing of insertion and type as primary insertion under general anaesthesia (Group P), secondary insertion under local anaesthesia (Group L), secondary insertion under general anaesthesia (Group G). The speech outcome and the procedure outcome were compared.

### Results

There were 148 patients who underwent laryngectomy, of which groups P, G, L were 12, 12 and 11. The rate of successful insertion was 100% in primary, 91.6% in secondary in general anaesthesia and 91% in secondary under local anaesthesia. All secondary TEP were done after surgery and radiotherapy. Complications related to the insertion techniques were minimal. Speech outcome were similar on intelligibility rating scale and longevity was not affected by the method.

### Conclusion

TEP in local anaesthesia is feasible and has comparable outcome with TEP in general anaesthesia. Financial burden was very much less in group L compared to the other two groups.

## Peres et al., 2021

### Title

Associated Factors With the Prosthetic Vocal Rehabilitation Outcome in Older Patients (Over 70 Years)

### Authors

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### Journal and year of publication

J Voice. 2021 Nov 12:S0892-1997(21)00314-3. doi: 10.1016/j.jvoice.2021.09.011. Epub ahead of print.

### Type of publication

Retrospective cohort study

### Introduction

Tracheoesophageal puncture (TEP) with voice prosthesis (VP) is considered the gold standard in vocal rehabilitation of total laryngectomized patients, for generating better speech intelligibility and good vocal result. The aspects of aging that may be related to the success of this method of rehabilitation are rarely discussed in the literature.

### Subjects and Methods

Objective: To describe the factors that influence the rehabilitation outcome of the total laryngectomized older patients with voice prosthesis.

A retrospective cohort study enrolled in the Head and Neck Cancer Surgery Section of the Brazilian National Cancer Institute. Secondary data were collected through physical and electronic medical records of patients undergoing vocal rehabilitation using tracheoesophageal prosthesis, from 2006 to 2019. Descriptive analysis presented the distribution of the demographic and clinical characteristics of this population.

### Results

Thirty patients rehabilitated with VP over 70 years old (mean age: 73.7 years), of which 93.3% were male. Married (73.3%), with low education (70%) and had a tumor of size T4a (60%). Adjuvant radiotherapy was performed in 66.7% of patients, 16.7% to previous radical radiotherapy. Complication rate was 53.3%, (68.7% granuloma and 18.7% shunt enlargement). All patients with shunt enlargement removed the prosthesis, whereas the prevalence of removal among those patients without complications was 14.3%. Logistic regression indicated that secondary TEP had 96% less chance of failure for phonation than primary TEP.

### Conclusion

Patients with more complications are more likely to have phonation issues and to remove the prosthesis. Older patients with larger tumors and who underwent salvage laryngectomy or were submitted to a primary puncture seem to be more likely to have complications and/or aphonia.

## Parrilla et al., 2020

### Title

A one-year time frame for voice prosthesis management. What should the physician expect? Is it an overrated job?

### Authors

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### Journal and year of publication

Acta Otorhinolaryngol Ital 2020 Vol. 40 Issue 4 Pages 270-276

### Type of publication

Retrospective review

### Introduction

Management of late complications represents the main reason for reluctance in using voice prosthesis rehabilitation. The aim of this paper is to report our experience by describing the one-year management of a large cohort of patients in order to clarify how demanding management is in terms of burden on clinicians.

### Subjects and Methods

Between June 2017 and June 2018, each access made at the Otolaryngology Clinic of our Institute for issues related to prosthesis by 70 laryngectomized patients rehabilitated by voice prosthesis was registered in a specific database. A review of the data provided information on the incidence, management and outcomes of adverse events encountered during the selected time frame. In addition, a T test was used to evaluate the differences between irradiated and non-irradiated patients and between primary and secondary tracheoesophageal-puncture.

### Results

Leakage through the prosthesis was the most common cause for access (51.86%). The median number of accesses per patient per year was 3.47. The speech therapist autonomously managed 18.1% of accesses. The median number of accesses per patient per year needing a physician was 2.84. The median lifetime of the prosthesis was 4.85 months. Radiotherapy or modality (primary or secondary) of the puncture did not influence the number of accesses per year or the prosthesis lifetime.

### Conclusion

This retrospective analysis of results highlighted the most frequent issues and the most effective measures to deal with them, which allowed us to define a systematic algorithm to standardize and ease long-term outpatient management.

[Link to open access article](#)

## Iype et al., 2020

### Title

Voice Rehabilitation After Laryngectomy: A Regional Cancer Centre Experience and Review of Literature

### Authors

Elizabeth Mathew Iype<sup>1</sup>, Deepak Janardhanan<sup>1</sup>, Shirish Patil<sup>1</sup>, Sandeep Suresh<sup>1</sup>, Bipin T Varghese<sup>1</sup>, Shaji Thomas<sup>1</sup>

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### Journal and year of publication

Indian J Otolaryngol Head Neck Surg. 2020 Dec

### Type of publication

Retrospective study and literature review

### Introduction

Alaryngeal speech in laryngectomees has revolutionized the patient outlook toward the morbid procedure and the concept of permanent stoma unlike olden era when stigma of stoma with loss of voice was rampant. Aim to analyze acceptance of voice rehabilitation options and their success and management of complications in a tertiary care center.

### Subjects and Methods

All patients who underwent laryngectomy from August 2014 to 2018 June at our institution were included in the study. The voice rehabilitation options like oesophageal speech, tracheo-oesophageal puncture and voice prosthesis insertion (TEP), and electrolarynx were explained to the patients. The options put forward to the patients, the importance of Taub test, interval between treatment and secondary TEP insertion, life span of the prosthesis, Patients acceptance and success rates and the troubleshooting were noted.

### Results

A total of 96 patients underwent total laryngectomy, 72 patients were willing for rehabilitation. 15% (11) patients had primary TEP, 22% (16) had secondary TEP insertion, esophageal speech in 36% (26) patients and 27% (19) patients opted for the electrolarynx. The rest 24 patients were not keen on any further interventions after laryngectomy.

### Conclusion

Speech rehabilitation is an integral part in surgical management of carcinoma of the larynx. Alaryngeal speech in laryngectomees have revolutionized the patient outlook towards the morbid procedure. Esophageal speech is the least successful method of rehabilitation but still the cheapest method and requires a lot of motivation. Primary and Secondary TEP insertions have similar success rates. Successful treatment for cancer of larynx ends with successful voice rehabilitation.

[Link to open access article](#)

## Scherl et al., 2020

### Title

Secondary Tracheoesophageal Puncture After Laryngectomy Increases Complications With Shunt and Voice Prosthesis

### Authors

Claudia Scherl<sup>1</sup>, Julia Kauffels<sup>1</sup>, Anne Schützenberger<sup>1</sup>, Michael Döllinger<sup>1</sup>, Christopher Bohr<sup>1</sup>, Stephan Dürr<sup>1</sup>, Rainer Fietkau<sup>2</sup>, Marlen Haderlein<sup>2</sup>, Michael Koch<sup>1</sup>, Maximilian Traxdorf<sup>1</sup>, Konstantinos Mantsopoulos<sup>1</sup>, Sarina Müller<sup>1</sup>, Heinrich Iro<sup>1</sup>

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### Journal and year of publication

Laryngoscope. 2020 Feb 6. doi: 10.1002/lary.28517.

### Type of publication

Retrospective analysis

### Introduction

To evaluate the demographics, clinical features, management, and prognostic indicators of tracheoesophageal puncture complications in patients undergoing placement of voice prosthesis following cancer treatment.

### Subjects and Methods

A retrospective analysis was conducted of cases from a tertiary referral center diagnosed between 1996 and 2015. Multivariate logistic regression was used to determine factors associated with tracheoesophageal puncture (TEP) and voice prostheses-complication-free survival (TEP/VP-CFS).

### Results

One hundred fourteen cases were identified. Most patients were males (92.9%) with pT3 (26.8%) or pT4 (58.1%) N+ (53.6%) tumors. All patients received laryngectomy as the primary treatment, with 75% of patients receiving adjuvant radiation therapy or chemoradiotherapy. Complications with TEP were common (65.2%). The most frequent problem was salivary leakage (50.0%), which at the same time was the most common reason for changing the prosthesis. On univariate regression analysis, prosthesis placement time after adjuvant radiotherapy (hazard ratio [HR]: 4.17, 95% confidence interval [CI]: 2-8.69), secondary prosthesis placement after primary surgery (HR: 3.97, 95% CI: 1.99-7.9), and laryngectomy with flap reconstruction (HR: 1.96, 95% CI: 0.99-3.89) were significant prognosticators for complications. Multivariate regression analysis revealed secondary prosthesis placement after adjuvant radiotherapy (HR: 3.66, 95% CI: 1.39-9.68) or after primary surgery (HR: 2.57, 95% CI: 0.92-7.2) to be the strongest predictors of reduced TEP/VP-CFS.

### Conclusion

Secondary prosthesis placement after primary surgery, placement after previous irradiation, and laryngectomy with flap reconstruction are predictors of poor TEP/VP-CFS. Planned adjuvant radiotherapy is not a contraindication for TEP with prosthetic placement, but it is very important to place the prosthesis during the primary surgery or at least before scheduled radiotherapy. LEVEL OF EVIDENCE: 4

[Link to open access article](#)

## Luu et al, 2018

### Title

Primary versus secondary tracheoesophageal puncture for voice rehabilitation in laryngectomy patients: A systematic review

### Authors

Luu K<sup>1</sup>, Chang BA<sup>1</sup>, Valenzuela D<sup>1</sup>, Anderson D<sup>1</sup>.

### Affiliation(s)

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### Journal and year of publication

Clin Otolaryngol. 2018 May 16.

### Type of publication

Systematic review

### Introduction

Among voice restoration options following laryngectomy, tracheoesophageal puncture (TEP) appears to be the most common. Currently, there is no consensus that exists with regard to the timing of performing TEP and the decision to perform a primary or secondary TEP has mostly been based on physician preference and expert opinion rather than data.

### Subjects and Methods

The objective of this study was to compare primary and secondary tracheoesophageal puncture (TEP) for voice rehabilitation in laryngectomy patients in terms of success and complication rates. A systematic review of studies in the English literature was conducted for studies that directly compared primary and secondary TEP. A comprehensive search of MEDLINE (January 1948-15 July 2016), EMBASE (January 1974-15 July 2016) and Web of Science (January 1970-15 July 2016) was performed. Two authors (KL/BAC) independently reviewed titles and abstracts, read full-text papers, extracted data and assessed quality. Disagreements were resolved via consensus. A third author (DV) resolved disagreements between reviewers when consensus was not possible.

### Results

Eleven retrospective clinical cohort studies were included. No randomised controlled trials were identified. Newcastle-Ottawa score for assessment of quality ranged from 5 to 7. Success rate was defined differently across most studies. Two studies found higher success with primary TEP compared to secondary TEP; nine studies found no difference. Voice outcomes were inconsistently measured; no difference between groups was found in 4 studies. Complication rates were divided into TEP site related, infectious and stenosis. No difference between primary and secondary TEP was found in all but one study which showed a higher rate of pharyngocutaneous fistula in the primary TEP group in salvage laryngectomy patients.

### Conclusion

There is no robust evidence to suggest that primary TEP is associated with poorer outcomes compared to secondary TEP. A well-designed randomised controlled trial is required to appropriately answer this question.

## Panwar A et al 2017

### Title

Impact of Primary Tracheoesophageal puncture on outcomes after total laryngectomy

### Authors

Panwar A, Militsakh O, Lindau R, Coughlin A, Sayles H, Rieke KR, Lydiatt W, Lydiatt D, Smith R

### Affiliation(s)

Department of Head and Neck Surgery, University of Omaha, Nebraska US.

### Journal and year of publication

Otolaryngology Head and Neck Surgery Aug 2017

### Type of publication

Retrospective review

### Introduction

The objective of the study was to identify differences in postoperative wound complications associated with a primary tracheoesophageal puncture (TEP) at the time of laryngectomy versus no TEP.

### Subjects and Methods

The National Surgical Quality Improvement Program data set for years 2006 to 2012 identified 430 patients who underwent total laryngectomy with or without a primary TEP. Patients who underwent a TEP at the time of laryngectomy (n = 68) were compared with patients who underwent laryngectomy without a TEP (n = 362). Postoperative wound complications and secondary outcomes, including medical complications and length of hospitalization, were compared between the groups.

### Results

The incidence of “superficial” and “deep or organ space” surgical site infection, medical complications, return to the operating room, and length of hospitalization were similar between the groups. Patients in the TEP group had a higher overall wound complication rate (relative risk, 2.02; 95% CI = 1.06-3.84; attributable risk, 8.17%; number needed to harm, 12).

### Conclusion

Performance of a primary TEP concurrent to total laryngectomy contributed to a small increase in attributable risk for overall wound complications but did not add substantial risk for “superficial” or “deep or organ space” surgical site infection, medical complications, or increased burden for resource utilization. These data may help inform patient choice and physician recommendations for primary laryngeal speech rehabilitation.

## Barauna Neto JC et al.

### Title

Comparison between Primary and Secondary Tracheoesophageal Puncture Prosthesis: A Systematic Review.

### Authors

Barauna Neto JC, Dedivitis RA, Aires FT, Pfann RZ, Matos LL, Cernea CR.

### Affiliation(s)

Palmas Oncologic Center, Sao Paolo, Brazil

### Journal and year of publication

ORL J Otorhinolaryngol Relat Spec. 2017 Jul 29;79(4):222-229

### Type of publication

Systematic review

### Introduction

Since the introduction of tracheoesophageal puncture (TEP) and placement of voice prosthesis, this has become the method of choice to achieve speech rehabilitation after total laryngectomy. The objective of the study was to compare the complications and success in speech rehabilitation of patients undergoing rehabilitation after primary and secondary TEP (TEP1 and TEP2) through a systematic review.

### Subjects and Methods

The literature survey included research in MedLine, Scielo, Lilacs, Cochrane and Websco until June 2016.

### Results

The rate of leakage around the prosthesis was higher in TEP1 (22.5 vs. 6.9%,  $p = 0.03$ ). There were higher rates of wound infection (9.1 vs. 3.9%) and tracheal stenosis (8.5 vs. 4.5%) in the TEP1 group compared to TEP2, however with no statistical significance. The evaluation of speech quality was not possible due to the heterogeneity of the studies

### Conclusions

Performance of a primary TEP concurrent to total laryngectomy did not add substantial risk for "superficial" or "deep or organ space" surgical site infection, medical complications, or increased burden for resource utilization.

## Lewin et al 2017

### Title

Device life of the tracheoesophageal voice prosthesis revisited

### Authors

Lewin J, Leah, M, Baumgart BS, Barrow M, Hutcheson K.

### Affiliation(s)

Department of Head & Neck Surgery, University of Texas MD Anderson Cancer Clinic, Houston TX, USA.

### Journal and year of publication

JAMA Otolaryngol Head Neck Surg. 2017;143;(1)65-71

### Type of publication

Retrospective

### Introduction

Voice prosthesis life time is a limiting factor of tracheoesophageal voice restoration. Historic data shows that device lifetime is on average 3-6 months but these data are typically from small sample sizes using only 1-2 devices.

### Subjects and Methods

390 laryngectomized subjects with primary or secondary TEP who had a VP management between 2003 and 2013.

### Results

From the result section, it was observed a significant increase in device lifetime in patients with primary TEP compared to secondary TEP (63 days vs 54 days,  $p=0,003$ ).

### Conclusions

Although representing a short difference (less than two weeks), this demonstrates a longer device life time for patients with primary TEP based from a relatively large sample population of 390 laryngectomized patients

## Gitomer et al, 2016

### Title

Influence of timing, radiation, and reconstruction on complications and speech outcomes with tracheoesophageal puncture.

### Authors

Gitomer SA<sup>1,2</sup>, Hutcheson KA<sup>1</sup>, Christianson BL<sup>1</sup>, Samuelson MB<sup>1</sup>, Barringer DA<sup>1</sup>, Roberts DB<sup>1</sup>, Hessel AC<sup>1</sup>, Weber RS<sup>1</sup>, Lewin JS<sup>1</sup>, Zafereo ME<sup>1,2</sup>.

### Affiliation(s)

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<sup>2</sup>Bobby R. Alford Department of Otolaryngology - Head and Neck Surgery, Baylor College of Medicine, Houston, Texas, US

### Journal and year of publication

Head Neck. 2016 Dec;38(12):1765-1771.

### Type of publication

Retrospective

### Objective

To determine the impact of radiation, reconstruction, and timing of tracheoesophageal puncture (TEP) on complications and speech outcomes.

### Methods

Retrospective review identified 145 patients who underwent TEP between 2003 and 2007.

### Results

Ninety-nine patients (68%) had primary and 46 (32%) had secondary TEP, with complications occurring in 65% and 61%, respectively ( $p = .96$ ). Twenty-nine patients (20%) had major complications (18 primary and 11 secondary;  $p = .42$ ). Ninety-four patients (65%) had pre-TEP radiation, 39 (27%) post-TEP radiation, and 12 (8%) no radiation. With patients grouped by TEP timing and radiation history, there was no difference in complications, fluency, or TEP use. With mean 4.7-year follow-up, 82% primary and 85% secondary used TEP for primary communication ( $p = .66$ ). Free-flap patients used TEP more commonly for primary communication after secondary versus primary TEP (90% vs 50%;  $p = .02$ ).

### Conclusion

Careful selection of patients' candidacy for TEP provided similar TE speech outcomes and complication rates regardless of timing of TEP or radiation. For more complex patients who require extended surgical resection and reconstruction, secondary TEP may be a better option to achieve successful voice restoration because of the opportunity for enhanced pre-TEP testing, education, and selection.

## Moon et al, 2014

### Title

Changing trends of speech outcomes after total laryngectomy in the 21st century: a single-center study.

### Authors

Moon S, Raffa F, Ojo R, Landera MA, Weed DT, Sargi Z, Lundy D.

### Affiliation(s)

Department of Otolaryngology, University of Miami Miller School of Medicine, Miami, Florida, U.S.A.

### Journal and year of publication

Laryngoscope. 2014 Nov; 124:2508-2512

### Type of publication

Retrospective review

### Introduction

To describe the speech rehabilitation outcomes of patients undergoing total laryngectomy (TL) in the 21st century.

### Subjects and Methods

Retrospective review of 167 patients who underwent TL from June 2000 to February 2012. Demographics, disease variables, and surgical factors were reviewed. Primary alaryngeal speech modality, speech outcome, and tracheoesophageal puncture (TEP) complication rates were assessed.

### Results

Overall TEP speech success rate (primary or secondary) was 72%, with a success rate of 76% for primary punctures and 68% with secondary TEP. TEP speech success rates at first, second, and beyond second year were 75%, 72%, and 70%, respectively. Success rates for primary TL, salvage TL, primary TL with pharyngeal reconstruction, or salvage TL with pharyngeal reconstruction groups were 71%, 72%, 73%, and 71%, respectively. TEP-related complications occurred in 43% of patients, with no difference in complication rates between primary versus salvage TL or primary versus secondary TEP. For those with complications, TEP success rate was 65%.

### Conclusions

This study showed TEP speech-outcome success rates lower than what has been historically reported. There was no significant difference in TEP speech outcome between primary versus salvage TL or primary versus secondary TEP. Patients with TEP-related complications had TEP speech-outcome success rates comparable to those without any complication. TEP may continue to be a superior option as a mode of speech in patients with TL, including those undergoing salvage TL.

## Guttman et al, 2013

### Title

Post-laryngectomy voice rehabilitation: comparison of primary and secondary tracheoesophageal puncture

### Authors

Guttman D<sup>1</sup>, Mizrachi A<sup>1</sup>, Hadar T<sup>1</sup>, Bachar G<sup>1</sup>, Hamzani Y<sup>1</sup>, Marx S<sup>2</sup>, Shvero J<sup>1</sup>.

### Affiliation(s)

<sup>1</sup>Department of Otorhinolaryngology-Head and Neck Surgery, Rabin Medical Center (Beilinson Campus), Petah Tikva, affiliated with Sackler Faculty of Medicine, Tel Aviv University, Ramat Aviv, Israel.

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### Journal and year of publication

IMAJ 2013 Sept; 15:565-567

### Type of publication

Retrospective study

### Introduction

Voice restoration following total laryngectomy is an important part of patients' rehabilitation and long-term quality of life.

### Objective

To evaluate the long-term outcome of indwelling voice prostheses inserted during (primary procedure) or after (secondary procedure) total laryngectomy.

### Subjects and Methods

The study group included 90 patients who underwent total laryngectomy and tracheoesophageal puncture (TEP) with placement of voice prosthesis at a tertiary medical center during the period 1990-2008. Background, clinical and outcome data were collected by medical file review. Findings were compared between patients in whom TEP was performed as a primary or a secondary procedure.

### Results

TEP was performed as a primary procedure in 64 patients and a secondary procedure in 26. Corresponding rates of satisfactory voice rehabilitation were 84.4% and 88.5% respectively. There was no association of voice quality with either receipt of adjuvant radiation/chemoradiation or patient age. The average lifetime of the voice prosthesis was 4.2 months for primary TEP and 9.06 months for secondary TEP (P= 0.025).

### Conclusions

Primary TEP provides almost immediate and satisfactory voice rehabilitation. However, it is associated with a significantly shorter average prosthesis lifetime than secondary TEP. Chemoradiotherapy and patient age do not affect voice quality with either procedure.

[Link to open access article](#)

## Cocuzza et al, 2013

### Title

Post laryngectomy speech rehabilitation outcome in elderly patients.

### Authors

Cocuzza S, Bonfiglio M, Grillo C, Maiolino L, Malaguarnera M, Martines F, Serra A.

### Affiliation(s)

Department of Medical Surgical Specialties, ENT Clinic, University of Catania, Policlinico Universitario "Gaspare Rodolico", Via Santa Sofia, 68, 95125 Catania, Italy.

### Journal and year of publication

Eur Arch Otorhinolaryngol. 2013 May;270(6):1879-84

### Type of publication

Retrospective study

### Introduction

The aim of this study was to evaluate the different options of tracheoesophageal voice rehabilitation in over 70-year-old patients, who had undergone laryngectomy, assessing advantages and drawbacks of this method of vocal recovery.

### Subjects and Methods

A retrospective study has been carried out with 40 subjects, all aged more than 70 years old, and who have been referred to tracheoesophageal voice rehabilitation. Primary tracheoesophageal puncture (TEP) was performed in 18 cases, secondary TEP in 22 cases

### Results

The results gathered in these patients were compared with data obtained from a group of 39 patients, less than 70 years of age that therefore represented the control group. In primary tracheoesophageal puncture (TEP), the short-term success was 67%, while in the 22 cases that underwent secondary TEP the short-term success was 64%. After 2 years from TEP, the long-term success was 82.5%, with 78% in primary TEP and 86% in secondary TEP. In the control group, the short-term success was 65% in primary TEP and 73% in secondary TEP. After 2 years from TEP, the long-term success was 77%, with 70% in primary TEP and 82% in secondary TEP.

### Conclusions

No statistically significant difference was found for incidence of complications during and after surgery ( $p > 0.9$ ), and for overall success ratio of prosthesis implants between the two groups ( $p > 0.7$ ). The possibilities of tracheoesophageal recovery of elderly patients do not show dissimilarities in comparison with the results in younger subjects.

## Lorenz et al, 2013

### Title

[A novel puncture instrument: the Provox-Vega® puncture set. Its use in voice prosthesis insertion following laryngectomy]. [Article in German]

### Authors

Lorenz KJ<sup>1</sup>, Hilgers FM, Maier H.

### Affiliation

<sup>1</sup>Klinik für Hals-Nasen-Ohren-Heilkunde, Kopf-Hals-Chirurgie, Bundeswehrkrankenhaus Ulm, Oberer Eselsberg 40, 89081, Ulm, Deutschland.

### Journal and year of publication

HNO. 2013 Jan;61(1):30-7.

### Type of publication

Prospective study

### Introduction

The use of voice prostheses has been considered the gold standard in voice rehabilitation following laryngectomy for the last 20 years. Insertion is generally performed as a primary procedure during laryngectomy or as a secondary procedure with a re-usable trocar or rigid esophagoscope, a guidewire and anatomic hemostatic forceps. The use of these instruments requires a certain level of experience on the one hand, while on the other use of a trocar and subsequent manipulation with the hemostatic forceps can lead to tissue trauma around the membranous wall or damage to the voice prosthesis. This publication presents the results of a phase I/II study using a novel atraumatic puncture set for primary and secondary tracheoesophageal puncture with immediate insertion of voice prostheses.

### Subjects and Methods

Once patients had been fully informed and given their consent, the Provox-Vega® puncture set was used in 21 patients in either a primary (16) or a secondary (5) procedure. All procedures were documented on video, while approach, complications and surgical success were recorded using a questionnaire.

### Results

The average surgical time was 83.5 ( $\pm$ 19.12) seconds for primary puncture with voice prosthesis insertion and 212.57 ( $\pm$ 93.03) seconds in secondary procedures. The prosthesis could be inserted without complication in 19 patients, while a longer prosthesis needed to be selected intraoperatively in two patients due to a thick membranous wall. No serious complications were observed. One patient incurred a discrete injury to the mucosa of the esophageal posterior wall.

### Conclusion

The Provox-Vega® Puncture Set proved itself to be a safe aid in the insertion of voice prostheses. It is significantly easier to use than other systems and tissue trauma is minimal. This new puncture system is easy to learn and, in most cases, no further instruments were required. Compared to the conventional method, it was preferred by all surgeons. The Provox-Vega Puncture Set could increase the acceptance of prosthetic voice rehabilitation after laryngectomy and make this procedure of voice rehabilitation available to more patients.

## **Balm et al, 2011**

### **Title**

The indwelling voice prosthesis for speech rehabilitation after total laryngectomy: a safe approach.

### **Authors**

Balm AJ, van den Brekel MW, Tan IB, Hilgers FJ.

### **Affiliation(s)**

The Netherlands Cancer Institute, Amsterdam, the Netherlands

### **Journal and year of publication**

Otolaryngol Pol. 2011 Nov-Dec;65(6):402-9

### **Type of publication**

Editorial article

### **Summary**

This editorial article provides an overview of the current status of comprehensive rehabilitation after total laryngectomy and the current methods of choice. A section on methods of choice regarding the timing of the tracheoesophageal puncture (TEP) and placement of the voice prosthesis highlights the preferences for primary TEP with immediate placement of the voice prosthesis. The advantages of this approach that are mentioned are avoiding a second surgical procedure and better estimate of the length of the voice prosthesis needed, which is almost always 8 mm. The authors only recommend secondary TEP when the proximal esophagus has been dissected of the trachea. In that case the method of choice is to wait 4 to 5 weeks to allow healing and then create the secondary puncture, preferably prior to the start of radiotherapy.

## Sinclair et al, 2011

### Title

Primary versus delayed tracheoesophageal puncture for laryngopharyngectomy with free flap reconstruction.

### Authors

Sinclair CF, Rosenthal EL, McColloch NL, Magnuson JS, Desmond RA, Peters GE, Carroll WR.

### Affiliation(s)

Department of Surgery, Division of Otolaryngology-Head and Neck Surgery, University of Alabama at Birmingham, Birmingham, Alabama 35294-0012, USA.

### Journal and year of publication

Laryngoscope. 2011 Jul;121(7):1436-40.

### Type of publication

Retrospective study

### Introduction

To determine whether postoperative complication rates and speech outcomes differ between patients undergoing primary versus secondary tracheoesophageal puncture following total laryngectomy with free flap reconstruction.

### Subjects and Methods

A retrospective clinical study in a tertiary academic center was made. Between November 2004 and June 2010, 137 patients underwent total laryngectomy or laryngopharyngectomy with pharyngeal free flap reconstruction for malignant disease. Data was collected on patient and operative demographics, early postoperative complications, speech outcomes, and predictive factors for tracheoesophageal puncture failure.

### Results

Thirty patients (22%) had a primary tracheoesophageal puncture performed at the time of laryngectomy, 27 patients (20%) received secondary punctures (>3 months postlaryngectomy), and 80 patients (58%) never received a puncture. In both the primary and the secondary puncture group, the voice prosthesis was fitted secondarily with a median time of 4 weeks after the puncture. Median time to voice acquisition was 56 days for the primary TEP group and 200 days for the secondary group. Patient and operative demographics were similar between groups ( $P < .05$ ), apart from proportionately more hypopharyngeal tumors in the "no puncture" group ( $P < .002$ ). Similar numbers of patients in primary and secondary puncture groups achieved intelligible speech (67% vs. 71%,  $P = .82$ ) and both groups reported good patient-perceived voice-related quality of life. Salvage surgery and non-patch radial forearm free flap reconstruction both trended toward increased early postoperative complication rates ( $P = .09$ ).

### Conclusions

There is no difference in the early postoperative complication rate for primary versus secondary tracheoesophageal puncture following total laryngectomy with concurrent free flap reconstruction. The advantage of primary puncture appears to be earlier voice restoration.

## Hutcheson et al, 2011

### Title

Enlarged tracheoesophageal puncture after total laryngectomy: a systematic review and meta-analysis.

### Authors

Hutcheson KA, Lewin JS, Sturgis EM, Kapadia A, Risser J.

### Affiliation(s)

Dept of Head and Neck Surgery, The University of Texas M. D. Anderson Cancer Center, Houston, TX, USA

### Journal and year of publication

Head & Neck 2011 Jan; 33:20-30.

### Type of publication

Systematic review and meta-analysis

### Introduction

Enlargement of the tracheoesophageal puncture (TEP) is a challenging complication after laryngectomy with TEP. The aim of the analysis was to estimate the rate of enlarged puncture, associated pneumonia rates, potential risk factors, and conservative treatments excluding complete surgical TEP closure.

### Methods

A systematic review was conducted (1978-2008). A summary risk estimate was calculated using a random-effects meta-analysis model.

### Results

Twenty-seven peer-reviewed manuscripts were included. The rate of enlarged puncture and/or leakage around the prosthesis was reported in 23 articles (range, 1% to 29%; summary risk estimate, 7.2%; 95% confidence interval [CI], 4.8% to 9.6%). Temporary removal of the prosthesis and TEP-site injections were the most commonly reported conservative treatments. Specifically, with regards to timing of the TEP as a primary or secondary procedure, results showed that excluding 1 outlier, rates of enlarged TEP/leakage around the VP were similar ( $p = .297$ ) among cohorts exclusively treated with primary TEP (range, 2% to 13%; median, 4%) compared with those exclusively treated with secondary TEP (range, 5% to 13%; median, 11%).

### Conclusions

Rates of enlarged TEP/leakage around the VP showed a non-significant difference between primary puncture (median 4%) and secondary puncture (median 11%). The overall risk of enlarged puncture seems relatively low, but it remains a rehabilitative challenge. Future research should clearly establish risk factors for enlarged puncture and optimal conservative management.

[Link to open access article](#)

## Emerick et al, 2009

### Title

Primary versus secondary tracheoesophageal puncture in salvage total laryngectomy following chemoradiation.

### Authors

Emerick KS, Tomycz L, Bradford CR, Lyden TH, Chepeha DB, Wolf GT, Teknos TN.

### Affiliation(s)

Department of Otolaryngology-Head and Neck Surgery, University of Michigan, Ann Arbor, MI, USA.

### Journal and year of publication

Otolaryngol Head Neck Surg. 2009 Mar;140(3):386-90.

### Type of publication

Retrospective study

### Introduction

To compare the rate of postoperative wound-healing complications and voice fluency in primary vs secondary tracheoesophageal puncture (TEP) following chemoradiation.

### Subjects and Methods

Between 1998 and 2005, 30 patients underwent laryngectomy after chemoradiation therapy. Twenty patients underwent primary TEP and 10 patients underwent secondary TEP. In the primary TEP group the voice prosthesis was fitted 3-4 weeks after the procedure, in the secondary TEP group 1-2 weeks after the puncture. The decision to perform a primary or secondary procedure was exclusively decided by the operating surgeon. Comorbidities, postoperative complications, speech fluency, and time to speech fluency were evaluated in each patient.

### Results

Pharyngocutaneous fistula (PCF) occurred in 10 of 20 (50%) patients who underwent primary TEP and in 0 of 10 (0%) patients in the secondary TEP group ( $P < 0.05$ ). Overall, 25 of 25 (100%) patients who had placement of a tracheoesophageal prosthesis achieved fluent speech. Median time to fluency was 63 days in the primary TEP group and 125 days in the secondary TEP group.

### Conclusions

The authors concluded that there is an increased risk of PCF in patients undergoing primary TEP compared with secondary TEP (both with secondary fitting) following chemoradiation. No difference in acquisition of speech fluency was identified between the two groups. Patients undergoing primary TEP achieved fluent speech 62 days sooner than their secondary TEP counterparts.

## **Mastronikolis et al, 2008**

### **Title**

Voice restoration after total laryngectomy using Provox 2 (generation II) prosthesis.

### **Authors**

Mastronikolis NS, Stathas T, Papadas TA, Spyropoulos K, Naxakis S, Goumas PD.

### **Affiliation(s)**

Department of Otorhinolaryngology, University Hospital of Patras, School of Medicine, Patras, Greece.

### **Journal and year of publication**

Eur Rev Med Pharmacol Sci. 2008 Sep-Oct;12(5):327-30.

### **Type of publication**

Prospective study

### **Introduction**

Voice restoration after total laryngectomy is of utmost importance for patient and a therapeutic challenge for the surgeon and speech pathologist. Among various rehabilitation methods prosthetic voice yields nowadays the best results. This article describes the results of prosthetic voice rehabilitation in Greece.

### **Subjects and Methods**

A total of 12 patients underwent laryngectomy between February 2006 and May 2007. All patients had advanced laryngeal squamous cell carcinoma. Eight patients had primary voice prosthesis inserted and four patients had a tracheo-esophageal puncture (TEP) carried out as a secondary procedure. In all cases a Provox2 voice prosthesis was fitted immediately after the puncture was created. All patients received a cricopharyngeal myotomy at the time of the total laryngectomy.

### **Results**

The majority of the patients (80%) developed good and intelligible speech using the voice prosthesis. No significant difference in quality of speech was found between the primary and secondary puncture subgroups. In the primary TEP group 87.5% of the patients rated their speech as good or excellent, in the secondary TEP group 75% rated their speech as good or excellent.

### **Conclusions**

The authors conclude that TEP puncture and prosthesis insertion is a relatively simple, safe and effective surgical procedure for voice restoration after laryngectomy.

## Boscolo-Rizzo et al, 2008

### Title

Long-term results with tracheoesophageal voice prosthesis: primary versus secondary TEP.

### Authors

Boscolo-Rizzo P, Zanetti F, Carpené S, Da Mosto MC.

### Affiliation(s)

ENT Department and Regional Center for Head and Neck Cancer, University of Padua-School of Medicine, Treviso Regional Hospital, Treviso, Italy

### Journal and year of publication

Eur Arch Otorhinolaryngol. 2008 Jan;265(1):73-7.

### Type of publication

Retrospective study

### Introduction

The aim of this study was to evaluate the influence of timing of tracheoesophageal puncture (TEP) with indwelling voice prosthesis insertion on long-term success rates and postoperative complications.

### Subjects and Methods

A retrospective chart review was conducted in 93 laryngectomized patients with a follow-up longer than 2 years. All patients underwent immediate retrograde insertion of the voice prosthesis at the time of the puncture procedure. The Harrison-Robillard-Schultz rating scale was as an outcome measure to evaluate TE speech; 'success' was defined as a score of 11 or higher on this scale covering Use, Quality and Care of TE speech and voice prosthesis. Variables taken into account were postoperative radiotherapy, age and primary versus secondary TE procedure.

### Results

There were 75 patients with primary TEP (80.6%) and 18 with secondary TEP (19.3%). Long-term success rate was 81.7%, with 80.0% in primary TEP and 88.9% in secondary TEP. No significant differences in success scores were observed between patients with primary and secondary TEP ( $P=.596$ ). The overall complication rate was 20.3% in the primary group and 16.7% in the secondary group. This difference was not statistically significant ( $P>.99$ ).

### Conclusions

The authors conclude that their findings suggest that primary and secondary TEP are equally safe and effective procedures. They suggest that primary TEP should be preferred because of avoiding a second surgical intervention and allowing early voice restoration with a considerable psychological impact.

## Malik et al, 2007

### Title

Surgical complications of tracheo-oesophageal puncture and speech valves.

### Authors

Malik T, Bruce I, Cherry J.

### Affiliation(s)

Department of Otolaryngology Head and Neck Surgery, Royal Blackburn Hospital, Blackburn, UK.

### Journal and year of publication

Curr Opin Otolaryngol Head Neck Surg. 2007 Apr;15(2):117-22.

### Type of publication

Literature Review

### Purpose of Review

Speech rehabilitation following total laryngectomy is central to future quality of life. Although other options exist, surgical voice restoration has emerged as the 'gold standard' management strategy in the majority of laryngectomees. The purpose of this review is to provide a comprehensive review of this subject, with particular reference to technique, complications and outcome.

### Recent findings

As with any surgical intervention, complications may occur in the early postoperative period or later. The article provides a detailed explanation of the varying problems detailed in individual reports, and in case series. Primary or secondary tracheo-oesophageal puncture is also discussed, along with complications resulting from the speech valve itself.

### Conclusions

The positive impact of surgical voice restoration on quality of life in the alaryngeal patient considerably outweighs the complications commonly associated with the procedure. Greater knowledge of the potential problems should continue to reduce the complication rate. Primary puncture, in a patient selected and subsequently managed in a multidisciplinary environment, would appear to provide the best outcome for the patient

## Kummer et al, 2006

### Title

[Prosthetic voice rehabilitation after laryngectomy. Failures and complications after previous radiation therapy]. [Article in German]

### Authors

Kummer P<sup>1</sup>, Chahoud M, Schuster M, Eysholdt U, Rosanowski F.

### Affiliation(s)

<sup>1</sup>Abteilung für Phoniatrie und Pädaudiologie, Universitätsklinikum Erlangen, Germany

### Journal and year of publication

HNO. 2006 Apr;54(4):315-22.

### Type of publication

Retrospective study

### Introduction

Indwelling voice prostheses are state of the art for post-laryngectomy voice rehabilitation. The aim of this study was to identify the impact of radiation prior to tracheoesophageal puncture on success rate and complications.

### Subjects and Methods

There were 145 patients who had undergone prosthetic voice restoration between 1990 and 2002 (Provox and Provox2). Risks of functional failure and complications in 17 patients with previous radiation therapy were compared to those of 128 patients without such therapy.

### Results

Previous radiation increased not only the risk of functional failure by 2.9 (P=0.023), but also the risk of shunt-related complications such as aspiration around the prosthesis (1.51; P=0.046), widening of the shunt (2.32; P=0.014), esophageal (2.51; P=0.013) or tracheal (3.29; P=0.0023) dislocation of the prosthesis and spontaneous (2.51; P=0.047) or surgical closure (3.76; P=0.037) of the shunt.

### Conclusions

Primary tracheoesophageal puncture during laryngectomy is recommended in cases without previous radiation therapy, especially when post-laryngectomy radiation is likely. In patients with previous radiation therapy, generally good success rates decrease, however, without absolute contraindication of tracheoesophageal puncture. These results may affect salvage surgery concepts.

## Cheng et al, 2006

### Title

Outcomes of primary and secondary tracheoesophageal puncture: a 16-year retrospective analysis.

### Authors

Cheng E, Ho M, Ganz C, Shaha A, Boyle JO, Singh B, Wong RJ, Patel S, Shah J, Branski RC, Kraus DH.

### Affiliation(s)

Head and Neck Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York City, NY 10021, USA

### Journal and year of publication

Ear Nose Throat J. 2006 Apr;85(4):262, 264-7.

### Type of publication

Retrospective case review

### Introduction

A 16-year retrospective analysis was conducted to investigate outcomes of primary and secondary puncture.

### Subjects and Methods

A retrospective chart review was conducted for 68 patients who had undergone total laryngectomy and tracheoesophageal puncture (TEP) over a 16-year period. Fifty-one patients underwent primary TEP and 17 underwent secondary TEP. Outcomes that were reviewed were voice quality and complications. Variables taken into consideration were timing of puncture and radiotherapy.

### Results

Nearly 80% of patients who received primary TEP achieved excellent voice quality ratings. In contrast, only 50% of secondary TEP patients achieved excellent voice ratings. This difference was statistically significant ( $p = 0.03$ ). Although both surgical and prosthesis-related complications occurred more frequently following primary TEP, the complication rates did not differ significantly. Neither pre- nor postoperative radiotherapy had any effect on voice restoration or complication rates.

### Conclusions

The authors conclude that based on their data, primary TEP may be preferable for several reasons, including a greater likelihood of successful voice restoration, a shorter duration of postoperative aphonia, and the elimination of the need for a second operation and interim tube feedings.

## Chone et al, 2005

### Title

Speech rehabilitation after total laryngectomy: long-term results with indwelling voice prosthesis Blom-Singer.

### Authors

Chone CT, Spina AL, Crespo AN, Gripp FM.

### Affiliation(s)

Faculdade de Ciências Médicas, Universidade Estadual de Campinas. Brazil

### Journal and year of publication

Braz J Otorhinolaryngol. 2005 Jul-Aug;71(4):504-9.

\*Also published as: Chone CT, Gripp FM, Spina AL, Crespo AN. Primary versus secondary tracheoesophageal puncture for speech rehabilitation in total laryngectomy: long-term results with indwelling voice prosthesis. Otolaryngol Head Neck Surg. 2005 Jul;133(1):89-93.

### Type of publication

Prospective study

### Introduction

The aim of this study was to evaluate the influence of time of performance of tracheoesophageal puncture (TEP), use of radiotherapy (XRT), age of patients, length of follow-up, and the rate of success of use of Blom-Singer VP.

### Subjects and Methods

Seventy-one patients were submitted to TL and rehabilitated with indwelling VP between January 1995 and September 2001. Both otolaryngologist and speech pathologist evaluated all patients for the vocal functional issues during the follow-up. The relative data on time of placement of VP, time of use of VP, use of XRT, age, length of follow-up and interval of duration of each VP were recorded during the follow-up. All patients underwent secondary fitting of the voice prosthesis. A catheter was placed in the TE puncture initially. In the primary puncture group the VP was fitted after 14 days and in the secondary group after 3 days.

### Results

Sixty-two patients (87%) were submitted to primary TEP and nine patients (13%) to secondary TEP. The follow-up varied from 12 to 87 months, with average of 38 months for primary and 51 months for secondary TEP. There were 59% of patients submitted to XRT. The general rate of success was of 94%. In primary TEP it was of 97% and in the secondary, it was 78% ( $p=0.07$ ) and after two years, the success rate was of 96% in primary TEP and 75% in secondary TEP ( $p=0.07$ ). The use of XRT and patient age did not influence the success of use of VP among primary and secondary TEP, independently of length of follow-up.

### Conclusions

The success rate of vocal rehabilitation was significant higher after TL with primary TEP (97%), compared to secondary TEP (78%). Postoperative radiotherapy and age did not influence success rate.

## Kao et al, 1994

### Title

The outcome and techniques of primary and secondary tracheoesophageal puncture.

### Authors

Kao WW, Mohr RM, Kimmel CA, Getch C, Silverman C.

### Affiliation(s)

Dept of Otorhinolaryngology&Bronchoesophagology, Temple University School of Medicine, Philadelphia, PA.

### Journal and year of publication

Arch Otolaryngol Head Neck Surg. 1994 Mar;120(3):301-7.

### Type of publication

Retrospective study

### Introduction

The aim of the study was to evaluate the outcome of primary versus secondary tracheoesophageal puncture (TEP), in particular the effects of preoperative and postoperative radiotherapy on success and complication rates in primary TEPs, and to highlight modified surgical and management techniques.

### Subjects and Methods

One hundred six consecutive patients underwent primary TEPs and 30 underwent secondary TEPs over a period of 8 years with follow-ups ranging from 6 months to 8.5 years. A catheter was placed at the time of TEP and the voice prosthesis was fitted secondary. The group given primary TEP also includes 19 patients who received salvage laryngectomy after radiotherapy treatment and 75 who received full-course postoperative radiotherapy. Speech measures included (1) voice intensity, (2) pitch of speech, (3) duration of sustained phonation, and (4) rate of speech.

### Results

A success rate of 93% was achieved in the group of patients given primary TEP regardless of radiotherapy. An 83% success rate was achieved with patients given secondary TEP. There were no major complications related to TEPs.

### Conclusions

Primary TEP for patients requiring total laryngectomy is highly recommended since a second operative procedure can be avoided and speech obtained rapidly. Postoperative radiotherapy does not increase the complication rate of TEP.

## Appendix 2 – Publications with abstracts for “Primary puncture and pharyngocutaneous fistulae”

### Lansaat et al, 2018

#### Title

Predictive factors for pharyngocutaneous fistulization after total laryngectomy: a Dutch Head and Neck Society audit.

#### Authors

Lansaat L<sup>1</sup>, van der Noort V<sup>2</sup>, Bernard SE<sup>3</sup>, Eerenstein SEJ<sup>4</sup>, Plaat BEC<sup>5</sup>, Langeveld TAPM<sup>6</sup>, Lacko M<sup>7</sup>, Hilgers FJM<sup>1,8,9</sup>, de Bree R<sup>10</sup>, Takes RP<sup>11</sup>, van den Brekel MWM<sup>12,13,14</sup>; Dutch Head and Neck Society.

#### Affiliation

<sup>1</sup>Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute-Antoni van Leeuwenhoek, Amsterdam, The Netherlands

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<sup>8</sup>Department of Oral-Maxillofacial Surgery, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands

<sup>9</sup>Institute of Phonetic Sciences (ACLIC), University of Amsterdam, Amsterdam, The Netherlands.

<sup>10</sup>Department of Head and Neck Surgical Oncology, University Medical Center Utrecht, Utrecht, The Netherlands

<sup>11</sup>Department of Otorhinolaryngology-Head and Neck Surgery, Radboud University Medical Center, Nijmegen, The Netherlands

<sup>12</sup>Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute-Antoni van Leeuwenhoek, Amsterdam, The Netherlands

<sup>13</sup>Department of Oral-Maxillofacial Surgery, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands. m.vd.brekel@nki.nl

<sup>14</sup>Institute of Phonetic Sciences (ACLIC), University of Amsterdam, Amsterdam, The Netherlands. Department of Medical Science, Advanced Surgery ENT, University of Catania, Italy

#### Journal and year of publication

Eur Arch Otorhinolaryngol. 2018 Mar;275(3):783-794..

**Type of publication**

Retrospective chart review

**Introduction**

Incidences of pharyngocutaneous fistulization (PCF) after total laryngectomy (TL) reported in the literature vary widely, ranging from 2.6 to 65.5%. Comparison between different centers might identify risk factors, but also might enable improvements in quality of care. To enable this on a national level, an audit in the 8 principle Dutch Head and Neck Centers (DHNC) was initiated.

**Subjects and Methods**

A retrospective chart review of all 324 patients undergoing laryngectomy in a 2-year (2012 and 2013) period was performed. Overall PCF%, PCF% per center and factors predictive for PCF were identified. Furthermore, a prognostic model predicting the PCF% per center was developed. To provide additional data, a survey among the head and neck surgeons of the participating centers was carried out.

**Results**

Overall PCF% was 25.9. The multivariable prediction model revealed that previous treatment with (chemo)radiotherapy in combination with a long interval between primary treatment and TL, previous tracheotomy, near total pharyngectomy, neck dissection, and BMI < 18 were the best predictors for PCF. Also secondary TEP and no TEP were identified as significant factors predictive for pharyngocutaneous fistulae compared to primary TEP (OR 3.83; 95% CI 1.58-9.31;  $P=0.003$ , and OR 3.63; 95% CI 1.78-7.39;  $P<0.001$  respectively). Early oral intake did not influence PCF rate. PCF% varied quite widely between centers, but for a large extend this could be explained with the prediction model. PCF performance rate (difference between the PCF% and the predicted PCF%) per DHNC, though, shows that not all differences are explained by factors established in the prediction model. However, these factors explain enough of the differences that, compensating for these factors, hospital is no longer independently predictive for PCF.

**Conclusions**

This nationwide audit has provided valid comparative PCF data confirming the known risk factors from the literature which are important for counseling on PCF risks. Data show that variations in PCF% in the DHNCs (in part) are explainable by the variations in these predictive factors. Since elective neck dissection is a major risk factor for PCF, it only should be performed on well funded indication.

## Chakravarty et al, 2018

### Title

Primary versus secondary tracheoesophageal puncture: systematic review and meta-analysis.

### Authors

Chakravarty PD<sup>1</sup>, McMurrin AEL<sup>2</sup>, Banigo A<sup>3</sup>, Shakeel M<sup>3</sup>, Ah-See KW<sup>3</sup>.

### Affiliation

<sup>1</sup>Department of Otolaryngology, Head and Neck Surgery, Queen Elizabeth University Hospital, Glasgow

<sup>2</sup>Department of Otolaryngology, Ninewells Hospital, Dundee

<sup>3</sup>Department of Otolaryngology, Head and Neck Surgery, Aberdeen Royal Infirmary, Scotland, UK

### Journal and year of publication

J Laryngol Otol. 2018 Jan;132(1):14-21.

### Type of publication

Systematic review

### Introduction

Tracheoesophageal puncture represents the 'gold standard' for voice restoration following laryngectomy. Tracheoesophageal puncture can be undertaken primarily during laryngectomy or in a separate secondary procedure. There is no current consensus on which approach is superior. The current evidence comparing primary and secondary tracheoesophageal puncture was assessed.

### Subjects and Methods

A systematic review and meta-analysis of articles comparing outcomes for primary and secondary tracheoesophageal puncture after laryngectomy were conducted. Outcome measures were: voice success, overall complication rate and pharyngocutaneous fistula rate.

### Results

Eleven case series met the inclusion criteria, two prospective and nine retrospective. Meta-analysis did not demonstrate statistically significant differences in overall complication rate or voice outcomes, though it suggested a significantly increased risk of pharyngocutaneous fistula in primary compared to secondary tracheoesophageal puncture.

### Conclusions

Primary tracheoesophageal puncture is a safe and efficient approach for voice rehabilitation. However, secondary tracheoesophageal puncture should be preferred where there is a higher risk of pharyngocutaneous fistula.

## Serra et al, 2015

### Title

Post-laryngectomy voice rehabilitation with voice prosthesis: 15 years experience of the ENT Clinic of University of Catania. Retrospective data analysis and literature review.

### Authors

Serra A, Di Mauro P, Spataro D, Maiolino L, and Cocuzza, S.

### Affiliation

Department of Medical Science, Advanced Surgery ENT, University of Catania, Italy

### Journal and year of publication

Acta Otorhinolaryngol Ital. 2015 Dec; 35(6): 412–419.

### Type of publication

Retrospective study

### Introduction

The objective of this study is to report our 15-year experience, in Sicily, with the use of voice prostheses following total laryngectomy, analysing the variables that have influenced the success or failure of speech rehabilitation.

### Subjects and Methods

A retrospective study was carried out by examining the clinical outcomes of 15 years of experience (1998-2013) in trachea-oesophageal voice rehabilitation, during which period 95 patients with laryngeal cancer were subjected to TEP with vocal prosthesis. The following variables were analysed: age, type of tumor, type of surgery, use of prior radiation therapy, type of puncture, prosthesis used and its duration, number of replacements, complications and causes for prosthetic success or failure.

### Results

The rate of postoperative laryngectomy complications was 13%, and the most common were pharyngocutaneous fistulas in 90% of cases, followed by bleeding in 5% and medical complications in another 5%. The presence of postoperative complications did not have an overall significant impact on failure of TEP ( $P=0.716$ ).

### Conclusions

Retrospective analysis of 15 years of prosthetic rehabilitation in the Sicilian territory highlighted standard rehabilitation almost identical to those found in the recent literature in terms of intra- and postoperative complications, fistula-related pathologies and overall success.

## Scotton et al, 2014

### Title

Time interval between primary radiotherapy and salvage laryngectomy: a predictor of pharyngocutaneous fistula formation.

### Authors

Scotton WJ<sup>1</sup>, Nixon IJ, Pezier TF, Cobb R, Joshi A, Urbano TG, Oakley R, Jeannon JP, Simo RS.

### Affiliation

<sup>1</sup>Academic Neurosciences Foundation Programme, Addenbrookes Hospital, Cambridge, CB2 0QQ, UK

### Journal and year of publication

Eur Arch Otorhinolaryngol. 2014 Aug;271(8):2277-83.

### Type of publication

Retrospective study

### Introduction

Salvage laryngectomy (SL) is associated with high levels of morbidity. Rates of pharyngocutaneous fistulae (PCF) are as high as 35 % in some series. Patients at highest risk of such complications may be candidates for altered surgical management in terms of additional tissue transfer, or delayed tracheoesophageal puncture. This study investigates the relationship between the time from primary radiotherapy (RT) to salvage surgery and the development of PCF.

### Subjects and Methods

Twenty-six consecutive patients who underwent SL between 2000 and 2010 were identified from the institutional database. Demographics, staging, treatment and complication data were collected.

### Results

At time of salvage surgery overall stage was II in 2 patients, III in 7 patients and IV in 17 patients. The mean age was 61 years, and 24 were male. A total of 15 of the 26 patients (58 %) developed a PCF. On analysis of the time between pre-operative RT and surgery, a significant difference was seen, with a mean time of 19.5 months in those who developed a PCF versus 47.0 months in those who did not ( $p = 0.02$ ). Patient characteristics, treatment, and pathology results were comparable between the two groups. There was no significant difference in distribution of the other covariates between the PCF and non-PCF groups.

### Conclusions

This study found a significant association between PCF formation and a short time interval from primary RT to salvage laryngectomy. Identifying factors associated with higher rates of post-operative morbidity allows surgeons to adapt surgical planning in an attempt to minimize rates of PCF.

## Basheeth et al, 2014

### Title

Pharyngocutaneous fistula after salvage laryngectomy: impact of interval between radiotherapy and surgery, and performance of bilateral neck dissection.

### Authors

Basheeth N<sup>1</sup>, O'Leary G, Sheahan P.

### Affiliation

<sup>1</sup>Department of Otolaryngology - Head and Neck Surgery, South Infirmity Victoria University Hospital, Cork, Ireland.

### Journal and year of publication

Head Neck. 2014 Apr;36(4):580-4.

### Type of publication

Retrospective study

### Introduction

Pharyngocutaneous fistula is a serious complication of total laryngectomy. The purpose of this study was to examine predisposing factors at our institution.

### Subjects and Methods

A retrospective review was conducted of 94 consecutive patients undergoing total laryngectomy between 1996 and 2012. Cases with hypopharyngeal primary tumors or undergoing extended hypopharyngeal resection with flap augmentation of the pharynx were excluded. Most cases had a primary tracheoesophageal puncture and a red rubber catheter or feeding tube was inserted.

### Results

Seventy-four cases met the inclusion criteria. A total of 25.7% patients developed a pharyngocutaneous fistula. The fistula rate was higher after salvage laryngectomy than after primary surgery (34.0% vs 11.1%;  $p = .05$ ). Among salvage laryngectomies, performance of laryngectomy within 1 year of completion of radiotherapy ( $p = .006$ ) and performance of concomitant bilateral neck dissection ( $p = .02$ ) were significant risk factors for development of a fistula. Radiation dose, addition of chemotherapy, use of pectoralis major myofascial flap, preoperative tracheostomy, primary puncture, primary tumor subsite, and initial T classification were not significant.

### Conclusions

The incidence of pharyngocutaneous fistula is greater after salvage total laryngectomy compared to primary laryngectomy. The time interval between completion of radiotherapy and surgery, and performance of concomitant bilateral neck dissection are significantly associated with pharyngocutaneous fistula after salvage total laryngectomy.

## Johnson et al, 2013

### Title

Primary tracheoesophageal puncture in salvage laryngectomy patients.

### Authors

Johnson A<sup>1</sup>, Grammer T, Medina J.

### Affiliation

<sup>1</sup>Department of Otorhinolaryngology, University of Oklahoma Health Sciences, Oklahoma City, Oklahoma 73104, USA.

### Journal and year of publication

Laryngoscope. 2013 May;123(5):1227-30.

### Type of publication

Retrospective study

### Introduction

The purpose of this study was to determine the rate of complications in the immediate postoperative period following primary tracheoesophageal puncture (TEP) after salvage laryngectomy.

### Subjects and Methods

A retrospective review was done of 26 patients who underwent primary TEP with salvage total laryngectomy, between 2000 and 2010. To minimize variables, the patients included were operated on by a single surgeon and rehabilitated by a single speech-language pathologist. The outcomes evaluated were the frequency of leakage around the TEP, dehiscence of the stoma, dislodging of the prosthesis, pharyngocutaneous fistula, time to initiation of oral intake, and length of hospital stay.

### Results

The mean age of the patients was 60.8 years (range, 41-78 years). Previous treatment consisted of radiotherapy in 14 patients and chemotherapy and radiation in 12. Tumor site was glottic in 12 patients, supraglottic in seven, subglottic in two, vallecula in three, and overlapping in two. The pharynx was repaired primarily in all patients and then reinforced with a pectoralis muscle flap in 13. Leakage around the TEP was observed in 4% of the cases. There were no instances of dislodging of the TEP, and six patients (23%) developed pharyngocutaneous fistula; 12% had a wound dehiscence but none were around the stoma. The average time to begin oral feeding was 5.7 days (standard deviation, 1.93), and the average hospital stay was 8.4 days (standard deviation, 1.93).

### Conclusions

Primary TEP in the setting of a salvage laryngectomy is associated with a low rate of complications. A pharyngocutaneous fistula occurred in 23% of the cases. Placement of a TEP at time of salvage laryngectomy may not in itself predispose to the development of a pharyngocutaneous fistula. It is more likely it results from the effects of radiation, chemotherapy, or both on the pharyngeal tissues. However, the patient should be informed that a primary TEP might increase the risk of pharyngocutaneous fistula.

## Dowthwaite et al, 2012

### Title

Postlaryngectomy pharyngocutaneous fistula: determining the risk of preoperative tracheostomy and primary tracheoesophageal puncture.

### Authors

Dowthwaite SA, Penhearow J, Szeto C, Nichols A, Franklin J, Fung K, Yoo J

### Affiliation(s)

Department of Otolaryngology–Head and Neck Surgery, Schulich School of Medicine & Dentistry, Western University, London, ON, Canada.

### Journal and year of publication

J Otolaryngol Head Neck Surg. 2012 Jun 1;41(3):169-75.

### Type of publication

Retrospective study

### Introduction

This article considers whether preoperative tracheostomy and primary tracheoesophageal puncture (TEP) contribute as independent risk factors to the development of pharyngocutaneous fistula (PCF), as well as discusses the significant factors related to the perioperative management of these patients.

### Subjects and Methods

Retrospective data were collected on 145 patients treated with total laryngectomy/pharyngolaryngectomy between January 2003 and July 2010 at the Victoria Hospital in London, Ontario, including whether preoperative tracheostomy or primary TEP was performed.

### Results

One in four (25%) patients developed a postoperative PCF. No increase in PCF rates was observed with either preoperative tracheostomy or primary TEP. Salvage surgery PCFs achieved lower rates of spontaneous fistula closure compared to those undergoing primary surgery ( $p = .002$ ).

### Conclusions

Neither preoperative tracheostomy nor primary TEP was associated with the development of PCF. Surgical closure of PCF is more likely to be required in the setting of salvage surgery.

## Emerick et al, 2009

### Title

Primary versus secondary tracheoesophageal puncture in salvage total laryngectomy following chemoradiation.

### Authors

Emerick KS, Tomycz L, Bradford CR, Lyden TH, Chepeha DB, Wolf GT, Teknos TN.

### Affiliation(s)

Department of Otolaryngology-Head and Neck Surgery, University of Michigan, Ann Arbor, MI, USA.

### Journal and year of publication

Otolaryngol Head Neck Surg. 2009 Mar;140(3):386-90.

### Type of publication

Retrospective study

### Introduction

To compare the rate of postoperative wound-healing complications and voice fluency in primary vs secondary tracheoesophageal puncture (TEP) following chemoradiation.

### Subjects and Methods

Between 1998 and 2005, 30 patients underwent laryngectomy after chemoradiation therapy. Twenty patients underwent primary TEP and 10 patients underwent secondary TEP. In the primary TEP group the voice prosthesis was fitted 3-4 weeks after the procedure, in the secondary TEP group 1-2 weeks after the puncture. The decision to perform a primary or secondary procedure was exclusively decided by the operating surgeon. Comorbidities, postoperative complications, speech fluency, and time to speech fluency were evaluated in each patient.

### Results

Pharyngocutaneous fistula (PCF) occurred in 10 of 20 (50%) patients who underwent primary TEP and in 0 of 10 (0%) patients in the secondary TEP group ( $P < 0.05$ ). Overall, 25 of 25 (100%) patients who had placement of a tracheoesophageal prosthesis achieved fluent speech. Median time to fluency was 63 days in the primary TEP group and 125 days in the secondary TEP group. Even primary TEP patients who developed PCF still acquired fluency more quickly than secondary TEP patients (75 vs 125 days).

### Conclusions

The authors concluded that primary TEP is associated with an increased risk of PCF compared to secondary TEP, in patients undergoing TL following concurrent chemoradiation therapy. No difference in acquisition of speech fluency was identified between the two groups. Patients undergoing primary TEP achieved fluent speech 62 days sooner than their secondary TEP counterparts. Both primary and secondary TEP should be considered safe options in the setting of salvage total laryngectomy following chemoradiation. Surgeons must weigh the potential increased risk for PCF in the primary setting against the significant delay in speech acquisition for secondary TEP.

## Boscolo-Rizzo et al, 2008

### Title

Multivariate analysis of risk factors for pharyngocutaneous fistula after total laryngectomy.

### Authors

Boscolo-Rizzo P<sup>1</sup>, De Cillis G, Marchiori C, Carpenè S, Da Mosto MC.

### Affiliation(s)

<sup>1</sup>ENT Department and Regional Center for Head and Neck Cancer, University of Padua, School of Medicine, Treviso Regional Hospital, Padua, Italy.

### Journal and year of publication

Eur Arch Otorhinolaryngol. 2008 Aug;265(8):929-36.

### Type of publication

Retrospective longitudinal study

### Introduction

This investigation was conducted in order to better identify, particularly through multivariate analyses, the configuration of factors that most closely impact the development of pharyngocutaneous fistula (PCF). Incidence and treatment of PCF were also revisited.

### Subjects and Methods

Patients who underwent total laryngectomy between 1989 and 2006 were identified by searching computer-based medical records in a tertiary academic referral center.

### Results

A total of 218 patients were included. There were 47 patients (21.6%) developing PCF within 1 month after surgery (median 14 days, range 2-26 days). Non-surgical closure of the PCF was achieved in 36 patients (76.6%) within a median of 16.5 days (range 8-27 days). Eleven patients (23.4%) required a surgical closure of the PCF. In nine patients the surgical approach consisted in resuturing of the pharyngeal mucosa. Major surgery with the use of flaps (pectoralis major myocutaneous flap and free forearm flap) was required in two patients. Multivariate analysis revealed that diabetes mellitus (odd ratio 23.41 [95% CI 8.46-64.78]), preoperative hypoalbuminemia (odd ratio 9.42 [95% CI 3.60-24.61]), chronic pulmonary diseases (odd ratio 6.64 [95% CI 1.97-22.56]) and chronic hepatopathy (odd ratio 3.26 [95% CI 1.19-9.96]) were independent predictors for PCF formation.

### Conclusions

Primary trachea-esophageal fistula (TEP) with voice prosthesis insertion and pharyngeal constrictor myotomy was not associated to an increased incidence of PCF in univariate analysis.

Preoperative hypoalbuminemia and comorbidities, especially diabetes mellitus, were found to be significant predictors of PCF developing. Optimizing of comorbidities and correction of nutritional deficiencies should be achieved as early as possible to reduce the risk of PCF and to avoid a delayed TL.

## Parikh et al, 1998

### Title

Pharyngocutaneous fistulae in laryngectomy patients: the Toronto Hospital experience.

### Authors

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### Type of publication

Retrospective study

### Introduction

The purpose of this study was to determine the rate of post-laryngectomy pharyngocutaneous fistulae and its association with age, gender, preoperative radiation, TNM staging, comorbidity factors, choice of ablation, choice of reconstruction, modality of postoperative feeding, and whether or not a primary tracheoesophageal puncture was performed.

### Subjects and Methods

One hundred and twenty-five consecutive laryngectomy procedures performed between July 1, 1992, and October 1, 1996, were reviewed. Feeding route was through the primary TEP in 36, via nasogastric tube in 60, and via a pre-existing gastrostomy in 25.

### Results

There was an overall fistula rate of 22%. No association found was between fistula rates and age, gender, patient comorbidity factors, TNM stage, choice of ablation, choice of reconstruction, modality of postoperative feeding, or whether a primary tracheoesophageal puncture was performed or not. Within the subset of patients that underwent laryngectomy, laryngopharyngectomy or laryngoesophagolaryngectomy, the fistula rate in the puncture site tube fed group was 31% (12/39) versus 23% (15/66) in the nasogastric tube fed group ( $p=.65$ ). Concerning feeding route, non-significant differences were found between fistula rates for nasogastric tube feeding (18%), gastrostomy tube feeding (20%), or TEP site tube feeding (28%). Barium-swallow studies to predict fistula were found to have a false negative rate of 14%: of the 65 negative studies, 9 still developed a fistula.

### Conclusions

Although others have demonstrated or hypothesized patient variables in influencing pharyngocutaneous fistula, this study showed no evidence of increased fistula rates by patient gender, age, preoperative irradiation, or presence of neck nodes. At this tertiary care head and neck oncology center, pharyngocutaneous fistulae remain an unpredictable and serious complication with an estimated economic cost of Cdn \$400,000 per year.

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