

Laryngectomy

**Clinical Summary** 

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# Evidence-Based Recommendations in Primary Tracheoesophageal Puncture for Voice Prosthesis Rehabilitation.

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# Background

Larynx cancer is the most common Head and Neck cancer in Europe. In advanced stages, the treatment often involves a total laryngectomy (TL), which involves the surgical removal of the larynx resulting in loss of phonation. To compensate for this loss, tracheoesophageal voice rehabilitation is the current gold standard therapy, providing increased quality of life through better outcomes of vocal quality. The placement of the voice prosthesis involves performing a tracheoesophageal puncture (TEP), carried out either during total laryngectomy, known as primary TEP, or it can be delayed and performed after the patient has recovered from surgery, in which case it is referred to as secondary TEP. While evidence suggests primary TEP leads to quicker voice recovery, there is ongoing debate about the timing of TEP, contributing to the higher prevalence of secondary TEP.

# Objective

- Define evidence-based recommendations for primary TEP with VP placement.
- Establish conditions and requirements for performing primary TEP.
- Determine indications and contraindications of primary TEP.
- Outline complications and their management related to primary TEP.

# Results

The systematic review retrieved 91 articles. From these articles, 19 statements were formulated and given levels of evidence and recommendations.

Abbreviations: VP, voice prosthesis; RCT, randomized controlled trial PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analysis; RCTs, Randomized controlled trials; RT, radiotherapy; PE, pharyngoesophageal

## Aim

Provide evidence-based recommendations for HCPs to serve as a valuable tool in the choice of procedure enhancing the quality of life and care for patients undergoing TL.

#### Study design

Systematic Review, following the PICO-framework.

- First resource identification (7 databases)
- Initial screening (n=467 articles) => exclusion (n=376 articles)
- Inclusion (n=91 articles)

Grading evidence and recommendations:

• Level of evidence: 1-4 Grade of recommendation: A-C

#### **Outcome parameters**

- Description of the care-process around primary puncture.
- Evidence-based recommendations for HCPs.

#### **Key points**

- Given the potential benefits of primary TEP, the possibility of performing primary TEP should be considered in every patient undergoing TL.
- For the patient there does not appear greater surgical complications or higher mortality with primary TEP.
- It improves voice-related quality of life, thanks to earlier communication, and earlier initiation of voice rehabilitation which also links to the association with greater plasticity of the PE segment.
- Typically, rehabilitation with primary TEP starts day 10-14 post-op, and the time to achieve fluent speech is earlier than secondary TEP.

#### Reference

Mayo-Yáñez M, Klein-Rodríguez A, López-Eiroa A, Cabo-Varela I, Rivera-Rivera R, Parente-Arias P. Evidence-Based Recommendations in Primary Tracheoesophageal Puncture for Voice Prosthesis Rehabilitation. Healthcare (Basel). 2024;12(6).

## Recommendations for surgery, TEP Indications and contraindications

- The use of a surgical kit for safe and rapid execution (4, C).
- Can be performed in all patients undergoing TL regardless of the extent of the tumor (4, C).
- In salvage laryngectomies after chemo-radiotherapy no increased incidence of complications related to VP (4, C).
- Perform a multidisciplinary pre-operative evaluation for correct patient selection (3b, B).
- Centers with experience offer the best rehabilitative outcomes (2b, B).
- Procedure performance in centers without resources for rehabilitative outcomes and follow-up is not recommended (2b, B).

## Benefits of primary TEP over secondary

### For the patient (4, C):

- Does not appear to entail greater surgical complications or higher mortality than secondary TEP.
- Improves voice-related quality of life.
- Promotes earlier communication.
- Earlier initiation of voice rehabilitation and achieving proper phonation before receiving RT treatment if necessary.
- Rehabilitation can begin about 2 weeks (day 10-14) after surgery if there are no complications.
- Time to achieve fluent phonation is around 56 days in primary TEP and 200 days in secondary TEP.
- Quicker familiarization with the VP, phonation and care.
- Associated with earlier return to work.
- Associated with greater plasticity of the PE segment facilitating better short- and long-term voice outcomes. (4, C)

### For the healthcare system (4, C):

• Single procedure and avoidance of new admission, intervention and possible postop complications. Cost saving for healthcare system. (4, C)

## For HCPs (4, C):

- Less frequent voice prosthesis changes, longer duration of the first VP compared to a VP of secondary TEP.
- Reduced follow-up consultations.
- Primary TEP supposes better accessibility and surgical ease creating the fistula in a more natural and horizontal position, which can subsequently facilitate VP replacements.
- Pharyngeal stenosis associated with RT can complicate the secondary puncture technique and phonatory rehabilitation. (4, C)

## **Recommendations for complications management**

• For the management of periprosthetic leakage, the replacement of the prosthesis with a double flanged one, such as the Provox Vega XtraSeal, is recommended (3b, B).

## Influence of primary TEP on the occurrence of postoperative pharyngocutaneous fistula

• Primary TEP has not been shown to influence the incidence of pharyngocutaneous fistula following TL (4, C).

Abbreviations: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analysis; RCTs, Randomized controlled trials; VP, voice prosthesis; RT, radiotherapy; PE, pharyngoesophageal

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# Conclusions

Given the potential benefits of primary TEP, the possibility of performing primary TEP should be considered in every patient undergoing TL.

- No evidence-based recommendation/statements comparing the outcomes of primary versus secondary TEP have been formulated, as observational studies often are graded with lower level of evidence.
- Primary TEP does not appear to entail greater surgical complications or higher mortality than secondary TEP.
- Primary TEP has not been shown to influence the incidence of PCF.

# Methods

a) Systematic Review performed with PRISMA guidelines

Search restrictions: Participants (P): patients undergoing TL. Intervention (I): primary TEP. Comparison (C): secondary TEP. Outcome/Results (O): vocal outcomes, quality of life and complications.

Search-terms: prosthesis; total laryngectomy; tracheoesophageal puncture. Inclusion criteria: RCTs, observational studies, meta-analyses, and systematic reviews.

b) Grading of the evidence

Using the Oxford Levels of Evidence system to formulate gradings and recommendations.



**Figure 1.** PRISMA flow diagram of identification of new studies via databases and registers and generated outcomes.