

## Safety and Efficacy of Primary vs. Secondary Tracheo-Esophageal Puncture (TEP) for the Insertion of Voice Prosthesis

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### Introduction

The success of restoring vocal communication in total laryngectomees has improved significantly after the introduction of the trachea-oesophageal puncture (TEP) and insertion of voice prosthesis (VP) as first described by Singer and Blom in 1980; the procedure has progressively gained popularity to be universally recognised as a routine procedure for speech restoration after total laryngectomy [1].

This procedure has shown to be superior to previous others designed for restoring a laryngeal speech (eryngophonic speech, laryngophone) in terms of a more natural sounding voice, superior voice quality, improved success rates and more immediate voice rehabilitation [2,3], while the major limitations of TEP, apart from requiring a general anesthesia to be performed, is the need of a clinician to replace the prosthesis.

Progressive technological advancements and refinements of VP (Blom-Singer Classic®, Blom-Singer Dual Valve®, Provox2®, Provox Vega® and Provox ActiValve®) have furthermore allowed to meet the criteria of low air flow resistance, optimal retention in the tracheaoesophageal party wall, prolonged device lifetime and comfortable management of the prosthesis either by the patients or by their caregivers.

Though TEP has shown to provide a high success rate, discussions among scientists still exist about the opportunity of performing it at the same stage of the laryngectomy (primary TEP) or delaying the procedure (secondary TEP) once the patient recovers either from surgery or after adjuvant radiotherapy and on background risk factors to be considered before planning the insertion of the prosthesis.

With this regard, the case report published four years ago [4] urges the need for reviewing the literature upon indications, primary or secondary TEP insertion and its potential benefits and pitfalls, though, in the last decade, the formers overwhelm the latter.

Generally the benefits of primary TEP consist in avoiding a second procedure with immediate good voice restoration, particularly favorable issue when facing old patients, while the rate of reported intra- and/or postoperative life-threatening complications after a secondary puncture ranges between 15 to 25%. These include para-oesophageal abscess cellulitis, aspiration of the prosthesis, enlarged fistula, oesophageal perforation, oesophageal stenosis, death from aspiration pneumonia, fracture of the cervical spine, osteomyelitis, subcutaneous emphysema and wound infection [5,6].

More recently a case of quadriplegia caused by cervical spine abscess following voice prosthesis replacement [7] and one of mediastinitis due to a small lesion of the posterior wall of the oesophagus after secondary TEP [8] have been reported, while among minor (or

reversible) sequelae the presence of granulomas, periprosthetic leakage, fistula, prosthesis migration and abnormal colonisation of bacterial and fungal biofilms have been reported by many Authors, more frequently encountered after secondary than primary TEP [9].

Actually, the relative ease of VP insertion in primary TEP under general anesthesia should recommend this choice considering also the low complication rate of this procedure established in many clinical studies [10,11].

If compared, eventually, with secondary TEP, intraoperative voice prosthesis placement is associated with less frequent need for device changes for VP resizing, earlier commencement of voice rehabilitation, reduced length of hospital stay and, last but not least, cost savings (of \$559.83/person). Superior clinical and patient benefits are associated with intraoperative voice prosthesis placement during primary TEP [12].

The outcome of the procedure very much depends on the accuracy of patients' selection according to the parameters use, quality and care as stated by the Harrison-Robillard- Schultz (HRS) TEP rating scale [13] with the need to rule out pre-operatively an hypertonicity or spasm of the pharyngo-esophageal sphincter (PES) via a video-fluoroscopy to guarantee a regular swallowing, while the assessment of an adequate pulmonary function with the Taub test seems to have lost its significance.

Appropriate esophageal position and patency can be evaluated with barium swallow, while the correct selection of prosthesis length can be established by palpation of the thickness of the TE wall, either bi-digitally during primary TEP or by palpating the TE wall onto the esophagoscope during secondary TEP.

As reported in our experience [4], pre-operative radiotherapy (PORT) does not seem to affect the potential outcome nor overexposes to complications; this has been more recently confirmed in a more recent paper [14] in which background factors such as age and PORT do not correlate with a major frequency of complications. Moreover, the recent availability of disposable sets for immediate (primary or secondary) VP insertion facilitates the procedure while previously (as described in the article) this was carried out with a trocar and a cannula which need to be sterilized and sharpened [15].

To summarize, indwelling low-resistance voice prostheses have become the valves of choice in patients with TEP, reporting high success rates with excellent voice quality.

Due to the immediate voice restoration, the ease of the insertion, the cost-benefit ratio and, overall, the reduced risk of complications, primary TEP currently represents the best choice for restoring the voice after total laryngectomy. Even in experienced hands, in fact, secondary TEP has proven to be a potential source of life-threatening

complications, as the one reported in our experience, mainly due to an incorrect surgical procedure.

To minimize the failure rates, a thorough selection of patients and the availability of disposable sets for VP insertion are mandatory.

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