

Critical Review: Effect of primary versus secondary tracheoesophageal puncture (TEP) on voice rehabilitation in patients who have undergone total laryngectomy.

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This critical review outlines the effects of primary versus secondary tracheoesophageal puncture (TEP) on voice rehabilitation in patients who have undergone total laryngectomy. The study designs reviewed included non-randomized retrospective mixed group design(4) and non-randomized prospective mixed group design (1). Overall, the evidence fails to reach a consensus, although the research suggests a tendency towards more successful voice rehabilitation for primary versus secondary TEP. Concerns in the literature's methodology are discussed along with recommendations for future research and clinical implications.

Introduction

New advances in surgical techniques and radiation therapy have increased voice conservation and survivorship in patients with laryngeal cancer (Hartl et al., 2011); however, total laryngectomy remains the only curative option for patients with advanced or recurrent laryngeal cancer. This procedure causes detrimental functional and physiological effects for patients, such as the total loss of voice, which can result in decreased quality of life (Kapila, Deore, Palav, Shah, & Jagade, 2011; Robertson, Yeo, Dunnet, Young, & MacKenzie, 2011). Voice restoration, therefore, is a primary goal for patients who undergo total laryngectomy.

The tracheoesophageal puncture (TEP) and placement of a voice prosthesis is currently the most common method of voice restoration after total laryngectomy (Karlen & Maisel, 2001; Shuxin, 2010). Evidence suggests that, compared to other methods of voice restoration, tracheoesophageal speech provides the best speech outcomes, including higher rates of successful voicing, longer maximum phonation time and increased speech intelligibility. (Deschler, Bunting, Lin, Emerick, & Rocco, 2009; Roxburgh & Perry, 2004; Shuxin, 2010).

A TEP may be performed as a secondary, delayed procedure after total laryngectomy, as originally described by Singer and Blom (1980). The procedure involves creating a fistula in the tracheoesophageal wall in which a one-way voice prosthesis (VP) can be placed at a time deemed appropriate for the patient. Performing a primary TEP at the time of total laryngectomy has become increasingly popular due to evolved surgical techniques and identified advantages (Singer & Blom, 1980; Emerick et al., 2009). One identified advantage is that patients are not subjected to a secondary procedure for voice restoration. In addition,

patients may have a more immediate initiation of voice rehabilitation post-laryngectomy as compared to patients with a secondary TEP (Roxburgh & Perry, 2004). Despite these advantages, both primary and secondary TEP with VP placement have been found to be efficacious for voice restoration. Although voice restoration may be achieved regardless of timing of TEP, no consensus has yet been reached within the literature regarding which procedure provides the best voice restoration outcomes in patients who undergo total laryngectomy, (Saurajen, Chee, Siow, Lim, Mok, & Earnest, 2000; LeBert et al., 2009).

Objectives

The objective of this review is to critically evaluate the existing literature that investigates the effects of primary versus secondary TEP on voice restoration in patients who have undergone total laryngectomy.

Methods

Search Strategy

The search was completed using computerized databases including Web of Science, PubMed, and Scopus. Search words included (Laryngectom\$) AND [(Primary AND/OR Secondary)] AND (outcomes AND/OR speech OR voice)]. The reference section of selected articles were also reviewed for further articles related to the topic of this critical review.

Selection Criteria

All articles pertaining to the effects of primary versus secondary TEP on voicing outcomes were included in this critical review. Only articles that are peer reviewed and originally written in English were included. No limit was placed on the geographical location of the study; however, due to advances in the TEP procedure, this critical review only included articles published between 1990 and 2011.

Data Collection

Results of the literature search produced the following five articles that related to the selection criteria: non-randomized mixed-group design (5).

Results

The following studies are non-randomized mixed-group designs. In this study design, participants are not randomly allocated to the different treatment groups; therefore, allocation bias is not minimized and performance data may be impacted. In the mixed-group design, variables are compared within and between groups.

Study #1 Boscolo-Rizzo, Zanetti, Carpena, & Da Mosto (2007) investigated retrospectively the effects of indwelling VP in primary versus secondary TEP on long-term voice rehabilitation success rates and post-operative complication rates. For the interest of this critical review, only results of voice outcomes will be discussed. Voice rehabilitation outcomes were measured using the Harrison-Robillard-Schultz (HRS) TEP rating scale, which rated *use of speech, voice quality, and care of prosthesis* as assessed by the speech-language pathologist. Using this scale, parameters were scored on a 5 point scale with a maximum total of 15. Since an indwelling VP is not changed independently by the patient, a maximum score of 4 could be obtained in the care of prosthesis category during this study. Voice rehabilitation was considered successful for overall HRS scores of 11 or higher. All patients included in the study received voice restoration training by a speech-language pathologist 2 weeks prior to placement of an indwelling voice prosthesis.

Patients who had undergone total laryngectomy between 1996 and 2004 and had follow-up data longer than 2 years were included in this study. Ninety-four participants were divided into two groups. The first group comprised of 75 patients who underwent total laryngectomy after May 1998 and received primary TEP. A cricopharyngeal myotomy was performed on all patients with primary TEP in order to ensure proper vibration of the pharyngoesophageal segment (PES) for successful voicing. The second group comprised of 18 patients who underwent total laryngectomy between January 1996 and May 1998 and received secondary TEP. A speech-language pathologist evaluated the vibratory pattern of the PES in all patients with a secondary TEP. Those patients with hypertonicity or spasms of the PES were not included in this study.

Results were analysed using the Mann-Whitney's U test and indicated no statistically significant difference in

long-term voice restoration success between primary versus secondary TEP (80% and 88.9% respectively, $p=0.596$), although a tendency for a higher success in secondary TEP was demonstrated.

In addition, other contributing factors, such as age and use of post-operative radiotherapy, were also analysed within both TEP groups to determine possible effects on voice rehabilitation success rates. The authors noted that the primary TEP group had a statistically significant older median age (64 years) compared to the secondary TEP group (59.5 years). Results indicated that post-operative radiotherapy did not significantly influence success rates in either TEP group ($p=0.285$). In contrast, age older than 60 years significantly influenced success rates in the primary TEP group ($p=0.0012$) while having no significant effect in secondary TEP ($p=0.098$). Overall, the evidence suggested no significant difference in success rates between primary and secondary TEP with a tendency towards higher success in secondary TEP group.

This mixed-group study presents itself with many limitations and results should be interpreted with caution. Although strengths of this study include its appropriate outcome evaluation measures as well as its comprehensive statistical analysis of within-group influencing factors, the study's validity and reliability are questionable. The inclusion criteria for patients are problematic as primary and secondary patients were treated differently. Furthermore, only patients with follow-up data longer than 2 years were included, which may have skewed data toward increased success rates. In fact, the tendency for higher success in the secondary TEP group may be an artifact of the inclusion criteria as well as the younger median age in secondary TEP group. This study presents with level II statistical evidence. Overall, the evidence of this study is equivocal and results should be interpreted with caution. Replication of results is recommended.

Study#2 Similar to Boscolo-Rizzo et al. (2007), Cheng et al.(2006) also analysed retrospectively successful speech outcomes in primary versus secondary TEP. In this study, the incidence of successful speech outcomes and complication rates were analysed in patients who had undergone total laryngectomy and received either primary or secondary TEP between 1987 and 2002. Speech outcomes were evaluated by a speech-language pathologist, primarily on vocal duration, continuity, fluency and intensity, during a conversational sample. Voicing was then classified perceptually as *excellent, fair or poor* based on these measures. No further details of outcome criteria or definitions were given. The percentage of patients who use a prosthesis as their

primary mode of communication was also evaluated as part of successful speech outcomes.

Sixty-eight patients were included in the study and divided into two groups. Fifty-one patients who underwent primary TEP comprised the first group and 17 patients comprised the secondary TEP group. The median length of time to secondary TEP from laryngectomy was 23 months. Voice outcome data was available for only 50 out of the 68 included patients (36 in the primary group and 14 in secondary group).

Results were analysed appropriately, using the Fischer's exact test, and revealed significantly more patients in the primary TEP group (78%) achieved *excellent* voice quality compared to the secondary TEP group (50%, $p=0.03$). In addition, similar numbers of patients in primary versus secondary TEP groups achieved *fair* (14% versus 36%, respectively) and *poor* voice quality (8% versus 14%, respectively). Of the primary TEP group, 78% of patients consistently used a VP as their primary mode of communication compared to 71% in the secondary group. Overall, results suggest that primary TEP is preferable over secondary TEP due to superior quality of voice acquisition, indicating the results' clinical importance. Statistical analysis was also completed within groups regarding the impact of complication rates, and radiotherapy. Results indicated that these factors did not significantly influence successful voicing acquisition in either group ($p=0.40$).

This study of level II evidence demonstrates strengths and weaknesses. Cheng et al. (2006) recognized that the study's small number of participants in the secondary TEP group may have resulted in decreased statistical differences. Also, the study lacks definitions for speech outcome parameters. However, the clinical importance provided by this study and its overall strengths in statistical analysis and equal group treatment render the results as suggestive.

Study #3 In like manner to Boscolo-Rizzo et al. (2007) and Cheng et al. (2006), Sinclair et al. (2011) used a retrospective design to examine the effects of primary versus secondary TEP on post-operative speech outcomes and complication rates after total laryngectomy. However, Sinclair et al. chose to only include individuals who received a free flap reconstruction in this study because the type of surgical reconstruction received can impact voicing outcomes. Data was collected on TEP speech outcome measures including time to acquire voicing from laryngectomy, and the ability to produce intelligible speech as assessed by a speech-language pathologist at time of last follow-up. The Voice-Related Quality of Life (VRQOL) and Voice Handicap Index (VHI) were administered

retrospectively by phone to patients in order to assess their voice-related quality of life. Only two patients from each group ($n=6$) completed the surveys because the remainder of patients were unable to be contacted ($n=126$), were deceased ($n=3$), or had chosen to remove their VP ($n=2$, secondary TEP).

One hundred and thirty-seven patients were included in this study. Patient selection included individuals who underwent a laryngectomy or laryngopharyngectomy with free flap reconstruction between 2004 and 2010. Patients were grouped into primary TEP ($n=30$), secondary TEP ($n=27$) and no TEP ($n=80$) groups. Patients within the no TEP group comprised of those who had planned to receive a secondary TEP but never received one. Overall, 81% of included patients received a patch radial forearm free tissue flap during reconstruction. Within 2 to 4 weeks of the TEP, an indwelling VP was fitted and patients were assessed for speech intelligibility by a speech-language pathologist 1 to 2 weeks after the fitting.

Results were analysed appropriately across groups, using the Fischer's exact test for categorical data. Results indicated that, at the time of last follow-up, similar numbers of patients in the primary TEP group (67%) compared to the secondary TEP group (71%) achieved intelligible speech ($p=0.75$). Similarly, results showed overall good patient-related quality of life measures for the VRQOL ($p=0.92$) and VHI ($p=0.58$) for both primary and secondary TEP groups. For the primary TEP group, the median time to acquire voicing was 56 days and 200 days for the secondary TEP group. Sinclair et al. also indicated that the primary factor that delayed voice acquisition in secondary TEP included post-operative complications and disease recurrence. Given this factor and the drastic contrast in the median time to voice acquisition between primary versus secondary TEP, the authors suggested use of primary TEP, as this may result in immediate increases in short-term quality of life.

This well-formulated retrospective study presents with both strengths and weaknesses. Many of the study's strengths lay in its validity, as a virtue of its comprehensive methodological design and detail. Along with its large sample size, and similar group treatment, speech outcomes also comprised of quality of life measures. A limitation of this study, however, is its reduced reliability, which is impacted by the restricted number of participants who completed the quality of life surveys as well as lack of a definition for speech intelligibility. However, Sinclair et al. (2011) also stresses the study's clinical implications regarding time to voice acquisition. Due to its validity and the clinical

importance, this study provides level II statistical evidence and results are suggestive.

Study #4 In patients with recurrent carcinoma, chemoradiation may be introduced to improve survivorship (Nguyen, Sallah, Karlsson & Antoine, 2002). Chemoradiation, however, may impact tissue integrity, which can influence voicing outcomes. Emerick et al. (2009) investigated this influence on voicing outcomes by comparing retrospectively voice fluency and complication rates in patients who had received post-operative chemoradiation. In addition, they compared voicing outcomes in primary versus secondary TEP. Data was collected on complication rates and the time to acquire fluent speech from the time of laryngectomy, although no definition for voice fluency was given. For all patients in this study, VP placement and voice fluency assessments were performed by a speech-language pathologist.

This study included patients between 1998 and 2005 who received chemotherapy, followed by chemoradiation and total laryngectomy as a result of recurrent disease. Thirty patients were identified and split into a primary or secondary TEP group. Twenty patients received primary TEP and 10 patients received secondary TEP. Emerick et al. (2009) provided no details regarding type of VP used during voice rehabilitation. In total, 4 patients in the primary group and 1 in the secondary group did not have a prosthesis placed.

Voice fluency results were analysed using the Fischer's exact test. Results indicated that, overall, all patients who had a VP placed achieved fluent speech. The median time to achieve fluent voicing was 63 days for primary TEP and 125 days for secondary TEP. Upon further analysis, Emerick et al. (2009) noted that, strikingly, even the primary TEP patients who developed post-operative complications acquired voice fluency more quickly than the secondary TEP group (75 versus 125 days, respectively). Similar to Sinclair et al. (2011), Emerick et al. noted that this delay in voice acquisition may negatively influence patients' quality of life, and as a result, suggest primary TEP should be preferred over secondary TEP in this population.

This level II evidence study presents both strengths and weaknesses. Emerick et al. (2009) remarked that a major limitation of this study is the lack of data on voice quality. They also mentioned more formal voice evaluation measures are required in order to identify precise differences in patients' quality of speech. In addition to these limitations, the small sample size in the secondary TEP group and lack of definitions for voice

fluency negatively influences the study's reliability. However, strengths of this study comprise of its equal treatment of groups, overall validity and methodological design, as well as its comprehensive statistical analysis. Because of these strengths in addition to the clinical implications regarding the difference in time to acquire fluent voicing, results of this study are suggestive.

Study #5 Similar to the above mentioned studies, Chone, Gripp, Spina, & Crespo (2005) also studied voice rehabilitation success in primary versus secondary TEP; however, in contrast to the previous studies' retrospective design, Chone et al. use a prospective approach. The authors investigated the influence of TEP timing and the long-term use of the indwelling Blom-Singer VP on speech rehabilitation success. Other factors that can influence speech rehabilitation success rates, such as patient age, radiotherapy, and length of follow up, were also evaluated. Speech rehabilitation success was based on measures of maximum phonation time (MPT) and voice quality perceptual analysis as assessed by a speech-language pathologist and otolaryngologist. The study provides no detail on voice quality analysis. Voice quality and use of VP were evaluated at 1 month, every 3 months up until 1 year of follow-up and then every 6 months afterwards.

Participants of this study included 71 patients who underwent total laryngectomy between 1996 and 2001. Patients who submitted to laryngectomy prior to 1995 received secondary TEP (n=9), while patients who underwent laryngectomy after this date were rehabilitated with a primary TEP (n=62). An indwelling VP was placed either 2 weeks after laryngectomy for primary TEP, or 3 days after the TEP procedure for secondary. A speech-language pathologist evaluated all participants for functional voice quality once the VP was placed.

Statistical analysis of results was performed, using the Fischer's exact test. Results of the study showed that the overall rate of successful speech rehabilitation was 94%. The success rate was not significantly different between the two groups, with a 97% success rate for primary TEP, and 78% for secondary TEP (p=0.07). For patients who had a follow-up longer than 2 years, the success rate dropped similarly in both groups, dropping to 96% in primary TEP and 75% in secondary TEP (p=0.07). Further statistical analysis of factors indicated that age and radiotherapy did not significantly influence speech rehabilitation success rates in either primary or secondary TEP groups. Overall, results show high voicing success rates in both primary and secondary TEP, although results also demonstrate a tendency for higher success rates in primary TEP.

A need for more adequate definitions and more formal, comprehensive voice quality evaluations diminishes this study's reliability and validity. Likewise, the small number of participants in the secondary TEP group may have resulted in the higher success rates observed in primary TEP. Furthermore, the study lacks comprehensive methodological detail. Overall, this study provides a level II statistical evidence and due to its numerous limitations, results are equivocal and should be interpreted with caution.

Discussion

Upon review of the literature regarding the effect of TEP timing on voice rehabilitation outcomes, results are difficult to compare because of the large variety of voice rehabilitation measures exercised in the studies. Nonetheless, overall results suggest that the employment of primary TEP may be preferable over secondary TEP due to a tendency for increased vocal quality, success rates and the implications to the patient's short-term quality of life. The overall strength of the evidence, however, is diminished by many methodology concerns garnered by the critical evaluation of the literature.

One major methodological concern is the prevalent lack of formal, valid evaluation measures for voice restoration outcomes among all studies reviewed. Moreover, all studies' content validity could be improved by including more comprehensive evaluation measures, such as voice-related quality of life and speech intelligibility. Furthermore, all reviewed research lacked adequate descriptions for their evaluation measures, resulting in reduced external and internal validity and reliability. Different definitions for successful voice rehabilitation were also employed by each study, causing difficulty in cross-study comparisons. Additionally, patients who undergo total laryngectomy comprise a heterogeneous population. Consequently, the majority of reviewed studies exhibit a variety of subpopulations within the total laryngectomy community.

Recommendations

Based on the limitations exhibited by the literature, the following recommendations should be considered in future research:

- Research employing formal, comprehensive evaluation measures and adequate definitions in order to accurately compare results across studies.

- Implementing a prospective mixed group study design in order to increase research validity and reliability.
- For results to be considered as compelling, larger, proportional sample sizes and similar inclusion criteria for participants are imperative.
- Research the time between prosthesis placement and voice acquisition in order to provide further explanation to the differences observed in the voice acquisition timing between primary and secondary TEP.
- Further research is needed to examine the effects of delay in voice acquisition on patients' voice-related quality of life in primary versus secondary TEP.

Clinical Implications

Although the results of reviewed literature exhibit no consensus regarding the effect of TEP timing on voice restoration, the following suggestions should be considered when speech-language pathologists partake in clinical decision making:

- Primary TEP may be preferable over secondary TEP due to advantages, such as more rapid voice restoration and elimination of a secondary procedure, which may increase the patient's short-term quality of life.
- Speech-language pathologists are encouraged to know the research regarding voice restoration outcomes for primary and secondary TEP in order to adequately counsel patients in voice restoration methods.
- For best voice restoration outcomes and quality of life, holistic care is essential for patients with total laryngectomy. The patient's co-morbidities, motivation, level of independence, social, psychological and physical states must be considered before receiving a TEP.

Conclusion

In conclusion, no consensus was reached regarding which timing of TEP rendered better voice restoration outcomes due to difficulties in comparing results. However, the research indicates primary TEP may be preferable over secondary TEP due to a tendency towards better voice outcomes and short-term quality of life. A multitude of methodological concerns were raised from the critical review, suggesting that further research is highly needed in order to deem the evidence as compelling.

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