Complications That Affect Postlaryngectomy Voice Restoration

Primary Surgery vs Salvage Surgery

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Objective: To assess the effect of primary treatment on tracheoesophageal voice prosthesis (TEP) complications.

Design: Retrospective cohort study.

Setting: The Johns Hopkins Medical Institutions, Baltimore, Maryland.

Patients: Patients who underwent total laryngectomy and TEP between January 1, 1998, and December 31, 2008, were divided into 3 subgroups according to primary treatment: surgery (n=81), radiotherapy (n=61), and chemoradiotherapy (n=32).

Main Outcome Measures: Number of weeks before leakage through the TEP, occurrence of leakage around the TEP, TEP dislodgement, and size changes 6 months or longer after laryngectomy.

Results: A total of 174 patients met the study criteria. Of the 81 patients who underwent primary surgery, 81% (n=66) underwent adjuvant therapy with postoperative radiotherapy or chemoradiotherapy. The incidence of leakage around the prosthesis, prosthesis dislodgement, and size changes 6 months or longer after laryngectomy were significantly higher for patients who required salvage total laryngectomy after chemoradiotherapy or radiotherapy ($P<.05$). In addition, significantly more patients who underwent salvage total laryngectomy required extended laryngectomy or free tissue reconstruction.

Conclusions: Voice prosthesis complications are more frequently encountered in those who require salvage laryngectomy. Understanding the potential for such complications reinforces the need for close communication and follow-up with these patients by the speech language pathologist.


FOR MANY YEARS, TOTAL LARYNGECTOMY (TL) with postoperative radiotherapy has been considered the standard treatment for advanced laryngeal cancer. The substantial functional changes in speech and swallowing that result have made this option less than desirable for many patients. In an attempt to avoid the perceived mutilation of TL and preserve voice function, organ preservation approaches have increasingly been used to treat advanced laryngeal cancer since publication of the Department of Veterans Affairs Laryngeal Cancer Study Group data in 1991.1 This prospective randomized clinical trial revealed that approximately two-thirds of patients in the organ preservation group preserved their larynx, with survival equivalent to that of patients treated by TL up front. Further support for organ preservation approaches, in particular concurrent chemoradiotherapy, came with publication of the Radiation Therapy Oncology Group 91-11 protocol.2 This prospective randomized trial demonstrated improved locoregional control in patients treated with concomitant chemoradiotherapy compared with radiotherapy alone or induction chemoradiotherapy.

Despite these favorable results, a wealth of information regarding the functional affect of chemoradiotherapy is beginning to unfold. The profound negative effect of chemoradiotherapy on the oropharyngeal swallowing mechanism has been well established. Frequent deficits reported include decreased epiglottic tilt, decreased tongue base retraction, impaired bolus propulsion, laryngeal penetration/aspiration, and esophageal stricture.3-5 In addition, voice complications from organ preservation approaches have been reported, including impaired vocal fold mobility, increased supraglottic constriction, decreased vibratory characteristics of the true vocal folds, and glottic incompetence.6,7 Other functional impairments may include xerostomia8 and trismus.9,10 Studies that evalu-
ate the functional effect of primary organ preservation approaches on voice rehabilitation after salvage TL have been scarce to date. We reviewed our experience with voice prosthesis complications to identify risk factors for tracheoesophageal voice prosthesis (TEP) failure in patients who underwent salvage laryngectomy.

### METHODS

The medical records of all patients who underwent TL at The Johns Hopkins Medical Institutions, Baltimore, Maryland, between January 1, 1998, and December 31, 2008, were reviewed in compliance with the Health Insurance Portability and Accountability Act and in accord with previous approval by the Johns Hopkins institutional review board. Patients who did not undergo TEP, who did not complete treatment, or who did not receive follow-up TEP care at The Johns Hopkins Medical Institutions were excluded from analysis. Patients were divided into 3 treatment groups: primary surgery, primary radiotherapy, and primary chemoradiotherapy. Patient demographic factors and clinical outcomes were analyzed. Voice prosthesis–related outcomes of interest were time to leakage through the prosthesis, episodes of leakage around the prosthesis, episodes of spontaneous prosthesis dislodgment, and occurrence of prosthesis size changes after the first 6 months. These variables were chosen for their clinical relevance as the most frequent complications addressed by the speech language pathologist.

Standard statistical analyses, including χ² analysis and the Fisher exact test, were used to evaluate patient variables (GraphPad InStat; GraphPad Software, San Diego, California). Because categorical variables were not normally distributed, comparison of means was performed using the Kruskal-Wallis test. Analysis of differences in TEP outcomes between treatment groups was performed using simple and multivariable linear regression models. Kruskal-Wallis and regression analyses were performed using Stata 10 (StataCorp, College Station, Texas). Statistical significance was attributed at P < .05.

A total of 174 patients met the inclusion criteria for analysis (Table 1). Mean follow-up was 5.67 years and did not differ significantly among treatment groups. Primary TL was performed in 46.6% of patients, whereas salvage laryngectomy was performed after primary chemoradiotherapy failure in 18.4% and after primary radiotherapy failure in 35.1%. Adjuvant postoperative therapy (radiotherapy or chemoradiotherapy) was used in 81% (n = 66) of 81 patients who underwent primary surgery. The mean patient age was 62 years (age range, 32-87 years). No significant differences were found between treatment groups for age, sex, or duration of follow-up. Most patients (68.4%) had advanced-stage cancer (stage III/IV), with the glottic larynx being the most common primary site (54.6%). Extended laryngectomy, free tissue reconstruction, or both were performed in 20% of patients. Most of this group had primary sites outside of the larynx (58%), and 50% were

<table>
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<th>Characteristic</th>
<th>Total (N=174)</th>
<th>Primary Surgery (n=81)</th>
<th>Primary CRT (n=32)</th>
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Abbreviations: CRT, chemoradiotherapy; TEP, tracheoesophageal voice prosthesis.
treated initially with chemoradiotherapy. Primary TEP was performed in 80.5% of patients and was equally distributed among treatment groups. Decisions regarding the timing of TEP were made by preference of the surgeon or speech language pathologist. The primary site differed significantly between treatment groups, with significantly more glottic cancers treated initially with primary radiotherapy (P < .001) compared with supraglottic tumors. Primary TL was performed significantly more often for advanced-stage disease, whereas nonoperative treatment was the most common initial procedure for early-stage disease (Figure 1).

Regression models demonstrated significant differences among treatment groups regarding the need for extended TL and free tissue reconstruction. Simple linear regression models demonstrated that significantly more patients required extended laryngectomy procedures for surgical salvage after chemoradiotherapy failure (56%) compared with radiotherapy failure (8%) and with those who underwent primary TL (15%; P < .001) (Figure 2). Similarly, significantly more patients required free tissue reconstruction for surgical salvage after chemoradiotherapy failure (56%) compared with radiotherapy failure (10%) and with those who underwent primary TL (12%; P < .001) (Figure 3). There was overlap between these groups, with 89% of those requiring extended laryngectomy undergoing reconstruction and 89% of those requiring reconstruction undergoing extended laryngectomy. Despite the higher incidence of extended TL and reconstruction in the chemoradiotherapy group, Kruskal-Wallis analysis showed no difference between those who required extended surgery and reconstruction and those who did not regarding measured voice prostheses complications.

Significant differences existed among treatment groups during analysis of voice prostheses complications (Table 2). Using simple linear regression models, the mean frequency of leakage around the prosthesis (P = .04), frequency of prosthesis dislodgement (P = .02), and number of size changes in the first 6 months after laryngectomy (P = .006) were significantly higher for patients who required salvage TL after chemoradiotherapy or radiotherapy compared with patients who underwent primary TL (P < .001) (Table 2). There were no differences among treatment groups when comparing the number of weeks to leakage through the prosthesis (P = .42).

Multivariable linear regression was used to evaluate the primary outcomes of extended laryngectomy, free tissue reconstruction, and primary or secondary TEP placement based on the results of simple linear regression analysis. Salvage laryngectomy was associated with an increased incidence of TEP dislodgement (Table 3). Tracheoesophageal prosthesis size changes were significantly more common for extended laryngectomy and salvage laryngectomy. There was also a trend toward an association between leakage around the prosthesis and extended laryngectomy; however, this trend did not reach statistical significance (Table 3).

Kruskal-Wallis analysis did not reveal significant differences among groups for time to leakage through the prosthesis (P = .30) or number of leaks around the prosthesis (P = .27). Increases in prosthesis dislodgements and number of size changes after 6 months were observed in the chemoradiotherapy and radiotherapy groups (P = .11) compared with the primary TL group (P = .09), but this difference was not significant.

The effect of TL on communicative functioning and quality of life cannot be disputed. In 1981, McNeil et al11 administered a questionnaire to healthy individuals that explored quality of life vs quantity of life. Twenty percent of participants indicated a preference for radiotherapy over TL, even when this choice reduced the potential for survival. These early findings highlighted the magnitude of impact that quality of life issues may have in medical decision making. Disturbance of normal laryngeal voice production can be catastrophic for some individuals. Restoration of verbal communication must be considered paramount in rehabilitating patients after laryngectomy. Although esophageal and electrolaryngeal speech are viable options for the restoration of

![Figure 1](https://example.com/figure1.png)  
**Figure 1.** Tumor stage by treatment group.

![Figure 2](https://example.com/figure2.png)  
**Figure 2.** Extended laryngectomy by treatment group. Primary surgery was less likely to require extended laryngectomy than was salvage surgery (P < .001).

![Figure 3](https://example.com/figure3.png)  
**Figure 3.** Free tissue reconstruction by treatment group. Primary surgery was less likely to require reconstruction than was salvage surgery (P < .001).

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likely to require extended laryngectomy procedures and laryngectomy due to chemoradiotherapy failure was more frequent in prosthesis-related complication rates, salvage laryngectomy after primary organ preservation treatment in contrast to those who have had primary surgical treatment. The present findings are consistent with those of Kummer et al,23 who demonstrated an increased incidence of failures may occur more frequently in patients who require laryngectomy after primary surgical treatment. Although the number of patients who never received chemoradiotherapy or radiotherapy was too low to include in statistical analysis (n = 14), there were some interesting findings regarding their TEP success. In these individuals, the longevity of prosthesis life before leakage through the center was longer than that in the primary surgery group at large (22.8 vs 15.2 weeks). A slight advantage was also seen regarding leakage around the prosthesis, with a mean occurrence of 0.33 in the pure surgical group compared with 0.56 in the TL group receiving postoperative radiotherapy or chemoradiotherapy. The remaining TEP variables, however, were similar to the primary surgery group at large. Specifically, the mean number of dislodgements was 0.33 (compared with 0.28), and the mean number of size changes was 1.33 (compared with 1.20).

The results of this analysis demonstrate that patients who undergo salvage TL after chemoradiotherapy and radiotherapy have a higher incidence of prosthesis-related complications, such as leakage around the prosthesis, prosthesis dislodgement, and multiple size changes, compared with patients who undergo primary surgery. The greatest variance was seen between primary radiotherapy and primary TL in these measures. Although one might postulate that a greater difference would be seen in the chemoradiotherapy group given the additive effects of chemotherapy, this was not demonstrated in this data set, perhaps owing, in part, to the smaller sample size and the shorter mean follow-up for this group. In addition to increases in prosthesis-related complication rates, salvage laryngectomy due to chemoradiotherapy failure was more likely to require extended laryngectomy procedures and free tissue reconstruction, suggesting that organ preservation strategies have multiple soft-tissue effects that can affect voice rehabilitation efforts after salvage TL.
novel intraoperative and postoperative considerations, long-term patient management strategies, or prosthesis-specific intervention strategies. Although specific treatment modalities have not been validated for this population to date, to our knowledge, there is a clear role for patient education regarding potential prosthesis-related complications and close communication with and follow-up by the speech language pathologist.

Future investigations will be valuable in defining and investigating strategies that may reduce complications in the salvage laryngectomy population. It is postulated that treatments designed to minimize traction and trauma to the delicate tissues of the party wall may show promise for improving patient outcomes. Patient education regarding independent monitoring for early signs of complications and ways to address these complications show additional promise. A role for smaller-diameter voice prostheses in this population has also been proposed, although a formal investigation of this interventional strategy has not been published to date.

The results of this analysis demonstrate that the incidence of prosthesis-related complications is increased when laryngectomy is performed for salvage after organ preservation therapy compared with primary laryngectomy for the treatment of laryngeal cancer. Tracheoesophageal voice prosthesis dislodgement and multiple size changes within the first 6 months after laryngectomy were seen more frequently in the salvage laryngectomy population than in the primary surgery group. In addition, extended laryngectomy and free tissue reconstruction were more often required in patients who underwent salvage laryngectomy after chemoradiotherapy failure, suggesting that organ preservation strategies have multiple soft effects that can affect voice rehabilitation efforts after salvage laryngectomy. These data suggest the need for adjustment of clinical practice patterns in the salvage laryngectomy setting and further investigation into strategies that may reduce such risks.

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Author Contributions: All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Starmer. Acquisition of data: Starmer, Koch, Webster, and Tufano. Analysis and interpretation of data: Starmer, Ishman, Flint, Bhatti, Richmon, Koch, and Gourin. Drafting of the manuscript: Starmer. Critical revision of the manuscript for important intellectual content: Starmer, Ishman, Flint, Bhatti, Richmon, Koch, Webster, Tufano, and Gourin. Statistical analysis: Starmer, Ishman, and Gourin. Administrative, technical, and material support: Starmer, Flint, and Koch. Study supervision: Bhatti and Tufano.
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