

# Relationship Between Radiotherapy and Gastroesophageal Reflux Disease in Causing Tracheoesophageal Voice Rehabilitation Failure

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**Summary: Objective.** The objective was to analyze the association of radiotherapy with gastroesophageal reflux as determinant of fistula related pathology, in voice prosthesis patients.

**Study Design.** Retrospective study.

**Methods.** Sixty-one laryngectomy patients were enrolled between 2005 and 2012. All patients underwent phonatory rehabilitation with voice prosthesis, along with evidence of gastroesophageal reflux disease, for which proton pump inhibitors (PPIs) were prescribed. We analyzed the occurrence of fistula-related problems among patients who received postoperative radiotherapy and those patients who did not.

**Results.** We observed a higher rate of failure of speech rehabilitation in laryngectomy patients with gastroesophageal reflux: this occurred when they had a history of postoperative radiotherapy (45%) compared with patients who did not (17%) ( $P < 0.05$ ), although all patients were treated with PPIs.

**Conclusion.** Our results seem to confirm the importance of postoperative radiotherapy with gastroesophageal reflux for the determinism of fistula-related problems.

**Key Words:** Laryngectomy–Alaryngeal speech–Laryngeal prosthesis–Gastroesophageal reflux disease–Adjuvant radiotherapy.

## INTRODUCTION

The recent development of several strategies that address organ and tissue sparing, such as partial reconstructive surgery, radiation therapy alone, induction chemotherapy, or concurrent chemoradiotherapy, has gained a more significant role in the laryngological field. However, total laryngectomy remains the best approach in patients with transglottic tumors, as it deeply infiltrates the larynx and destroys the cartilage and in those with recurrent tumors. In these circumstances, postoperative anatomical and physiological changes, in particular, regarding swallowing and communication, have a significant impact on a patient's quality of life.<sup>1</sup>

In such cases, tracheoesophageal voice rehabilitation is the gold standard in terms of quality oral communication, patient satisfaction, and well being, when compared with the alternatives of esophageal speech and an artificial electrolarynx. Treatment with voice prosthesis can achieve a success rate of 90%, thereby representing the best option for voice rehabilitation.<sup>2</sup>

Since the introduction of tracheoesophageal puncture (TEP), with prosthesis placement by Blom and Singer in 1979, several clinical and technological improvements have been introduced toward a better understanding of how to obtain quality results. This elicited partial recovery of psychosocial impairment in laryngectomees, with the possibility of an

almost complete social reintegration after the first 6 months after laryngectomy.<sup>3</sup>

We have seen continuous improvements of fistulization and implant placement techniques, aimed at reducing intra- and postoperative complications with primary and secondary punctures, and enhancement of prosthesis home management. Nevertheless, puncture-related problems have been present in all patients, often requiring surgical treatment and creating temporary or definitive closure of the tracheoesophageal fistula, resulting in the failure of the rehabilitative process. Periprosthetic leakage, macrofistula, cellulitis of the periprosthetic tissue, fistula migration, tracheoesophageal granuloma, and voice prosthesis incarceration in the mucous membrane have frequently been related to improper management as far as fungal prophylaxis, well-timed prosthesis replacement, and appropriate length are concerned.<sup>4</sup>

Besides these problems, which cannot be ignored, other elements must be taken into account and evaluated: these include comorbidities that prosthetic patients could develop and that in turn play a causative role in the onset of fistula-related pathology. In such cases, gastroesophageal reflux disease (GERD) has been well recognized as a factor in determining TEP complications, especially periprosthetic leakage.<sup>5</sup>

In a previous retrospective study, examining esophagogastric endoscopic parameters, we observed how GERD could have an impact on the formation of tracheoesophageal granulomas, on the wear of voice prostheses by fungi and bacteria, as well as on voice restoration outcome.<sup>6</sup>

However, even with the use of antireflux treatment, with a loading dose and maintenance component, prescribed with regular management of the prosthesis that involves contamination prevention, we saw a significant incidence of fistula-related problems.

It is well known that among risk factors for fistula-related problems identified in the literature, hypertension, diabetes

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mellitus, postoperative radiotherapy, trauma during prosthesis replacement procedures, and pathologic gastroesophageal reflux all exist.<sup>7,8</sup>

Knowledge about fistula-related problems is growing; however, in previous reports, the risk factors were mainly evaluated as isolated entities. Patients often present complex conditions with several variables at the same time, although the role of these connections has not yet been explored. Therefore, we decided to focus our attention on the association of GERD and postoperative radiation therapy (PORT) in determining fistula-related pathologies. We hypothesized that fistula-related problems rates are higher in patients with both a history of GERD and PORT when compared with patients with only a history of GERD.

## MATERIALS AND METHODS

At the Otorhinolaryngology Unit of the Surgical and Medical Specialties Department of the University of Catania, we carried out a retrospective study from 2005 to 2012, enrolling 61 patients who had undergone laryngectomy and phonatory rehabilitation through voice prosthesis placement. This had been performed as TEP during the laryngectomy or as secondary puncture with the Provox trocar (Atos Medical AB, Hörby, Sweden), according to the method proposed by Blom, Hamaker and Singer.<sup>9,10</sup> In both cases, preparation of the fistula was carried out with the short myotomy of the circular proximal upper esophageal sphincter (cricopharyngeus) muscle, except in cases of a completely relaxed muscle, to prevent hypertonicity of the upper esophageal segment. Furthermore, special care was taken to assure the optimal diameter of the stoma and prevent excessively deep stomas. All patients were rehabilitated with indwelling Provox voice prostheses (Atos Medical AB).

The minimum time between TEP and inclusion in the study was 1.5 years. The evaluated patients were divided into two groups: group A comprised 31 people who had undergone PORT, with a control group of 30 people who had not undergone radiotherapy. Both groups included patients who had been diagnosed with GERD through esophagogastroduodenoscopy and pH-probe, for which proper medical therapy was used with daily PPIs. Diagnostic procedures at the beginning of the patient evaluation were executed without medication to ensure unbiased diagnosis.

At the time of the study in our hospital, the indications for PORT included clinically or microscopically positive surgical margins, pathologically confirmed positive neck nodes, and/or advanced clinical stages of primary laryngeal cancer (T3, T4). Only patients with good health and no distant metastases were considered for PORT, both being prerequisite for treatment, so that patients with systemic pathologies, such as decompensated diabetes and hypertension, were excluded.

The total radiation dose in the clinical target volume area ranged from 34 to 78 Gy, with a mean value of 59 Gy in the primary tumor site, and irradiation of 48 Gy in the lymphatic drainage pathways. No patient had undergone preoperative radiotherapy or chemotherapy.

The *Statistical Package for Social Sciences (SPSS, Version 18.0 for Windows; SPSS Inc., Chicago, IL)* was used for data analysis. Chi-square testing was used to assess the difference between categorical variables and the odds ratio (OR), and 95% confidence intervals (CI) were calculated. *P* value <0.05 was considered statistically significant.

## RESULTS

Of 61 patients reviewed, there were 56 men and five women, in which 35 underwent a secondary TEP, and the remaining 26 had the fistula prepared during the laryngectomy. Group A included 28 men and three women who received radiotherapy, with the age range falling between 41 and 75 years; whereas group B included 28 men and two women who did not receive any adjuvant therapy, with their age range falling between 42 and 72 years (Table 1).

Group A had 18 patients who underwent secondary TEP, whereas the remaining 13 underwent primary TEP; in group B, there were 13 cases of primary TEP and 17 cases of secondary TEP (Table 2).

Considering all secondary procedures, the interval between total laryngectomy and prosthesis implantation in secondary TEP, there was a variation of 4 months to 1.5 years, although none of the cases involved pharyngeal reconstruction.

All patients had a follow-up of at least 6 years. In group A, there were nine cases of relapsing tracheoesophageal granulomas, with recurrence after CO<sup>2</sup> laser removal. Among these, we had two patients whose valve were pushed by exorbitant growth of the granulation from the esophagus into the trachea (Figure 1), whereas three patients had partial obstruction of the stoma (Figure 2); a cannula was required to provide an airway. In five patients, we saw an enlargement of the fistula. In 17 patients, no fistula-related problems were observed.

In group B, 25 patients showed no fistula-related problems, whereas two patients showed the presence of granulomas that did not relapse after laser removal (Figure 3). Moreover, three patients in this group showed fistula enlargement. Patient results are shown in Table 3.

Both granulomas and fistula enlargement determined a dramatic loss of prosthesis function and were counted as voice rehabilitation failures.

Data analysis showed a significant difference between groups ( $\chi^2 = 5.77$ ,  $P < 0.05$ ) with a greater incidence of fistula-related problems in the group of patients who had undergone PORT

**TABLE 1.**  
**Groups of Study: Gender Distribution and Age Range**

Gender Distribution and Age Range	Group A: GERD+ With PORT	Group B: GERD+ Without PORT
Male	28	28
Females	3	2
Total	31	30
Age range (y)	41–75	42–72

*Abbreviations:* GERD+, presence of gastroesophageal reflux disease; PORT, postoperative radiation therapy.

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