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## Laryngectomy and Reflux

- ❖ Incidence of reflux in laryngectomees
- ❖ Consequences and treatment of reflux in laryngectomees

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## Preface

This document contains a bibliography and summaries of selected publications relating to the incidence, consequences, and treatment of reflux in laryngectomized individuals. The document is part of a growing, and regularly updated collection of documents, the Atos Medical Clinical Evidence Series, covering various clinical topics related to Atos Medical's areas of expertise. The topics are chosen based on questions, suggestions and requests that we receive from our customers.

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## Incidence of reflux in laryngectomees

Incidence of reflux in laryngectomees is reported to be rather high. In the immediate postoperative period pathological reflux is reported in 30-40%<sup>3</sup>. In the long-term, rates as high as 80% are reported<sup>4</sup>. In 58% of patients, pepsin was found in the tracheoesophageal puncture site<sup>2</sup>. A recent study suggests that treatment of laryngeal cancer with surgery (TL) as well as radiation therapy may increase the incidence of pharyngeal reflux<sup>1</sup>.

The publications listed below concern the publications regarding incidence of reflux in laryngectomees that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

<sup>1</sup>[LeBlanc B et al. Increased Pharyngeal Reflux in Patients Treated for Laryngeal Cancer: A Pilot Study. Otolaryngol Head Neck Surg. 2015 Nov;153\(5\):791-4.](#)

<sup>2</sup>[Bock et al. Analysis of pepsin in tracheoesophageal puncture sites. Ann Otol Rhinol Laryngol. 2010 Dec;119\(12\):799-805.](#)

<sup>3</sup>[Marín Garrido et al. \[Study of laryngopharyngeal reflux using pH-metering in immediate post-op of laryngectomized patients\]. Acta Otorrinolaringol Esp. 2007 Aug-Sep;58\(7\):284-9.](#)

<sup>4</sup>[Smit et al. High incidence of gastropharyngeal and gastroesophageal reflux after total laryngectomy. Head Neck. 1998 Oct;20\(7\):619-22.](#)

## LeBlanc et al, 2015

### Title

Increased Pharyngeal Reflux in Patients Treated for Laryngeal Cancer: A Pilot Study.

### Authors

LeBlanc B<sup>1</sup>, Lewis E<sup>1</sup>, Caldito G<sup>2</sup>, Nathan CA<sup>3</sup>.

### Affiliations

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<sup>2</sup>Department of Biometry, LSU Health-Shreveport, and Feist-Weiller Cancer Center, Shreveport, Louisiana, USA.

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### Journal and year of publication

Otolaryngol Head Neck Surg. 2015 Nov;153(5):791-4.

### Type of publication

Prospective study

### Objective

Laryngopharyngeal reflux may cause significant morbidity in the head and neck cancer population. The goal was to determine if pharyngeal reflux is increased as a result of treatment for laryngeal cancer.

### Subjects and Methods

SUBJECTS: Head and neck cancer patients treated at LSU Health-Shreveport with a plan for total laryngectomy. METHODS: Pharyngeal pH probes with resultant reflux scores were utilized in patients with laryngeal/pharyngeal cancer with a plan for total laryngectomy.

### Results

Twenty-four patients completed the prelaryngectomy pH-testing. Patients who had prior radiation (n=8) had a significantly higher average preoperative upright Ryan score of 238.4 (a composite score for pharyngeal acid), compared with 22.0 in those without radiation therapy (n=16). The supine score was 12.7 in the radiotherapy group and 2.7 in those without radiotherapy (P = .12). Of the 24 patients with prelaryngectomy pH testing, 10 agreed to have postlaryngectomy pH probe testing. The post-TL Ryan scores were significantly higher than their corresponding pre-TL scores. The mean upright Ryan score increased from 106.32 to 209.0, the mean supine score from 3.9 to 8.1.

### Conclusion

This study suggests that treatment of laryngeal cancer with surgery (TL) as well as radiation therapy may increase the incidence of pharyngeal reflux. Given the potential morbidity of reflux and the ease of treatment, consider screening for reflux in this at-risk patients population.

## **Bock et al, 2010**

### **Title**

Analysis of pepsin in tracheoesophageal puncture sites.

### **Authors**

Bock JM, Brawley MK, Johnston N, Samuels T, Massey BL, Campbell BH, Toohill RJ, Blumin JH.

### **Affiliation(s)**

Department of Otolaryngology and Communication Sciences, Medical College of Wisconsin, Milwaukee, Wisconsin 53226, USA.

### **Journal and year of publication**

Ann Otol Rhinol Laryngol. 2010 Dec;119(12):799-805.

### **Type of publication**

Prospective study

### **Introduction**

Gastroesophageal reflux has been proposed as a cause of problems with the tracheoesophageal (TE) puncture site in laryngectomized patients using a voice prosthesis. In this study the TE puncture sites were evaluated for the presence of pepsin in tissue biopsy specimens and tract secretions to explore this association.

### **Subjects and Methods**

Seventeen laryngectomized patients with TE punctures were interviewed for a history of symptoms related to reflux, medication use history, voice quality, and incidence of complications, such as granulation, leakage and prosthetic debris. Tissue biopsy specimens and tract secretions were obtained from TE puncture sites and analyzed for the presence of pepsin via sodium dodecyl sulfate-polyacrylamide gel electrophoresis Western blot analysis.

### **Results**

Twelve of 17 patients (47%) had some history of preoperative or postoperative symptoms of gastroesophageal reflux disease or laryngopharyngeal reflux. Pepsin was present within the TE puncture site in a total of 10 of 17 patients (58%). Acid suppressive medications were commonly used, but were unrelated to pepsin positivity of the tract biopsy. Voicing was judged as good in 13 patients, fair in 2 patients, and poor in 2 patients. There were no statistically significant associations between the presence of pepsin and the frequency of prosthesis changes, history of radiotherapy, or incidence of various TEP complications.

### **Conclusions**

Reflux with subsequent pepsin deposition into the TE puncture tract occurs in a majority of laryngectomy patients. Further studies on the effect of reflux on the health and function of the TE puncture tract are warranted.

## Marín Garrido et al, 2007

### Title

Study of laryngopharyngeal reflux using pH-metering in immediate post-op of laryngectomized patients.

### Authors

Marín Garrido C, Fernández Liesa R, Vallès Varela H, Naya Gálvez MJ.

### Affiliation(s)

Fundació Hospital de l'Esperit Sant, Santa Coloma de Gramenet, Barcelona, Spain.

### Journal and year of publication

Acta Otorrinolaringol Esp. 2007 Aug-Sep;58(7):284-9.

### Type of publication

Prospective study

### Introduction

Little is known about incidence of laryngo-pharyngeal reflux (LPR) and gastroesophageal reflux (GER) in the early postoperative period after total laryngectomy. This study evaluated the effect and characteristics of the LPR and GER in laryngectomized patients, by means of double pH-metry during the first 48 hours after surgery.

### Subjects and Methods

In 50 laryngectomized patients, 48-hour double-probe pH monitoring was performed during the first 48 hours after total laryngectomy, after intraoperative placement of the probe.

### Results

The incidence of LPR in the postoperative period ranged between 30% and 40%. GER was observed in 40%.

### Conclusions

A high incidence of LPR and GER was observed in the immediate postoperative period after total laryngectomy.

### Link to free download

<http://www.elsevier.es/en/linksolver/ft/ivp/0001-6519/58/284?s=tr&ty=616148>

## Smit et al, 1998

### Title

High incidence of gastropharyngeal and gastroesophageal reflux after total laryngectomy.

### Authors

Smit CF, Tan J, Mathus-Vliegen LM, Devriese PP, Brandsen M, Grolman W, Schouwenburg PF.

### Affiliation(s)

Department of Otorhinolaryngology Head and Neck Surgery, Academic Medical Center, University of Amsterdam, The Netherlands.

### Journal and year of publication

Head Neck. 1998 Oct;20(7):619-22.

### Type of publication

Prospective study

### Introduction

Gastroesophageal reflux (GER) appears to be related to laryngeal carcinoma. Little is known about GER and gastropharyngeal reflux (GPR) in the laryngectomized patient. Therefore, GER and GPR were studied in laryngectomized patients.

### Methods

In 11 patients, 24-hour double-probe pH monitoring was performed in an ambulant setting. An optic fiberscope was used for the accurate positioning of the proximal probe in the upper esophageal sphincter.

### Results

In 9 of 11 patients pathologic GPR was found. Four of these 9 patients had reflux in upright and supine position, 5 patients had reflux only in upright position.

### Conclusions

A high incidence of GPR in laryngectomized patients was found. The authors raise the question whether all laryngectomized patients should be investigated for reflux and in the presence of pathologic reflux findings should be treated with reflux prophylaxis.

## Consequences and treatment of reflux in laryngectomees

Reflux in laryngectomized patients can lead to voice problems<sup>7,8,13</sup>, puncture problems<sup>6,7,9,10,12</sup>, and/or voice prosthesis problems<sup>6,7,14</sup>. In patients with proven pathological reflux, relationships have been found between the presence of reflux and problems such as voice quality problems<sup>7,8,13</sup>, reduced voice-related quality of life (VHI)<sup>8</sup>, reduced overall quality of life<sup>8</sup>, increased incidence of peri-prosthetic leakage<sup>3,9</sup>, recurrent peri-prosthetic leakage<sup>12</sup>, increased incidence of enlarged tracheoesophageal punctures<sup>1,2,10,11</sup>, formation of granulation tissue in the area of the tracheoesophageal puncture<sup>7,13</sup>, shortened device life of the voice prosthesis<sup>7,14</sup>, and increased incidence of postoperative pharyngocutaneous fistulae<sup>17</sup>. In patients with gastroesophageal reflux, the rate of failure of speech rehabilitation due to fistula-related problems was higher with a history of postoperative radiotherapy.<sup>5</sup>

It is reported that aggressive pharmacological anti-reflux treatment reduces reflux symptoms<sup>1,9,11</sup> and can lead to improved voice quality<sup>7</sup>, improved voice-related quality of life<sup>8</sup>, improved overall quality of life<sup>8</sup>, healing of enlarged tracheoesophageal punctures/reduced peri-prosthetic leakage<sup>2,9,11</sup>, reduction or elimination of granulation tissue<sup>7,13</sup>, and improved device life of the voice prosthesis<sup>7,14</sup>. During the postoperative period, aggressive anti-reflux therapy can reduce the incidence of pharyngocutaneous fistulae<sup>4,16,17</sup>. In some cases, surgical treatment to prevent reflux may be indicated, although this has also been related to increased bloating and hyperflatulence<sup>15</sup>.

The publications listed below all concern publications regarding consequences and treatment of reflux in laryngectomees that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

<sup>1</sup>[Lorenz KJ et al. Role of reflux-induced epithelial-mesenchymal transition in periprosthetic leakage after prosthetic voice rehabilitation. Head Neck. 2015 Apr;37\(4\):530-6.](#)

<sup>2</sup>[Lorenz KJ. The development and treatment of periprosthetic leakage after prosthetic voice restoration: a literature review and personal experience. Part II: conservative and surgical management. Eur Arch Otorhinolaryngol. 2015 Mar;272\(3\):661-72.](#)

<sup>3</sup>[Lorenz KJ. The development and treatment of periprosthetic leakage after prosthetic voice restoration. A literature review and personal experience part I: the development of periprosthetic leakage. Eur Arch Otorhinolaryngol. 2015 Mar;272\(3\):641-59.](#)

<sup>4</sup>[Stephenson KA and Fagan JJ. Effect of perioperative proton pump inhibitors on the incidence of pharyngocutaneous fistula after total laryngectomy: a prospective randomized controlled trial. Head Neck. 2015 Feb;37\(2\):255-9.](#)

<sup>5</sup>[Cocuzza et al. Relationship between radiotherapy and gastroesophageal reflux disease in causing tracheoesophageal voice rehabilitation failure. J Voice. 2014 Mar;28\(2\):245-9.](#)

<sup>6</sup>[Hadzibegovic et al. Analysis of saliva pepsin level in patients with tracheoesophageal fistula and voice prosthesis complications. Coll Antropol. 2012 Nov;36 Suppl 2:93-7.](#)

<sup>7</sup>[Cocuzza et al. Gastroesophageal reflux disease and postlaryngectomy tracheoesophageal fistula. Eur Arch Otorhinolaryngol. 2012 May;269\(5\):1483-8.](#)

<sup>8</sup>[Lorenz et al. \[Laryngectomised patients with voice prostheses: influence of supra-esophageal reflux on voice quality and quality of life\]. HNO. 2011 Feb;59\(2\):179-87.](#)

<sup>9</sup>[Lorenz et al. The management of periprosthetic leakage in the presence of supra-oesophageal reflux after prosthetic voice rehabilitation. Eur Arch Otorhinolaryngol. 2011 May;268\(5\):695-702.](#)

<sup>10</sup>[Lorenz et al. Role of reflux in tracheoesophageal fistula problems after laryngectomy. Ann Otol Rhinol Laryngol. 2010 Nov;119\(11\):719-28.](#)

<sup>11</sup>[Lorenz et al. \[Prosthetic voice restoration after laryngectomy: the management of fistula complications with anti-reflux medications\]. HNO. 2010 Sep;58\(9\):919-26.](#)

<sup>12</sup>[Lorenz et al. \[Coincidence of fistula enlargement and supra-oesophageal reflux in patients after laryngectomy and prosthetic voice restoration\]. HNO. 2009 Dec;57\(12\):1253-61.](#)

<sup>13</sup>[Pattani et al. Reflux as a cause of tracheoesophageal puncture failure. Laryngoscope. 2009 Jan;119\(1\):121-5.](#)

<sup>14</sup>[Boscolo-Rizzo et al. The impact of radiotherapy and GERD on in situ lifetime of indwelling voice prostheses. Eur Arch Otorhinolaryngol. 2008 Jul;265\(7\):791-6.](#)

<sup>15</sup>[Jobe et al. Surgical management of gastroesophageal reflux and outcome after laryngectomy in patients using tracheoesophageal speech. Am J Surg. 2002 May;183\(5\):539-43.](#)

<sup>16</sup>[Sarría Echegaray et al. \[Pharmacological prophylaxis of gastroesophageal reflux. Incidence of pharyngocutaneous fistula after total laryngectomy\]. Acta Otorrinolaringol Esp. 2000 Apr;51\(3\):239-42.](#)

<sup>17</sup>[Seikaly and Park. Gastroesophageal reflux prophylaxis decreases the incidence of pharyngocutaneous fistula after total laryngectomy. Laryngoscope. 1995 Nov;105\(11\):1220-2.](#)

## Lorenz et al, 2015

### Title

Role of reflux-induced epithelial-mesenchymal transition in periprosthetic leakage after prosthetic voice rehabilitation.

### Authors

Lorenz KJ, Kraft K, Graf F, Pröpper C, Steinestel K.

### Affiliation

Department of Otorhinolaryngology - Head and Neck Surgery, Bundeswehrkrankenhaus Ulm, Ulm, Germany.

### Journal and year of publication

Head Neck. 2015 Apr;37(4):530-6.

### Type of publication

Prospective study

### Background

Gastroesophageal reflux (GER) contributes to periprosthetic leakage after prosthetic voice rehabilitation. However, underlying mechanisms are unclear, and markers predicting anti-reflux therapy response are missing.

### Methods

Authors assessed epithelial-mesenchymal transition in 148 consecutive biopsies from 44 patients with/without fistula enlargement under dual-probe pH monitoring before and after proton-pump inhibitor (PPI) therapy applying immunohistochemistry. Results were correlated with reflux intensity and clinical and histologic findings.

### Results

Epithelial-mesenchymal transition correlated with GER in all samples, and patients with fistula enlargement showed higher epithelial-mesenchymal transition scores. Contrary to patients without enlargement, epithelial-mesenchymal transition scores did not regress during therapy in this group. Furthermore, pre-therapeutic epithelial-mesenchymal transition scores were lower in therapy responders than in non-responders without reaching significance ( $p = .07$ ).

### Conclusion

Authors demonstrate that epithelial-mesenchymal transition correlates with severity of GER and presence of periprosthetic fistula enlargement in patients who underwent prosthetic voice rehabilitation, but epithelial-mesenchymal transition seems to be reversible upon PPI treatment in early stages only.

## Lorenz, 2015 Part II

### Title

The development and treatment of periprosthetic leakage after prosthetic voice restoration: a literature review and personal experience. Part II: conservative and surgical management.

### Authors

Lorenz KJ

### Affiliation

Department of Otolaryngology/Head and Neck Surgery, German Armed Forces Hospital, Oberer Eselsberg 40, 89081, Ulm, Germany,

### Journal and year of publication

Eur Arch Otorhinolaryngol. 2015 Mar;272(3):661-72.

### Type of publication

Literature review and personal experience

### Introduction

The placement of a voice prosthesis is a simple procedure that is associated with only a minor increase in operating time and a low rate of complications. Most problems with voice prostheses are minor and can be easily managed. Enlargement of the tracheo-oesophageal fistula, however, can be a severe complication. In this review, the treatment of periprosthetic leakage after prosthetic voice restoration is discussed.

### Subjects and Methods

The records of all patients who had been seen from 1994 to 2013 were retrospectively analysed for demographic data. The number of periprosthetic leaks and the procedures that these leaks required were documented as well. Treatments were divided into conservative and surgical options. The number of procedures was documented and success rates were calculated. Publications were identified on periprosthetic leakage after the insertion of a voice prosthesis using PubMed. Studies that provided information about the number of patients, the occurrence of periprosthetic leakage, and the type of treatment for peri-prosthetic leakage or fistula enlargement were included in the present analysis.

### Results

Approximately 25 % of all patients with voice prostheses develop periprosthetic leakage with aspiration within 1-4 years after the placement of a voice prosthesis. Depending on the severity of fistula enlargement, treatment ranges from conservative approaches to maximally invasive procedures. In some cases, however, these measures prove unsuccessful. The causes of treatment failure and fistula enlargement are not yet fully understood. Apart from a discussion of treatment options, an algorithm for the management of this complication is presented on the basis of the literature and the experience that the author has accumulated at his institution during the past 20 years in the treatment of 232 laryngectomised patients. For conservative management, downsizing the prosthesis, silicone collars, shrinking the fistula, and tissue augmentation (injections), and anti-reflux medications are discussed. For surgical management, several techniques for the surgical closure (such as purse-string suture, interpositioning of a local flap, distant flap or free flaps), and the use of conventional and customized stents are reported.

## **Conclusion**

In conclusion, many patients with fistula enlargement can be managed with minimally or moderately invasive procedures on the basis of a thorough analysis of the causes underlying periprosthetic leakage, provided the patients are simultaneously treated with anti-reflux medications and undergo a fistula treatment that is tailored to the requirements of each individual case. Only a few patients require a complex surgical procedure for the closure of their fistulas and the interposition of pedicled or free flaps. Following the closure of a tracheo-oesophageal fistula, a secondary tracheo-oesophageal puncture can be performed and a new voice prosthesis can be inserted after 3–4 months.

## Lorenz, 2015 Part I

### Title

The development and treatment of periprosthetic leakage after prosthetic voice restoration. A literature review and personal experience part I: the development of periprosthetic leakage.

### Authors

Lorenz KJ

### Affiliation

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### Journal and year of publication

Eur Arch Otorhinolaryngol. 2015 Mar;272(3):641-59.

### Type of publication

Literature review and retrospective study

### Introduction

The use of a voice prosthesis has become the treatment of choice for the restoration of speech following laryngectomy. The placement of a voice prosthesis is a simple surgical procedure with a low rate of complications and an excellent success rate. Approximately 20–30 % of all patients with voice prostheses develop periprosthetic leakage with aspiration over time. Periprosthetic leakage is usually caused by an enlargement of the tracheo-oesophageal fistula and substantially affects the quality of life of the patients concerned. In this review, the various causes of fistula enlargement are discussed on the basis of the literature and the experience that was accumulated during the past 20 years in the management of patients with voice prostheses. In part II the treatment, conservative and surgical, of periprosthetic leakage after prosthetic voice restoration will be discussed.

### Subjects and Methods

The records of all patients who had been seen from 1994 to 2013 were retrospectively analysed for demographic data. The number of periprosthetic leaks and the procedures that these leaks required were documented as well. In addition, leaks were correlated with possible risk factors such as radiation, reflux and time of insertion of the prosthesis.

PubMed was searched to identify publications on periprosthetic leakage after the insertion of a voice prosthesis. Studies that provided information about the number of patients, the occurrence of periprosthetic leakage, radiation therapy, the time of insertion of a voice prosthesis, the type of prosthesis used, or possible complications were included in the present analysis.

### Results

In the literature, the incidence of periprosthetic leakage is reported to range between 10 and 53 %. Massive fistula enlargement, i.e. a fistula diameter of more than 12 to 15 mm, occurs in only 5–8 % of patients with a voice prosthesis. In a retrospective analysis of the patients, the incidence of peri-prosthetic leakage was 35.7 % in a total of 232 patients who underwent laryngectomy during a period of 20 years. Substantial enlargement of the tracheo-oesophageal fistula which required multiple treatments occurred in 12.5 % of the patients.

Several studies report that no significant correlation was found between voice prosthesis diameter and the incidence of fistula enlargement (Hutcheson et al. 2010, Starmer et al. 2009), nor was a significant difference in incidence of periprosthetic leakage found between patients who underwent primary tracheo-oesophageal puncture and those who had a secondary puncture (Hutcheson et al. 2010). However, there is evidence that gastro-oesophageal reflux increases the risk for periprosthetic leakage (Lorenz et al. 2009, Cocuzza 2012), as does radio-chemotherapy. Further risk factors discussed are nutritional status, diabetes, lymph node metastases, length of follow-up, tumour recurrence, thyroid dysfunction and tobacco exposure.

### **Conclusion**

The placement of a voice prosthesis is a simple procedure for the rehabilitation of voice after total laryngectomy and is associated with a low rate of complications. Severe complications are extremely rare. Tracheo-oesophageal fistula enlargement and periprosthetic leakage is, however, a serious problem and occurs with an incidence of approximately 13 %. Voice prosthesis diameter and post-operative radiotherapy alone can be largely ruled out as underlying causes. By contrast, reflux disease and radio-chemotherapy can considerably elevate the risk of fistula leakage.

## Stephenson and Fagan, 2015

### Title

Effect of perioperative proton pump inhibitors on the incidence of pharyngocutaneous fistula after total laryngectomy: a prospective randomized controlled trial.

### Authors

Stephenson KA, Fagan JJ.

### Affiliation

Division of Otorhinolaryngology, University of Cape Town, Groote Schuur Hospital, Cape Town, South Africa.

### Journal and year of publication

Head Neck. 2015 Feb;37(2):255-9.

### Type of publication

Prospective placebo-controlled double blind randomized controlled trial

### Background

Pharyngocutaneous fistula is a common complication of total laryngectomy. It was hypothesized that perioperative proton pump inhibitor (PPI) treatment could reduce the incidence of pharyngocutaneous fistulae.

### Methods

This prospective placebo-controlled double-blind randomized controlled trial compared PPI treatment (14 days enteral omeprazole) with a placebo in patients undergoing primary total laryngectomy.

### Results

Forty patients were randomized into PPI (n = 21) and placebo arms (n = 19). A total of 7 patients (17.5%) developed a pharyngocutaneous fistula. A statistically significant difference was observed between the placebo and PPI treatment groups. Six fistulae occurred in the placebo arm of 19 patients (31.6%), whereas 1 fistula occurred in 21 patients in the PPI group (4.8%). No other statistically significant risk factors for pharyngocutaneous fistula were identified. The mean hospital stay of patients with and without a fistula was 32 and 7.5 days, respectively.

### Conclusion

The development of a pharyngocutaneous fistula is a common complication after total laryngectomy. Pharyngocutaneous fistulae result in prolonged hospitalization and morbidity. The use of perioperative enteral omeprazole significantly reduced the incidence of fistulae. Therefore PPIs are recommended for patients undergoing total laryngectomy. Further research to better define the role of reflux and antacid management is suggested.

## Cocuzza et al, 2014

### Title

Relationship between radiotherapy and gastroesophageal reflux disease in causing tracheoesophageal voice rehabilitation failure.

### Authors

Cocuzza S<sup>1</sup>, Bonfiglio M<sup>2</sup>, Chiaramonte R<sup>2</sup>, Serra A<sup>2</sup>.

### Affiliations

<sup>1</sup>Department of Medical Surgical Specialties, ENT Unit, University of Catania, Catania, Italy.

<sup>2</sup>Department of Medical Surgical Specialties, ENT Unit, University of Catania, Catania, Italy.

### Journal and year of publication

J Voice. 2014 Mar;28(2):245-9.

### Type of publication

Retrospective study

### Objective

The objective was to analyze the association of radiotherapy with gastroesophageal reflux as determinant of fistula related pathology, in voice prosthesis patients. It was hypothesized that fistula-related problems are higher in patients with both a history of GERD and postoperative radiotherapy when compared with patients with only a history of GERD.

### Methods

Sixty-one laryngectomy patients were enrolled between 2005 and 2012. All patients underwent phonatory rehabilitation with voice prosthesis. All patients had been diagnosed with gastroesophageal reflux disease, for which proton pump inhibitors (PPIs) were prescribed. The occurrence of fistula-related problems among patients who received postoperative radiotherapy (n=31) and those patients who did not (n=30) was analyzed.

### Results

A higher rate of failure of speech rehabilitation in laryngectomy patients with gastroesophageal reflux was observed in the patients with a history of postoperative radiotherapy (45%) compared to patients who did not have postoperative radiotherapy (17%), although all patients were treated with PPIs.

### Conclusion

The results seem to confirm the importance of the association of postoperative radiotherapy with gastroesophageal reflux in the determinism of fistula-related problems.

## Hadzibegovic et al, 2012

### Title

Analysis of saliva Pepsin Level in Patients with Tracheoesophageal Fistula and Voice Prosthesis complications.

### Authors

Hadzibegović AD<sup>1</sup>, Danić D<sup>1</sup>, Prgomet D<sup>2</sup>, Tićac R<sup>3</sup>, Kozmar A<sup>4</sup>.

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<sup>4</sup>University of Zagreb, Zagreb University Hospital Center, Department of Immunology, Clinical Institute of laboratory diagnostics, Zagreb, Croatia

### Journal and year of publication

Coll Antropol. 2012 Nov;36 Suppl 2:93-7.

### Type of publication

Prospective cross-sectional study

### Introduction

The aim of this study was to investigate the relationship between pepsin concentration in saliva and the occurrence of tracheoesophageal fistula (TEF) complications and voice prosthesis (VP) complications in patients who have undergone total laryngectomy.

### Subjects and Methods

The concentrations of pepsin in the saliva of 41 laryngectomized patients was assessed and correlated with the incidence of TEF complications (periprosthetic leakage, atrophy, esophageal mucosa hypertrophy, granulations, fistula enlargement and VP dislocation), VP complications(transprosthetic leakage, Candida infection) and voice quality.

### Results

In all, 17 patients (42%) had complications. All of them had TEF complications, whereas VP complication, together with TEF was found in 9 patients (22%). No significant correlation was found between adjuvant radiotherapy and TEF complications. Most patients, 30 (73%), had positive pepsin level in saliva. Median pepsin concentration was higher in patients free of TEF or VP complications, but the difference was not significant. In addition, a negative correlation was found between pepsin levels and voice quality, but not significant.

### Conclusion

It was demonstrated that pepsin was present in the saliva of the majority of the patients, suggesting ongoing reflux in laryngectomized patients. Although reflux was proposed to be associated with TEF complications, and pepsin proven as a most sensitive and specific marker of supra-esophageal reflux, the authors found no statistically significant correlation between pepsin levels and the occurrence of TEF or VP complications. Further studies of the impact of pepsin and supra-esophageal reflux on TEF and VP are needed.

## Cocuzza et al, 2012

### Title

Gastroesophageal reflux disease and postlaryngectomy tracheoesophageal fistula.

### Authors

Cocuzza S, Bonfiglio M, Chiaramonte R, Aprile G, Mistretta A, Grosso G, Serra A.

### Affiliation(s)

ENT Department, University of Catania, Via Santa Sofia, 78, Catania 95123, Italy.

### Journal and year of publication

Eur Arch Otorhinolaryngol. 2012 May;269(5):1483-8.

### Type of publication

Retrospective study

### Introduction

The objective of this study was to evaluate the incidence of pathologic gastroesophageal reflux in laryngectomized patients using a voice prosthesis, to analyze potential related problems, and to evaluate the effectiveness of a therapeutic protocol.

### Subjects and Methods

A retrospective study was conducted in 43 laryngectomized patients using a voice prosthesis and who had problems with regard to recurrent tracheoesophageal granulation, the need of frequent prosthesis replacement (< 3 months), and unsatisfactory vocal results. All patients underwent physical examination of the puncture region and of the neopharynx and were submitted to esophagogastroduodenoscopy. All patients underwent a therapeutic anti-reflux protocol and were re-evaluated afterwards by examining the puncture region both on the tracheal side and on the esophageal side through videolaryngostroboscopy.

### Results

Of the 43 recruited patients 13 (30%) presented with tracheoesophageal granulation, 20 (46.5%) with unsatisfactory vocal results, and 10 (23.5%) with frequent prosthesis replacement. Of the 13 patients who had recurrent granulations, the evaluation results revealed the presence of gastroesophageal reflux disease (GERD) in 6 cases (46%). In the group of patients presenting unsatisfactory vocal results GERD was shown in 13 cases (65%). In the group of patients with short prosthesis device life, GERD was found in two cases (20%). Overall analysis of the data identified GERD in 21 (49%) of the 43 patients studied. The results of the therapeutic anti-reflux protocol in these 21 patients showed the disappearance or a significant (>75%) volume reduction of granulation formation in five cases (38%,  $p = 0.002$ ), an overall improvement in the quality of voice in 12 patients (60%,  $p = 0.0001$ ), and an increase of the prosthesis life in 4 patients (40%,  $p = 0.05$ ). Also the 22 GERD negative cases (51%) underwent the therapeutic anti-reflux protocol, serving as a control group. In this group, the treatment only showed substantial improvements in only two cases (9%)

### Conclusions

The data obtained suggest a high degree of correlation between the presence of pathologic gastric reflux and voice prosthesis, voice and/or tracheoesophageal puncture problems. The introduction of a specific therapeutic anti-reflux protocol has led to significant improvements in 22 out of 43 patients ( $p < 0.001$ ).

## Lorenz et al, 2011

### Title

[Laryngectomised patients with voice prostheses: influence of supra-esophageal reflux on voice quality and quality of life].

### Authors

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### Journal and year of publication

HNO. 2011 Feb;59(2):179-87. Article in German.

### Type of publication

Prospective study

### Introduction

This prospective study aimed to assess the influence of supra-esophageal reflux on voice quality and quality of life in patients who have undergone total laryngectomy and prosthetic voice rehabilitation.

### Subjects and Methods

Subject were 60 laryngectomized patients whom were assessed using 24-h dual-probe pH monitoring before and 6 months after oral anti-reflux treatment with proton pump inhibitors (PPIs). Quality of life was assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC- QLQ- C30). Voice quality was quantified using the voice handicap index (VHI10). Quality of life and voice quality parameters were then correlated with the severity of reflux disease.

### Results

Patients with physiological reflux area index (RAI) scores had a mean VHI10 score of 46.4 ( $\pm 11.4$ ). VHI scores were found to increase to up to 64.1 ( $\pm 9.6$ ) with reflux severity ( $p=0.025$ ). Total quality of life scores ranged from 115.8 ( $\pm 24.7$ ) in patients with physiological RAI scores to 131.0 ( $\pm 33.1$ ) in patients with highly pathological RAI scores ( $p=0.007$ ). After 6 months of treatment with PPIs, VHI scores improved to a total score of 57.5 ( $\pm 20.6$ ,  $p=0.003$ ). Quality of life scores improved to 123.3 ( $\pm 29.0$ ,  $p=0.045$ ). Anti-reflux treatment with PPI decreased reflux severity and improved voice quality, particularly in patients reaching normal RAI scores with antireflux medication

### Conclusions

Supra-esophageal reflux influences voice quality and quality of life in laryngectomized patients with voice prostheses. This can be explained, for example, by an increased incidence of periprosthetic leakage, the presence of edema in the pharyngo-esophageal segment (where speech is produced), and general reflux symptoms. Rigorous treatment with anti-reflux medications leads to an improvement in reflux parameters that can be assessed objectively (RAI) and in correlated quality of life and voice quality parameters. For this reason, the authors recommend rigorous oral treatment with PPIs in laryngectomized patients with a confirmed diagnosis of supra-esophageal reflux.

## Lorenz et al, 2011

### Title

The management of periprosthetic leakage in the presence of supra-oesophageal reflux after prosthetic voice rehabilitation.

### Authors

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### Journal and year of publication

Eur Arch Otorhinolaryngol. 2011 May;268(5):695-702.

### Type of publication

Prospective study

### Introduction

The objective of the study was to investigate the influence of anti-reflux medications on the management of periprosthetic leakage in laryngectomized patients with prosthetic voice rehabilitation.

### Subjects and Methods

Subjects were 60 patients who underwent total laryngectomy and prosthetic voice rehabilitation. In a prospective non-randomized study, subjects were assessed clinically and by means of 24-h dual-probe pH monitoring before and 6 months after oral anti-reflux treatment with proton pump inhibitors (PPIs). The severity of reflux, the effectiveness of anti-reflux therapy, and the clinical success of treatment were evaluated. Reflux parameters before and after anti-reflux therapy as well as the severity and incidence of periprosthetic leakage before and after PPI therapy were the main outcome measures.

### Results

The absolute number of reflux events was 162.2 ( $\pm$ 144.3) before treatment and 63.1 ( $\pm$ 87.9) after treatment with PPIs ( $p = 0.031$ ). The reflux area index score (RAI) decreased from 327.1 ( $\pm$ 419.3) without PPIs to 123.8 ( $\pm$ 249.7) with PPIs ( $p = 0.0228$ ). The mean DeMeester score (a composite score for reflux) was 108.3 ( $\pm$ 85.4) before treatment and 47.4 ( $\pm$ 61.7) after 6 months of treatment ( $p = 0.0557$ ). The relative risk of periprosthetic leakage decreased to 0.5 after anti-reflux treatment. In 19 patients, periprosthetic leakage problems were successfully managed by rigorous treatment with PPIs. No further surgical procedures were required in these cases.

### Conclusions

Rigorous anti-reflux treatment leads to an improvement in parameters that can be assessed objectively by 24-h dual-probe pH monitoring. In the majority of patients, the symptoms associated with periprosthetic leakage can be improved or cured by anti-reflux treatment.

## Lorenz et al, 2010

### Title

Role of reflux in tracheoesophageal fistula problems after laryngectomy.

### Authors

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### Journal and year of publication

Ann Otol Rhinol Laryngol. 2010 Nov;119(11):719-28.

### Type of publication

Prospective study

### Introduction

The purpose of this 2-year prospective non-randomized study was to investigate the relationship between pathological supra-esophageal reflux and the occurrence of tracheoesophageal (TE) puncture complications, especially severe TE puncture enlargement, in patients who underwent total laryngectomy and prosthetic voice restoration.

### Subjects and Methods

The study included 60 laryngectomized patients using a voice prosthesis. The presence of reflux disease was objectively assessed using 24-hour dual-probe pH monitoring in 60 laryngectomized patients. The relationship between the severity of reflux and the incidence of tracheoesophageal (TE) puncture complications was investigated. The risk for TE puncture problems was assessed by determining the absolute number of reflux events at the level of the TE puncture, the reflux area index score, and the DeMeester score (a composite score for reflux).

### Results

All patients with TE puncture enlargement showed highly pathological results in the diagnostic tests for reflux disease. Depending on reflux severity, the relative risk of developing TE puncture complications was up to 10 times higher for these patients.

### Conclusions

A significant correlation was found between the occurrence of TE puncture complications and the severity of supraesophageal reflux. Potential chronic irritation of the esophageal and tracheal mucosa can possibly contribute to the development of these problems. If the presence of reflux disease has been confirmed by 24-hour dual-probe pH monitoring, patients with TE puncture complications should be treated with proton pump inhibitors.

## Lorenz et al, 2010

### Title

[Prosthetic voice restoration after laryngectomy: the management of fistula complications with anti-reflux medications].

### Authors

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### Journal and year of publication

HNO. 2010 Sep;58(9):919-26. Article in German.

### Type of publication

Prospective study

### Introduction

This prospective study aims to investigate the role of aggressive anti-reflux therapy in periprosthetic leakage problems in laryngectomized patients using a voice prosthesis.

### Subjects and Methods

A total of 48 patients were assigned to one of two groups. Group A consisted of 16 patients with recurrent periprosthetic leakage. Group B comprised 32 patients without periprosthetic leakage. The presence of reflux was objectively assessed using 24-h dual-probe pH monitoring. All patients with pathological reflux underwent proton pump inhibitor (PPI) therapy. After 6 months, patients were re-evaluated for fistula complications and objective reflux parameters.

### Results

The mean absolute number of reflux events was 202.8 (+/-44) before and 74.5 (+/-22.9) after PPI therapy ( $p=0.025$ ). The reflux area index decreased from 419.5 (+/-112.5) before treatment to 105.8 (+/-54.7) after treatment ( $p=0.0005$ ). The mean DeMeester score (a composite score for reflux) was 104.4 (+/-21.3) without PPIs and 43.5 (+/-9.3) after 6 months with PPIs ( $p=0.028$ ). A risk analysis for patients with both periprosthetic leakage and pathological reflux (15 patients at the beginning of the study, four patients after therapy) showed that the relative risk of periprosthetic leakage decreased to 0.3 ( $p=0.0054$ ) with PPI therapy.

### Conclusions

Patients with recurrent periprosthetic leakage in the region of the TE puncture showed a significantly higher number of supra-oesophageal reflux episodes. Rigorous anti-reflux treatment can help manage or prevent periprosthetic leakage problems in a large proportion of patients.

## Lorenz et al, 2009

### Title

[Coincidence of fistula enlargement and supra-oesophageal reflux in patients after laryngectomy and prosthetic voice restoration].

### Authors

Lorenz KJ, Ehrhart T, Grieser L, Maier H.

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### Journal and year of publication

HNO. 2009 Dec;57(12):1253-61. Article in German.

### Type of publication

Prospective study

### Introduction

The prospective study investigates if there was an increased incidence of supra-esophageal reflux in patients who developed recurrent periprosthetic leakage in the region of the tracheoesophageal (TE) puncture after laryngectomy and prosthetic voice restoration.

### Subjects and Methods

A total of 48 patients was included: 16 patients with recurrent periprosthetic leakage (group A) and 32 patients without periprosthetic leakage (group B). The presence of reflux was objectively assessed using 24-hour dual-probe pH monitoring. The number of supra-esophageal reflux events, the reflux area index (RAI) and the DeMeester score (a composite score for reflux) were determined as well as the relative risk of TE puncture enlargement in relation to the presence of reflux and postoperative radiotherapy.

### Results

In group A pathological reflux events were detected in 100% of the cases. The mean number of supra-esophageal reflux episodes was 414.8, the RAI was 419.5 (+/-212.45) and the DeMeester score was 104.4 (+/-21.3). In group B pathological reflux events were found in only 50% of the cases. The mean number of supra-esophageal reflux episodes was 11.8, the RAI was 146.9 (+/-40.4) and the DeMeester score was 42.9 (+/-11.8). All reflux parameter results for group A patients were significantly higher than those obtained for group B patients. The relative risk of TE puncture enlargement was 1.8-2.3 times higher in the presence of reflux. Postoperative radiotherapy did not increase the risk of TE puncture enlargement (relative risk 0.75-0.93).

### Conclusions

A significantly higher number of supra-oesophageal reflux episodes occurred in patients with recurrent periprosthetic leakage. As reflux events may cause problems in the region of the TE puncture, prophylactic treatment with proton pump inhibitors is recommended.

## Pattani et al, 2009

### Title

Reflux as a cause of tracheoesophageal puncture failure.

### Authors

Pattani KM, Morgan M, Nathan CO.

### Affiliation(s)

Department of Otolaryngology Head and Neck Surgery, Louisiana State University Health Sciences Center, Feist-Weiller Cancer Center, Shreveport, Louisiana 71130, USA.

### Journal and year of publication

Laryngoscope. 2009 Jan;119(1):121-5.

### Type of publication

Retrospective chart review

### Introduction

This study evaluates the response to empiric reflux management in treatment of tracheoesophageal voicing difficulties in patients without any documented anatomic cause for the voice problems.

### Methods

A retrospective chart review was performed to identify laryngectomized patients using a voice prosthesis who had voicing problems (n = 37). Only those patients without any documented anatomic cause for failure (n = 22) were then further reviewed to determine if empiric treatment for reflux improved voicing. Evidence of reflux was determined by either using video-flexible scope of the neopharynx, barium swallows, 24-hour pH probes, and /or transnasal esophagoscopy (TNE). In 13 of 22 patients who had voicing difficulties and no evidence of reflux on these tests, empiric treatment with anti-reflux medications had been documented. The 22 patients were closely monitored to determine the role of reflux therapy and subsequent voicing outcomes.

### Results

Of the 22 patients studied, 9 were noted to have granulation tissue on the tracheal side of the prosthesis. All nine patients had complete resolution of the granulation tissue after anti-reflux treatment, and seven of nine were able to voice again. Of the patients with no obvious reason for their voicing problems, who were empirically treated for reflux, 62% (8 of 13) had voice after treatment. Overall, 77% of the patients (17 of 22) had a positive response to treatment with aggressive reflux therapy.

### Conclusions

Previous studies have demonstrated patients with a total laryngectomy and/or radiation therapy have increased reflux. This study addresses reflux as a potential cause of tracheoesophageal voicing problems. Results showed that 41% (9 of 22) of patients with voicing difficulties had granulation tissue surrounding the prosthesis as a result of reflux. Aggressive anti-reflux therapy proved beneficial in eradicating this problem. Prophylactic anti-reflux therapy may be warranted for patients undergoing TE puncture to reduce voicing problems.

## Boscolo-Rizzo et al, 2008

### Title

The impact of radiotherapy and GERD on in situ lifetime of indwelling voice prostheses.

### Authors

Boscolo-Rizzo P, Marchiori C, Gava A, Da Mosto MC.

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### Journal and year of publication

Eur Arch Otorhinolaryngol. 2008 Jul;265(7):791-6.

### Type of publication

Retrospective study

### Introduction

The aim of this study was (1) to analyze the in situ lifetime of indwelling voice prostheses (VPs) and (2) to investigate the role of some variables on device lifetime.

### Subjects and Methods

A retrospective clinical study was conducted that included 106 laryngectomized patients using a voice prosthesis that had visited the outpatient clinic for problems related to their VP between August 1998 and March 2006.

### Results

The overall mean in situ voice prosthesis device lifetime was 180.9 days (95% CI 162.6-199.2). In irradiated patients average device life was significantly shorter (163.3 days) compared to non-irradiated patients (202.9 days;  $P = 0.008$ ). In patients with endoscopic evidence of gastroesophageal reflux (GERD) the average device life was significantly shorter (126.5 days) compared to patients without evidence for GERD (215.7,  $P < 0.001$ ). Multivariate analysis confirmed that radiotherapy and presence of GERD significantly affected the in situ voice prosthesis device lifetime.

### Conclusions

This study confirmed the relationship between short voice prosthesis device lifetime and radiation therapy, and showed a possible association between GERD and limited device lifetime.

## Jobe et al, 2002

### Title

Surgical management of gastroesophageal reflux and outcome after laryngectomy in patients using tracheoesophageal speech.

### Authors

Jobe BA, Rosenthal E, Wiesberg TT, Cohen JI, Domreis JS, Deveney CW, Sheppard B.

### Affiliation(s)

Department of Surgery, Oregon Health Sciences University, Portland, OR, USA.

### Journal and year of publication

Am J Surg. 2002 May;183(5):539-43.

### Type of publication

Prospective study

### Introduction

This study investigates the effects of surgical management (laparoscopic fundoplication) of Gastro Esophageal reflux disease (GERD) in laryngectomized patients using a voice prosthesis.

### Subjects and Methods

Nine laryngectomy patients who use tracheoesophageal speech underwent laparoscopic fundoplication for documented reflux. Preoperative and postoperative symptoms were recorded. Quality of speech was documented before and after fundoplication.

### Results

Although 88% of patients had resolution of GERD symptoms, all developed bloating and hyperflatulence. There was no difference in quality of tracheoesophageal speech after laparoscopic fundoplication.

### Conclusion

Fundoplication in laryngectomy patients that use tracheoesophageal speech eliminates symptoms of gastroesophageal reflux and resolves regurgitation associated prosthesis erosion. Although nearly all patients are satisfied with outcome, there is a high incidence of post-fundoplication bloating and hyperflatulence that may be life limiting. Poor quality tracheoesophageal speech should not be used as an indication for antireflux surgery.

## Sarría Echegaray et al, 2000

### Title

[Pharmacological prophylaxis of gastroesophageal reflux. Incidence of pharyngocutaneous fistula after total laryngectomy].

### Authors

Sarría Echegaray P, Tomás Barberán M, Mas Mercant S, Soler Vilarrasa R, Romaguera Lliso A.

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### Journal and year of publication

Acta Otorrinolaringol Esp. 2000 Apr;51(3):239-42. Article in Spanish.

### Type of publication

Prospective study

### Introduction

Development of a pharyngocutaneous fistula is a serious complication of total laryngectomy. The problem increases morbidity, prolongs hospitalization, and occasionally causes death. The authors propose that gastroesophageal reflux, which often is subclinical, is an important trigger and should be prevented.

### Methods

Evaluation of the effect of associating an anti-reflux agent like metoclopramide hydrochloride to the usual ranitidine of the protocol after total laryngectomy on reducing the incidence of pharyngocutaneous fistula.

### Results

Incidence of pharyngocutaneous fistula reduced significantly ( $p < .05$ )

## Seikaly and Park, 1995

### Title

Gastroesophageal reflux prophylaxis decreases the incidence of pharyngocutaneous fistula after total laryngectomy.

### Authors

Seikaly H, Park P.

### Affiliation(s)

Department of Surgery, University of Alberta, Canada.

### Journal and year of publication

Laryngoscope. 1995 Nov;105(11):1220-2.

### Type of publication

Prospective study

### Introduction

Pharyngocutaneous fistula is a serious complication after laryngectomy. Gastric fluid is known to cause severe laryngopharyngeal injury and poor mucosal healing. This study was designed to evaluate the effects of a gastroesophageal reflux prophylaxis regimen on the incidence of fistulae after total laryngectomy.

### Subjects and Methods

Twenty-one consecutive patients were entered in the study. Patients with positive resection margins were excluded from the overall analysis. All patients had a Connell's two-layer closure of the pharynx with absorbable suture, suction drainage of the neck, postoperative tube feeding, and prophylactic antibiotics. All patients were started on an anti-reflux regimen postoperatively composed of continuous tube feeds, intravenous ranitidine, and intravenous metoclopramide hydrochloride. Patients were followed postoperatively with Gastrografin swallows and clinically for 8 weeks. The control group consisted of retrospectively studied patients managed identically except for the anti-reflux prophylaxis.

### Results

The two groups were well matched for factors reported to influence the rate of pharyngocutaneous fistulae formation. The control group had six fistulae (26%) and an average of 16.5 days of hospital stay. The study group had no fistulae and an average of 11.5 days of hospital stay ( $P = .02$ ).

### Conclusion

This study suggests that gastroesophageal reflux may predispose to fistula formation after laryngectomy and that mechanical and pharmacological prophylaxis decreases postoperative morbidity and length of hospital stay.