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Short Article

Complications of voice prostheses and their management in patients after laryngectomy

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Abstract

Total laryngectomy remains the treatment of choice for advanced stages of laryngeal cancer. Voice prostheses are considered by many authors to be the gold standard for restoring speech after total laryngectomy. Their effectiveness has led to their widespread adoption in clinical practice. As a result, the population of patients using such devices is steadily increasing, which is reflected in a growing scientific interest in this area. This trend has generated an expanding number of studies focused on the analysis of potential complications, available treatment

methods in this group of patients. The aim of this review is to analyze potential complications and their management options in patients with tracheoesophageal voice prostheses.

All authors independently searched the PubMed database using the following keywords: “tracheoesophageal voice prosthesis,” “primary tracheoesophageal puncture,” “tracheoesophageal fistula,” “laryngectomy,” and “voice prosthesis complications.” Particular attention was paid to reflux therapy with proton pump inhibitors and the potential benefits for patients after laryngectomy. Another important issue discussed in the article concerns methods aimed at reducing biofilm formation on voice prostheses, which consequently translates into longer device lifespan. The effectiveness of botulinum toxin type A was compared with surgical treatment in patients with impaired voice due to spasm of the middle and inferior pharyngeal constrictor muscles (PCM). The studies discussed in this article contribute to improving the quality of life of patients with voice prostheses after laryngectomy. Nevertheless, further research is needed to determine the safety and long-term outcomes of the methods used to manage complications.

Key words: tracheoesophageal voice prosthesis, primary tracheoesophageal puncture, tracheoesophageal fistula, laryngectomy, voice prosthesis complications

Introduction

Laryngeal cancer is a significant clinical problem. According to the *Global Cancer Statistics 2022*, there are 188 960 new cases of laryngeal cancer annually, of which 103 216 result in death. The median age of patients with laryngeal cancer is 61 years in Brazil, 65 years in the United States, and 69 years in Sweden [1–3]. The life

expectancy of a 70-year-old person is approximately 15 years or more in developed countries. Therefore, patients who undergo total laryngectomy with surgical voice rehabilitation through primary tracheoesophageal puncture and implantation of a voice prosthesis—the method of choice—will face the long-term consequences of this therapy [3,4].

The use of tracheoesophageal punctures and voice prostheses is considered the *gold standard* for voice restoration. However, it is associated with certain complications. In a study on complications conducted by Tong et al., the most commonly reported patient-related adverse events included prosthesis aspiration, presence of a foreign body during placement, aspiration pneumonia, and aspiration of the cleaning brush tip [5]. The most frequent device-related adverse events included detachment of the brush tip, leakage, and tearing of the esophageal flange [5]. The researchers emphasized that complications related to tracheoesophageal puncture and voice prosthesis placement often result from improper use [5]. Therefore, to reduce the incidence of these complications, it is essential to raise awareness and educate both physicians and patients about the procedure and the care of the voice prosthesis [5].

Methodology

To create this review, a thorough search of scientific publications was conducted, taking into account the most recent and up-to-date data on the subject. The literature search strategy was carried out using the PubMed database based on a combination of the following keywords: *tracheoesophageal voice prosthesis*, *primary tracheoesophageal puncture*, *tracheoesophageal fistula*, *laryngectomy*, and *voice prosthesis complications*. Additionally, references from selected publications were analyzed to identify related studies. After reviewing the titles and abstracts, incomplete articles and those not directly related to complications of voice prostheses and their management in patients after laryngectomy were excluded. The final analysis included 27 publications that met the inclusion criteria.

Results and discussion

Below, we present the clinical issues encountered by specialists caring for patients with voice prostheses after total laryngectomy, in order to highlight the continuously evolving therapeutic methods aimed at improving patients' quality of life.

Periprosthetic Leakage

In patients who have undergone laryngectomy, the most common reason for voice prosthesis replacement has been shown to be leakage through or around the prosthesis [6]. Studies indicate that the management of periprosthetic leakage can become less problematic by applying a systematic algorithm with a stepwise, standardized approach [7]. The therapeutic algorithm is as follows [7]:

- Inspection of local condition
- Prosthesis replacement
- Widening of the flanges
- Tissue augmentation
- Fistula shrinkage
- Fistula closure

An example confirming the effectiveness of this algorithm is a study that involved individualized fitting of voice prostheses to prevent leakage around the prosthesis in patients with enlarged tracheoesophageal fistulas [8]. This approach proved effective, allowing the preservation of tracheoesophageal speech and avoiding the need for surgical fistula closure in that patient group [8]. Another study by Acton et al. showed that leakage around the voice prosthesis could be minimized or avoided by initially fitting and continuing the use of smaller-diameter (16 F, French) prostheses, as leakage was more common with 20 F prostheses [9]. However, researchers from Boston found no statistically significant differences between 16 F and 20 F voice prostheses regarding postoperative complications, including leakage and voice outcomes. Both prosthesis sizes were found to be effective and safe for voice restoration in laryngectomized patients [10].

Further evidence supporting the effectiveness of the above-mentioned algorithm comes from a meta-analysis evaluating the efficacy and safety of tissue augmentation therapy, which involves injecting a biocompatible material to increase the volume of tissues surrounding the tracheoesophageal fistula [11]. The meta-analysis included 97 patients from 15 studies. In 58.8% of patients, periprosthetic leakage did not occur after more than six months of follow-up, and periprosthetic leakage resolved in 88.7% of tissue augmentation procedures [11]. This method is minimally invasive and safe and often provides temporary resolution of periprosthetic leakage, delaying the need for more invasive treatments [11].

In some cases, surgical treatment will be the preferred method, such as in the presence of pharyngoesophageal strictures, which predispose to the enlargement of the tracheoesophageal fistula along with leakage [12]. Surgical reconstruction of enlarging tracheoesophageal fistulas containing voice prostheses has been shown to be effective, particularly when combined with the management of pharyngoesophageal strictures [12]. The use of free radial forearm flaps with a long vascular pedicle provides an additional advantage by enabling access to more distant and less irradiated vessels [12].

The development of voice prosthesis complications, including leakage, is also influenced by prolonged prosthesis use. Acton et al. emphasized the importance of patient education to ensure early and reliable identification of prosthesis leakage, allowing for timely replacement and prevention of potential pulmonary complications [9]. Their study showed that leakage went unrecognized in 21 of 92 cases (23%), even though 15 of those 21 patients (71%) exhibited a cough reflex [9].

Reflux

Some studies report an association between gastroesophageal reflux and the incidence of voice prosthesis complications in patients after laryngectomy [13]. Researchers from Croatia investigated the relationship between salivary pepsin concentration—considered the most sensitive and specific biomarker of extraesophageal reflux (EER)—and the occurrence of voice prosthesis complications before and after three months of proton pump inhibitor (PPI) therapy [13]. The results showed that a three-month course of pantoprazole at a dose of 40 mg reduced the relative risk of voice prosthesis complications by 33%, although this reduction was not statistically significant [13]. Additional insights on this topic come from a study evaluating the effect of PPI therapy on intercellular junctions, specifically epithelial–mesenchymal transition, in patients with periprosthetic leakage after laryngectomy [14]. Following oral PPI treatment, an increase in membranous E-cadherin expression was observed in patients who showed clinical improvement of fistula-related problems, whereas patients with persistent fistula enlargement demonstrated a continued decrease in E-cadherin levels despite PPI therapy [14]. These findings contribute to a better understanding of treatment-resistant tracheoesophageal fistula enlargement in patients after total laryngectomy [14]. Further research is needed to determine whether patients with voice prostheses may benefit from PPI therapy.

Biofilm

The main cause of complications associated with voice prostheses is the development of biofilm [15]. From the very first minute after a voice prosthesis is placed in the tracheoesophageal fistula, it becomes colonized by microorganisms [15]. Biofilm plays an important role in the longevity of voice prostheses. In a study investigating biofilm formation on voice prostheses, results showed that most patients with suboptimal prosthesis lifespan had bacterial or polymicrobial contamination (bacteria and fungi) [16]. Researchers emphasized that common pathogens were found between the oral microbiota and the voice prosthesis. These findings led to studies on broad-spectrum and targeted oral decontamination regimens, which in preliminary trials were associated with a 1.4-fold improvement in prosthesis lifespan. This provides evidence that such approaches may be more beneficial for patients than prolonged nonspecific antifungal therapy [16]. Another study demonstrated that mouth rinses containing nystatin and **Biotène Oral Rinse** showed similar effectiveness in reducing bacterial counts, although nystatin achieved significantly better results compared to standard oral hygiene [17]. **Biotène Oral Rinse** is a cheaper alternative to nystatin and has a simpler treatment protocol, which may make it more preferable for both patients and physicians [17].

In India, a study on patients' dietary habits was conducted to identify factors that could contribute to longer prosthesis lifespan [15]. It was shown that regular consumption of **curd**—an easily achievable lifestyle modification—likely prolongs prosthesis longevity and reduces the frequency of replacements [15]. This effect is attributed to dairy products inhibiting the growth of *Candida albicans*, which produces enzymes that lead to prosthesis degradation and dysfunction [15]. Another described method for reducing biofilm formation on voice prostheses involves the use of **vibrational stimuli**, which resulted in a statistically significant 5.56-fold reduction in biofilm accumulation *in vitro* [18]. A further and highly promising approach to minimizing biofilm formation

on silicone rubber prostheses is the use of **passive or combined active–passive surface modification techniques** [19]. These methods alter the susceptibility of prostheses to microbial colonization, particularly by yeast species [19]. However, both approaches require clinical studies to confirm that the *in vitro* biofilm reduction translates into longer device lifespan *in vivo* and to verify their safety for patients.

Voice Impairment Due to PCM Spasm

Another complication associated with the use of voice prostheses is voice impairment caused by spasm of the middle and inferior pharyngeal constrictor muscle (PCM). In a study by Bartolomei et al., the efficacy of botulinum toxin type A (BTXA) was evaluated as an alternative to surgical intervention to facilitate phonation in post-laryngectomy patients who were unable to produce tracheoesophageal voice due to PCM spasm [20]. A dose of 100 U of BTXA was injected into the pharyngeal constrictor muscle in 10 patients, and 50 U in 2 patients, under electromyographic (EMG) guidance. All patients subsequently participated in a voice therapy program. In 11 out of 12 patients, phonation improvement was observed within 24–48 hours, with a sustained long-term effect. Given its non-invasive nature, BTXA appears to be a treatment of choice for managing PCM spasm [20].

Primary vs. Secondary Voice Prosthesis Placement

Depending on the timing of the tracheoesophageal puncture relative to the laryngectomy, primary (performed simultaneously with laryngectomy) and secondary (performed in a subsequent procedure) punctures are distinguished. Studies have not shown that the timing of prosthesis placement significantly affects the overall incidence of complications [21–23]. However, some reports suggest that one type of tracheoesophageal puncture may offer advantages over the other regarding the risk of specific complications.

Robinson R.A. and colleagues demonstrated that **primary prosthesis placement** is associated with a reduced need for device replacement due to size mismatch and with a longer interval before the first prosthesis change. Moreover, the primary procedure allows for earlier initiation of voice rehabilitation and a shorter hospital stay, which represents a substantial cost saving for the healthcare system [24].

On the other hand, support for **secondary voice prosthesis placement** comes from a study by Barauna Neto et al., which found that the risk of periprosthetic leakage was approximately 10% lower in patients who underwent secondary tracheoesophageal puncture compared with those who had a primary puncture [25]. Furthermore, a meta-analysis conducted by Chakravarty P.D. and co-authors indicated that secondary punctures are associated with a lower risk of pharyngocutaneous fistula formation. Therefore, performing the puncture as a separate procedure should be considered particularly for patients with risk factors such as anemia, COPD, prior radiotherapy, chemotherapy, or neck dissection [21,26].

Secondary prosthesis placement after the primary operation, prosthesis implantation following prior radiotherapy, and laryngectomy with flap reconstruction have been identified as independent predictors of reduced fistula- and prosthesis-related complication-free survival, based on a long-term follow-up of 112 patients between 1996 and

2015 [27]. The same study also demonstrated that it is not adjuvant radiotherapy itself, but rather tracheoesophageal puncture following radiotherapy and secondary prosthesis placement, that is significantly associated with an increased risk of complications [27]. Similar conclusions were drawn by Kummer P. and colleagues, who emphasized that **primary tracheoesophageal puncture** should be recommended for patients scheduled to undergo postoperative radiotherapy following laryngectomy [28].

In conclusion, both primary and secondary punctures should be regarded as safe and equally effective methods for restoring speech ability. However, primary punctures are generally preferred because they eliminate the need for an additional surgical procedure and expedite the recovery of communication skills, which has a positive impact on patients' mental well-being [23]. Nevertheless, the optimal timing for performing a tracheoesophageal puncture should be determined individually, based on a comprehensive assessment of the patient's clinical condition, including comorbidities, previous surgical interventions, therapeutic strategies used, and future treatment plans.

Prosthesis Longevity

Historical data suggest that the average lifespan of a tracheoesophageal prosthesis ranges from 3 to 6 months. However, a 10-year follow-up of a cohort of 390 patients between 2003 and 2013 showed that the median lifespan of all prostheses was 61 days, which may reflect the intensification of cancer treatment protocols in the organ-preservation era [29].

Researchers from Warsaw investigated potential factors affecting the longevity of voice prostheses, focusing on cytokine levels (IL-1 β , IL-6, IL-8, IL-10, TNF α) and salivary pepsin [30]. Patients were randomly assigned to two groups according to the prosthesis replacement schedule: regular (every 3 months) or irregular (only when complications occurred) [30]. The study found that levels of IL-1 β , IL-6, IL-8, IL-10, TNF α , and pepsin did not differ according to the regularity of prosthesis replacement. However, IL-6 levels were significantly higher when voice prosthesis complications occurred [30].

Reduced prosthesis longevity leads to another problem faced by patients: an increased number of prosthesis replacements due to leakage. A beneficial solution is the **Provox ActiValve**, which features a magnetic valve system that allows active valve closure to manage leakage [31]. Each replacement avoided using the Provox ActiValve saved €133.97 compared to what would have been required without it, confirming that it is an economical option that reduces both the number of replacements and overall costs compared with the **Provox Vega** [31].

In another study, prostheses with single and dual valves were compared in terms of durability. The mean lifespan of single-valve prostheses was 60 days (median 51 days), whereas the mean lifespan of dual-valve prostheses was

164 days (median 84 days), a statistically significant difference [32]. The **Dual Valve prosthesis** provides greater durability compared with the single valve without affecting speech quality, making it the preferred option for patients whose single-valve prosthesis fails in less than three months [32].

Conclusions

Voice prostheses currently represent the best method for voice rehabilitation after laryngectomy. In the examples of prosthesis-related complications and their management presented above, a personalized medicine approach is evident, where the patient—with their symptoms, medical history, chronic diseases, and other burdens influencing treatment outcomes—is the central focus. Developing effective therapeutic strategies to manage these complications requires further research and analysis to improve the quality of life for patients with voice prostheses following laryngectomy.

Disclosure

Author's Contribution

Conceptualization: Kamila Bała, Natalia Staszko

Methodology: Kamila Bała, Natalia Staszko

Formal analysis: Kamila Bała, Natalia Staszko

Investigation: Kamila Bała, Natalia Staszko

Writing rough preparation: Kamila Bała, Natalia Staszko

Writing review and editing: Kamila Bała, Natalia Staszko

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