Total Closure of Enlarged Tracheoesophageal Puncture with Septal Button: Long-Term Results

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Abstract
Tracheoesophageal puncture enlargement in laryngectomized patients is a significant problem due to complications such as aspiration pneumonia. There are several management methods including conservative and nonconservative techniques. A total closure of the enlarged tracheoesophageal puncture is needed in some cases when conservative approaches have failed. At this point, the insertion of a silicone septal button in the puncture site is a useful, inexpensive, and simple technique. The follow-up of 4 patients managed with this technique revealed satisfactory long-term results.

Introduction
Tracheoesophageal puncture (TEP) is the gold standard technique for speech restoration after total laryngectomy. Tracheoesophageal (TE) speech is produced with the insertion of a unidirectional voice prosthesis (VP) through a puncture that is created between the posterior tracheal and anterior esophageal wall. The VP provides shunting of pulmonary airflow into the esophagus while avoiding aspiration during swallowing.

There are a number of complications of TEP, such as enlargement with leakage around the VP. Aspiration pneumonia associated with TEP enlargement is a significant and life-threatening complication. The underlying etiological factors for enlarged TEP include tumor recurrence, radiotherapy, malnutrition, uncontrolled diabetes, and smoking [1].
Various treatment options have been described for the management of enlarged TEP, including temporary removal of VP, injection to the puncture site, and submucosal purse-string suturing around the TEP. Aside from the conservative methods, complete closure of the TEP is also performed [2].

To our knowledge, although the septal button insertion technique was defined previously and a few cases were reported, the long-term results have not been analyzed [3, 4]. The aim of the present report is to describe the technique of septal button insertion and evaluate the long-term clinical outcomes of this approach.

**Case Report**

**Case 1**
A 68-year-old male patient with a history of total laryngectomy, bilateral neck dissection, and postoperative radiotherapy 8 years ago had complaints of leakage around his VP, coughing, and difficulty during eating. His medical history consisted of coronary heart disease and hypothyroidism that had been managed with hormone replacement therapy. An otolaryngological examination revealed enlarged TEP and a low body mass index (<20).

Our primary approach is to remove the VP and insert a new prosthesis with larger flanges. In unresponsive cases, waiting for puncture stenosis after insertion of a small (14–16 Fr) catheter or injection to the puncture site are other management choices.

Insertion of a VP with larger flanges did not solve the problem in this case. A two-way Foley catheter (14 Fr) was inserted to administer a high-calorie, high-protein diet while simultaneously avoiding oral intake to provide stenosis of the TEP. Because the width of the TEP did not change and injection failed, total surgical closure of the TEP was planned. However, due to cardiac risks, insertion of a septal button was preferred.

The patient was started on oral nutrition just after the procedure. Due to satisfactory oral intake and absence of leakage around the septal button, he was discharged on the second postprocedural day. The patient had weekly and monthly follow-ups for a total follow-up period of 30 months. During this period, aspiration pneumonia and local complications such as infection, granulation tissue formation, and enlargement of the puncture site were not encountered. Crusting was the main complication seen on the septal button.

**Case 2**
A 64-year-old male patient with a history of diabetes mellitus, total laryngectomy, bilateral neck dissection, and postoperative radiotherapy was admitted with the diagnosis of enlarged TEP and leakage (fig. 1). Surgical closure of the TEP was preferred due to an inability to achieve stenosis of the puncture site with conservative methods. Surgical closure with a sternocleidomastoid muscle flap was performed, but it was unsuccessful due to flap failure. As an alternative management option, a septal button was inserted to close the TEP. The patient was discharged on the second postprocedural day. He was followed for 15 months. During the follow-up period, neither aspiration pneumonia nor local complications around the TEP were observed.

**Case 3**
A 66-year-old male patient was referred with the complaint of leakage around the VP. His medical history revealed hypopharynx carcinoma that was managed through total laryngectomy, partial pharyngectomy, bilateral neck dissection, and postoperative radiotherapy in 2011. Multiple biopsies were taken around the puncture site to rule out recurrent malignancy; these biopsies were reported as benign. The patient had cachexia with a low body mass index. A high-protein, high-calorie diet was provided through a Foley catheter to improve cachexia. Stenosis of the TEP was not obtained with conservative methods, and a septal button was inserted instead of surgical closure. On the 13th month of follow-up, the patient is without any major complication and can manage esophageal speech. Crusting on the button was an acceptable complication during this period.

**Case 4**
A 56-year-old male patient with the complaint of leakage around his VP had a history of total laryngectomy and bilateral neck dissection along with postoperative radiotherapy 4 years ago due to laryngeal...
carcinoma. Our first step in treatment was customization of his VP with a silicone washer. Due to persistent leakage, a 14-Fr Foley catheter was inserted through the enlarged puncture, and oral intake was stopped. The stenosis of the TEP was unsatisfactory after 1 week, and injection around the puncture was performed. Since the stenosis required for insertion of a VP could not be achieved, the enlarged TEP was closed completely with a septal button. The patient has been followed for 8 months without aspiration or local complications, and the TEP is getting smaller.

These 4 patients with enlarged TEP were unresponsive to conservative methods and were managed through the insertion of a 32-mm wide, 100% silicone septal button (Invotec, Jacksonville, Fla, USA). The size of the septal button was determined through visual inspection of the TEP. Silicone septal buttons with two inseparable flanges connected tightly in the middle were preferred (fig. 2). Septal buttons with separable flanges may fall into the esophagus and trachea. If necessary, the septal button flanges were trimmed and customized according to the TEP size (fig. 3). The septal button was introduced to the puncture site with a clamp (fig. 4). Once embedded, the two flanges were checked to ensure they had been securely placed in the trachea and the esophagus. We tested for the presence of leakage with methylene blue-colored water. Success was defined as the absence of leakage following insertion of the septal button. The leakage-free patients were started on oral nutrition and were hospitalized for 2 days. The patients with adequate oral intake and without leakage around the TEP were discharged and followed on a weekly and later on a monthly basis to evaluate long-term outcomes. In the follow-up, the presence of local pathologies, including infection, granulation tissue formation, enlargement of puncture size, and aspiration pneumonia, was assessed.

**Discussion**

An enlarged TEP is characterized by the presence of leakage around the VP that is unresponsive to standard prosthetic management. The incidence of enlarged TEP with leakage around the VP is reported as 1–29% [5]. Enlargement of the TEP may result in aspiration pneumonia through the leakage of foods, liquids, and saliva into the airway. A previous study revealed that the risk of pneumonia in cases of enlarged TEP is 39%. Half of the patients may require temporary enteral feeding. Cases of enlarged TEP with therapy-resistant leakage were reported to have a 14% permanent feeding tube risk [2].

**Fig. 1.** Enlarged TEP.
**Fig. 2.** Silicone septal button (Invotec) with inseparable flanges.
The risk factors for TEP enlargement may include a history of smoking, thyroid dysfunction, acid reflux, diabetes, esophageal stricture, malnutrition, and/or radiotherapy. The enlarged TEP may be encountered as a late complication of radiotherapy manifesting months or years after treatment. The use of a large-diameter VP is another potential risk factor. Higher rates of enlarged TEP were reported in cohorts that used a 22-Fr or larger-diameter prosthesis [5, 6].

The first-line treatment for enlarged TEP is still unclear. Therapeutic interventions to prevent leakage around the prosthesis can be classified as (1) complete closure of the TEP and (2) conservative management. A complete closure of the TEP can be accomplished through surgical or nonsurgical means. Complete closure eliminates leakage, but it also interrupts TE voice production.

The reported rate of complete surgical closure of TEP was 14–50% [5]. Suturing of esophageal and tracheal mucosa separately after dissecting the TE space and dividing the TE tract as well as inset of well-vascularized tissue and muscular flaps including sternohyoid, sternocleidomastoid, intercostal, latissimus dorsi, pectoralis major, or radial free flaps between the trachea and esophagus constitute the mainstay of the surgical repair of enlarged TEP [7, 8]. However, surgery for closure of enlarged TEP is challenging due to the poor healing capacity of the radiated tissue in many patients [9].

To date, a number of conservative methods, such as temporary removal and modification of the prosthesis, TEP site injection, cautery, and purse-string suture placement around the TEP, have been defined [2, 10–12]. An effective long-term solution has not yet been reported.

In patients with persistent leakage despite conservative treatment methods, closure of the TEP was accomplished with a silicone septal button. The septal button placement provides closure of the TEP and allows oral intake while avoiding aspiration. This technique is noninvasive, cost-effective, and practical. It requires only a short hospital stay and does not necessitate general or local anesthesia. The disadvantage of septal button insertion is loss of the TE speech function. The longest follow-up duration among the reported cases was 30 months. Aspiration pneumonia and local complications were not encountered during the follow-up period.
Conclusion

The first line of treatment for enlarged TEP should include conservative methods that preserve TE speech. On the other hand, in cases with persistent leakage around the prosthesis that require total closure, the septal button closure technique seems to be a simple, safe, and inexpensive method with satisfactory long-term results.

Disclosure Statement

The authors declare that they have no financial and personal relationships with other people or organizations that could inappropriately influence their work.

References