

# Complications of tracheoesophageal puncture and speech valves: retrospective analysis of 47 patients

## Trakeaözofageal fistül açılması ve konuşma protezinin komplikasyonları: 47 hastanın retrospektif analizi

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**Objectives:** This study aims to evaluate the complications of tracheoesophageal puncture (TEP) for voice restoration and speech valves in patients undergoing total laryngectomy.

**Patients and Methods:** Between January 2006 and June 2011, 47 male patients (mean age 62.8±1.2 years; range 41 to 80 years) who underwent TEP and speech valve for voice restoration after total laryngectomy were retrospectively analyzed. Secondary TEP was performed and Provox indwelling voice prosthesis were inserted in all patients. Demographic, disease and treatment characteristics of patients were recorded. Complications related to TEP and speech valves, the management of complications and clinical conditions of complete closure of TEP were also recorded.

**Results:** Tracheoesophageal puncture and speech valve related complications were observed in 20 patients. The majority of complications were minor complications including granulation tissue formation (n=2, 4.2%), deglutition of prosthesis (n=6, 12.7%) and TEP enlargement/leakage around prosthesis (n=9, 19.1%). Major complications were observed in three patients. Two of them were life-threatening complications; a mediastinitis (n=1, 3.1%) and paraesophageal abscess (n=1, 3.1%), and both appeared in the first month of the postoperative period. The overall complication rate was 42.6% during mean follow-up of 15.3 months. Tracheoesophageal fistula enlargement (n=9, 19.1%) was the most common minor complication and the most common cause of complete closure of TEP in this study.

**Conclusion:** Tracheoesophageal puncture for voice restoration is not an entirely innocent procedure without any complications. Patients should be monitored for TEP-related complications in the early and late postoperative period.

**Key Words:** Complications; speech valves; total laryngectomy; tracheoesophageal puncture.

**Amaç:** Bu çalışmada total larenjektomili hastalarda ses restorasyonu için trakeoözofageal fistül (TÖF) açılması ve konuşma protezi uygulamasının komplikasyonları değerlendirildi.

**Hastalar ve Yöntemler:** Ocak 2006 - Haziran 2011 tarihleri arasında total larenjektomi sonrası ses restorasyonu için TÖF açılması ve konuşma protezi uygulanan 47 erkek hasta (ort. yaş 62.8±1.2 yıl; dağılım 41-80 yıl) retrospektif olarak incelendi. Tüm hastalara sekonder TÖF açılması ve Provox ses protezi uygulaması yapıldı. Hastaların demografik, hastalık ve tedavi özellikleri kaydedildi. Trakeaözofageal fistül ve konuşma protezi ile ilişkili komplikasyonlar, tedavisi ve TÖF kapatılmasını gerektiren klinik durumlar da kaydedildi.

**Bulgular:** Yirmi hastada trakeoözofageal fistül açılması ve ses protezi ile ilişkili komplikasyon saptandı. Komplikasyonların büyük çoğunluğunu granülasyon dokusu oluşumu (n=2, 4.2%), protez yutulması (n=6, 12.7%) ve TÖF traktı genişlemesi/protez etrafı kaçak (n=9, 19.1%) gibi minör komplikasyonlar oluşturuyordu. Üç hastada majör komplikasyon gözlemlendi. Bunlardan ikisi [mediastinit (n=1, 3.1%) ve paraözofageal apse (n=1, 3.1%)] hayatı tehdit eden komplikasyondur ve ameliyat sonrası 1. ay içerisinde ortaya çıktı. Genel komplikasyon oranı, 15.3 aylık ortalama takip süresince %42.6 idi. Fistül traktı genişlemesi/protez etrafı kaçak (n=9, 19.1%) bu çalışmada görülen en sık minör komplikasyondur ve ses protezinin çıkarılarak TÖF kapatılmasının en sık nedeni olarak saptandı.

**Sonuç:** Ses restorasyonu için oluşturulan trakeoözofageal fistül açılması işlemi komplikasyonu olmayan tamamen masum bir işlem değildir. Hastalar işlem sonrası TÖF ile ilişkili olarak, erken ve geç dönemde ortaya çıkabilecek komplikasyonlar açısından izlenmelidir.

**Anahtar Sözcükler:** Komplikasyonlar; konuşma protezi; total larenjektomi; trakeoözofageal fistül.



Speech rehabilitation following total laryngectomy (TL) is the major point of interest for future quality of life. Throughout the years, esophageal speech and artificial electro-larynx techniques have been used with varying success. However, approximately 50% of the patients are unable to learn esophageal speech.<sup>[1]</sup> In 1980, Singer and Blom<sup>[2]</sup> introduced a new voice rehabilitation technique that relies on placement of a silicone prosthesis into a small, surgically created tracheoesophageal puncture (TEP). The voice rehabilitation process has been much improved by this technique. Faster rates of speech acquisition, better intelligibility of speech and increased duration of phonation were achieved with speech valves (VP) when compared with esophageal speech and artificial electrolarynges.<sup>[3]</sup>

On the other hand, the TEP technique is not entirely perfect. The literature has demonstrated various minor and life-threatening complications of TEP including, TEP enlargement, aspiration pneumonia, deep neck space infection, cervical osteomyelitis, esophageal stenosis, tracheostomal stenosis and mediastinitis. The overall complication rate of TEP varies from 23% to 52%.<sup>[4-7]</sup> Although minor complications comprise the majority, major complications may threaten life or require further surgery.<sup>[5]</sup> In particular, enlargement of TEP can be a challenging problem that results in leakage of foods, liquids, or saliva around the prosthesis into the airway and may eventually result in aspiration pneumonia.<sup>[6]</sup>

We sought to evaluate the complications of TEP in this retrospective study.

#### PATIENTS AND METHODS

A retrospective case series was conducted using our institution database (Probel). Forty-seven patients who underwent TEP for voice restoration after total laryngectomy (TL) at a tertiary hospital between January 2006 and June 2011 were included in this study. The study was approved by the Research Ethics Board of Dokuz Eylül University (2012/17-27). Patients included 47 (100%) males with a mean age of 62.8±1.2 years (range 41-80). The mean follow-up was 15.3 months (range, 1-72 months). Most patients had transglottic carcinoma (n=35). All patients had a pathologic diagnosis of squamous cell carcinoma (SCC) but two patients had basaloid SCC. All patients had advanced stage laryngeal cancer. Neck metastases were observed in 25% of the patients. Patients demographic and disease characteristics are illustrated in Table 1.

Tracheoesophageal puncture was mainly performed in patients who were unable to learn esophageal speech. Secondary TEP procedure was performed in all patients. A Provox indwelling voice prosthesis (Atos Medical, Hörby, Sweden) was used in all patients. The procedure was performed under general anesthesia with the help of a rigid esophagoscope. A puncture was created through the posterior wall of the trachea into the anterior wall of the esophagus using a trocar. The indwelling VP was inserted through the TEP and the esophageal flange was visualized open and flat at the anterior esophageal wall by esophagoscope. The operation was ended after controlling the position of the VP by rotating it in the fistula tract. Patients were routinely followed in the postoperative period for exchange of the VP and TEP problems.

Complications of TEP and their management were analyzed. Demographic and disease characteristics of patients (gender, age, site of tumor, T stage, N stage, histopathologic diagnosis,

**Table 1.** Patients demographic and disease characteristics (n=47)

Characteristics	n	%
Age (years)		
<70	35	74.5
≥70	12	25.5
Tumor site		
Glottic	4	8.5
Supraglottic	1	2.1
Transglottic	35	74.5
Hypopharynx	4	8.5
Recurrent	3	6.4
T stage		
T <sub>3</sub>	38	80.9
T <sub>4</sub>	9	19.1
N stage		
N <sub>0</sub>	36	76.6
N <sub>1</sub>	3	6.4
N <sub>2</sub> (a,b or c)	8	17.0
Neck metastases		
No	35	74.5
Yes	12	25.5
Pathologic diagnosis		
Squamous cell carcinoma	45	95.7
Basaloid Squamous cell carcinoma	2	4.3

n: Number of patients.

neck metastases), treatment characteristics of patients (type of surgery, flap reconstruction, pharyngocutaneous fistulas after TL, radiotherapy, locoregional recurrence, second primary cancer, TEP delay time after TL, complete closure of TEP, follow-up time) were analyzed. Causes of complete closure of TEP and reinsertion of prosthesis were also analyzed. The patients were staged according to the 2002 American Joint Committee on Cancer staging system.

In this study, leakage around the VP which was not remedied by replacement of a standard VP, was accepted as 'TEP enlargement'. Temporary removal and replacement of prosthesis after shrinking of TEP site, enlarged irregular TEP contour, requirement of enlarged flange and surgical intervention were also accepted as 'TEP enlargement' in this study.

## RESULTS

### Treatment characteristics

Tracheoesophageal puncture was performed as a secondary procedure in all patients with a mean delay after TL of 22±17 months (range 2-72 months).

Primary TL (n=40), TL with partial pharyngectomy (n=3) and salvage TL (n=4) were performed as surgical treatment. Salvage TL was performed in patients with recurrent tumor (n=3) and after failure of radiotherapy (n=1). Most patients (n=36, 76.7%) had postoperative radiation therapy. Seven (14.9%) pharyngocutaneous fistulas were observed after TL. Two patients developed locoregional recurrence (4.2%) and died in the first year of recurrence. Three patients developed new primary cancers (6.3%) including prostate gland adenocarcinoma (n=1) and lung cancer (n=2). Treatment characteristics are illustrated in Table 2.

### Prosthesis related complications

Tracheoesophageal puncture and prosthesis related complications occurred in 20 patients. The overall complication rate was 42.6% during a mean follow-up of 15.3 months. Minor complications including granulation tissue, prosthesis deglutition, and leakage around the prosthesis due to TEP enlargement comprised the majority. However, we observed three major complications; mediastinitis (n=1, 2.1%), paraesophageal abscess (n=1, 2.1%) and pharyngocutaneous fistulas (n=1, 2.1%). Major complications appeared in the first

month of the postoperative period. The patient who complicated with mediastinitis died due to intractable infection.

Leakage around the prosthesis due to TEP enlargement appeared in nine patients (19.1%). Three of them were treated with conservative management by temporary removal and replacement of prosthesis after shrinking of the TEP site. However, in the remaining six patients, the problem was unresolved with conservative treatment. A nasogastric feeding tube was inserted, the prosthesis was removed permanently and the fistula closed with spontaneous healing in three patients. One patient treated by inserting an individualized prosthesis with enlarged flange. Surgical closure of an enlarged TEP with fistula wall necrosis associated with peristomal necrosis was managed by interposing a pectoralis major flap in two patients on postoperative days seven and 24, respectively. Complications are illustrated in Table 3.

**Table 2.** Treatment characteristics (n=47)

Characteristics	n	%
Type of surgery		
Primary TL	40	85.1
TL + pharyngectomy (partial)	3	6.4
Salvage TL	4	8.3
Flap reconstruction		
No	44	93.6
Yes	3	6.4
Pharyngocutaneous fistulas after TL		
No	40	85.1
Yes	7	14.9
Radiotherapy		
Absent	9	19.1
Preoperative	2	4.2
Postoperative	36	76.7
Locoregional recurrence after TL		
No	45	95.8
Yes	2	4.2
Second (new) primary cancer		
No	44	93.6
Yes	3	6.4
TEP delay time after TL		
<6 months	3	6.3
6-12 months	17	36.2
≥12 months	27	57.5

n: Number of patients; TL: Total laryngectomy; TEP: Tracheoesophageal puncture.

**Table 3.** Complications of tracheoesophageal puncture

Complications	n	%	Total %
		(n=20)	(n=47)
Tracheoesophageal puncture enlargement	9	45	19.1
Prosthesis deglutition	6	30	12.7
Granulation tissue	2	10	4.2
Pharyngocutaneous fistulas	1	5	2.1
Paraesophageal abscess	1	5	2.1
Mediastinitis	1	5	2.1

n: Number of patients.

### Causes of reinsertion/change of prosthesis

Prosthesis were changed one hundred nine times during the follow-up period. The mean times of reinsertion was 2.3 (range 0-7 times). Deformation of the prosthesis (n=43, 39.5%) was the most common cause of reinsertion. The remaining causes of reinsertion including leakage around/through prosthesis, spontaneous/accidental dislodgement, TEP enlargement, deglutition of prosthesis, failure to produce speech and granulation tissue formation are illustrated in Table 4.

### Causes of complete closure

Thirty-three of 47 patients (70.2%) continued to use VP as the primary speech method. In 14 patients (29.8%) fistulas were closed. Closure of TEP was performed in six of nine (n=6, 66.7%) patients with enlarged TEP (n=9). However, closure of TEP was performed in eight patients (n=8, 21%) in the remaining 38 patients without enlarged TEP. The most common cause of complete closure was persistent salivary leakage due to TEP enlargement (n=6, 12.7%). In two patients who did not want repuncture, the prosthesis was dislodged accidentally and the fistulas closed spontaneously.

Finally, the fistula closed in 17% of patients due to medical complications including TEP enlargement and recurrent deglutition. The remaining causes of complete closure are illustrated in Table 5.

### DISCUSSION

Tracheoesophageal puncture is relatively a simple procedure for voice rehabilitation, but despite its relative simplicity it is not an innocent procedure without complications. Complications of this procedure are frequently minor problems and usually can be treated successfully.

Perifistular granulation, polyp formation and displacement of prosthesis are common minor problems and can be treated easily. Granulation tissue and polyp formation can occlude the speech valve lumen and deteriorate speech. This is easily resolved by excision and silver nitrate cauterization. An incidence rate of 15% has been reported.<sup>[8]</sup> In our series we found granulation tissue in 6% of patients. Recurrent deglutition of prosthesis is usually associated with a too-short valve. If the valve is too short, the esophageal or tracheal flange of the prosthesis invaginates into the fistula tract gradually and eventually the prosthesis is either swallowed or dislocated spontaneously. In two of

**Table 4.** Causes of reinsertion/change of prosthesis (n=109)

Causes	n	%
Deformation of prosthesis	43	39.5
Leakage around/through prosthesis	21	19.2
Spontaneous/accidental dislodgement	14	12.9
Tracheoesophageal puncture enlargement	13	11.9
Prosthesis deglutition	9	8.3
Failure to produce speech	7	6.4
Granulation tissue	2	1.8

n: No. of reinsertion

**Table 5.** Causes of complete closure of tracheoesophageal puncture

Causes	n	%	Total %
		(n=14)	(n=47)
TEP enlargement (persistent salivary leakage)	6	42.9	12.7
Failure to produce speech	4	28.5	8.5
Recurrent deglutition	2	14.3	4.2
Spontaneous closure	2	14.3	4.2

n: Number of patients; TEP: Tracheoesophageal puncture.

our patients the problem was solved by increasing the length of the valve.

Persistent salivary leakage around the prosthesis owing to TEP enlargement is one of the most common minor complications. Tracheoesophageal puncture enlargement was reported at between 1%<sup>[7]</sup> to 29%<sup>[9]</sup> in the literature. Recently, Hutcheson et al.<sup>[10]</sup> conducted a meta-analysis including 23 studies, and they reported an overall risk of TEP enlargement and/or leakage around the voice prosthesis of approximately 8%. Tracheoesophageal puncture enlargement was found in 19% of patients in our case series. This result is relatively high when compared with this meta-analysis.

Tracheoesophageal puncture enlargement is usually managed with conservative treatments, but it occasionally worsens and becomes a challenging problem.<sup>[11,12]</sup> Surgical closure of the enlarged fistula, particularly in previously irradiated patients, can be complicated with peristomal tissue necrosis due to devascularization and impaired healing. In our series, two patients underwent flap reconstruction due to fistula wall necrosis associated with peristomal necrosis after TEP. Tracheoesophageal puncture enlargement may also increase likelihood of prosthesis dislodgement.<sup>[6]</sup> In our series, multiple spontaneous dislodgement of prosthesis was observed in only one patient due to enlarged TEP and irregular TEP contour. All dislodgements in this patient occurred in the first month after reinsertion of prosthesis. The patient was treated by modification of prosthesis with largest flange and shorter valve. In such cases various conservative treatments have been reported in the literature including temporary removal,<sup>[5]</sup> TEP-site fat injection<sup>[13]</sup> and purse-string suture around the TEP.<sup>[14]</sup>

On the other hand, major complications have also been reported with rates up to 25%.<sup>[4,7,15,16]</sup>

In our series, overall and major complication rates were 42% and 10%, respectively. We observed a pharyngocutaneous fistula, which was located 2 cm above the stoma, following peristomal cellulitis after TEP. The fistula closed with conservative management after resolution of peristomal cellulitis and the patient continued to use a speech valve. Another major complication, mediastinitis, is the most catastrophic complication of TEP. Iatrogenic perforation of the posterior esophageal wall and creation of false dissection plane in the tracheoesophageal party wall may lead to this dreadful complication.<sup>[16]</sup> Fortunately, these complications comprise a minority of the overall complications.

Several authors have recently described various puncture techniques to alleviate the traumatic and septic complications of TEP.<sup>[17-20]</sup> First, Lichtenberger drew attention to the necessity of improving the puncture technique to avoid complications and suggested meticulous, inside to outside puncture technique. Subsequently, video laryngoscopy-assisted secondary tracheoesophageal puncture<sup>[18]</sup> or other flexible endoscopic techniques<sup>[17,19]</sup> have been introduced as the treatment of choice for patients with severely limited neck extension.

In conclusion, the main goal of the surgical voice rehabilitation in alaryngeal patients is to achieve better voice outcomes without complications. Tracheaeosephageal voice restoration is not an entirely innocent procedure. Patients should be kept under follow-up for TEP related complications in the early and late postoperative period.

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