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Key points:
- The delegation of some clinical tasks from the otolaryngologist-head and neck surgeon to the speech-language pathologist (SLP) is a current topical issue that may be associated with many advantages.
- SLP may perform voice prosthesis (VP) changes without significant complications or need of physician.
- The mean duration of SLP consultation and VP changes was 20 min.
- More than 90% of VP change procedure were assessed as adequately performed by patients.
- The delegation of VP change procedure to SLP may be interesting in some rural regions with otolaryngologist shortage.

Key words: Total Laryngectomy; Cancer; Voice; Voice prosthesis; Otolaryngology; Head Neck Surgery; Speech Therapists.

Introduction:
Total laryngectomy (TL) is one of the most common procedures in head and neck surgery. The post-TL voice rehabilitation is challenging for both patients and practitioners due to the complex nature of patient presentation and the involvement of many motivational and oncological factors [1,2]. To date, tracheoesophageal speech is considered as the gold standard for post-TL voice rehabilitation [1,2]. The mean duration of voice prosthesis (VP) life-time ranged from 3 to 6-month, which supports the need of adequate follow-up and VP changes [3]. In most countries, the VP changes are performed by physicians because it is considered as a medical act.

In the present study, we assessed the feasibility and success outcomes of VP changes when performed by speech-language pathologist SLP.

Material and methods:

Ethical consideration
The local institutional review board approved the study protocol (APHP-HEGP-2018). A waiver of informed consent of participants was granted because participant data were protected and anonymized.

**Subjects and setting**

Patients treated with TL from January 2020 to December 2020 were prospectively recruited from our medical center. Patients benefited from tracheoesophageal puncture and 1-month post-TL VP. The surgeon used the Provox® 2 type prosthesis (Atos Medical AB, Hörby, Sweden). Patients were followed by an experienced otolaryngologist and SLP for the voice rehabilitation and the oncological follow-up. The first VP change was performed by the senior SLP (GD) who was supervised by the senior head and neck surgeon (SH). The rest of the VP changes were performed by the same SLP without surgeon supervision; the surgeon being however called in case of problems.

**Practitioner and patient outcomes**

The following outcomes were considered: gender; age; primary tumor site; cTNM classification; primary treatment; TL indication (primary, salvage, second primary, and dysfunctional larynx); surgical characteristics (e.g., neck dissection and flap reconstruction); driving distance to the hospital; and survival outcome. The following data were collected for each VP change: date of placement; change or removal; VP type and size; reason for change or removal; and use of a washer for periprosthetic leakage.

A patient-reported outcome questionnaire including 6 items was proposed to patients at each VP change (Appendix 1). Items were assessed with a 10-point Likert-scale.

**Results**

Ten patients completed the evaluations. The epidemiological and clinical outcomes of patients are available in Table 1. There were 8 males and 2 females, respectively. The median age was 63.2 yo (range 48-79 yo). TL was performed for the following indications: low-grade cricoid chondrosarcoma (N=2); recurrent laryngeal cancer after radiation (N=3) or chemoradiation (N=5).

Fifty-two VP changes were performed by the senior SLP during the study period. The mean duration of the SLP consultation, including patient history, examination and VP change procedure was 20 min (range: 15-30). The median prosthesis life-time was 88 days. The main reasons for VP changes were transprosthetic (N=34; 79%) and periprosthetic (N=7; 21%) leakages, respectively. SLP successfully performed all VP changes. He did not change one VP but used a periprosthetic silastic to stop the periprosthetic leakages. In two cases, SLP needed the surgeon examination to discuss about the following indication: implant mucosa inclusion and autologous fat injection.

The patient satisfaction was high according to the speed and the quality of care by the SLP (Table 2).

**Discussion:**

Voice rehabilitation after TL is an important postoperative issue for the patient quality of life [4,5]. In practice, the VP change is a simple procedure that is usually performed by residents or board-certified physicians. In this study, we reported adequate SLP and patient-reported outcome perception about the SLP-related VP change. The delegation of some clinical tasks from the otolaryngologist-head and neck surgeon to the SLP is a current topical issue that may be associated with many advantages.

First, it is commonly accepted that the development of post-TL tracheoesophageal speech involves important speech rehabilitation work and adequate follow-up for the management of VP leakage, which may be time-consuming for the physician [4]. Currently, the number and the availability of otolaryngologists in rural areas may be limited in some European regions regarding some government hospital reforms that led to significant reduction of medical centers and physicians [6,7]. In our country, the shortage of otolaryngologists in rural regions may lead to patient proposition of post-TL esophageal speech rather than tracheoesophageal speech to limit the need of post-TL care [8]. In that way, the availability of SLPs in the management of VP changes may, therefore, be an advantage for the patient accessibility to health care and follow-up.
Second, in some world regions, SLPs already perform routine videolaryngostroboscopy, which was associated with enhancement of the SLP role in the decision-making process in voice restoration [9]. According to the voice rehabilitation process, SLPs well-know their patients, and a trusting relationship may develop throughout the rehabilitation sessions. In the present study, more than 90% of patients reported high rate of satisfaction outcomes about the SLP-VP change procedure, which may be explained by the trusting relationship between SLP and patient and the feasibility of the procedure.

The delegation of VP changes to SLP makes particularly sense in our country because SLPs may prescribe respiratory or phonatory rehabilitation equipment for TL patients for the last 4 years (March 30, 2017 law). Interestingly, a recent Italian study reported that physicians were not opposed to the delegation of this task to other health professionals, which strengthens the need of debate about this task delegation issue [10].

The primary limitations of the present study were the low number of procedures performed by the SLP (42 procedures) and the low number of patients, which limited the realization of statistical analysis. The lack of use of validated patient-reported outcome questionnaire assessing the VP change procedure is an additional limitation. To the best of our knowledge, there is no similar study available in the literature, which is the main strength of this preliminary study.

**Conclusion:** The VP change is a feasible procedure for SLP associated with few complications, rare need of physician intervention and adequate patient-reported outcome perception. Future controlled studies are needed to compare VP change outcomes between physicians and SLPs and to evaluate its cost-effectiveness.

**References:**


Table 1: Characteristics of Patients followed by the Speech Therapist

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Age (year)</th>
<th>Gender</th>
<th>Comorbidities</th>
<th>Initial treatment</th>
<th>Indications</th>
<th>cTNM</th>
<th>VP (nb)</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75</td>
<td>F</td>
<td>Tobacco</td>
<td>RT</td>
<td>Rec. LSCC</td>
<td>T3N0</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>79</td>
<td>M</td>
<td>Tobacco</td>
<td>RT</td>
<td>Rec. LSCC</td>
<td>T2N0</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>64</td>
<td>M</td>
<td>Tobacco, HTA</td>
<td>CRT</td>
<td>Rec. LSCC</td>
<td>T3N1</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>58</td>
<td>M</td>
<td>HTA</td>
<td>-</td>
<td>CS</td>
<td>-</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>61</td>
<td>F</td>
<td>Tobacco</td>
<td>CRT</td>
<td>Rec. LSCC</td>
<td>T3N0</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>68</td>
<td>M</td>
<td>Tobacco</td>
<td>CRT</td>
<td>Rec. LSCC</td>
<td>T2N1</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>57</td>
<td>M</td>
<td>Tobacco</td>
<td>RT</td>
<td>Rec. LSCC</td>
<td>T1N0</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>48</td>
<td>M</td>
<td>Tobacco</td>
<td>CRT</td>
<td>Rec. LSCC</td>
<td>T3N0</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>52</td>
<td>M</td>
<td>Tobacco</td>
<td>CRT</td>
<td>Rec. LSCC</td>
<td>T3N0</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>70</td>
<td>M</td>
<td>-</td>
<td>-</td>
<td>CS</td>
<td>-</td>
<td>4</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 1 footnotes: Abbreviations: CS=chondrosarcoma; RT: radiation therapy; CRT:chemoradiation; F/M= female/male; HTA:hypertension; m=minutes; Rec. LSCC=recurrent laryngeal squamous cell carcinoma; VP=Voice prosthesis; nb : number of prosthesis during the study period.

Table 2: Responses to questionnaires

<table>
<thead>
<tr>
<th>Questions/Answers</th>
<th>1</th>
<th>2-3</th>
<th>4-5</th>
<th>6-7</th>
<th>8-9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early appointment</td>
<td>39 (93)</td>
<td>2 (5)</td>
<td>1 (2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Speed and availability of practitioner</td>
<td>39 (93)</td>
<td>2 (5)</td>
<td>1 (2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Quality of care</td>
<td>40 (95)</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Voice prosthesis change speed</td>
<td>39 (93)</td>
<td>-</td>
<td>2 (5)</td>
<td>-</td>
<td>1 (2)</td>
<td>-</td>
</tr>
<tr>
<td>Discomfort during change</td>
<td>32 (75)</td>
<td>4 (10)</td>
<td>4 (10)</td>
<td>-</td>
<td>2 (5)</td>
<td>-</td>
</tr>
<tr>
<td>Speech-therapist for voice prosthesis change in the future</td>
<td>40 (95)</td>
<td>1 (5)</td>
<td>1 (5)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2 footnotes: Forty-two patients completed a 10-point evaluation of quality and speed of care, ranging from 1 (very high satisfaction) to 10 (very low satisfaction).