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Laryngectomy: Phonation Alternatives and Impact on Quality of Life

Ana Sofia de Sousa Rodrigues



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Laryngectomy: Phonation Alternatives And Impact On Life Quality

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Estudante: Ana Sofia de Sousa Rodrigues

Mestrado Integrado em Medicina Instituto de Ciências Biomédicas Abel Salazar **Endereço eletrónico:** up201704378@up.pt

Orientador: Dr. João José Vale Lino

Médico Assistente de Otorrinolaringologia no Centro Hospitalar Universitário de SantoAntónio Assistente Convidado do Mestrado Integrado em Medicina do Instituto de CiênciasBiomédicas Abel Salazar/CHUdSA

Endereço eletrónico: joaovalelino@gmail.com

Co-orientador: Prof. Doutor Ricardo Jorge Marcos-Pinto

Médico Assistente Graduado de Gastroenterologia no Centro Hospitalar Universitário deSanto António

Professor Associado Convidado do Mestrado Integrado em Medicina do Instituto deCiências Biomédicas Abel Salazar/CHUdSA

Endereço eletrónico: ricardomarcospinto@sapo.pt

Declaração de Integridade

Assinaturas

refetiadefensefectupers

Estudante, junho de 2023

el. L.

Orientador, junho de 2023

Rudo Fullos

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Resumo

Introdução: A decisão de consentir a cirurgia é um momento de mudança de vida. Esta dissertação tem como objetivo compreender o impacto da laringectomia total na fonação e o respetivo impacto na qualidade de vida dos doentes do CHUdSA. O objetivo primário deste estudo de coorte é comparar as alternativas de reabilitação fonatória e o objetivo secundário é avaliar os preditores do resultado vocal.

Métodos: Para uma análise abrangente, foram revistos os dados de doentes submetidos a Laringectomia Total com dissecção ganglionar cervical bilateral no Serviço de Otorrinolaringologia, Cirurgia de Cabeça e Pescoço do Centro Hospitalar Universitário de Santo António entre janeiro de 2010 e outubro de 2022. Foram incluídos doentes adultos, que aceitaram participar no estudo e nos quais foi realizada avaliação subjetiva. A análise estatística foi realizada utilizando o SPSS (IBM SPSS Statistics 26). Sendo realizada uma análise bi-variada das variáveis basais recolhidas dos registos clínicos vs os resultados vocais avaliados pelo questionário *Self Evaluation of Comunication Experiences After Laryngectomy* (SECEL). Foram executados modelos lineares gerais tendo em consideração os scores do SECEL como resultado. Todos os valores de p mencionados são bicaudais, com um valor de p \leq 0,05 indicando significância estatística.

Resultados: A primeira pesquisa identificou um total de 124 pacientes operados durante o período pré-selecionado: 63 pacientes ainda vivos no seguimento atual, com 61 óbitos (49%). Dos 63 pacientes vivos, 26 (do género masculino) concluíram o SECEL, com idade média ao diagnóstico de $62,2 \pm 10,6$ anos. A média de idade durante a avaliação subjetiva com SECEL foi de $66,3 \pm 10,4$ anos. O tempo médio de *follow-up* após o diagnóstico inicial foi de $4 \pm 3,8$ anos. Uma diferença estatisticamente significativa foi observada em relação à voz esofágica (ES – *Esophageal Speech*), que foi inferior a outras modalidades (*score* SECEL total médio para ES: $46,6 \pm 12,2$ vs *score* total SECEL médio para todas as outras modalidades: $33 \pm 15,1$, p = 0,03). O tempo de *follow-up* demonstrou correlacionar-se significativamente com a função vocal, (p= 0.013). Não foram encontradas diferenças estatísticas entre TES1 (Voz/Prótese Traqueoesofágica Primária) e TES2 (Voz/Prótese Traqueoesofágica Secundária) (p=0.652), bem como entre o estadiamento TNM e o *outcome* vocal (p=0.151).

Conclusão: Pacientes submetidos a Laringectomia Total precisam de reaprender a comunicar com o mundo. A utilização do SECEL como ferramenta de avaliação de qualidadede vida, pode ser útil para identificar o impacto psicológico consequente da função vocal, neste grupo de doentes. O ES parece ser inferior quando comparado com outras alternativas fonatórias. Concluímos que o tempo de *follow-up* terá influência na função vocal.

Palavras-chave: Laringectomia; Alternativas Fonatórias; Qualidade de Vida; SECEL

Abstract

Introduction: Deciding to have surgery can change your livelihood. In the set of patients treated at CHUdSA, this thesis discusses how total laryngectomy affects phonation and how it impacts patients' quality of life. This cohort study's main aim is to assess the alternatives for phonation rehabilitation, and its secondary objectives are to assess the factors that influencevocal outcome.

Methods: In order to perform a comprehensive analysis, data from patients who underwent total Laryngectomy with bilateral lymph neck dissection at the Department of Otolaryngology, Head and Neck surgery of Centro Hospitalar Universitário de Santo António between January 2010 and October 2022 were reviewed. Adult patients who were still alive, consented to engage in the study, and had a subjective evaluation done on them were included. Utilizing SPSS, a statistical study was carriedout (IBM SPSS Statistics 26). The baseline factors recorded in the clinical records and the vocal outcomes determined by the SECEL questionnaire were subjected to a bivariate analysis. SECEL ratings were used as the outcome in general linear models. Statistical significance is indicated by a p value of 0.05 or lower. All stated p values are two-tailed.

Results: A total of 124 patients who underwent surgery during the preselected time were found by the initial thorough search: At the most recent check-up, 63 patients were still living,but 61 had passed away (49%). 26 (all male) of the 63 patients who were still living finished the SECEL.Patients were all men. At diagnosis, the average age was 62.2 10.6 years. The average patient age at the time of perceived vocal evaluation with SECEL was 66.3 10.4 years. ES was found to be less effective than other modalities, with a statistically significant difference (mean SECEL total score for ES: 46.6 12.2 vs mean SECEL total score for all other modalities: 33 15.1, p = 0.03). Follow-up time and vocal ability as determined by SECEL showed a significant correlation (p = 0.013). There were no discernible variations between TES1 and TES2 (p=0.652), nor was there any relationship between TNM staging and vocal outcome (p=0.151).

Conclusion: Patients who have undergone Total Laryngectomy (TL) must relearn how to interact with others. SECEL can be a helpful tool to assess laryngectomized patients' quality of life because it canbe used to gauge the psychological effects of vocal functionality on this population. In terms of voice-related quality of life, ES appears to be weaker to other modalities. We came to the conclusion that follow-up period might affect vocal function.

Keywords: Laryngectomy; Phonation Alternatives; Quality of Life; SECEL

Abbreviations

CT – Computed Tomography

CHUdSA – Centro Hospitalar Universitário de Santo António

EL – Electronic Larynx (Laringe Eletrónica)

ES – Esophageal Speech (Voz Esofágica)

ECOG – Eastern Cooperative Oncology Group

QoL – Quality of Life (Qualidade de Vida)

MRI – Magnetic Resonance Imaging

PET-CT – Positron Emission Tomography and Computed Tomography

SECEL – Self Evaluation of Comunication Experiences After Laryngectomy

TEP – Tracheoesophageal Prothesis (Prótese Traqueoesofágica)

TES – Tracheoesophageal Speech (Voz Traqueoesofágica)

TL – Total Laryngectomy (Laringectomia Total)

TNM – Classification System: T for size and extent of the primary tumor, N for the lymph nodes affected by the tumor, M for the metastasis

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1. Introduction

There were 184 615 new laryngeal tumor cases reported globally in 2020. Despite not being the most prevalent tumor, it affects a significant portion of patients and claimed the lives of about 19.6% of patients in Europe (of both sexes) in the same year¹. Eastern and South-Central Asia were the areas most severely impacted. According to data, men globally experience more new cases and deaths than women¹. In 2020, Portugal reported 529 new cases and 329 deaths from laryngeal tumors².

Billroth carried out the first total laryngectomy in Vienna, Austria, in 1873. The effects of laryngectomy-related morbidity on voice production were already a cause for worry during this time³. Thus Gussenbauer developed the first artificial larynx, which was composed of a tracheostomy and pharyngeal cannula³. The prognosis and patient survival improved dramatically as a result of these techniques that revolutionized the treatment of larynx tumors³. Researchers developed a number of phonation options in the XX and XXI centuries, including the tracheoesophageal prosthesis, electronic larynx, and esophageal voice¹. The rehabilitation of the patients was greatly impacted by this. However, surgery is still very mutilating, with a significant impact on everyday life, so rehabilitation is frequently a lifetime endeavor.²

It is essential to have knowledge of the subject's theoretical underpinnings in order to understand this research. The larynx, also referred to as the voice box, is a neuromuscular organ that controls breathing, airway protection, and phonation¹. Males between the ages of 50 and 60, smoking, which is the primary risk factor, and alcohol are risk factors for malignant lesions of the larynx³. Radiation exposure and premalignant tumors are some additional risk factors such as reflux or Human Papillomavirus^{1,3}. Chemotherapy, radiation, and surgery are the most frequently used treatments. The decision will be influenced by the tumor's characteristics, behavior, ECOG, and socioeconomic circumstances of the patient.⁴

Total laryngectomy, occasionally combined with adjuvant radiotherapy and/or chemotherapy, is the recommended course of treatment given the effects of the larynx growth on patients³. In this manner, patients who undergo total laryngectomy experience significant voice changes. Their ability to interact with the outside world is hampered, and the decision to consent to surgery is a significant turning point in their lives: "Relearning to speak and communicate is essential to recovering life quality."⁵. The patient may be given an esophageal voice, a TEP or even an EL as part

of their rehabilitation^{1,3,4}.

Consenting to surgery is a major life choice. This thesis seeks to comprehend how total laryngectomy affects phonation and how it affects patients' quality of life among the CHUdSA patient population. This cohort study's main goal is to contrast the effectiveness of phonation rehabilitation, while its secondary goal is to assess the factors that predict vocal outcome.

The study conducted a questionnaire that was applied on CHUdSA patients submitted to this surgery from 2010 to 2022. The enrolled patients are ongoingly followed at the ORL Department from the same Institution.

2. Theoretical Background

2.1. Larynx Anatomy

The larynx is a sophisticated neuromuscular organ that controls phonation, breathing, and airway defense. It is sustained by a cartilage skeleton made up of the cuneiform, corniculates, thyroid, arytenoids, and epiglottis. With the exception of the epiglottis, this structure begins to calcify around age 20 and finishes around age 65⁶.

Both the superior and recurrent laryngeal nerves, which are divisions of the Xth cranial nerve, innervate this organ. Superior and inferior laryngeal arteries, which are branches of thesuperior thyroid artery, provide it with an arterial flow (Figure 1⁷). While the glottis has little lymphatic supply, cervical lymph nodes perform the lymphatic draining of both the supra and subglottic area.⁶(Figure 2⁷).



Figure 1 – Anatomy of the Larynx, Innervation Branches⁷



Figure 2 – Lymphatic Drainage of the Larynx⁷

2.2. Physiology of the Phonatory System

The primary organ called the larynx vibrates, producing the voice sound. The force of air passing through the lungs pushing against the vibrating vocal cords creates the larynx sound. That will experience some acoustic changes as each person's pharynx, oral chamber, and nasal cavities take on their own distinct sounds. At birth we cry at a frequency of 500 Hz and only half that by the age of 8, our voices will change as we mature. Hormones produced by the pituitary, thyroid, and pancreas have an impact on the human voice.⁶.

2.3. Larynx Pathology

The group of larynx pathology includes infections and inflammatory diseases, congenital malformations, neurological, functional and tumoral pathology.

2.3.1 Larynx Tumor

These are the most common tumors of head and neck cancer. Males between the ages of 50 and 60, smoking, which is the primary risk factor, and alcohol are risk factors formalignant lesions of the larynx. Pre-malignant tumors and radiation exposure are some additional risk factors (such as reflux or Human Papillomavirus). 95% of malign carcinomas have their origin in the mucosal

epithelium that lines the larynx.^{4,6} Patients with more risk factors have a worse prognosis.

Patients are sent to ORL monitoring if their clinical presentation includes dysphonia, pharyngeal paresthesias, dyspnea and dysphagia and lasts for more than three weeks. Some signs may be more common than others depending on the tumor's location, whether it is supraglottic, glottic, or subglottic: The most common symptom of glottic tumors is dysphonia and subglottic tumors have the worst prognosis with dyspnea and stridor as the main symptoms. Supraglottic tumors are silentand may have laryngeal pruritus as the main symptom. Only later stages manifest with odynophagia, reflex otalgia and dysphonia.⁶.

Direct observation of the lesion and a pathological investigation serve to confirm the diagnosis. The precise position of the lesion and its origin should be noted. Direct laryngoscopy or endoscopic nasofibrolaryngoscopy are used to achieve this. The biopsy provides the final diagnosis. The growth is then staged using the TNM Classification. Stage locally with CT, MRI of the larynx, and distance staging with chest CT or PET-CT in order to establish TNM (Table I).^{8,9}.

Primary Tumor(T)	
Тх	Primary tumor cannot be assessed
то	No evidence of primary tumor
Tis	Carcinoma in situ
Larynx cancer: Supraglottis	
T1	Tumor limited to one subsite of supraglottis with normal vocal cord mobility
Т2	Tumor invades mucosa of more than one adjacent substitute of supraglottisor glottis or region outside supraglottis without fixation of the larynx
Т3	Tumor limited to larynx with vocal cord fixation and/or invades of the following: Postericoid area, pre-epiglottic space, paraglottic space and/orinner cortex of thyroid cartilage
T4a	Tumor invades through the thyroid cartilage and/or invades tissues beyond the larynx, e.g trachea, soft tissues of the neck including deep/extrinsic muscle of the tongue, strap muscles, thyroid or esophagus
T4b	Tumor invades prevertebral space, encases carotid artery or mediastinal structures

Table I – TNM of Larynx Tumors (adapted from ESMO Guidelines of Head and Neck Cancer)⁹

Larynx cancer:Glottis	
Τ1	 Tumor limited to vocal cord(s) (may involve anterior or posterior commissure) with normal mobility T1a- Tumor limited to one vocal cord T1b - Tumor involves both vocal cords
Т2	Tumor extends to supraglottis and/or subglottis and/or with impaired vocalcord mobility
Т3	Tumor limited to larynx with vocal cord fixation and/or invades paraglottic space and/or inner cortex of the thyroid cartilage
T4a	Tumor invades through the outer cortex of the thyroid cartilage and/or invades tissues beyond the larynx, e.g. trachea, soft tissues of the neck including deep/extrinsic muscle of the tongue, strap muscles, thyroid or esophagus
T4b	Tumor invades prevertebral space, encases carotid artery or mediastinal structures
Larynx Cancer:Subglottis	
Т1	Tumor limited to subglottis
Т2	Tumor extends to vocal cord(s) with normal or impaired mobility
ТЗ	Tumor limited to larynx with vocal cord fixation
T4a	Tumor invades cricoid or thyroid cartilage and/or invades tissues beyond the larynx, e.g., trachea. soft tissues of the neck including deep/extrinsic muscle of the tongue, strap muscles, thyroid or oesophagus
T4b	Tumor invades prevertebral space, encases carotid artery or mediastinal structures
Regional Lymph Nodes (N)	
NX	Regional lymph nodes cannot be assessed
NO	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node ≤ 3 cm in greatest dimension without extranodal extension
N2	 Metastasis described as: N2a - Metastasis in a single ipsilateral lymph node > 3 cm but ≤ 6 cm in greatest dimension without extranodal extension N2b - Metastasis in multiple ipsilateral lymph nodes, none > 6 cm in greatest dimension without extranodal extension N2c - Metastasis in bilateral or controlateral lymph nodes, none > 6 cm in greatest dimension without extranodal extension
N3a	Metastasis in a lymph node > 6 cm in greatest dimension without extranodal extension

N3b	Metastasis in a single or multiple lymph nodes with clinical extranodal extensions
Distant Metastasis (M)	
M0	No distant metastasis
M1	Distant metastasis

Table II – Staging of Larynx Tumors (adapted from ESMO Guidelines of Head and Neck Cancer)⁹

Staging	
0	TisN0M0
1	T1N0M0
	T2N0M0
- 111	ТЗN0М0
	T1/T2/T3N1M0
IVA	T1/T2/T3N2M0
	T4aN0/N/N2
IVB	T4bAny NM0
	Any TN3M0
IVC	Any T Any N M1

Chemotherapy, radiation, and surgery (for example TL) are the most frequently used treatments. The decision will be based on the tumor's features, including its histology and staging (Table II), behavior, the patient's ECOG, and its social circumstances, but primarily the patient's decision⁹.

The prognosis is influenced by the prevalence of adenopathies, which are more common in supra and subglottic tumors. In addition to the danger of secondary tumors in the lungs and esophagus, which is about 20%; relapses happen 80% of the time within two years of treatment.

2.4. Phonation Alternatives

Total laryngectomy forces the separation of the airway from the digestive system, which demands a creation of a definitive tracheostoma. Rehabilitation of this patients may include an esophageal voice or a tracheoesophageal fistula with the insertion of a prothesis.

2.4.1 Tracheoesophageal Prosthesis (TEP)

When it comes to vocal rehabilitation TEP is the gold standard. The larynx, also referred to as the vocal

box, is taken out when a patient undergoes a complete laryngectomy. Thus, one of the choices is a device (TEP) placed between the trachea from the esophagus creating a fistula, that allows voice production. Additionally, it has a one-way valve that helps the oxygen to pass more easily from the lungs through the trachea and onto the esophagus, where the upper esophageal sphincter vibrates and creates a new voice known as tracheoesophageal speech (TES). Being a one-way valve also safeguards the lungs from the passage of liquids or food, avoiding aspiration pneumonia among other complications.¹⁰

The surgeon can either create a stoma and place the TEP right away (primary tracheoesophageal puncture) or they can wait at least ten days after the initial procedure to place the TEP in order to enable the pharynx to heal (secondary tracheoesophageal puncture). Both methods have advantages and disadvantages. There are a number of issues with Primary Tracheoesophageal Puncture, including a higher chance of fistula development, leakage at the puncture site, stomal stenosis, and local infection¹¹. As opposed to the Secundary Tracheoesophageal Puncture, which enables speech quality and TEP compatibility testing. According to Chone et al. (2005) ¹², the primary tracheoesophageal incision had a higher success rate than the secondary procedure, and this success rate held true after two years of follow-up. Additionally, neither the patient's age nor the style of therapy has any bearing on the rehabilitation.

As contraindications to TEP, Brook and Goodman (2020) ¹³, list altered pulmonary function, mental status, a lackluster support network, the risk of aspiration, and expense. On the other hand, it is necessary to consider the patient's medical and surgical background, the chosen treatment approach, and the health of the stoma and upper esophageal sphincter. TEP-related consequences include leakage, biofilm development, infection, and even airway obstruction^{11,13}.

The patient's quality of life may also be affected by this treatment. The patient must follow up with a doctor every two to three months after the device is implanted, as well as with a speech therapist, to assess the device's efficacy and whether it needs to be replaced orcleaned, among other things.¹⁴.

2.4.2 Esophageal Speech

Although it is the most straightforward approach, it is also the most labor- and time- intensive for the patient during the voice-recovery process. It can take place using the idea of pressure differences and the air moving from high to low pressure regions. This can be accomplished by either using the muscles in the oral cavity to create a pressure that is greater than the pressure on the stomach or by reducing the pressure by inhaling more quickly. Both techniques need a great deal of practice. ¹⁵

2.4.3 Electronic Larynx

Patients can create sound by using an external instrument to cause vibrations on the oral or pharyngeal mucosa at a constant frequency. The transcervical and the intraoral are the two available kinds. When compared to the esophageal voice¹⁶. the main benefits are not requiring any extra surgical procedure and being simpler to use¹⁶. However, this is a costly piece of equipment that also needs to be maintained, in addition to using a voice-producing technique that is very dissimilar from the patients' natural voice (robot-like voice) and has a significant negative effect on the patients' quality of life.¹⁵

2.5 Rehabilitation

It begins prior to operation and aids in controlling expectations. Relearning basic skills that are now difficult, like speaking and swallowing, is part of it. To improve results, patients should be accompanied by a speech therapist starting on the day that TL is chosen as the treatment option¹⁷. The main voice and speech production differences before and after laryngectomy are demonstrated in the following table (Table III), which explains why a speech therapist is crucial to these patients' recovery.

Table III – Comparison of speech production before and after laryngectomy (adapted
from Scott-Browns, Otorhinolaryngology and Head and Neck Surgery) ⁴	

Physical requirements	Normal voice production	ES production				
Initiator	Moving column of air from the lungs	Moving column of air from the esophagus				
Vibrator	Vocal cords	Vibratory/pharyngo-esophageal segment				
Resonators	Nose, mouth and pharynx	Nose, mouth and pharynx				

3. Materials and Methods

3.1 Sample enrollment and evaluation

In order to perform a comprehensive analysis, data from patients who underwent Total Laryngectomy with bilateral lymph neck dissection at the Department of Otolaryngology, Head and Neck surgery of Centro Hospitalar Universitário de Santo António between January 2010 and October 2022 were reviewed. Of those, only alive patients were selected. Data such as gender, alcohol and tobacco abuse, date of diagnosis, concurrent comorbidities, tumor location (supraglottic, glottic or subglottic), TNM staging, adjuvant therapy (radiation or chemotherapy), time of follow-up and type of vocal rehabilitation were primarily collected on the platform "*SClínico*". Finally, only adult patients who accepted to participate in the study and in whom subjective evaluation was performed were included.

3.2 Subjective measurements (SECEL questionnaire)

From October 2022 to March 2023, the previously selected patients were recruited and vocal outcomes were measured by the Self-evaluation of communication experiences after laryngectomy (SECEL) questionnaire, during the follow-up medical appointments. SECEL was specifically developed for assessing communication dysfunction in patients with laryngectomies and has demonstrated adequate psychometric properties¹⁸. It was also validated for European Portuguese¹⁹. The questionnaire comprises 35 items that explore communication experiences and dysfunction (Figure 3). 34 elements are grouped into three subscales. Theinitial subscale, General (5 items), indicates overall attitudes toward relaxation or calmness, as well as recognition of the illness and therapy. The second subscale, Environmental (14 questions), focuses on how the patient perceives his or her voice in various settings. The third subscale, Attitudinal (15 questions), measures attitudes toward speech, as well as thoughts regarding self-assessment and perceptions of others. Each item is scored on a 4-point category scale ranging from 0 (never) to 3 (always), with the latest 30 days addressed. Subscales and a total scale are scored using basic addition. As a result, the summary scalescores vary from 0 to 15 for General, 0-42 for Environmental, 0-45 for Attitudinal, and 0-102 for Overall. A higher score indicates worse perception of functional communication. Finally, the 35th item is a categorical one, including three response options, Yes/More/Less, and is not scored.

Leia com atenção as seguintes informações:

Encontra-se abaixo um questionário composto por 35 questões sobre comunicação e qualidade de vida após laringectomia. Deve assinalar o número que melhor descreve o último mês.

	Sempre	Quase	Às	Nunca
		Sempre	Vezes	
1) Sente-se descontraído e confortável em situações de diálogo?	3	2	1	0
2) Descreve-se como uma pessoa discreta e calma?	3	2	1	0
3) Descreve-se como uma pessoa ativa, extrovertida e faladora?	3	2	1	0
4) Assume perante a pessoa com quem fala que fez uma laringectomia?	3	2	1	0
5) A sua fala melhora com mais tempo de uso?	3	2	1	0
6) Vai menos vezes a cafés, a bares, a encontros ou outros eventos por causa da fala?	3	2	1	0
7) Tem dificuldade em captar a atenção dos outros para falar?	3	2	1	0
8) Sente dificuldade a gritar ou a chamar de longe as pessoas?	3	2	1	0
9) Acha que as pessoas não conseguem entendê-lo?	3	2	1	0
10) Acha que tem que repetir várias vezes o que diz, durante as conversas,	3	2	1	0
para ser entendido?				
Tem problemas em falar:				
11) Num grande grupo de pessoas?	3	2	1	0
12) Num pequeno grupo de pessoas?	3	2	1	0
13) Com uma pessoa?	3	2	1	0
14) De uma divisão da casa para outra?	3	2	1	0
15) Em locais barulhentos ou ruidosos?	3	2	1	0
16) Ao telefone?	3	2	1	0
17) No carro, autocarro ou em viagem?	3	2	1	0
A sua fala faz com que:				
18) Tenha dificuldades em participar em festas ou encontros sociais?	3	2	1	0
19) Fale menos ao telefone do que gostaria?	3	2	1	0
20) Se sinta posto de parte num grupo?	3	2	1	0
21) Tenha limitações na vida privada ou social?	3	2	1	0
A sua fala faz com que se sinta:				
22) Deprimido?	3	2	1	0
23) Frustrado quando a família e amigos não entendem o que diz?	3	2	1	0
24) Diferente ou peculiar?	3	2	1	0
25) Hesita conhecer e falar com novas pessoas por causa da sua fala?	3	2	1	0
26) É posto de parte nas conversas por causa da sua fala?	3	2	1	0
27) Evita falar com as outras pessoas por causa da sua fala?	3	2	1	0
28) As pessoas completem palavras ou frases por si?	3	2	1	0
29) As pessoas interrompem-no enquanto fala?	3	2	1	0
30) As pessoas dizem-lhe que não o entendem?	3	2	1	0
31) As pessoas ficam sem paciência consigo por causa da sua fala?	3	2	1	0
32) As pessoas evitam-no por causa da sua fala?	3	2	1	0
33) As pessoas falam de maneira diferente consigo por causa da sua fala?	3	2	1	0
34) Os familiares e amigos não conseguem compreender como é	3	2	1	0
comunicar com este género de fala?				
35) Fala agora tanto como antes da sua laringectomia?	Sim	Mais	Ме	enos

Figure 3 – Translated version of the SECEL questionnaire in European Portuguese (translated originally by Sandra Antunes ¹⁹).

3.3 Ethics

Informed consent was obtained for all patients. The study was approved by the local Ethics Committee (Number: (181-DEFI/184-CE)) and the design complies with the Declaration of Helsinki ethical standards.

3.4 Statistical analysis

Statistical analysis was performed using SPSS (IBM SPSS Statistics 26). In the descriptive analysis, categorical variables are presented as percentages, and continuous variables as means and standard deviations, or medians and interquartile range for variables with skewed distributions. Normal distribution was checked using skewness and kurtosis. A bivariate analysis regarding baseline variables collected in the clinical records versus vocal outcomes measured by SECEL questionnaire was undertaken. The associations were analyzed using either independent t-test (parametric analysis) or Mann-Whitney test (non-parametric analysis) depending on the tests for normality, Pearson Chi-square/Fisher's tests (95% confidence intervals) for categories and Spearman's test for continuous variables. Finally, general linear models taking SECEL scores as the outcome were performed. All reported p values are two-tailed, with a p value \leq 0.05 indicating statistical significance.

4. Results

4.1 Study population

The first wide search identified a total of 124 operated patients during the pre-selected period. Of those, 63 patients were still alive at current follow-up, with 61 deaths (49%). 26 out of the 63 alive patients completed the SECEL questionnaire and were therefore included in the final sample.

All of the patients (100%) were male. The mean age at diagnosis was 62.2 ± 10.6 years (range: 38-83 years). The mean age at subjective vocal assessment with SECEL was 66.3 ± 10.4 years (range: 46-87). The mean time of follow-up after initial diagnosis was 4 ± 3.8 years. Other relevant description of the population characteristics is displayed in TableIV.

Categorical variables	Frequency (%)	Continuous variables	Mean/Median (SD, IQR*)
Primary tumor location		Age at diagnosis (years)	62.2 (10.6)
Supraglottic	65.4	Age at SECEL (years)	66.3 (10.4)
Glottic	34.6	Follow-up time (years)	4 (3.8)
Subglottic	0	SECEL guestion	nnaire (question)
TNM staging		One	2 (1-3)
Stage II	11.5	Тwo	2.5 (2-3)
Stage III	34.6	Three	1.5 (0-3)
Stage IV	53.8	Four	3 (3-3)
Risk factors		Five	1 (0-3)
Alcohol abuse	61.5	Six	0 (0-2)
Smoking	88.5	Seven	1 (0-1.25)
Adjuvant therapy		Eight	3 (1-3)
None	26.9	Nine	1 (1-2)
Radiotherapy	34.6	Ten	3 (1-3)
Chemotherapy	3.8	Eleven	2 (1-3)
Radiotherapy + chemotherapy	34.6	Twelve	1 (0-3)
Type of vocal rehabilitation		Thirteen	0 (0-1)
None ^a	11.5	Fourteen	3 (1-3)
		Fifteen	3 (1-3)
Esophageal speech (ES)	38.5	Sixteen	2.5 (0.75-3)
		Seventeen	1 (0-3)
Electrolaryngeal speech (ELS)	19.2	Eighteen	1 (0-3)
		Nineteen	3 (0.75-3)
Tracheoesophageal speech (TES)	30.8	Twenty	0 (0-1)
Primary (TES1) ^b	7.7	Twenty-one	0 (0-1)
Secondary (TES2) ^b	23.1	Twenty-two	1 (0-2)
Question 35 SECEL		Twenty-three	0.5 (0-2)
Yes	11.5	Twenty-four	0 (0-1.25)
More	3.8	Twenty-five	1 (0-3)
Less	84.6	Twenty-six	0 (0-0.25)
Other comorbidites		Twenty-seven	0 (0-1)
Hypertension	38.5	Twenty-eight	0 (0-1)
Diabetes	30.8	Twenty-nine	0 (0-1)
Dyslipidemia	38.5	Thirty	1 (0-1)
Sleep disturbance	38.5	Thirty-one	0 (0-0)
Gastrointestinal	19.2	Thirty-two	0 (0-0)
Previous neoplasia	11.5	Thirty-three	0 (0-1)
Neurologic	7.7	Thirty-four	0 (0-1)
Cardiac	11.5	SECEL scores	
Pulmonary	23.1	General	9.6 (3)
Auto-immune	7.7	Environmental	20.4 (11.1)
Immunosuppression	15.3	Attitudinal	10.1 (7.6)
Depression	11.5	Total	40.1 (16)

			· · · ·	
Table IV – General	descriptive	analysis	of registered	relevant variables.

*: SD- Standard deviation; IQR- Interquartile range (25-75)

a: Refers to patients who did not successfully achieved any source of vocal rehabilitation despite attempts (including the inaptitude to use b: Primary (TES1) refers to tracheoesophageal prothesis placement in the same operatory time as laryngectomy procedure; Secondary (TES2) refers to tracheoesophageal voice prothesis placement at a different (later) operation with that specific purpose

4.2 Types of vocal rehabilitation: impact on vocal outcome

In this segment 3 patients were excluded from further analysis for not using any phonation alternative (**Table V**). When comparing different modalities of successful vocal rehabilitation, a statistically significant difference was observed regarding ES, which was inferior to other modalities (mean SECEL total score for ES: 46.6 ± 12.2 vs mean SECEL total score for all other modalities: 33 ± 15.1 , p = 0.03). When analyzing subscores, this wasparticularly observed in the environmental domain (mean environmental SECEL subscore for ES: 24.4 ± 7.7 vs mean environmental SECEL subscore for all other modalities: 14.6 ± 10.1 , p = 0.019). No significant differences were observed regarding general SECEL subscore between ES and other groups (mean general SECEL subscore for ES: 10.4 ± 3.1 vs mean general SECEL subscore for all other modalities: 9.9 ± 2.6 , p = 0.690). Likewise, no significant differences were observed regarding attitudinal SECEL subscore between ES and the other modalities (mean attitudinal SECEL subscore for ES: 11.8 ± 8.6 vs mean attitudinal SECEL subscore for ES: 11.8 ± 8.6 vs mean attitudinal SECEL subscore for all other modalities: 8.5 ± 6 , p = 0.285).

When the same statistical technique is employed for TES against all other modalities, no significant differences are observed (mean SECEL total score for TES: 39.1 ± 20.5 vs mean SECEL total score for all other modalities: 38.8 ± 11.6 , p = 0.962; mean general SECEL subscore for TES: 9.7 ± 3.6 vs mean general SECEL subscore for all other modalities: 10.4 ± 2.1 , p = 0.578; mean environmental SECEL subscore for TES: 18.6 ± 12.9 vs mean environmental SECEL subscore for all other modalities: 19.1 ± 8.6 , p = 0.917; mean attitudinal SECEL subscore for TES: 10.9 ± 9.8 vs mean attitudinal SECEL subscore for all other modalities: 9.3 ± 5.4 , p = 0.617).

When the same statistical method is employed for ELS against all other modalities, no significant differences are observed (mean SECEL total score for ELS: 35.6 ± 24.2 vs mean SECEL total score for all other modalities: 39.8 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 2.7 vs mean general SECEL subscore for all other modalities: 10.3 ± 2.8 , p = 0.521; mean environmental SECEL subscore for ELS: $17.2 \pm y15.5$ vs mean environmental SECEL subscore for all other modalities: 19.3 ± 8.8 , p = 0.689; mean attitudinal SECEL subscore for ELS: 9 ± 9.5 vs mean attitudinal SECEL subscore for all other modalities: 10.1 ± 6.8 , p = 0.808). If interest in bivariate comparison of subgroups, consult the table **Table V**.

Variable	Esophage (1	eal speech (1 = 31)	ES)		Electrola	aryngeal (n=22	speech (l ː)	ELS)
	Mean (± SD)	p val	ue agair	nst	Mean (± SD)	p	value aga	inst
		ELS	TES	NS		ES	TES	NS
Age at diagnosis (years)	63.9 ± 11	0.310	0.886	0.769	55.4 ± 15.3	0.310	0.334	0.242
Age at SECEL (years)	67.1 ± 10.1	0.381	0.669	0.903	60.2 ± 14.7	0.381	0.271	0.430
Follow-up time (Years)	10 ± 3.2	0.442	0.175	0.122	4.8 ± 3.6	0.442	0.630	0.130
SECEL total	46.6 ± 12.2	0.254	0.005	0.002	35.6 ± 24.2	0.254	0.644	<0.001
SECEL general	10.4 ± 3.1	0.534	0.913	0.047	9.4 ± 2.7	0.534	0.593	0133
SECEL	24.4 ± 7.7	0.243	0.002		17.2 ± 15.5	0.243	0.488	
SECEL	11.8 ± 8.5	0.596	0.235		9 ± 9.5	0.596	0.812	

Table V – Matched comparison between vocal renabilitation modaliti

	Tracheoesophageal speech (TES) (n=13)				No speech (NS) (n=3)				
	Mean (± SD)	p	value aga	ainst	Mean (± SD)	p value against			
		ES	ELS	NS		ES	ELS	TES	
Age at diagnosis (years)	63.2 ± 7.9	0.886	0.334	0.642	65.3 ± 5.5	0.769	0.242	0.642	
Age at SECEL (years)	69.1 ± 9.5	0.669	0.271	0.549	66.3 ± 5	0.903	0.430	0.549	
Follow-up time (Years)	5.9 ± 4.1	0.175	0.630	0.013	1 ± 0.5	0.122	0.130	0.013	
SECEL total	31.4 ± 6.9	0.005	0.644	<0.001	62.1 ± 22.5	0.002	<0.001	< 0.001	
SECEL general	10.3 ± 2.7	0.913	0.593	0.042	6 ± 2.6	0.047	0.133	0.042	
SECEL	13 ± 5.3	0.002	0.488		32 ± 8.2	0.002	< 0.001	< 0.001	
environmental SECEL attitudinal	8.1 ± 3.2	0.235	0.812		19 ± 10.3	0.047	0.015	0.02	

At last, no significant associations were found between the answer to the question 35 and any factor (p > 0.05 for every studied variable). Likewise, no significant differenceswere found regarding tumor location (glottic vs supraglottic) and SECEL total score (p = 0.235). No significant differences were found between primary (TES1) and secondary (TES2) rehabilitation concerning SECEL total score (p = 0.652).

4.3 Other potential predictors of vocal outcome

A significant inverse correlation was found between follow-up time and SECEL total score (p = 0.013), so that increased follow-up time associated with better perceived vocal function. A similarly significant inverse correlation existed between environmental subscore (p = 0.005). The two other subscores did not reveal any significant correlation with follow-up time (general: p = 0.638; attitudinal: p = 0.199).

No association was found between the age of diagnosis and SECEL total score (p = 0.743). Likewise, no associations were found between age of diagnosis and any of the SECEL subscores (general: p = 0.884; environmental: p = 0.716; attitudinal: p = 0.907). Age at SECEL did not correlate with SECEL total score (p = 0.531). Similarly, no associations were found between age at SECEL and any of the

SECEL subscores (general: p = 0.825; environmental: p = 0.576; attitudinal: p = 0.525).

No significant correlations were found between TNM staging and vocal outcomes measured by SECEL total score (p = 0.151), as displayed in **Figure 4**. Likewise, no significant differences were observed between different adjuvant therapy groups regarding vocal outcomes (neither SECEL total or subscores, p > 0.05 in all matched comparisons from independent t-test). Also, tumor location did not associate with significant differences regarding the SECEL total score (glottic mean SECEL total score: 37.1 ± 14.1 vs supraglottic mean SECEL total score: 45.9 ± 18.6 , p = 0.235). Regarding tobacco or alcohol abuse, there was no association between these factors and SECEL outcomes (p > 0.05). The same was observed concerning comorbidities, without any particular comorbidity relating to SECEL outcomes (p > 0.05 for all measured comorbidities).

4.4 Multivariate analysis for vocal outcome predictors

This section parts from the above identified variables correlating significantly with SECEL scores (namely: type of vocal rehabilitation and follow-up time). A linear regression model was calculated to predict SECEL total score based on vocal rehabilitation subgroup as independent variable (ES or other modality). A significant regression equation was found (F (1,21) = 5.394, p = 0.03), with an R² of 2.204. The fitted model equation was SECEL totalscore = 33 + 13.6x (x = 1 if ES or x = 0 if another modality). Using the same method but taking follow-up time as independent variable resulted in a non-significant model (p = 0.099). Also when both independent variables are accounted simultaneously in the same regression the result is a non-significant model (vocal rehabilitation modality: p = 0.74 and follow-up time: p = 0.250).



Figure 4 – Box Plot display of mean SECEL total among different staging groups.

Figure 5 – Mean SECEL total scores matched to follow-up time: ES vs other modalities.

5. Discussion

Being unable to produce voice sounds is a major life altering incident that significantly lowers quality of life. The study's main goals were achieved. Our findings imply that in terms of vocal outcomes, ES appears to be less effective than other rehabilitation methods. This is consistent with the majority of recent literature on post-laryngectomy phonation options.^{5–8}However, some investigations, including the one from Mourkarbel *et al*, assert that there is no statistically significant distinction between ES and TEP²⁴. In contrast, Salturk *et al* went on to state that patients with ES had better outcomes than thosewith EL or even TEP²⁵. Chone *et al*¹², came to the conclusion that main tracheoesophagealpunctures had a higher success rate than secondary ones. However, no discernible differences between primary (TES1) and secondary (TES2) rehabilitation were discovered in this research. Although TEP is the gold standard and produces better results, it also has a number of drawbacks that are not present with ES rehabilitation, including leakage, biofilm formation, infections and a greater risk of pneumonia⁹. Meaning that many factors, most importantly the choice of the patient, must be taken into account when choosing between the available options.

We discovered that follow-up time may have an impact on vocal function as the secondary goals were to investigate concurrent baseline predictors of vocal outcomes in laryngectomized patients. This is presumably due to the fact that learning how to produce voice and communicate is more effective when there is more rehabilitation time and voice use occurs naturally in daily life. The length of the follow-up period also affects the prothesis lifespan. Meaning that the quality of life for these people is significantly impacted by rehabilitation²⁰.

The same is true for various adjuvant therapy groups, tumor locations, risk factors (tobacco or alcohol abuse), or comorbidities, with no specific comorbidity being related to SECEL outcomes. Furthermore, no significant correlations between TNM staging and vocaloutcomes were identified.

From the patients' point of view, TL may imply mutilation, since there is impact on their voices, breathing, swallowing and even taste and smell ³. It is a life changing moment, so there is, without a doubt a change in their quality of life. According to WHO, "quality of life is defined as people' perceptions of their place in life in relation to their goals, expectations, standards, and concerns, as well as the culture and value systems in which they lived. (...) influenced by one's physical condition, degree of independence, social connections, external circumstances, and personal

convictions." The findings of a study on the quality of life of laryngectomy patients (both partial and total) revealed that the social and emotional functions of the group of patients who underwent TL were most adversely impacted.²⁵ Additionally, the findings indicate that all parameters for this group have gotten worse overall. Voice quality is undoubtedly one of the factors that affects quality of life, but other factors include changes in the body's appearance, communication, mental state, and social interactions.²² Primarily as a result of stigmatization, as the majority of these patients are unable to keep their jobs and occasionally exhibit aggressive behavior toward those who do not comprehend them. This also occurs in women, but it usually takes second place to physical looks.²⁶ Studies have shown that patients with head and neck cancer may exhibit high rates of psychiatric affection, linked to the disease itself and their treatments, which makes the assessment of how phonation alternatives have an impact on quality of life crucial.³

Numerous restrictions applied to this research, including the population sample. Only 63 of the 124 patients who underwent surgery during the pre-selected period were stillliving at the time of the current follow-up, which meant that nearly half (49%) of the pre-sample had passed away. In addition, only 26 of the 63 patients who were still alive completed the SECEL questionnaire. These are difficult patients who frequently do not want to reveal their frailties, and not having a voice posed a significant challenge because the majority of patients did not even want to attempt to respond to the questionnaire. In addition, it was a small sample at first, and the assessment of how it affects a person's life dependson a variety of variables, including "financial stability, degree of independence, social relationships, environmental factors, and personal views" (WHO)²⁸.

However, this is the first research to compare different phonation methods using the SECEL questionnaire. This tool can help healthcare professionals create a rehabilitation²⁹ plan that includes "caring, informing, and accompanying" but is most helpful in identifying the psychologic impact in this group of patients. ³.

6. Conclusion

Patients who have undergone TL must relearn how to interact with others. This is a very difficult group of patients because they experience such a great deal of change in their lives, from their voices, breathing, and swallowing to their emotional and social contacts, which are impacted by things like their physical appearance and personal views.

In this research, we found that TEP is the gold standard for patient voice rehabilitation, and that ES appears to be inferior to other rehabilitation modalities in terms of voice-related quality of life. The quality of life for these patients is significantly impacted by rehabilitation, in addition to the possibility that follow-up time may have an effect on vocalfunction²¹.

SECEL can be a helpful tool to assess laryngectomized patients' quality of life because it can be used to gauge the psychological effects of vocal functionality on this population. As healthcare experts, it is our duty to give each patient the highest possible standard of living given their individual circumstances.

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Annexes

Annex I – Authorization of the study by the Management Board of CHUdSA

Exma. Sra. Ana Rodrigues Estudante do ICBAS

<u>ASSUNTO:</u> Trabalho Académico - MIM - "Laryngectomy: phonation alternatives and the impact on quality of life" - N/ REF.^a 2022.222(181-DEFI/184-CE)

O Conselho de Administração do Santo António na reunião de 15 de fevereiro de 2023 emitiu a seguinte deliberação: "Autorizado" para a realização do estudo acima mencionado, a decorrer no Serviço de Otorrinolaringologia desta Instituição e tendo como Investigador Principal Ana Rodrigues, estudante do ICBAS.

O estudo foi previamente analisado pela Comissão de Ética do Santo António | ICBAS, pelo Serviço de Investigação Clínica, pela Direção do Departamento de Ensino, Formação e Investigação do Santo António e pelo Presidente do Conselho de Administração, tendo obtido parecer favorável.

> Assinado por : **Cláudia Alexandra Oliveira Santos** Num. de Identificação: BI11089889 Data: 2023.03.09 10:11:50 Hora padrão de GMT

* Em todas as eventuais comunicações posteriores sobre este estudo <u>é indispensável</u> indicar a nossa ref.ª.

Annex II – SECEL questionnaire applied to CHUdSA patients

Self-Evaluation of Communication Experiences after Laryngectomy (SECEL)

Leia com atenção as seguintes informações.

Encontra-se abaixo um questionário composto por 35 questões sobre comunicação e qualidade de vida após laringectomia. Deve assinalar o número que melhor descreve o último mês.

	Sempre	Quase	Às	Nunca
		Sempre	Vezes	
1) Sente-se descontraído e confortável em situações de diálogo?	3	2	1	0
2) Descreve-se como uma pessoa discreta e calma?	3	2	1	0
3) Descreve-se como uma pessoa ativa, extrovertida e faladora?	3	2	1	0
4) Assume perante a pessoa com quem fala que fez uma laringectomia?	3	2	1	0
5) A sua fala melhora com mais tempo de uso?	3	2	1	0
6) Vai menos vezes a cafés, a bares, a encontros ou outros eventos por causa da fala?	3	2	1	0
7) Tem dificuldade em captar a atenção dos outros para falar?	3	2	1	0
8) Sente dificuldade a gritar ou a chamar de longe as pessoas?	3	2	1	0
9) Acha que as pessoas não conseguem entendê-lo?	3	2	1	0
10) Acha que tem que repetir várias vezes o que diz, durante as conversas, para ser entendido?	3	2	1	0
Tem problemas em falar:				
11) Num grande grupo de pessoas?	3	2	1	0
12) Num pequeno grupo de pessoas?	3	2	1	0
13) Com uma pessoa?	3	2	1	0
14) De uma divisão da casa para outra?	3	2	1	0
15) Em locais barulhentos ou ruidosos?	3	2	1	0
16) Ao telefone?	3	2	1	0
17) No carro, autocarro ou em viagem?	3	2	1	0
A sua fala faz com que:				
18) Tenha dificuldades em participar em festas ou encontros sociais?	3	2	1	0
19) Fale menos ao telefone do que gostaria?	3	2	1	0
20) Se sinta posto de parte num grupo?	3	2	1	0
21) Tenha limitações na vida privada ou social?	3	2	1	0
A sua fala faz com que se sinta:				
22) Deprimido?	3	2	1	0
23) Frustrado quando a família e amigos não entendem o que diz?	3	2	1	0
24) Diferente ou peculiar?	3	2	1	0
25) Hesita conhecer e falar com novas pessoas por causa da sua fala?	3	2	1	0
26) É posto de parte nas conversas por causa da sua fala?	3	2	1	0
27) Evita falar com as outras pessoas por causa da sua fala?	3	2	1	0
28) As pessoas completem palavras ou frases por si?	3	2	1	0
29) As pessoas interrompem-no enquanto fala?	3	2	1	0
30) As pessoas dizem-lhe que não o entendem?	3	2	1	0
31) As pessoas ficam sem paciência consigo por causa da sua fala?	3	2	1	0
32) As pessoas evitam-no por causa da sua fala?	3	2	1	0
33) As pessoas falam de maneira diferente consigo por causa da sua fala?	3	2	1	0
34) Os familiares e amigos não conseguem compreender como é	3	2	1	0
comunicar com este género de fala?				
35) Fala agora tanto como antes da sua laringectomia?	Sim	Mais	Me	nos

Annex III - Original SECEL questionnaire (English version)

	Always	Often	Sometimes	Never
1. Are you relaxed and comfortable around other people in speaking situations?	3	2	1	0
2. Would you describe yourself as a low-keyed, calm person?	3	2	1	0
3. Are you an active, "outgoing", talkative person?	3	2	1	0
4. Do you admit to the person you are speaking to that you had a laryngectomy?	3	2	1	0
5. Do you think your speech improves with the amount of time you use it?	3	2	1	0
6. Do you find that you frequent clubs, meetings, or lodges less often because of your speech?	3	2	1	0
7. Do you have difficulty having getting people's attention to speak?	3	2	1	0
8. Do you have difficulty yelling or calling out to people?	3	2	1	0
9. Do you find that people are unable to understand you?	3	2	1	0
10. Do you find you have to repeat things a number of times during conversations to be understood?	3	2	1	0
Do you have trouble with speaking:	3	2	1	0
11. In large groups of people?	3	2	1	0
12. In small groups of people?	3	2	1	0
13. With one person?	3	2	1	0
14. In different rooms of your house (apartment, residence)	3	2	1	0
15. In loud or noisy places?	3	2	1	0
16. On the telephone?	3	2	1	0
17. In the car, bus or while traveling?	3	2	1	0
Does your speech cause you to:				
18. Have difficulty when attending parties or social gatherings?	3	2	1	0
19. Use the telephone less often than you would like?	3	2	1	0
20. Feel left out when you are with a group of people?	3	2	1	0
21. Limit your social life or personal life?	3	2	1	0
Does your speech cause you to feel:				
22. Depressed?	3	2	1	0
23. Frustrated when talking to family and friends and they can't understand you?	3	2	1	0
24. Different or peculiar?	3	2	1	0
25. Do you hesitate to meet new people because of your speech?	3	2	1	0
26. Do you get left out of conversations because of your speech?	3	2	1	0
27. Do you avoid speaking with other people because of your speech?	3	2	1	0
28. Do people tend to fill in words or complete sentences for you?	3	2	1	0
29. Do people interrupt you while you are speaking?	3	2	1	0
30. Do people tell you that they can't understand you?	3	2	1	0
31. Do the people you speak with get annoyed with you because of your speech?	3	2	1	0
32. Do people avoid you because of your speech?	3	2	1	0
33. Do people speak to you differently because of your speech?	3	2	1	0
34. Do your family and friends fail to understand what it's like to communicate with this type of speech?	3	2	1	0
35. Do you talk the same amount now as before your laryngectomy?	Yes	More	Less	

*Questionnaire developed by Gordon Blood¹⁸

Annex IV - Informed Consent presented to patients that answered SECEL

DECLARAÇÃO DE CONSENTIMENTO INFORMADO

"Laryngectomy: Phonation Alternatives And Impact On Life Quality"

A presente declaração de consentimento surge no âmbito da Tese de Mestrado de Ana Sofia de Sousa Rodrigues (Número Mecanográfico: 201704378), para obtenção do Grau de Mestre em Medicina. O estudo tem como objetivo avaliar as alternativas à fonação e impacto na qualidade de vida nos doentes do Centro Hospitalar Universitário do Porto, Hospital de Santo António, através da aplicação de questões de enquadramento populacional e de um questionário SECEL (Self-Evaluation of Communication Experiences after Laryngectomy). As respostas e os dados tratados são obtidos de forma anónima e confidencial. Não existe qualquer risco associado à participação neste questionário. A participação nesta investigação é voluntária, sem qualquer custo ou consequências para os participantes.

CONSENTIMENTO INFORMADO

Eu, abaixo-assinado(a)_

compreendi a informação acima descrita sobre a investigação em que irei participar, tendo realizado as questões necessárias para o meu esclarecimento. Foi-me garantido o anonimato e confidencialidade dos dados obtidos, bem como a ausência de riscos ou consequências na participação do estudo.

Assim, consinto em participar nesta investigação, respondendo às questões colocadas e ao questionário acima indicado.

_____, _____ de ______ de ______ de 20____

O (A) participante:

O (A) observador:

Annex V - Published Article in Cureus Journal

DOI: 10.7759/cureus.39093

Cureus

Open Access Original Article

DOI: 10.7759/cureus.

Laryngectomy: Phonation Alternatives and Their Impact on the Quality of Life

Ana Rodrigues 1 , Francisco Alves de Sous
a 2 , Maria J. Casanova 2 , Ana Silv
a 2 , Telma Feliciano 2 , Susana Vaz Freita
s 3 , Ricardo Pinto 4 , João Lin
o 2

 Otolaryngology - Head and Neck Surgery, Instituto de Cièncias Biomédicas Abel Salazar, Centro Hospitalar Universitário do Porto, Porto, PRT 2. Otolaryngology - Head and Neck Surgery, Centro Hospitalar Universitário de Santo António, Porto, PRT 3. Speech Therapy, Otolaryngology - Head and Neck Surgery, Centro Hospitalar Universitário de Santo António, Porto, PRT 4. Gastroenterology, Centro Hospitalar Universitário de Santo António, Porto, PRT

Corresponding author: Ana Rodrigues, anassrodrigues312@gmail.com

Abstract

Background

The decision to consent to surgery is a life-changing moment. This study addresses the impact of total laryngectomy (TL) on phonation and its effect on the quality of life (QoL) of patients. The primary objective of this cohort study is to compare the alternatives in phonation rehabilitation, and the secondary objective is to identify concurrent predictors of vocal outcomes.

Methodology

To perform a comprehensive analysis, we reviewed data from patients who underwent TL with bilateral radical neck dissection in the Department of Otolaryngology, Head and Neck Surgery at Centro Hospitalar Universitário de Santo António between January 2010 and October 2022. Adult patients who consented to participate in the study and underwent subjective evaluation were included in this study. Data regarding clinical history was primarily collected. Statistical analysis was performed using SPSS version 26 (IBM Corp., Armonk, NY, USA). Different types of vocal rehabilitation formed the subgroups to be compared. An additional analysis was performed for baseline variables collected in the clinical records, and vocal outcomes were measured using the Self-Evaluation of Communication Experiences After Laryngectomy (SECEL) questionnaire. Furthermore, linear models taking SECEL scores as the outcome were developed.

Results

The first search identified a total of 124 patients operated during the study period. In total, 63 patients were alive at the time of the current follow-up, with 61 deaths (49%). Overall, 26 of the 63 alive patients completed the SECEL questionnaire. All patients were male. The mean age at diagnosis was 62.2 ± 10.6 years. The mean age at the time of subjective vocal assessment with the SECEL questionnaire was 66.3 ± 10.4 years. The mean time of follow-up after the initial diagnosis was 4 ± 3.8 years. A statistically significant difference was observed in esophageal speech (ES), which was inferior to other modalities (mean SECEL total score for ES: 46.6 ± 12.2 vs. mean SECEL total score for all other modalities: 33 ± 15.1 ; p = 0.03). The follow-up time correlated significantly with vocal function, as measured by the SECEL questionnaire (p = 0.013).

Conclusions

The SECEL questionnaire can be a valuable tool to evaluate QoL in laryngectomy patients, given its usefulness in assessing the psychological impact derived from vocal functionality in this group. ES appears inferior to other modalities regarding voice-related QoL.

Categories: Pathology, Physical Medicine & Rehabilitation, Oncology Keywords: carcinoma of larynx, voice rehabilitation, secel, rehabilitation, phonation, quality of life, esophageal speech, electronic larynx, tracheoesophageal speech, total laryngectomy

Introduction

Although laryngeal cancer is not the most prevalent tumor, it affects a significant portion of patients worldwide. Eastern and South-Central Asia are the most severely impacted regions [1]. According to data, the incidence and mortality of laryngeal cancer are globally higher in men than women [1]. In 2020, Portugal reported 529 new cases and 329 deaths from laryngeal tumors [2]. The larynx controls breathing, protects the airway, and is involved in phonation. Smoking is the primary risk factor. Other known risk factors are alcohol abuse, radiation exposure, and premalignant lesions (from reflux or human papillomavirus) [3]. Chemotherapy, radiation, and surgery are the most frequently used treatments. The treatment decision is influenced by the tumor's characteristics and the patient's behavior, performance status, and socioeconomic circumstances [4].

How to cite this article

Total laryngectomy (TL) usually involves the removal of all of the thyroid and cricoid cartilage, the arytenoid cartilage, the epiglottis, the hyoid bone, and the prelaryngeal muscles [3]. The pharyngeal tube is closed using a horizontal or T-shaped suture [3]. The cut end of the trachea is sutured to the skin of the neck and an end stoma is created [3]. The removal of the larynx has profound consequences for a patient [3]. The separation of the airway from the mouth, nose, and esophagus leads not only to the loss of the ability to speak but also to the separation of the nasal and pharyngeal segments from the lower airways, as well as the loss of the air conditioning mechanism and active smelling [3]. Patients must learn to cope with a tracheostom and the associated disadvantages [3].

Billroth performed the first TL in Vienna, Austria, in 1873. The effects of laryngectomy-related morbidity on voice production were already a cause of worry at the time [3]. Hence, Gussenbauer developed the first mechanical larynx, which comprised a tracheostomy and pharyngeal cannula [3]. The prognosis and patient survival improved dramatically as a result of these techniques which revolutionized the treatment of tumors of the larynx [3]. Researchers continued to develop several phonation options in the 20th and 21st centuries, and alternatives such as tracheoesophageal prosthesis (TEP), electronic larynx (EL), and esophageal speech (ES) were proposed [3]. Nevertheless, surgery continues to be very intrusive, with a significant impact on everyday life and making rehabilitation a lifetime endeavor [5].

TL, occasionally combined with adjuvant radiotherapy and/or chemotherapy, is the recommended course of treatment in many cases of advanced laryngeal cancers [3]. The decision to consent to surgery is a significant turning point in patients' lives. Post-laryngectomy quality of life (QoL) has long been associated with the ability to regain communication skills [6]. Nowadays, the most common forms of rehabilitation are ES, TEP, and EL [1,3,4].

The first aim of this study is to assess and compare the impact of different speech rehabilitation alternatives on laryngectomy patients' QoL. The second aim is to identify and predict factors of vocal outcomes within the study cohort.

Materials And Methods

Sample enrollment and evaluation

To perform a comprehensive analysis, we reviewed data from patients who underwent TL with bilateral radical neck dissection at the Department of Otolaryngology, Head and Neck Surgery of Centro Hospitalar Universitário de Santo António between January 2010 and October 2022. Of those, only living patients were selected. Data including sex, alcohol and tobacco abuse, date of diagnosis, concurrent comorbidities, tumor location (supraglottic, glottic, or subglottic), TNM staging (classification of malignant tumors), adjuvant therapy (radiation or chemotherapy), time of follow-up, and type of vocal rehabilitation were primarily collected. Finally, only adult patients who consented to participate in the study and who underwent subjective evaluation were included in this study.

Subjective measurements (Self-Evaluation of Communication Experiences After Laryngectomy questionnaire)

From October 2022 to March 2023, the previously selected patients were recruited, and vocal outcomes were measured by the Self-Evaluation of Communication Experiences After Laryngectomy (SECEL) questionnaire. The SECEL questionnaire was specifically developed for assessing communication dysfunction in patients with laryngectomies and has demonstrated adequate psychometric properties [7]. It was also validated for European Portuguese [8]. The questionnaire comprises 35 items that explore communication experiences and dysfunction (see Appendices). In total, 54 elements are grouped into three subscales. The initial subscale, General (five items), indicates overall attitudes toward relaxation or calmess, as well as recognition of the illness and therapy. The second subscale, Environmental (14 questions), focuses on how the patient perceives his/her voice in various settings. The third subscale, Attitudinal (15 questions), measures attitudes toward speech, as well as thoughts regarding self-assessment and preception of others. Each item is scored on a four-point scale ranging from 0 (never) to 3 (always), with the latest 30 days addressed. Subscales and the total scale are scored using basic addition. As a result, the summary scale scores range from 0 to 15 for General, 0 to 42 for Environmental, 0 to 45 for Attitudinal d to 102 for Overall. A higher score indicates a worse perception of functional communication. Finally, the 35th item is a categorical item, including three response options, namely, Yes/More/Less, and is not scored.

Ethics

Informed consent was obtained from all patients. The study was approved by the local ethics committee (approval number: 181-DEFI/184-CE), and the study design complied with the ethical standards of the Declaration of Helsinki.

Statistical analysis

Statistical analysis was performed using SPSS version 26 (IBM Corp., Armonk, NY, USA). In the descriptive

analysis, categorical variables are presented as percentages, and continuous variables are presented as means and standard deviations, or medians and interquartile ranges for variables with skewed distributions. Normal distribution was checked using skewness and kurtosis. A bivariate analysis regarding baseline variables collected in the clinical records versus vocal outcomes measured by the SECEL questionnaire was undertaken. The associations were analyzed using either the independent t-test (parametric analysis) or the Mann-Whitney test (non-parametric analysis) depending on the tests for normality, Pearson chi-square/Fisher's tests (95% confidence intervals) for categories, and Spearman's test for continuous variables. Finally, general linear models taking SECEL scores as the outcome were developed. All reported p-values are two-tailed, with a p-value <0.05 indicating statistical significance.

Results

Study population

The first search identified a total of 124 patients who had undergone an operation during the study period. Of those, 63 patients were still alive at the time of the current follow-up, with 61 deaths (49%). In total, 26 of the 63 living patients completed the SECEL questionnaire (41.3%) and were included in the final sample.

All patients (100%) were male. The mean age at diagnosis was 62.2 ± 10.6 years (range = 38-83 years). The mean age at the subjective vocal assessment with the SECEL questionnaire was 66.3 ± 10.4 years (range = 46-87). The mean time of follow-up after the initial diagnosis was 4 ± 3.8 years. Other relevant descriptions of the population characteristics are displayed in Table 1.

Primary tumor locationSea diagnosi (years)62 (2 (0.6)Supragiottic654Ag at SECEL (years)63 (0.4)Glottic34.6Folow-up time (years)4 (3.8)Subjottic0SECEL questionnaire (questic)TM staging1.5On2 (3.9)Stage II1.5Two2 (3.9)Stage II34.6Three3 (3.9)Stage IV5.8Four3 (3.9)Alcohol abuse6.15Six Acon0 (0.2)Snoking6.15Six Acon0 (0.2)Andoni abuse6.9Seven1 (0.3)None26.9Nine1 (0.3)Adotherapy3.8Four (acons)1 (1.2)None3.8Four (acons)1 (3.9)Adotherapy chemotherapt3.8Four (acons)1 (3.9)None ^a 1.6Sinten1 (3.9)Adotherapy chemotherapt3.8Four (acons)1 (3.9)None ^a 1.6Sinten1 (3.9)Adotherapy chemotherapt3.6Sinten3 (3.9)None ^a 1.6Sinten3 (3.9)Anone ^a 1.6Sinten3 (3.9)Adotherapt chemotherapt3.6Sinten3 (3.9)Anone ^a SintenSinten3 (3.9)Anone ^a 1.6Sinten3 (3.9)Anone ^a SintenSinten3 (3.9)Anone ^a SintenSinten3 (3.9)Anone ^a SintenSinten3 (3.9)Anone ^a	Categorical variables	Frequency (%)	Continuous variables	Mean/Median (SD, IQR*)
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Glötic94.6Follow-up time (years)4.0.8Subjottic0SCEL questionnaire (questionnaire (quest	Supraglottic	65.4	Age at SECEL (years)	66.3 (10.4)
Styleptic0SEEE questionnair (Questionnair (Questionn	Glottic	34.6	Follow-up time (years)	4 (3.8)
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Radiotherapy + chemotherapy 34.6 Twelve 1 (0-3) Type of vocal rehabilitation Thirteen 0 (0-1) None a 11.5 Fourteen 3 (1-3) Esophageal speech (ES) 38.5 Sixteen 2.5 (0.75-3) Einbleen 1 (0-3) 1 (0-3)	Chemotherapy	3.8	Eleven	2 (1-3)
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Esophageal speech (ES) 38.5 Sixteen 2.5 (0.75-3) Seventeen 1 (0-3)	None "	11.5	Fifteen	3 (1-3)
Seventeen 1 (0-3)	Econhageal speech (ES)	29.5	Sixteen	2.5 (0.75-3)
Fighteen 1 (0-3)	Esophageal speech (ES)	36.5	Seventeen	1 (0-3)
Electrology accel (FLS) 10.2	Electrology poor (ELS)	10.2	Eighteen	1 (0-3)
Nineteen 3 (0.75-3)	Electrolaryngeal speech (ELS)	19.2	Nineteen	3 (0.75-3)
Tracheoesophageal speech (TES) 30.8 Twenty 0 (0-1)	Tracheoesophageal speech (TES)	30.8	Twenty	0 (0-1)
Primary (TES1) ^b 7.7 Twenty-one 0 (0-1)	Primary (TES1) ^b	7.7	Twenty-one	0 (0-1)

Secondary (TES2) ^b	23.1	Twenty-two	1 (0-2)
Question 35 SECEL		Twenty-three	0.5 (0-2)
Yes	11.5	Twenty-four	0 (0-1.25)
More	3.8	Twenty-five	1 (0-3)
Less	84.6	Twenty-six	0 (0-0.25)
Other comorbidities		Twenty-seven	0 (0-1)
Hypertension	38.5	Twenty-eight	0 (0-1)
Diabetes	30.8	Twenty-nine	0 (0-1)
Dyslipidemia	38.5	Thirty	1 (0-1)
Sleep disturbance	38.5	Thirty-one	0 (0-0)
Gastrointestinal	19.2	Thirty-two	0 (0-0)
Previous neoplasia	11.5	Thirty-three	0 (0-1)
Neurologic	7.7	Thirty-four	0 (0-1)
Cardiac	11.5	SECEL scores	
Pulmonary	23.1	General	9.6 (3)
Autoimmune	7.7	Environmental	20.4 (11.1)
Immunosuppression	15.3	Attitudinal	10.1 (7.6)
Depression	11.5	Total	40.1 (16)

TABLE 1: General descriptive analysis of registered relevant variables.

SD = standard deviation; IQR = interquartile range (25-75)

a: Refers to patients who did not successfully achieve any source of vocal rehabilitation despite attempts (including the inaptitude to use ELS).

b: Primary (TES1) refers to tracheoesophageal prosthesis placement in the same operating time as the laryngectomy procedure. Secondary (TES2) refers to tracheoesophageal voice prosthesis placement at a different (later) operation with that specific purpose.

Types of vocal rehabilitation: impact on vocal outcomes

Three patients were excluded from further analysis for not using any phonation alternative. When comparing different modalities of successful vocal rehabilitation, we observed a statistically significant difference regarding ES, which was inferior to other modalities (mean SECEL total score for ES: 46.6 \pm 12.2 vs. mean SECEL total score for all other modalities: 33 \pm 15.1, p = 0.03). When analyzing subscores, this was particularly noted in the environmental domain (mean environmental SECEL subscore for ES: 24.4 \pm 7.7 vs. mean environmental SECEL subscore for all other modalities: 14.6 \pm 10.1, p = 0.019). No significant differences were observed regarding the general SECEL subscore for all other modalities: 9.9 \pm 2.6, p = 0.690). Likewise, no significant differences were observed regarding the general SECEL subscore for all other modalities: 9.9 \pm 2.6, p = 0.690). Likewise, no significant differences were observed regarding the attitudinal SECEL subscore between ES and other modalities: 9.8 \pm 0.6 ye. Subscore for ES: 11.8 \pm 8.6 vs. mean attitudinal SECEL subscore for all other modalities: 8.5 \pm 6, p = 0.285).

When the same statistical technique was employed for TES against all other modalities, no significant differences were observed (mean SECEL total score for TES: 39.1 ± 20.5 vs. mean SECEL total score for all other modalities: 38.8 ± 11.6 , p = 0.962; mean general SECEL subscore for TES: 9.7 ± 3.6 vs. mean general SECEL subscore for all other modalities: 10.4 ± 2.1 , p = 0.578; mean environmental SECEL subscore for TES: 19.1 ± 8.6 , p = 0.917; and mean attitudinal SECEL subscore for TES: 10.9 ± 9.8 vs. mean attitudinal SECEL subscore for all other modalities: 9.3 ± 5.4 , p = 0.617).

When the same statistical method is employed for electronic larynx speech (ELS) against all other modalities, no significant differences were observed (mean SECEL total score for ELS: 35.6 ± 24.2 vs. mean SECEL total score for all other modalities: 39.8 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general SECEL subscore for ELS: 9.4 ± 12.6 , p = 0.595; mean general secter se

2.7 vs. mean general SECEL subscore for all other modalities: 10.3 ± 2.8, p = 0.521; mean environmental SECEL subscore for ELS: 17.2 ± 15.5 vs. mean environmental SECEL subscore for all other modalities: 19.3 ± 8.8, p = 0.689; and mean attitudinal SECEL subscore for ELS: 9 ± 9.5 vs. mean attitudinal SECEL subscore for all other modalities: 10.1 ± 6.8, p = 0.608). Other relevant one-to-one comparisons between vocal rehabilitation modalities are displayed in Table 2.

	ES (n = 31)				ELS (n = 22)			
Variable	Maan (+CD)	P-value	against		No	P-value against		
	Mean (ISD)	ELS	TES	NS	wean (15D)	ES	TES	NS
Age at diagnosis (years)	63.9 ± 11	0.310	0.886	0.769	55.4 ± 15.3	0.310	0.334	0.242
Age at SECEL (years)	67.1 ± 10.1	0.381	0.669	0.903	60.2 ± 14.7	0.381	0.271	0.430
Follow-up time (years)	10 ± 3.2	0.442	0.175	0.122	4.8 ± 3.6	0.442	0.630	0.130
SECEL total	46.6 ± 12.2	0.254	0.005	0.002	35.6 ± 24.2	0.254	0.644	<0.001
SECEL general	10.4 ± 3.1	0.534	0.913	0.047	9.4 ± 2.7	0.534	0.593	0133
SECEL environmental	24.4 ± 7.7	0.243	0.002		17.2 ± 15.5	0.243	0.488	
SECEL attitudinal	11.8 ± 8.5	0.596	0.235		9 ± 9.5	0.596	0.812	
	TES (n = 13)				NS (n = 3)			
	Mean (±SD)	P-value against			Mean (#SD)	P-value against		
		ES	ELS	NS	wean (15D)	ES	ELS	TES
Age at diagnosis (years)	63.2 ± 7.9	0.886	0.334	0.642	65.3 ± 5.5	0.769	0.242	0.642
Age at SECEL (years)	69.1 ± 9.5	0.669	0.271	0.549	66.3 ± 5	0.903	0.430	0.549
Follow-up time (years)	5.9 ± 4.1	0.175	0.630	0.013	1 ± 0.5	0.122	0.130	0.013
SECEL total	31.4 ± 6.9	0.005	0.644	<0.001	62.1 ± 22.5	0.002	<0.001	<0.001
SECEL general	10.3 ± 2.7	0.913	0.593	0.042	6 ± 2.6	0.047	0.133	0.042
SECEL environmental	13 ± 5.3	0.002	0.488		32 ± 8.2	0.002	<0.001	<0.001
SECEL attitudinal	8.1 ± 3.2	0.235	0.812		19 ± 10.3	0.047	0.015	0.02

TABLE 2: Matched comparison between vocal rehabilitation modalities.

SD = standard deviation; ELS = electronic larynx speech; TES = tracheoesophageal speech; ES = esophageal speech; NS = no speech

Finally, no significant associations were found between the answer to question 35 and any factor (p > 0.05 for every studied variable). Likewise, no significant differences were found regarding tumor location (glottic vs. supraglottic) and SECEL total score (p = 0.235). No significant differences were found between primary (TES1) and secondary (TES2) rehabilitation concerning SECEL total score (p = 0.652).

Other potential predictors of vocal outcomes

A significant inverse correlation was found between follow-up time and SECEL total score (p = 0.013); hence, increased follow-up time was associated with better perceived vocal function. A similarly significant inverse correlation existed between environmental subscores (p = 0.005). The two other subscores did not reveal any significant correlation with follow-up time (general: p = 0.638; attitudinal: p = 0.199).

No association was found between the age of diagnosis and SECEL total score (p = 0.743). Likewise, no associations were found between the age of diagnosis and any of the SECEL subscores (general: p = 0.884; environmental: p = 0.716; attitudinal: p = 0.907). Age at SECEL did not correlate with the SECEL total score (p = 0.531). Similarly, no associations were found between age at SECEL and any of the SECEL subscores (general: p = 0.825; environmental: p = 0.576; attitudinal: p = 0.525).

No significant correlations were found between TNM staging and vocal outcomes measured by SECEL total score (p = 0.151), as displayed in Figure 1. Likewise, no significant differences were observed between

different adjuvant therapy groups regarding vocal outcomes (neither SECEL total nor subscores, p > 0.05 in all matched comparisons from independent t-test). Furthermore, tumor location was not associated with significant differences in the SECEL total score (glottic mean SECEL total score: 37.1 ± 14.1 vs. supraglottic mean SECEL total score: 45.9 ± 18.6 , p = 0.235). Regarding tobacco or alcohol abuse, there was no association between these factors and SECEL outcomes (p > 0.05). The same was observed concerning comorbidities, without any particular comorbidity relating to SECEL outcomes (p > 0.05 for all measured comorbidities).

FIGURE 1: Box plot of mean SECEL total scores among different staging groups.

SECEL = Self-Evaluation of Communication Experiences After Laryngectomy

Multivariate analysis for vocal outcome predictors

This section departs from the above-identified variables correlating significantly with SECEL scores, namely, type of vocal rehabilitation and follow-up time. A linear regression model was calculated to predict SECEL total score based on the vocal rehabilitation subgroup as independent variables (ES or other modality). A significant regression equation was found (F (1,21) = 5.394, p = 0.03), with an \mathbb{R}^2 of 2.204. The fitted model equation was the SECEL total score = 33 + 13.6x (x = 1 if ES or x = 0 if another modality). Using the same method but taking follow-up time as an independent variable resulted in a non-significant model (p = 0.099). Moreover, when both independent variables were accounted for simultaneously in the same regression, the result was a non-significant model (vocal rehabilitation modality: p = 0.74 and follow-up time: p = 0.250). Figure 2 displays the findings related to the time and type of speech rehabilitation.

FIGURE 2: Mean SECEL total scores matched to follow-up time: ES versus other modalities.

SECEL = Self-Evaluation of Communication Experiences After Laryngectomy; ES = esophageal speech

Discussion

Being unable to produce a voice is a major life-altering event that significantly lowers QoL. Our findings suggest that ES is less effective than other rehabilitation methods concerning QoL-related vocal outcomes. This is consistent with the majority of recently reported literature on post-laryngectomy phonation options [9-12]. However, some studies, including the one by Mourkarbel et al., assert that there is no statistically significant difference in outcomes between ES and TEP [13]. In contrast, Salturk et al. reported that patients with ES showed better outcomes between ES and TEP [14]. Chone et al. [15] concluded that primary tracheoesophageal punctures had a higher success rate than secondary ones. However, no discernible differences between primary (TES1) and secondary (TES2) TES rehabilitation were found in our study. Although TES is considered the gold standard and produces better vocal results, it has drawbacks that are not present with ES rehabilitation, including leakage, biofilm formation, infections, and a greater risk of pneumonia [5]. Therefore, many factors, including the patient's opinion, must be taken into account when choosing between the available options [3].

The secondary goal of this study was to investigate the concurrent baseline predictors of vocal outcomes in laryngectomy patients. We found that follow-up time may have a positive impact on vocal function. This may relate to the learning curve on how to produce adequate voice and communication. Longer rehabilitation time and longer voice usage in daily life may help explain these findings. Additionally, QoL for these patients appears to be significantly impacted by rehabilitation [9].

Regarding other potential baseline predictors, no significant correlations were found between SECEL outcomes and various adjuvant therapy groups, tumor locations, risk factors (tobacco or alcohol abuse), or comorbidities. Furthermore, no significant correlations were identified between TNM staging and vocal outcomes.

From the patients' viewpoint, TL may imply mutilation, given that there is an impact on their voice, breathing, swallowing, and even taste and smell [3]. It is a life-changing moment with a considerable impact on QoL. QoL is influenced by one's physical condition, degree of independence, social connections, external circumstances, and personal convictions. A study on the QoL of laryngectomy patients (both partial and total) revealed that the social and emotional functions of the group of patients who underwent TL were most adversely impacted [16]. Additionally, results suggested that all parameters for this group worsened overall [16]. Voice quality is undoubtedly one of the factors that affect the quality of life, but other factors include changes in the body's appearance, communication, mental state, and social interactions after TL [11]. Body appearance in women undergoing TL appears to pose a higher impact than in men [17]. This lowering of QoL is largely modulated by stigmatization, as a large portion of these patients are unable to keep their jobs and occasionally exhibit aggressive behavior toward those who do not comprehend them [17]. Studies have shown that patients with head and neck cancer may exhibit high rates of psychiatric affection. This may be linked to the disease itself or treatment, which makes the assessment of how phonation has an impact on QoL even more crucial [3].

This study has multiple limitations. The study had a small sample size. Only 63 of the 124 patients who underwent surgery during the study period were alive at the time of the current follow-up, which meant that nearly half (49%) of the study sample had passed away. In addition, only about 41% of patients who were alive completed the SECEL questionnaire. In our experience, it is difficult to deal with TL patients who frequently do not want to reveal their frailties. Besides, communicational limitations may also pose a significant challenge in answering the questionnaire. In addition, the assessment of how it affects QoL depends on various factors that were not directly assessed, such as financial stability, degree of independence, social relationships, environmental factors, and personal views [18]. Therefore, further studies with larger sample sizes and wider assessments of QoL domains are required.

This study has some strengths. It is the first research to compare different phonation methods using the SECEL questionnaire. This tool can help healthcare professionals create a rehabilitation plan more targeted to the patient's needs. SECEL is helpful in identifying the psychological impact and QoL in TL patients. Caring, informing, and accompanying are key to any treatment.

Conclusions

Patients who have undergone TL must relearn how to interact with others. TL poses many challenges ranging from alterations in voice production, breathing, and swallowing to emotional and social impingement. The post-TL adaptation is always modulated by the effects of physical appearance on selfesteem and personal views.

Rehabilitation has a significant impact on the QoL of TL patients. SECEL questionnaire can be a helpful tool to assess TL patients' QoL because it measures the psychological effects of vocal functionality on this population. In this study, we found that TES leads to the best outcomes concerning SECEL scores for voice-related QoL and that ES appears to be inferior to other rehabilitation modalities. Importantly, follow-up time correlated positively with QoL vocal outcomes measured by the SECEL questionnaire.

Appendices

1. Are you relixed and comfortable around other people in speaking situations? 2. Would you describe yourself as a low-keyed, calm person? 3. Are you an active, "outgoing", talkative person? 4. Do you and to the person you are speaking to that you had a laryngectomy? 5. Do you think your speech improves with the amount of time you use it? 6. Do you indy having getting people's attention to speak? 8. Do you are difficulty having getting people's attention to speak? 8. Do you have difficulty having getting people's attention to speak? 8. Do you have difficulty having cetting people's attention to speak? 8. Do you have difficulty setting or calling out to people? 9. Do you find that people are unable to understand you? 10. Do you find you have to repeat things a number of times during conversations to be understood? Do you have trouble with speaking: 11. In large groups of people? 12. In small groups of people? 13. With one person? 14. In different tooms of your house (apartment, residence) 15. In loud or noisy places? 16. On the telephone? 17. In the car, bus or while traveling?	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
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14. In different rooms of your house (apartment, residence) 15. In loud or noisy places? 16. On the telephone? 17. In the car, bus or while traveling?	3	2	1	0
15. In loud or noisy places? 16. On the telephone? 17. In the car, bus or while traveling?		2	1	0
16. On the telephone? 17. In the car, bus or while traveling?	3	2	1	0
17. In the car, bus or while traveling?	3	2	1	0
	3	2	1	0
Does your speech cause you to:				
18. Have difficulty when attending parties or social gatherings?	3	2	1	0
19. Use the telephone less often than you would like?	3	2	1	0
20. Feel left out when you are with a group of people?	3	2	1	0
21. Limit your social life or personal life?	3	2	1	0
Does your speech cause you to feel:				
22. Depressed?	3	2	1	0
23. Frustrated when talking to family and friends and they can't understand you?	3	2	1	0
24. Different or peculiar?	3	2	1	0
25. Do you hesitate to meet new people because of your speech?	3	2	1	0
26. Do you get left out of conversations because of your speech?	3	2	1	0
27. Do you avoid speaking with other people because of your speech?	3	2	1	0
28. Do people tend to fill in words or complete sentences for you?	3	2	1	0
29. Do people interrupt you while you are speaking?	3	2	1	0
30. Do people tell you that they can't understand you?	3	2	1	0
31. Do the people you speak with get annoyed with you because of your speech?	3	2	1	0
32. Do people avoid you because of your speech?	3	2	1	0
33. Do people speak to you differently because of your speech?	3	2	1	0
34. Do your family and friends fail to understand what it's like to communicate with this type of speech?	3	2	1	0
35. Do you talk the same amount now as before your laryngectomy?	Yes	More	Less	

FIGURE 3: Original Self-Evaluation of Communication Experiences After Laryngectomy questionnaire (English-language version).

The questionnaire was developed by Blood GW [7].

	Sempre	Quase	Ås	Nunca
		Sempre	Vezes	
1) Sente-se descontraído e confortável em situações de diálogo?	3	2	1	0
2) Descreve-se como uma pessoa discreta e calma?	3	2	1	0
3) Descreve-se como uma pessoa ativa, extrovertida e faladora?	3	2	1	0
4) Assume perante a pessoa com quem fala que fez uma laringectomia?	3	2	1	0
5) A sua fala melhora com mais tempo de uso?	3	2	1	0
6) Vai menos vezes a cafés, a bares, a encontros ou outros eventos por causa da fala?	3	2	1	0
7) Tem dificuldade em captar a atenção dos outros para falar?	3	2	1	0
8) Sente dificuldade a gritar ou a chamar de longe as pessoas?	3	2	1	0
9) Acha que as pessoas não conseguem entendê-lo?	3	2	1	0
 Acha que tem que repetir várias vezes o que diz, durante as conversas, para ser entendido? 	3	2	1	0
Tem problemas em falar:				
11) Num grande grupo de pessoas?	3	2	1	0
12) Num pequeno grupo de pessoas?	3	2	1	0
13) Com uma pessoa?	3	2	1	0
14) De uma divisão da casa para outra?	3	2	1	0
15) Em locais barulhentos ou ruidosos?	3	2	1	0
16) Ao telefone?	3	2	1	0
17) No carro, autocarro ou em viagem?	3	2	1	0
A sua fala faz com que:				
18) Tenha dificuldades em participar em festas ou encontros sociais?	3	2	1	0
19) Fale menos ao telefone do que gostaria?	3	2	1	0
20) Se sinta posto de parte num grupo?	3	2	1	0
21) Tenha limitações na vida privada ou social?	3	2	1	0
A sua fala faz com que se sinta:				
22) Deprimido?	3	2	1	0
23) Frustrado quando a família e amigos não entendem o que diz?	3	2	1	0
24) Diferente ou peculiar?	3	2	1	0
25) Hesita conhecer e falar com novas pessoas por causa da sua fala?	3	2	1	0
26) É posto de parte nas conversas por causa da sua fala?	3	2	1	0
27) Evita falar com as outras pessoas por causa da sua fala?	3	2	1	0
28) As pessoas completem palavras ou frases por si?	3	2	1	0
29) As pessoas interrompem-no enquanto fala?	3	2	1	0
30) As pessoas dizem-lhe que não o entendem?	3	2	1	0
31) As pessoas ficam sem paciência consigo por causa da sua fala?	3	2	1	0
32) As pessoas evitam-no por causa da sua fala?	3	2	1	0
33) As pessoas falam de maneira diferente consigo por causa da sua fala?	3	2	1	0
34) Os familiares e amigos não conseguem compreender como é comunicar com este género de fala?	3	2	1	0
35) Fala agora tanto como antes da sua laringectomia?	Sim	Mais	Ме	nos

FIGURE 4: The translated version of the Self-Evaluation of Communication Experiences After Laryngectomy questionnaire in

European Portuguese.

Originally translated by Antunes S [8].

Additional Information

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. Instituto de Ciências Biomédicas Abel Salazar, Centro Hospitalar Universitário do Porto issued approval 181-DEFI/184-CE. Informed consent was obtained from all patients. The study was approved by the local ethics committee (approval number: 181-DEFI/184-CE), and the study design complies with the Declaration of Helsinki's ethical standards. Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three yeas with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the

submitted work.

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