Study protocol and statistical analysis plan

Phonatory Movement of the Pharyngoesophageal Mucosa in Laryngectomy Patients

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Background

The treatment of advanced laryngeal cancer involves the removal of the entire larynx. After removal of the larynx, the pharyngoesophageal segment (PES) is created by reconstructing the soft tissue of the pharynx and oesophagus, and its vibration creates a substitute voice. High-speed video endoscopy (HSV) is the only method that visualises and measures the vibration of the PES after a laryngectomy. The acoustic characteristics of three forms of rehabilitated voice of laryngectomised individuals (oesophageal voice, tracheoesophageal voice using a voice prosthesis and electrolarynx) have been satisfactorily described, but the interdependence of acoustic and visual representations of the phonatory movement of the PES is still insufficiently studied. In recent years, biomechanical models have been developed to analyse the vibration of the PES, but consistent results have not yet been obtained that would explain whether the parameters from the analysis of the waveform of the PES can be compared with the parameters obtained from the acoustic analysis of the voice of a laryngectomised patient.

Effective rehabilitation focuses on optimising speech and swallowing, which leads to a good integration of the laryngectomised person into society. One step towards achieving this goal is a thorough assessment of their voice and communication experiences, as well as analysing the phonatory movements of the PES using HSV technology. Therefore, the primary aim of this study was to investigate the relationship between the morphological characteristics of the PES and the acoustic parameters of the tracheoesophageal voice (TE) with voice prosthesis, as determined by acoustic analysis and biomechanical model. In addition, the aim was to investigate the impact of loss of voice in terms of psychological and socioeconomic problems in laryngectomy patients using Croatian version of the Self-Evaluation of Communication Experiences after Laryngectomy (SECEL:HR) questionnaire.

Design of a research

The study is designed as a prospective observational study and includes patients who have undergone a total laryngectomy, who have completed oncological treatment and undergone voice rehabilitation, who have had regular follow-up visits to the ENT clinic and who meet the study criteria. A consent form will be signed.

Materials and Methods

A total of 55 participants were included in this study. They had all undergone a total laryngectomy, TE voice with a voice prosthesis rehabilitation and oncological treatment at least six months prior to participation. Exclusion criteria included individuals with acute upper or lower respiratory tract infections, a second primary cancer in the upper aerodigestive tract or lungs, and individuals with neurological or psychiatric disorders.

Each participant underwent a complete otolaryngological examination. The video recordings of the PES were made with a 90° rigid HSV system Wolf 5562 HRES ENDOCAM (frame rate: 4000 fps, resolution: 256×256 pixels). All subjects phonated the vowel “a” at a comfortable pitch and volume. Visual assessment of the HSV recordings was performed including the assessments of the overall quality of the recordings and the assessments of anatomical and morphological features of the PES: amount of saliva, visibility and shape of

the PES, location of visible vibration, presence of a mucosal wave and regularity of the vibration.

Each respondent completed the Croatian version of the Self-Evaluation of Communication Experiences after Laryngectomy (SECEL:HR) questionnaire, specifically designed to address the communication needs of patients who have undergone a laryngectomy. The first part of SECEL:HR examines patient-relevant data, while the second part consists of 35 items designed as questions or statements to explore communication experiences. Patients rate the frequency of these communication difficulties on a Likert scale (0-never, 1-sometimes, 2-often, 3-always). The 35 items are divided into 3 subscales: General (0-15 points), Environment (0-42 points) and Attitude (0-45 points). Item number 35 is a separate question: "Do you talk the same amount now as you did before your laryngectomy?" and is scored with the rating categories "yes"," "more" and "less". The total numerical score ranges from 0 to 102, with a higher score indicating greater difficulty and poorer postoperative adaptation of speech communication.

The acoustic analysis of the TE voice with a voice prosthesis was performed in a quiet room (ambient noise < 50 dB) with a microphone placed 30 cm from the mouth to create optimal conditions for recording and analysis. Three consecutive measurements were taken. The voice recordings were analysed using the acoustic programme lingWAVES (Voice and speech analyser version 2.x software). The following parameters were recorded from the central part of the best recording: fundamental frequency (F0) (Hz), jitter (%), shimmer (%) and the intensity of substitute voice (dB). The value of the maximal phonation time (MPT; ms) was taken as the value of the longest possible relaxed phonation of the vowel “a”.

A multi-mass coupled biomechanical model was developed as a multidimensional time sequence of PES mucosal contractions in the form of the opening width observed for each frame of the video time sequence at different angles.

The biomechanical model of the PES analyses non-stationary pharyngoesophageal vibrations and draws conclusions about the temporal characteristics of tissue stiffness, oscillatory mass, pressure and geometric distributions within the PES. The biomechanical model identifies mathematical dependencies and analyses extracted time signals of the PES opening and contours (i.e. the opening and closing of the vibrating mucosa of the PES). Using the PES waveform, we were able to calculate cycle duration, open and closed phase duration (s), fundamental frequency (Hz), mean shimmer (dB), relative shimmer (%), mean jitter (s) and relative jitter (%).

Statistical analysis

Categorical variables were presented as absolute and relative frequencies. Fisher's exact test was employed to analyse differences in proportions and to compare categorical data between groups. The normality of the distribution of continuous variables was assessed using the Shapiro-Wilk test. Descriptive statistics for numerical data were reported using the median and interquartile range. Comparisons across three or more groups were conducted using the Kruskal-Walli’s test. All reported p-values were two-tailed, with statistical significance set at an alpha level of 0.05. Statistical analyses were performed using MedCalc® Statistical Software version 23.1.1 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2025) and IBM SPSS Statistics version 23.0 (IBM Corp., Armonk, NY, USA, released in 2015).