

# **Study protocol and statistical analysis plan**

Validation and Cross-cultural Adaptation of  
Croatian SECEL Questionnaire

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## **Background**

Total laryngectomy is surgical removal of the entire larynx and it is performed in cases of advanced larynx cancer, resulting in permanent disconnection of the upper and lower airways, loss of natural voice and difficulty swallowing in some cases. There are three methods of restoring voice after this kind of procedure: electrolaryngeal voice, oesophageal voice or tracheoesophageal voice with voice prosthesis. Verbal communication is very important in everyday life; therefore, it is clear that laryngectomized persons experience an increased feeling of insecurity, depression, psychological and social problems that ultimately reduce the quality of life. The few questionnaires designed for measuring the quality of life of patients with head and neck cancers (e.g., Performance Status Scale for Head and Neck, the Head and Neck Survey, EORTC QLQ-C30 and EORTC QLQ-H&N35) are insufficient, because these questionnaires have resulted in a better understanding of the impact of treatment in head and neck oncology and lack sensitive and important questions about voice and communication dysfunction which is an important issue for laryngeal cancer patients.

Self-Evaluation of Communication Experiences after Laryngectomy (SECEL) questionnaire has been developed, with the aim of evaluating rehabilitation needs and the psychosocial care for patients with laryngeal cancer. This short but comprehensive self-report instrument measures the perceived adjustment to communication experiences and is intended to aid in determining counselling needs in patients with laryngeal cancer who are treated with a laryngectomy. The first aim of this study is to evaluate the translation, psychometric properties and cultural adaptation of a Croatian version of the SECEL questionnaire. Secondary aim is to examine relationship between the Croatian version of the SECEL and the Short Form Health Survey (SF-36) and the Voice Handicap Index (VHI) questionnaires and to examine relationship between objective voice measures and Self-Evaluation of Communication Experiences after Laryngectomy (SECEL:HR).

## **Design of a research**

The research will be designed as prospective observational research, and will include patients who have undergone total laryngectomy, who regularly attended follow-up visits in the ENT clinic and fulfilled the study criteria. Informed consent will be signed. The validation process will be formed according to the guidelines of the World Health Organization for the translation and cross-cultural adaptation of the measuring instrument.

## **Materials and Methods**

Patients who have undergone total laryngectomy and completed minimal their 12-month period without disease after surgery and post-operative treatments such as radiotherapy or chemotherapy will be included in this cross-sectional study. Patients who regularly followed up and have preserved their reading skills. Exclusion criteria will be define considering the absence of any factors which could interfere with data collection (e.g., acute respiratory infection of the upper or lower respiratory tract, presence of neurologic or pulmonary diseases, recurrence of cancer, deviation from the research protocol).

At the first visit all patients included in the study will complete the Croatian version of the Voice Handicap Index (VHI), Short Form Health Survey (SF-36) and Self-Evaluation of Communication Experiences after Laryngectomy (SECEL:HR) questionnaire.

SECEL questionnaire consists of two parts. The first part examines the relevant general data on the person filling out the questionnaire, while the second part consists of 35 items questionably or statement-designed to examine communication experiences. Patients estimates the incidence of these communication difficulties on the Likert scale (0-never, 1-sometimes, 2-often, 3-always). 35 items are grouped according to 3 subscales named General (0-15 score range), Environment (0-42 score range) and Attitude (0-45 score range), and item number 35 is a separate question: "Do you talk the same amount now as before your laryngectomy?" and is rated with a "yes," "more," and "less" rating category. The overall numerical score varies from 0 to 102, and the higher score indicates greater difficulties and worse postoperative speech-communication adjustment. The Voice Handicap Index (VHI) questionnaire consist of 30 items organized in three subscales functional, physical and emotional and also scored with Likert scale with overall score from 0 to 120. Higher scores indicate a greater handicap. The Short Form Health Survey (SF-36) is a multi-purpose short-form health survey that consist of 36 questions divided in eight scales and clustered into two groups: physical and mental health. Each item was standardized (range 0-100), with a higher score representing better QoL. The objective assessment will include the MPT (maximal phonation time) measured in seconds as common clinical measure of glottal efficiency, the DDK (diadochokinesis) of the articulation organs of the 3-syllable "pa-ta-ka" in 5 seconds (rated in syll/s), or how quickly subjects can produce a series of rapid sounds which is a measure of speech efficiency. MPT and DDK of articulation organs are simple tests that can be easily performed in everyday clinical practice. In view of different acoustic outcomes of the alaryngeal speech and due to the lack of specific information on the relationship between the subjective impression of the laryngectomised person and voice measure, it is necessary to perform aerodynamic tests and tests of the articulation organs in order to identify and exclude laryngectomised patients with respiratory and articulation disorders.

All patients will fulfil the SECEL:HR questionnaire twice, two weeks after the initial test and that will be considered as a re-test of the SECEL reliability analysis.

## **Statistical analysis**

Absolute and relative frequencies will be used to represent categorical data. The Shapiro–Willk test will be used to assess the normal distribution of continuous variables. In the case of deviation from the normal distribution, continuous data will be described using the median and interquartile range. The variance of the category variables will be tested using the Fisher's exact test. The differences between three groups of patients (oesophageal, tracheoesophageal speech and electrolarynx) will be tested using the Kruskal-Walli's test (post hoc Conover test). The test–retest reliability will be evaluated with a Pearson's correlation test and 2-way mixed-effects model (consistency definition) intraclass correlation coefficients (ICCs). The correlation between continuous variables will be evaluated by Pearson's correlation coefficient ( $r$ ). Reliability measurements determined the internal consistency of the items, subscales and the total scores for the SECEL, SF-36 and VHI, by using the Cronbach

Alpha coefficient. All P values will be two-sided. The level of significance will be set to Alpha = 0.05. The analysis will be conducted using the MedCalc® Statistical Software version 20.100 (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>; 2022) and the IBM SPSS Statistics 23 (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.)