Statistical Analysis Plan (SAP)

Quality of life in patients undergoing tracheostomy

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Abbreviations

OST	Open surgical tracheostomy
PDT	Percutaneus dilatational tracheostomy

1. Introduction

Tracheostomy is a commonly performed procedure and is intended to provide a long-term surgical airway for patients who are dependent on mechanical ventilation. Due to its invasive and physiologically critical nature, tracheostomy can be associated with morbidity and have significant effects on patients' quality of life. The aim of this study is to assess the quality of life of patients undergoing an elective tracheostomy in Intensive Care Units (ICU), revealing late tracheostomy-related complications and conditions for further health improving.

This statistical analysis plan (SAP) will give more detailed descriptions of the endpoints in the study and the corresponding analyses.

2. Study design

This prospective, single-center, observational, case-control study was conducted from May 2019 to March 2020. Persons were recruited from the ENT and Maxillofacial Surgery Department of "Heratsi" №1 University Hospital in Yerevan, Republic of Armenia.

Written informed consent was obtained from all participants after providing written and oral information about the study. The study protocol was approved by the Ethics Committee of Yerevan State Medical University.

The Patient and Observer Scar Assessment Scale (POSAS), which was developed by Draaijers et al., was designed for a subjective evaluation of various types of scar formation and is an appropriate subjective tool for the evaluation of linear scars.

The Dermatology Life Quality Index (DLQI) was developed in 1994 by Finlay and Khan [18] and was designed to measure the impact of skin conditions on quality of life.

One hundred fifty-six persons with post-tracheostomy surgical scars were observed using the POSAS scale. The time period of these persons' treatment was 2013-2018 years. The follow-up range was from 12 to 84 months, with an average time of 39.6 months. All participants provided written informed consent for trial participation. The inclusion criteria were 1) persons undergoing tracheostomy in the ICU of Heratsi University Hospital from January 2013 to December 2018. Long-term mechanical ventilation in intensive care units was the main indication for tracheostomy in participants. The exclusion criteria were 1) persons undergoing emergency tracheostomy, 2) persons with a previous history of neck trauma and scarring, 3) persons with previous radiotherapy, 4) persons with keloid or hypertrophic scar history, and 5) persons with autoimmune diseases.

Of the 156 recruited persons, 76 underwent OST and 80 underwent PDT. All persons were Armenians with a mean age of 54.7 years (range, 16-87 years).

2.1 Statistical analyses

Statistical analyses were performed using SPSS ver. 16.0 (SPSS Inc., Chicago, IL, USA), and *p value*s of <0.05 were considered significant.

Internal consistency was assessed using Cronbach's alpha statistics, which considered values greater than or equal to 0.70 to be acceptable. Interobserver reliability was defined as "the extent of agreement between three observers" and was assessed by computing the intraclass correlation coefficient (ICC) using a two-way mixed model with measures of consistency. An ICC within the range of 0 to 0.20 was considered "slight", 0.21 to 0.40 as "fair", 0.41 to 0.60 as "moderate", 0.61 to 0.80 as "substantial", and 0.81 to 1.0 as "almost perfect".
The internal consistency was acceptable for the observer components of the POSAS, with Cronbach's alpha values of 0.889, and 0.770 respectively.

The interobserver reliability was "almost perfect" for the OST group and "substantial" for the PDT group for the observer component of the POSAS in terms of the total score (the average ICCs were 0.876 and 0.728, respectively). For the individual observer component of the POSAS in the OST group, interobserver reliability was "almost perfect" for vascularity, relief, and surface area (0.913, 0.913, and 0.947, respectively) and “substantial” for pigmentation, thickness, and pliability (0.768, 0.802, and 0.627, respectively). In the PDT group, interobserver reliability was “substantial” for pigmentation, thickness, relief, pliability,y and surface area (0.647, 0.672, 0.779 0.693 and 0.713, respectively), and was “moderate” for vascularity (0.440). On simple linear regression analysis, the patients' overall opinion regarding their own scars was significantly influenced by scar-related itchiness, color, stiffness, thickness, and irregularity (p<0.005).

The total scores for patients’ self-assessment parameters in both groups were also not significantly different. They were 9.51±0.441 in the OST group and 9.49±0.392 in the PDT group. The minimal value of the total scores for each group was 6, and the maximum was 60. Therefore, generally, the total score for both groups could be interpreted as close to normal skin.

However, when comparing the total scores of the patient assessment scale between persons who underwent tracheostomy intubation for less than 15 days with those who were cannulated for more than 15 days, the results were different, similar to the observer assessment scale: 6.76±0.232 for the OST group and 7.08 ±0.396 in persons with less than 15 days of cannulation period and 13.12 ±0.442 and 12.5±0.696, respectively, for persons cannulated for longer than 15 days.

3. Aims and objectives

The aim of this study is to assess the quality of life of patients undergoing an elective tracheostomy in Intensive Care Units (ICU), revealing late tracheostomy-related complications and conditions for further health improving.

4. Outcomes

This section will present the outcomes investigated to answer the study aims and objectives.

4.1 Primary outcomes

1. Airway comfort measured using spirometry at baseline from the fourth month after decannulation
2. Dyspnea measured using the Medical Research Council (MRC) scale at baseline from the fourth month after decannulation
3. Wheezing and whistling while breathing measured using the acoustic value at baseline from the fourth month after decannulation
4. Pain measured using numerical rating scale (NRS) requires the patient to rate their pain on a defined scale from 0–10 where 0 is no pain and 10 is the worst pain imaginable, at baseline from the fourth month after decannulation
5. Scar comfort and scar aesthetic measured using Patient and Observer Scar Assessment Scale (POSAS) at baseline from the fourth month after decannulation
6. Neck mobility restriction measured using the range of back bend neck flexion at baseline from the fourth month after decannulation
7. Voice/speech disorders measured using Individual's Self Assessment of how voice problem affects emotions and self-image and ability to communicate effectively in everyday activities and in social and work settings at baseline from the fourth month after decannulation
8. Sleep disturbance measured using Subjective Assessment Measures by FOSQ-10 at baseline from the fourth month after decannulation
9. Swallowing disorders measured using a simple water swallowing test using standard 150 ml of water. Swallowing process assessed under three categories - swallowing speed (ml/s), swallowing volume (ml/swallow) and swallowing duration (s/swallow) at baseline from the fourth month after decannulation
10. Tracheostomy-related operations measured using anamnesis data: yes/no, if yes which kind of operation
11. Feeling of illness measured using standardized Acceptance of Illness Scale (AIS) at baseline from the fourth month after decannulation

12. Quality of life measured using the Severe Respiratory Insufficiency Questionnaire (SRI) at baseline from the fourth month after decannulation.

4.2 Secondary outcomes

1. Tracheal stenosis assessment
2. Granulation tissue formation assessment
3. Tracheocutaneus fistula presence

Surveys

Health-related quality of life

4.3 Safety outcomes

Adverse events

None

5. Populations and subgroups to be analysed

Persons undergoing tracheostomy in the ICU of Heratsi University Hospital from January 2013 to December 2018. Long-term mechanical ventilation in intensive care units was the main indication for tracheostomy in participants.

Subgroups

All including population were divided into two groups, dependence on metod of tracheostomy:
Group 1 –open surgical tracheostomy
Group II –punction dilatational tracheostomy

6. Analyses

All outcomes will be presented using descriptive statistics; normally distributed data by the mean and standard deviation (SD) and skewed distributions by the median and interquartile range (IQR). All statistical analyses were performed using SPSS ver. 16.0 (SPSS Inc., Chicago, IL, USA), and *p value*s of <0.05 were considered significant.

6.1 Primary outcomes

The primary analysis will compare open surgical tracheostomy group with percutaneus dilatational tracheostomy group on their mean parameters. The estimated difference in mean change from baseline four months after decanulation and the corresponding 95 % confidence interval (CI) will be presented.

6.2 Secondary outcomes

Neck CT scan will be analysed using logistic regression, the odds ratio (OR) including 95 % CI will be presented.In addition, correlation(s) between change in copeptin and change in cardiometabolic risk factors, other blood laboratory parameters and urine laboratory parameters may be calculated.

7. Missing data

The limitations of this study include a small sample size (156 persosns). The lack of hematological parameters could directly or indirectly affect the wound healing process. Fixing a 15-day period for scar evaluation is arbitrary and not scientifically based.

SIGNATURE PAGE

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