Effects of Endotracheal Tube Cuff Pressure Control on Microaspiration of Gastric Contents

Trial registration: ClinicalTrials.gov Identifier, Number NCT04061083. Registered in 2019.

Study Protocol

Aim

The aim of this randomized controlled trial was to determine the effect of three different ETT cuff pressure controls used in ICU patients receiving mechanical ventilator support using an ETT on preventing microaspiration of gastric content and on VAP development within 48 hours after intubation.

Study design

This is a single-blind randomized controlled trial that compares finger palpation of the pilot balloon, intermittent and continuous ETT cuff pressure used to prevent microaspiration of gastric content for ICU patients.

Study population

The population of the study consists of the patients hospitalized in the Internal Medicine, Neurology, Neurosurgery, General Surgery, Anesthesia, Isolation and Diseases ICU of University Hospital. Inclusion criteria for the sampling of the study are as follows: being 18 years and above, voluntariness of the patients or their relatives, and having a need of mechanical ventilator support with an ETT for 48 hours. The criteria of exclusion from the sample are as follows: having contraindication of semi-sitting position, having a contraindication to enteral nutrition, patients who have spent more than 48 hours on a mechanical ventilator at the initial assessment, having tracheostomy, gastroesophageal reflux disease (GERD), aspiration pneumonia or any suspicion of it, and nasal ETT intubation. Power analysis was done to determine the number of patients to be distributed to Group 1, Group 2, and the control groups. The power analysis was done using GPower 1.3.9.2 software. Thus, the significance level was $\alpha=0.05$ (%5), the effect size was $d=0.5$, and the number of patients in each group was 51 for the power at $1-\beta=0.80$. Missing, bad or lost data (in case patients were exitus) were considered and the number of patients was designed to be 56 for each group

Intervention and Assessment

The appropriateness of patients who have received mechanical ventilator support using an ETT in the ICUs will be evaluated based on the inclusion and exclusion criteria. The patients who have been included in the study will be evaluated in terms of age, gender, height, weight, body mass index, medical diagnosis, chronic diseases, consciousness, presence of nasogastric (NG) tube, position, the reason for intubation, type of nutrition, drugs used (antibiotics, stress ulcer prophylaxis and sedative agents), Ramsay Sedation Score (RSS), transport and transfusion status, ventilator, respiration and hemodynamic values.

The cuff pressure of the patients in all groups will be controlled every eight hours. Smart cuff manager will be attached to the patients in study group 2. Samples will be taken from the

patients through open aspiration. The first deep tracheal secretion sample to be used to determine pepsin I level will be taken four hours after intubation. A sampling of the tracheal secretion samples to be used in the determination of pepsin II level will be initiated from the 5th hour after intubation and collected by the 24th hour of the intubation. A sampling of the tracheal secretion samples to be used in determination of pepsin III levels will be initiated from the 25th hour after intubation and collected by the 48th hour of the intubation or the patient is discharged or exitus.

Statistical analysis

The data will be analyzed using Statistical Package for the Social Sciences (SPSS) for Windows 21.0 (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) Software. They will be divided into groups by ensuring homogeneity according to gender. Patients' socio-demographic and clinical attributes, frequencies, percentage distribution, mean, and standard deviation will be provided.

Kolmogorov–Smirnov Test will be used to check the appropriateness of data to normal distribution. Independent two-sample t-test, one-way analysis of variance will be used for the relationships between the variables that fit the normal distribution, and the Mann Whitney U test will be used for the variables that do not fit the normal distribution. Pearson Chi-square significance test and Fisher Exact will be applied in the analysis of categorical data. All p values lower than 0.05 will be taken as significant in all results ($p<0.05$).