VIE SCOPE VERSUS MACINTOSH LARYNGOSCOPE IN EXPECTED EASY AIRWAYS: A RANDOMIZED CONTROLLED TRIAL

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STUDY PROTOCOL

Ethics

The study protocol was approved by the Scientific Committee (approval number: 141/09.07.2023). Since the strategies employed in both study groups are considered components of standard care, and the study involved patients undergoing elective and nonelective surgery or being treated in the emergency settings, the committee waived the necessity for written informed consent. The study was registered on ClinicalTrials.gov (NCT06149338) on 04.01.2024 and was in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

Study design

A prospective, randomized, single-blind, superiority, clinical trial has been conducted since 26.01.2024. The intubations were performed by the same resident of anesthesiology, who had already completed successfully at least 50 intubation attempts with each one of the two examined laryngoscopes, before the beginning of the patient enrollment into the study, in order to eliminate any impact from a different learning curve of any laryngoscope and to gain competency, although concurrently there are limited data for Vie Scope, fostering its short learning curve, despite the mentioned necessity of previous practice with straight blade devices. Every intervention was made under the supervision of an experienced Anesthesiologist consultant. In case of certified or possible COVID-19 infection of the patient, the airway operator was instructed to use the required PPE.

The current study included patients of both sexes. Apart from the gender, the age (≥ 18 years old) and the Body Mass Index (B.M.I.: 18.5 – 30 kg/m2) were considered as inclusion criteria of this study. A positive or negative rapid test for COVID-19 or possible contamination of the patient was documented as well, without affecting the patient's eligibility for the study inclusion. Also, every patient underwent an adequate airway assessment, including airway history and physical examination, preoperatively or in the emergency settings, when feasible, to distinguish the patients with anticipated easy airways management. The chin protrusion (upper lip bite test), the thyromental distance and the Mallampati score were mostly evaluated, due to their efficacy in detecting an anticipated difficult airway. Consequently, the higher a patient could bite the upper lip with the lower incisors, the thyromental distance > 3 ordinary fingerbreadths and the Mallampati scores 1, 2 were positive predictive factors of an expected easy airway. Despite the high sensitivity of the upper lip bite test, the low sensitivities of other tests, such as the Mallampati score, and the confined airway assessment in emergency settings or patient cooperation necessitated the adoption of the Cormack - Lehane classification as a recruitment criterion of this study. According to this scale, the glottis visualization grades 1, 2a, 2b, after direct laryngoscopy, were compatible with easy endotracheal intubation, making these patients eligible participants in the present study. In contrast, patients with age under 18 years old, with BMI under 18.5 kg/m2 and over 30 kg/m2, inability to bring mandibular incisors anterior to maxillary incisors, thyromental distance < 3 ordinary

fingerbreadths, Mallampati scores 3, 4 and Cormack - Lehane classification grades 3 and 4 were excluded from this clinical trial.

The randomization of the patients was generated immediately before the anesthesia induction, after the investigator Anesthesiologist trainee was assigned to the patient, either in the operating room or in the emergency settings, using sealed opaque envelopes, that contained demographic data and medical background of the participants in pseudonymized form. The allocation ratio was 1:1 to either Vie Scope or Macintosh laryngoscope. The patients remained blinded to the intervention procedure, while this was not feasible for the airway operator, due to the study's nature.

Patients, being randomized into the intervention group, underwent direct laryngoscopy and subsequent intubation attempt with the Macintosh laryngoscope (HEINE Optotechnik GmbH & Co. KG, Gilching, Germany), (Figure 1). The size of the blade (3 or 4) was chosen at the discretion of the Anesthesiologist trainee. The airway operator implemented the midline approach for the displacement of the tongue from the area of view and placed the tip of the Macintosh blade in the epiglottic vallecula, so as to achieve the indirect elevation of the epiglottis and exposure of the vocal cords, followed by the endotracheal intubation.

Patients, being randomized into the control group, received direct laryngoscopy and ensued intubation attempt with the Vie Scope® (Adroit Surgical LLC, Oklahoma City, OK, USA) (Figure 2). The introduction of the Vie Scope into the patient's mouth could be performed by either of the mouth corners, according to the patient's anatomical characteristics. The gentle back tilt of the head was followed by the application of the paraglossal or retromolar approach, for aligning the oral, pharyngeal and laryngeal axis. After its forwarding, until the glottis was visualized, by elevating directly the epiglottis, a 15 Fr bougie with colorful bands, the VOIR Bougie (Adroit Surgical LLC, Oklahoma City, USA), was introduced appropriately endotracheally, through the cylindrical lumen of the intubation channel of the Vie Scope. The careful removal of the Vie Scope was followed by the endotracheal tube (ETT)'s railroading over the bougie. As soon as the ETT was positioned, the bougie was removed too.

After the tube's cuff was inflated, until there was no air leak from the trachea, the correct ETT's placement was verified in both groups by the patient's ventilation. The choice of the size and the type of the ETT was at the discretion of the airway operator. In addition, the laryngeal view was estimated, under direct laryngoscopy with each laryngoscope, according to the Cormack - Lehane grading system. The airway operator was prompted to perform any external laryngeal manipulation, such as the backward, upward, rightward pressure (BURP), or to use any assistant equipment, like bougies, stylets, forceps, lubricant gel or spray, for optimizing the laryngeal view and facilitating the intubation process. The supervisor consultant would be involved in case of two failed intubation attempts by the trainee, or whenever the situation required the intervention of an experienced Anesthesiologist.

Outcome measures

The primary outcome measures were the first attempt intubation success rate and the required mean intubation time. The intubation time was defined as the time interval from the insertion of the laryngoscope into the patient's mouth, until the inflation of the ETT's cuff of each patient.

Contrarywise, the overall intubation success rate and the glottis visualization, based on the Cormack - Lehane classification, were regarded as the secondary outcomes.

STATISTICAL ANALYSIS

The statistical analysis was performed with SAS version 9.4 (SAS Institute, Cary, NC, USA) along with Microsoft Excel 2007 for data collection. For the descriptive statistics, quantitative variables were presented as means and standard deviations (SD) as well as using medians and quartiles 1 and 3 (Q1 and Q3 respectively). Qualitative variables were presented using the relative frequencies and the relevant percentages. For the inferential part of the analysis, the Kruskal – Wallis test was applied for the analysis of numerical data, because they did not follow a normal distribution, according to the Kolmogorov - Smirnov test, while the x2 test and, if required, the Fisher's exact test were performed for the categorical data. All tests were two-sided, the confidence intervals (CIs) were determined as 0.95 and thus significance cut-off level was for $p < 0.05$.