Comparison of training effect for tracheal intubation following training with McGrath video laryngoscope as direct laryngoscope versus training with McGrath video laryngoscope as video laryngoscope

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Brief Title: Learning Direct Laryngoscopy Using a McGrath Video Laryngoscope as Direct Versus Indirect Laryngoscope

Official Title: Comparison of training effect for tracheal intubation following training with McGrath video laryngoscope as direct laryngoscope versus training with McGrath video laryngoscope as video laryngoscope

Study Type: Intervention

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Objective

Tracheal intubation using a direct laryngoscope is an essential skill but is difficult to teach. Video laryngoscopes enhance the teaching ability for direct laryngoscopy and can be used with direct or indirect methods. We compared the effect on the skill improvement of Macintosh direct laryngoscopy following training with a McGrath video laryngoscope as a direct versus an indirect laryngoscope.

Design

prospective, cluster-randomized controlled trial

Methods

This study was a single-center, prospective, cluster-randomized controlled trial with two parallel groups that was carried out at Ajou University Hospital from March 2018 to July 2018. The trial was approved by the institutional review board of Ajou University Hospital (AJIRB-SBR-OBS-17-507, Feb 20, 2018) and was registered at ClinicalTrials.gov (NCT03471975).

Eligible participants were medical students who are novices at direct laryngoscopy. All of the participants agreed to have their performances evaluated and anonymously used for scientific and educational purposes.

Rotation groups (including 11 groups that each included 3–4 students) were randomly divided into one of two groups in ratio of 1:1 by the cluster randomization method, using a computer-generated random number table. The allocation process was conducted by a colleague who remained independent of this research project. The randomization result was concealed within serially numbered opaque envelopes, which were opened prior to teaching and lecture. One group was trained using direct laryngoscopy with a video laryngoscope (direct group), and the other group was trained using indirect (video) laryngoscopy with a video laryngoscope (indirect group). Cluster randomization was adopted to eliminate possible contamination between students due to individual randomization within each rotation. The blinding of participants and instructors was not possible due to the nature of the interventions

The study took place on the first day of the rotation. First, an initial evaluation of the students' intubation skills was performed on a standardized manikin (Laerdal® Airway Management Trainer; Laerdal, Stavanger, Norway) using a Macintosh laryngoscope (Diamond range; Penlon, Abingdon, UK; Macintosh blade size 3). The instructor evaluated each attempt and gave no feedback. Then, a lecture on airway anatomy, evaluation, and Cormack-Lehane classification (degree of glottis exposure), as well as airway management, was given, followed by tutorial videos on the technique of direct laryngoscopy and introduction of the McGrath™ MAC video laryngoscope

(Medtronic, Minneapolis, MN, USA). Following the lecture, a teaching sequence with the McGrath™ MAC video laryngoscope was conducted. All participants performed five intubations in the manikin using the McGrath™ MAC video laryngoscope (blade size 3) with the instructor's direct feedback. The direct group intubated using the video laryngoscope as a direct laryngoscope, where only the instructor could observe the video screen and give feedback. The indirect group used the video laryngoscope as an indirect laryngoscope, so that they shared the video view with the instructor and received feedback.

Then, a final evaluation was performed in which the students performed tracheal intubation using the Macintosh direct laryngoscope in the same manikin in the following scenarios: 1) normal airway in the supine position and 2) cervical immobilization with a semi-rigid foam neck collar (Philadelphia cervical collar; A-Mi Global, Busan, South Korea). Each student performed the intubation twice for each scenario, and the instructor evaluated each attempt. For all intubation attempts, a standard beveled Portex® tracheal tube (Smiths Medical, Hythe, UK; 7.0 mm internal diameter, 9.6 mm outer diameter) was used with a stylet inserted in the tube. The tube was bent into a "hockey-stick" curvature. The outcome assessors did not involve in training and were kept blinded to the allocation.

The primary endpoint was the intubation time, defined as the time taken from insertion of the blade between the teeth until the cuff of the tube was inflated. Unilateral bronchial intubation was considered successful for the purpose of this study. A failed intubation was defined as when it was not completed within 120 seconds or it resulted in an esophageal intubation. Additional data obtained included the rate of successful tracheal intubation, dental trauma, and degree of difficulty. Dental trauma was counted based on the number of audible teeth clicks (0, 1, and 2) in the Laerdal airway trainer. After the students completed the attempts, they were asked to score the degree of difficulty using each device with a 10-point numeric rating scale (NRS; 0 = easy, 10 = difficult).

Statistical Analysis Plan

All statistical analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA).

Data are presented as the mean and SD when normally distributed, as the median and interquartile range when non-normally distributed, and percentage when appropriate.

We used the linear mixed effects model to analyze intubation times and the degree of difficulty.

We also applied the generalized linear mixed model with binomial distribution and generalized estimating equations methods to analyze the intubation success rate.

As fixed effects, we included baseline intubation time, age, sex, group, manikin, time, and time by group interactions.

As random effects, we used a random intercept and slope for intubation time after education and a random intercept only for the degree of difficulty.

The variance-covariance structures were chosen with the smallest Akaike Information Criterion criteria. In regard to the selection of working correlation matrix in the generalized estimating equations model, Quasi-likelihood under the Independence model Criterion was used to assess the goodness-of-fit. We also specified and partitioned different variance-covariance structures for each level of manikin. For comparing times before training with those after training, we used the paired t-test, Mann-Whitney U test, or McNemar's test, as appropriate. A p-value < 0.05 was considered statistically significant.