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Original Contribution

Comparison of the Macintosh laryngoscope and blind intubation via the iGEL for Intubation With C-spine immobilization: A Randomized, crossover, manikin trial

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ABSTRACT

Introduction: Endotracheal intubation (ETI) using a Macintosh laryngoscope (MAC) requires the head to be positioned in a modified Jackson position, slightly reclined and elevated. Intubation of trauma patients with an injured neck or spine is therefore difficult, since the neck usually cannot be turned or is already immobilized in order to prevent further injury. The iGEL supraglottic airway seems optimal for such conditions due to its blind insertion without the need of a modified Jackson position.
Methods: Prospective, randomized, crossover study in 46 paramedics. Participants performing standard intubation and blind intubation via iGEL supraglottic airway device in three airway scenarios: Scenario A – normal airway; Scenario B - manual inline cervical immobilization, performed by an independent instructor; scenario C: cervical immobilization using a standard Patriot cervical extraction collar.
Results: In Scenario A, nearly all participants performed ETI successfully both with MAC and iGEL (100% vs. 95.7%). The time to intubation (TTI) using the MAC and iGEL amounted to 19 [IQR, 18–21]s vs. 12 [IQR, 11–13]s ($P < 0.001$). Head extension angle as well as tooth compression were significantly better with the iGEL compared to the MAC ($P < 0.001$). In scenario B and C, the results with the iGEL were significantly better than with MAC for all analyzed variables (TTI, success of first intubation attempt, head extension angle, tooth compression and VAS scores).
Conclusion: We showed that blind intubation with the iGEL supraglottic airway was superior to ETI performed by paramedics in a simulated cervical immobilization scenario in a manikin in terms of success rate, time to definite tube placement, head extension angle, tooth compression, and rating.

1. Introduction

Securing an airway is pivotal in an emergency situation, with endotracheal intubation being the gold standard. Endotracheal intubation (ETI) with a standard endotracheal tube (ETT) using a Macintosh laryngoscope (MAC) usually requires the head to be positioned in a modified Jackson position ("sniffing"), slightly reclined and elevated. In this position, the axis of pharynx, larynx, and trachea nearly align, thereby facilitating the entry of the ETT through the glottis into the trachea. Intubation of trauma patients with an injured neck or spine is therefore difficult, since the neck usually cannot be turned or is already immobilized in order to prevent further injury [1,2]. Conventional ETI of trauma patients with cervical injuries always poses the risk of cervical dislocation, prolapse, or nerve damage.

In the past decades, several devices have been developed that can be inserted blindly without the use of a laryngoscope and therefore the need of putting the head in the modified Jackson position. The Combitube was the first widely used supraglottic airway device [3,4]. Recently, more devices of that kind have been developed, most of them can be inserted blindly and usually enter the esophagus [5,6]. The major advantages of these devices are that they can be inserted by non-airway specialists with relatively little formal training [7], that sufficient ventilation and oxygenation is feasible and safe, and that the rate of complications is comparable to ETT [8]. The ERC and AHA guidelines recommend supraglottic airway control in circumstances where ETI is not possible or not within the competency of the individuals managing the patient's airway [9,10].

The iGEL (Fig. 1) is a supraglottic airway device that has been developed in 2007 and is used in anesthesia and resuscitation across the globe [11-13]. Its biggest difference to similar devices is that it uses a soft, gel-like, non-inflatable cuff, designed to provide an anatomical impression fit over the laryngeal inlet. This design prevents compression and displacement trauma as seen in cuff-based devices and can be

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Fig. 1. i-GEL supraglottic airway device.

placed significantly faster than other supraglottic airway devices [14]. Due to its blind insertion, the iGEL seems optimal for securing an airway in patients with neck or spine trauma. Other advantages comprise minimizing compression of the mucosa or non-impaired blood flow due to lack of cuff balloons. The iGEL can be used safely in patients undergoing lumbar surgery even in prone position [15]. However, literature on the use in trauma patients is scarce, with the iGEL not having been evaluated with this regard.

The aim of this study was therefore to compare the success rate, the time to definite tube placement, head extension angle, tooth compression, and rating of ETI using the Macintosh laryngoscope and blind intubation using the iGEL supraglottic airway performed by paramedics during cervical immobilization in a manikin.

2. Methods

This was a prospective, randomized, crossover study. The study was approved by Institutional Review Board of the Polish Society of Disaster Medicine (Approval: IRB N16.08.2016). Following written informed consent, 46 paramedics with no prior training in intubation using supraglottic airway devices and with at least one year experience in emergency medicine were recruited. The study was conducted in August 2016.

2.1. Study scenarios

Each participant performed intubation on an airway assessment training manikin (BT-CSIE; BT Inc., Republic of Korea), placed on a trauma stretcher (M-1® Roll-in System - Ambulance Cots by Stryker). Three airway scenarios were randomly cycled:

1) scenario A: normal airway (without cervical immobilization);
2) scenario B: manual inline cervical immobilization, performed by an independent instructor;
3) scenario C: cervical immobilization using a standard Patriot cervical extraction collar (Össur Americas, Foothill Ranch, CA, USA), applied to the manikin's neck by an independent instructor.

ETI was performed using a standard Macintosh laryngoscope with blade #3 (MAC; Mercury Medical, Clearwater, FL, USA), and an iGEL supraglottic airway device, size 4 (iGEL; Intersurgical Ltd., Berkshire, UK, Fig. 1). A standard 7.5 cuffed endotracheal tube lubricated with silicon was used. For intubation with MAC, also tubes used were fashioned with a hockey-stick shaped stylette and prepared by an experienced senior researcher in airway management. If necessary, study participants were allowed to adjust the stylette by their own needs.

2.2. Study conduct

Prior the study, all participants completed a 30-minute training session, which included an introduction to the anatomy and physiology of the airway and techniques of intubation using different supraglottic airway devices. After the training session, a computerized software [www.randomizer.org] was used to randomly assign the volunteers to 6 groups. The first group conducted intubation using MAC in scenario A; the second group using MAC in scenario B; the third group, using MAC in scenario C; the fourth group, using iGEL in scenario A; the fifth group, using iGEL in scenario B; and the sixth group using iGEL in scenario C. After completing the run, participants had a 10-minute break before attempting intubation using the next method. Participants were not allowed to watch each other during any of the intubation attempts to avoid learning effects throughout the procedure. Participants had a maximum of one attempt in each condition.

2.3. Measurements

The primary outcome was time to definite intubation (TTI), defined as the time point from first contact with the device until first successful ventilation of the lungs. Additionally, in case of blind intubation, the time was also recorded from first contact with iGEL device until successful placement of the device. The time was recorded using a stopwatch. If the tube was not placed correctly or the lungs were not inflated correctly, the attempt was defined as a failure. Moreover we measured head extension angle and force on incisors (N) by indicators on the manikin. After each attempt, the participants were asked to assess the subjective opinions about the difficulty of the procedure on a visual analogue scale (VAS) with the score from 1 (extremely easy) to 10 (extremely difficult).

2.4. Power calculation

Based on pilot data, the following assumptions were made to calculate the number of participants to be included: we used an alpha risk of 0.05, and a beta risk of 0.2 for calculation of sample size. The success rate of first ETI attempt in manual in-line stabilization in pilot data amounted to 86.5% vs. 95.5% in the MAC and iGEL, respectively. Using the *t*-test, paired, two-sided, at least 35 participants were required and randomized to the respective groups with a 1:1 ratio.

2.5. Statistical analysis

All statistical analyses were performed with the use of the Statistica 12 EN for Windows software (StatSoft, Inc.; Tulsa, OK, USA). Data were presented as median and interquartile range (IQR); mean and standard deviation ($\pm$SD); or number and percent (%). Normal distribution was confirmed by the Kolmogorov-Smirnov test. T-test for paired observations was applied for data with normal distribution, and the Wilcoxon test for paired observations in the case of data with non-normal distribution. In order to compare TTI the Wilcoxon test for paired observations was used. The McNemar test was applied to evaluate differences in the success of intubation, and the Stuart-Maxwell test allowed to compare the degree of pressure distribution, head extension angel, and the VAS score. All statistical tests were two-sided. The results were considered statistically significant at $P < 0.05$.

3. Results

A total of 46 paramedics (20 female, 43.5%) participated in this study. All subjects worked in teams of emergency medical services. Mean age was 31.5 $\pm$ 6.5 years, and mean work time experience was 5.4 $\pm$ 3.2 years.

3.1. Scenario A: normal airway

Nearly all participants performed intubation successfully both with MAC and iGEL (100% vs. 95.7%, respectively; Table 1). The TTI using the MAC and iGEL varied and amounted to 19 [IQR; 18–21]s vs. 12