The Journal of Emergency Medicine, Vol. ■, No. ■, pp. 1–7, 2017
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0736-4679/$ - see front matter

http://dx.doi.org/10.1016/j.jemermed.2017.06.041

ELSEVIER

Brief Report

EFFECT OF CRICOID PRESSURE ON THE INSERTION EFFICACY OF SIX SUPRAGLOTTIC DEVICES: A CROSSOVER RANDOMIZED SIMULATION TRIAL

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□ **Abstract—Background: No study has ever compared the efficacy of various types of supraglottic devices (SGDs) for securing the airway under cricoid pressure. Objective: This study aimed to evaluate the efficacy of six SGDs, LMA-ProSeal (ProSeal), LMA-Classic (Classic), Laryngeal Tube (LT), LMA-Supreme (Supreme), air-Q (air-Q), and i-gel (i-gel), in airway management under cricoid pressure using a manikin. Methods: Fifteen novice doctors and 16 experienced doctors used the six SGDs under cricoid or sham pressure on an adult manikin. Insertion time, successful ventilation rate, and subjective insertion difficulty on a visual analogue scale (VAS) were measured. Results: Both novice and experienced doctors had a significantly lower ventilation success rate under cricoid pressure than under sham pressure when using the ProSeal, Classic, and LT, but not when using the other three SGDs. Novice doctors required a significantly longer insertion time under cricoid pressure than under sham pressure with all SGDs. Experienced doctors required a significantly longer insertion time under cricoid pressure than with sham pressure when using the ProSeal, Classic, and LT, but not when using the other three SGDs. Subjective insertion difficulty on VAS was significantly higher under cricoid pressure than under sham pressure with all six SGDs. Conclusion: Ventilation success rate under cricoid pressure was significantly lower than under sham pressure when using the ProSeal, Classic, and LT, but not when using the other three SGDs in both novice and experienced doctors.** **© 2017 Elsevier Inc. All rights reserved.**

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□ **Keywords—cricoid pressure; experienced doctor; manikin; novice doctor; supraglottic devices**

INTRODUCTION

Securing the airway during cardiopulmonary resuscitation (CPR) is technically challenging, and success is influenced by the condition of the patient as well as rescuer skill. The American Heart Association 2015 guideline recommends the use of supraglottic devices (SGDs), such as the laryngeal mask airway (LMA), as an acceptable alternative to tracheal intubation during cardiopulmonary resuscitation (1). The guideline suggests that SGDs have advantages over ordinary tracheal intubation for airway management in emergent situations (2).

Cricoid pressure is a technique used to occlude the esophagus by compressing it between the cricoid cartilage and cervical vertebrae, and its use by well-trained rescuers is suggested by the American Heart Association 2010 guideline (3). Cricoid pressure physically compresses the pharyngeal structure, and technique inevitably affects airway device insertion (4). Cricoid pressure has been reported to inhibit the insertion efficacy of some SGDs (4–6). However, no study has ever compared the efficacy of various types of SGDs for securing the airway under cricoid pressure (1).

We hypothesized that some SGDs would demonstrate better insertion efficacy than others under cricoid pressure. However, because a comprehensive evaluation in

RECEIVED: 18 January 2017; FINAL SUBMISSION RECEIVED: 3 May 2017;
ACCEPTED: 29 June 2017

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clinical settings is unethical and complex, we performed these evaluations using simulations. To this end, we compared the performance of six SGDs: air-Q (Cookgas LLC, Mercury Medical, Clearwater, FL), i-gel (InterSurgical, Liverpool, NY), Laryngeal Tube (LT; Smiths Medical, Minneapolis, MN), LMA-Classic, LMA-ProSeal, and LMA-Supreme (Classic, ProSeal, and Supreme; Laryngeal Mask Company, Prodol Meditec, Vizcaya, Spain), with the primary endpoint of insertion efficacy under cricoid or sham pressure, and the secondary endpoint of subjective insertion difficulty under both conditions (5–10).

MATERIALS AND METHODS

This study was approved by the Institutional Review Board of Osaka Medical College, and written informed consent was obtained from each participant. Novice doctors and experienced anesthesiologists were recruited for an evaluation by clinical experience (11). Between December 2015 and March 2016, 15 novice doctors who attended an anesthesiology training module at Osaka Medical College were recruited. Novice doctors performed trials after completing 1 month of anesthesia training. Sixteen experienced anesthesiologists with >2 years of clinical experience (mean 6.9 ± 2.9 years) were recruited from an anesthesiology training simulation course, which was held on December 19 and 20, 2015, and July 3, 2016. Participants completed a questionnaire regarding their previous clinical experience with six SGDs for airway management during general anesthesia.

The Airway Trainer (Laerdal, Sentrum, Stavanger, Norway) manikin was used for SGD insertion. A size 4.5 air-Q and size 4 ProSeal, Classic, Supreme, i-gel, and air-Q devices were used (12). The necessary equipment for each simulation was placed in a box next to the manikin. Participants were given 15 min to practice insertion with each of the six SGDs before trials. They were then instructed to insert the SGDs by placing them firmly against the hard palate of the manikin.

Cricoid pressure was applied at a standardized force of 30 Newton, which sufficiently prevents regurgitation into the pharynx, even in patients with a full stomach undergoing caesarean section (13). An independent anesthesiologist was trained to apply the force by practicing on a weighing scale with a top board, within an error of 5%. Sham pressure was applied by placing a finger on the cricoid cartilage without exerting force. While applying cricoid or sham pressure, the anesthesiologist also supported the patient's neck by placing the free hand under the neck, preventing flexion of the head (bimanual method) (13). Both the simulator's neck and the assistant's hands were covered by an opaque sheet to blind the participants.

Participants inserted each of the six SGDs, inflated the cuff with 20 mL (ProSeal, Classic, and Supreme) or 60 mL of air (LT), connected the device to a bag valve mask, and attempted to ventilate the manikin's lungs. Air volume in the cuff was determined based on the results of our preliminary study. The SGDs and an injector filled with a fixed volume of air were connected before measurements. Air was not administered during the air-Q trial based on the manufacturer's instructions. Insertion time from the start to the end point was recorded; the start was defined as when the participant picked up the SGD, and the end point as when manual ventilation was performed after insertion, regardless of success or failure of ventilation. After insertion, participants were told to perform ventilation with a 2-L bag valve mask (Laerdal Silicone Resuscitator, Sentrum). Ventilation was considered successful when the manikin's chest visibly rose. The same independent investigator evaluated successful ventilation and insertion time with stopwatch.

At the end of insertion, participants rated the difficulty of insertion on a visual analog scale (VAS) from 0 mm (extremely easy) to 100 mm (extremely difficult) (14).

This study adopted a randomized crossover design to minimize learning effects. Each participant inserted all six SGDs under both sham or cricoid pressure conditions (12 trials). For crossover design development, a random number list was used for the randomization process.

Statistical Analysis

Results obtained from each trial were compared by two-way repeated measures analysis of variance for insertion time and the VAS. Fisher's exact test was used to compare rates of successful ventilation with sham or cricoid pressure. Data are presented as mean ± standard deviation (SD). $p < 0.05$ was considered statistically significant.

Sample Size Calculation

We performed a preliminary study in a crossover design with experienced anesthesiologists with >2 years of clinical experience. We evaluated the successful ventilation by visible chest rise. The results showed that the ventilation success rate under sham pressure is 100% and that under cricoid pressure is about 60% with the ProSeal. Using a type I error of 0.05 and type II error of 0.2, we estimated that 12 participants would be required for effect evaluation.

RESULTS

The average number of times of clinical SGD usage among novice doctors was 2.2 ± 1.3 times for the

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