J Anesth
DOI 10.1007/s00540-015-2050-8

ORIGINAL ARTICLE

Evaluation of the efficacy of six supraglottic devices for airway management in dark conditions: a crossover randomized simulation trial

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Received: 29 May 2015 / Accepted: 7 July 2015

Abstract
Purpose During out-of-hospital cardiopulmonary resuscitation, several factors can render tracheal intubation more difficult, such as when rescuers must secure the airway in complete darkness or with limited illumination. The purpose of this study was to evaluate the efficacy of six supraglottic devices (SGDs), ProSeal® (ProSeal), Classic® (Classic), Supreme® (Supreme), Laryngeal Tube® (LT), air-Q® (air-Q), and i-gel® (i-gel), for airway management under light and dark conditions using a manikin.
Methods Seventeen novice doctors and 15 experienced doctors performed insertion of six SGDs under light and dark conditions using 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 in the dark than in the light when ProSeal and Classic were used, but not with the other four SGDs. Novice doctors required a significantly longer insertion time in the dark than in the light with all SGDs. Experienced doctors required a significantly longer insertion time in the dark than in the light with ProSeal or Classic, but not with the other four SGDs. VAS was significantly higher for both novice and experienced doctors when ProSeal and Classic were used, as compared with the other four SGDs in the dark.
Conclusions Compared to ProSeal and Classic, Supreme, i-gel, LT, and air-Q are more effective for airway management in the dark. Our findings suggest that anatomically shaped SGDs may help novice doctors secure the airway under dark conditions.

Keywords Supraglottic devices · Dark · Manikin · Novice doctor · Experienced doctor

Introduction

Securing the airway during cardiopulmonary resuscitation (CPR) is technically challenging, and success is influenced by the situation and position of the patient as well as rescuer skills. The European Resuscitation Council (ERC) 2010 guidelines recommend use of supraglottic devices (SGDs), such as a laryngeal mask airway (LMA), as an alternative to tracheal intubation during CPR [1]. A number of reports suggest that SGDs have advantages over ordinary tracheal intubation for airway management under emergency situations [2].

During out-of-hospital CPR, several factors can make tracheal intubation more difficult, including limited illumination. In some cases, rescuers must secure the airway in complete darkness or with limited light [3]. Even in hospitals, similar situations might arise due to power outages.

SGDs have unique features that render them useful for difficult or emergency airway management [4, 5]. However, no study has ever compared the efficacy of SGDs for securing the airway under dark conditions. As a direct clinical evaluation is not feasible given ethical considerations, we decided to perform a simulation study to evaluate the efficacy of various SGDs for insertion during airway management in the dark.

In this study, we compared the performance of six SGDs: air-Q® (air-Q; Cookgas LLC, Mercury Medical, USA), i-gel® (i-gel; InterSurgical, USA), Laryngeal Tube® (LT;

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Published online: 24 July 2015

Smith Medical, USA), LMA-Classic®, LMA-ProSeal®, and LMA-Supreme® (Classic, ProSeal, and Supreme; Laryngeal Mask Company, Prodol Meditec, Spain) [6–11], with the primary endpoint of insertion efficacy under light and dark conditions, and the secondary endpoint of subjective insertion difficulty under both conditions. We hypothesized that these six SGDs would demonstrate good insertion efficacy in the dark.

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 [12]. From December 2014 to March 2015, 15 novice doctors who attended an anesthesiology training module at Osaka Medical College were recruited. Novice doctors performed trials after completing one month of anesthesia training. Seventeen experienced anesthesiologists with more than two years of clinical experience (average 6.6 ± 3.6 years) were recruited from an anesthesiology training simulation course, which was held on December 13 and 14, 2014, and January 31, 2015. Participants completed a questionnaire regarding their previous experience with six SGDs for airway management.

The Airway Trainer® (Laerdal, Sentrum, Stavanger, Norway) manikin was used for SGD insertion. Size 4.5 air-Q, and size 4 ProSeal, Classic, Supreme, i-gel, and air-Q devices were used. The necessary equipment for each simulation was placed in a box next to the manikin. Participants were given 10 min to practice insertion with each of the six SGDs before trials. Participants were instructed to insert the SGDs with original insertion technique by putting them firmly to the hard palate of the manikin. The manikin was placed on the floor of the operating room, which lacked windows. For the light condition, the ceiling lights were kept on. For the dark condition, each participant was handed the airway device, and an assistant turned off the room lights. Participants stood at the cranial side of the manikin and confirmed the location of the head and mouth, cuff injector, and bag-valve-mask before turning off the light. In the dark condition, participants could not see the manikin and airway management devices visually. The participant then attempted to insert the SGD, while another assistant measured time and used a pen light to hand the cuff injector or bag-valve-mask, without aiming the light toward the manikin. We did not use blindfolds because participants could not see the light provided by the assistant with this and we could simulate sufficient darkness for this study only by turning off the light.

Participants inserted each of the six SGDs, inflated the cuff with 20 ml of air (ProSeal, Classis, 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 volumes into cuff were determined based on the results of our preliminary study [13]. The SGD and the injector filled with the 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-point to the end-point was recorded; the start-point 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 in inflating the manikin's lungs. After insertion, participants were told to perform ventilation with a 2-l bag-valve-mask (Laerdal Silicone Resuscitator, Sentrum). In the dark condition, participants announced insertion of SGD at the timing of the connection to bag-valve mask, and the same assistant turned on the light of operation room. Then, the assistant promptly judged the success or failure of the SGD insertion. Ventilation was considered successful when the manikin's chest visibly rose. At the end of insertion, participants rated the difficulty of SGD 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. Participants inserted each of the six SGDs under light and dark conditions. A random number list was used for the randomization process, resulting in a total of 12 trials per participant.

Results obtained from each trial were compared by two-way repeated measures analysis of variance for insertion time and the VAS. The Chi-squared test was used to compare rates for successful ventilation and successful intubation during chest compression. Data are presented as mean ± SD. $p < 0.05$ was considered statistically significant.

Results of our preliminary study with eight novice doctors showed that the time required to ventilate the lungs after successful insertion of the air-Q device was approximately 12 ± 3 s. We considered 4 s to be clinically meaningful for differences between the groups. Using an α error of 0.05 and β error of 0.2, we estimated that 14 participants would be required for effect evaluation (i.e., dark condition).

Results

The average number of times of clinical SGD usage among novice doctors was 2.3 ± 1.3 times for ProSeal, 0.5 ± 0.7 times for Classic, 3.4 ± 2.4 times for i-gel, and zero for Supreme, air-Q, and LT. The average number of times

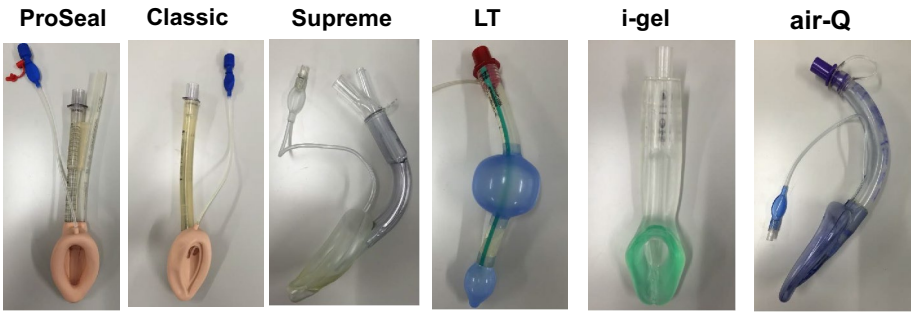

Fig. 1 Images of the six supraglottic devices used in the study. *ProSeal* LMA-ProSeal®, *Classic* LMA-Classic®, *Supreme* LMA-Supreme®, *LT* air-Q laryngeal tube®, *i-gel* i-gel supraglottic airway®, *air-Q* air-Q laryngeal mask airway®

Table 1 Number of successful ventilations performed by novice doctors under light and dark conditions

	ProSeal	Classic	Supreme	LT	i-gel	Air-Q
Light	15/17	15/17	17/17	16/17	17/17	16/17
Dark	8/17	9/17	15/17	14/17	14/17	14/17
p value	0.010*	0.024*	0.145	0.287	0.070	0.287

Data are presented as number of successful ventilations/total number of attempts

ProSeal LMA-ProSeal®, *Classic* LMA-Classic®, *Supreme* LMA-Supreme®, *LT* air-Q laryngeal tube®, *i-gel* i-gel supraglottic airway®, *air-Q* air-Q laryngeal mask airway®

* $p < 0.05$ compared to light

Table 2 Number of successful ventilations performed by experienced doctors under light and dark conditions

	ProSeal	Classic	Supreme	LT	i-gel	Air-Q
Light	15/15	15/15	15/15	15/15	15/15	15/15
Dark	11/15	10/15	13/15	14/15	14/15	14/15
p value	0.032*	0.014*	0.143	0.309	0.309	0.309

Data are presented as number of successful ventilations/total number of attempts

ProSeal LMA-ProSeal®, *Classic* LMA-Classic®, *Supreme* LMA-Supreme®, *LT* air-Q laryngeal tube®, *i-gel* i-gel supraglottic airway®, *air-Q* air-Q laryngeal mask airway®

* $p < 0.05$ compared to light

of clinical SGD usage among experienced doctors was 246.0 ± 182.3 times for ProSeal, 86.3 ± 87.3 times for Classic, 23.0 ± 23.1 times for Supreme, 1.3 ± 3.5 times for LT, 88.0 ± 51.6 times for i-gel, and 10.3 ± 6.7 times for air-Q (see Fig. 1).

Number of successful ventilations under light and dark conditions

Tables 1 and 2 show the number of successful ventilations performed by novice doctors and experienced doctors, respectively. For both novice and experienced doctors, the ventilation success rate was significantly lower in the dark than in the light when ProSeal and Classic were used, but not with the other four SGDs. Among experienced doctors, all trials with the six SGDs were successful in the light.

Insertion times under light and dark conditions

Figure 2 shows insertion times for the six SGDs under light and dark conditions. Novice doctors required a significantly longer insertion time in the dark than in the light with all SGDs. No significant differences in insertion time were observed among the six SGDs in the light. In contrast, insertion time was significantly longer with ProSeal and Classic compared with the other four SGDs in the dark (Fig. 2a).

Experienced doctors required a significantly longer insertion time in the light than in the dark with ProSeal or Classic, but not with the other four SGDs. As in the case of novice doctors, no significant differences in insertion time were observed among the six SGDs in the light. In contrast, insertion time was significantly longer with ProSeal and Classic compared with other four SGDs in the dark (Fig. 2b).

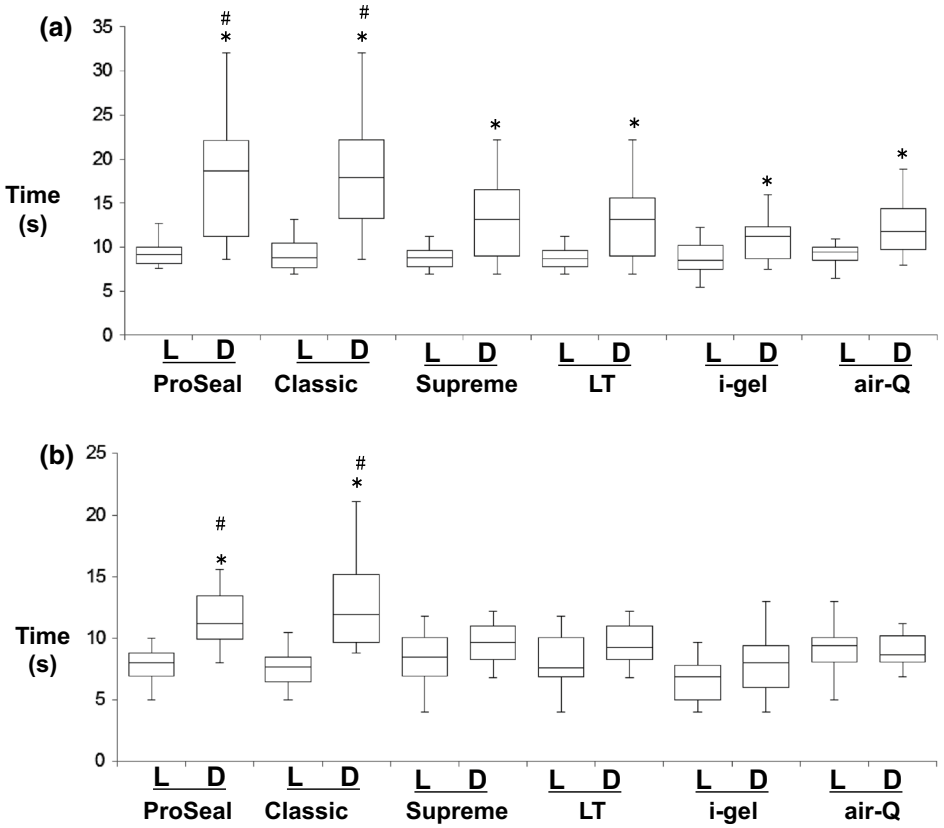

Fig. 2 *Box-and-whisker plot* (median, IQR, and range) of insertion time after successful insertion under light and dark conditions. **a** Insertion time by novice doctors and **b** insertion time by experienced doctors. *L* light, *D* dark, *ProSeal* LMA-ProSeal®, *Classic* LMA-Classic®, *Supreme* LMA-Supreme®, *LT* air-Q laryngeal tube®, *i-gel* i-gel supraglottic airway®, *air-Q* air-Q laryngeal mask airway®. *$p < 0.05$ compared to light. #$p < 0.05$ compared to Supreme, LT, i-gel, and air-Q

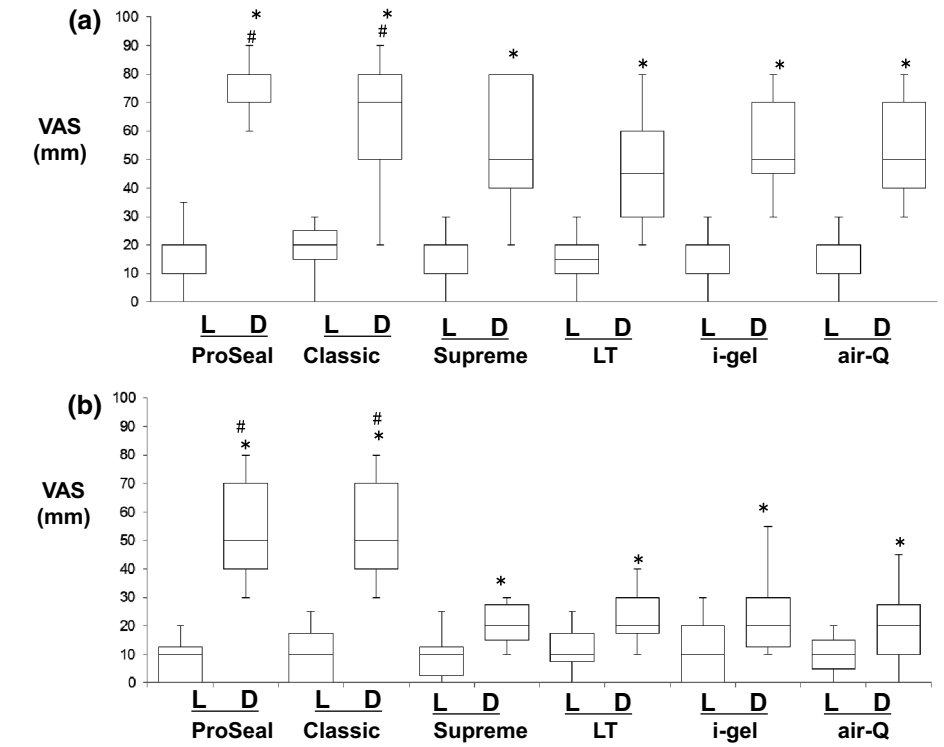

Fig. 3 *Box-and-whisker* plot (median, IQR, and range) of subjective insertion difficulty measured by the visual analogue scale (VAS) after successful insertion under light and dark conditions. **a** VAS for novice doctors and **b** VAS for experienced doctors. *L* light, *D* dark, *ProSeal* LMA-ProSeal®, *Classic* LMA-Classic®, *Supreme* LMA-Supreme®, *LT* air-Q laryngeal tube®, *i-gel* i-gel supraglottic airway®, *air-Q* air-Q laryngeal mask airway®. *$p < 0.05$ compared to light. #$p < 0.05$ compared to Supreme, LT, i-gel, and air-Q

Subjective difficulty of SGD insertion under light and dark conditions

Figure 3 shows the subjective difficulty of SGD insertion under light and dark conditions, as measured by the VAS. In both trials performed by novice and experienced doctors, insertion time was significantly longer in the dark than in the light with all six SGDs. A comparison of the six SGDs revealed no significant differences in the light for both novice and experienced doctors. In contrast, the VAS was significantly higher when ProSeal and Classic were used in the dark for both novice and experienced doctors, compared to the other four SGDs.

Discussion

SGDs are recommended for rescue ventilation in cases of failed intubation [15]. The conventional straight-type laryngeal masks, such as the LMA-Classic®, LMA-ProSeal®, and Soft Seal® laryngeal mask, were initially developed for rescue ventilation. New SGDs, or anatomically curved SGDs, such as the LMA-Supreme®, air-Q, and i-gel, have been developed as improved laryngeal masks that allow for easy insertion [16, 17]. Esophageal blocker-type SGDs, such as the LT and the combitube, have also been developed [7].

The concept of "difficult airway management" includes both physical difficulties associated with the patient (e.g., small jaw, restricted mouth opening) and difficulties arising from challenging circumstances [5]. For instance, airway management during an emergency is often performed under various restrictions, due to, for example, severe head and neck trauma, victim position [18], or dark setting. Thus, SGDs have potential not only as useful devices for overcoming physical difficulties, but also as situation-specific devices for managing difficult airways.

A previous study evaluated the usefulness of videolaryngoscopes and conventional Macintosh laryngoscopes for tracheal intubation under light and dark conditions [19]. The utility of tracheal intubation with videolaryngoscopes in these settings was clearly demonstrated. Although tracheal intubation is the most widely used method for airway management, it is considered difficult for those who do not routinely perform the technique [2]. As such, the ERC guidelines do not always recommend tracheal intubation, and instead propose the alternative use of SGDs in emergency situations [2].

In the present study, insertion success rate was significantly lower, with a prolonged insertion time in the dark, when ProSeal and Classic were used as compared to the other four SGDs for both novice and experienced doctors. One possible reason for this is that ProSeal and Classic, which are straight-shaped and relatively soft [20], might have caused malpositioning, as the insertion movement could not be observed in the dark. In contrast, Supreme, LT, i-gel, and air-Q are anatomically shaped and/or relatively hard, and could thus be placed securely even without visibility. In experienced doctors, though the subjective difficulty of Supreme, LT, i-gel, and air-Q insertion were significantly higher than in the light condition, the insertion time did not significantly differ between the two conditions. This suggests that experienced doctors could manage to insert these anatomical SGDs with tactile sensation without vision.

Anatomically shaped SGDs (e.g., Supreme, LT, i-gel, and air-Q) have another advantage, that is, they can be easily handled by novice operators. In emergency situations, airway management is often performed by less experienced doctors. SGDs reportedly require less professional skill and are suited for use by novice and occasional operators [9, 21]. In this study, although participants did not have much previous experience with these four types of SGDs, success rates of ventilation in the dark were more than 80 %. A short training period with these SGDs may help improve emergent airway management under dark conditions.

This study has several limitations. First, we used a manikin rather than real patients. Simulations with a manikin cannot mimic certain factors encountered in the clinical setting, such as blood, vomit, or sputum in the oropharynx [22]. Second, use of SGDs may not be feasible in patients with severely restricted mouth opening, or those with foreign bodies or tumors in the mouth. Third, the time required for airway intervention in a manikin is generally shorter than that required in actual patients [23]. Fourth, in clinical situations such as real trauma or accident scene in the field, considerable brightness by flashlight or illuminated screen of a mobile phone, can be secured. It may be significant to evaluate the insertion efficacy of these SGDs in various level of darkness in the future study. Accumulation of data on the clinical use of SGDs in emergency airway management during resuscitation is warranted.

Our simulation study demonstrated that Supreme, i-gel, LT, and air-Q are superior to ProSeal and Classic for use in airway management under dark conditions. Thus, anatomically shaped SGDs may help novice doctors secure the airway in the dark.

Compliance with ethical standards

Conflict of interest The authors have no affiliation with any manufacturer of any device described in the manuscript and declare no financial interest in relation to the material described here. Financial support for the study was provided by our institution and department.

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