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ORIGINAL ARTICLE

Comparison of Laryngeal Mask Supreme® and Soft Seal® for airway management in several positions

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Abstract
Purpose In emergency situations, rescuers occasionally must secure the airway while the patient is in a position other than the ideal supine position. We hypothesized that the laryngeal mask airway Supreme® (Supreme) may be useful for emergent airway management in several positions and compared the utility of the Supreme with that of the conventional Soft Seal® (Soft Seal) device.
Methods Nineteen novice doctors in our anesthesia department attempted insertion of the Supreme or Soft Seal device on a simulated manikin in the supine, left lateral decubitus (left-LT), right lateral decubitus (right-LT), prone, and sitting positions. For each device, successful ventilation attempts, mean time to secure the airway, and difficulty of use [using the visual analog scale (VAS)] were evaluated.
Results The success rate of ventilation was significantly higher with the Supreme than the Soft Seal in the prone and sitting positions ($P < 0.05$). Compared with the Soft Seal, time to secure the airway was significantly shorter with the Supreme when the manikin was in the sitting position but not in the other four positions. VAS scores for Supreme use were significantly higher than those for Soft Seal use in the right-LT, prone, and sitting positions.
Conclusion Airway management attempts by novice doctors were more successful with the Supreme than the Soft Seal in the right-LT, prone, and sitting positions in the manikin. The Supreme may therefore be useful for emergent airway management.

Keywords Laryngeal Mask Supreme® · Laryngeal Mask Soft Seal® · Airway management · Manikin · Body position

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Introduction

Accidental airway disruption is a life-threatening event during surgery. Emergent airway management can be difficult when the patient is not in the ideal supine position [1]. For example, in cervical spine or neurosurgical procedures, patients may be in the sitting or prone position [2]. Tracheal intubation with the Macintosh laryngoscope (McL) is the most widely used technique for securing the airway. In nonsupine positions, however, tracheal intubation with the McL is difficult even for professionals [3].

If emergent intervention is necessary, the most important goal is effective ventilation to increase oxygenation of the lungs [4, 5]. Supraglottic airway devices are reported to be effective for maintaining the open airway and facilitating ventilation [6, 7]. Several studies have reported the utility of laryngeal mask airways (LMAs) in emergent airway management [2, 8].

The Laryngeal Mask Supreme® (Supreme; Laryngeal Mask Company, Henley-on-Thames, UK) is a single-use supraglottic airway device featuring elements of the ILMA

Fastrach® (Laryngeal Mask Company) and the LMA Pro-Seal® (Laryngeal Mask Company) [9]. Because of these features, the Supreme is reported to be useful in emergent situations [10].

We hypothesized that the Supreme would be effective for airway management in a variety of patient positions. To test our hypothesis, we compared the performance of the Supreme with that of a conventional single-use laryngeal mask, Soft Seal® (Soft Seal; Smiths Medical, USA), with a manikin in five positions: supine, left-lateral (left-LT), right-lateral (right-LT), prone, and sitting.

Materials and methods

We obtained approval for this study from the Research Ethics Committee of our college. From August 2010 to October 2010, 22 anesthesia residents or trainees who worked temporarily in the anesthesia department of our hospital were invited to participate in the study; all had less than 1 year experience in anesthesia. A total of 19 doctors agreed to participate. Each doctor was asked about their prior experience with general anesthesia and provided written consent before participating in the study.

To evaluate the devices, we compared the time required to secure the airway of a SimMan® manikin (Laerdal, Sentrum, Stavenger, Norway) in the supine, left-LT, right-LT, prone, and sitting positions. The trial took place in an operation room, and manikin positions were established by adjusting the operating bed as previously reported [11]. A size 4 mask of each device was used. Before each insertion, the airway device and the manikin's upper airway were well lubricated, in accordance with the manufacturer's instructions [12].

The trial was a randomized crossover study. To minimize learning effects during the trial, the order of the five positions was randomized for each participant with a random number table (120 different patterns were possible). In addition, the order of LMA use (Supreme or Soft Seal) was randomized.

For insertion with the manikin in the supine, left-LT, right-LT, or prone position, the participant stood at the head of the manikin, but for the sitting position, the participant stood in front of the manikin. Insertion equipment was placed in a box next to the manikin's head. When the manikin was in the prone position, the study member designated as the "second rescuer" held the manikin's head [11].

Each participant was instructed to insert the LMA, inflate its cuff with 20 ml air, connect a 3-l bag-valve-mask, and then attempt to ventilate the lungs of the manikin as quickly as possible.

For the insertion method of LMA, the thumb insertion method was applied for Soft Seal. For Supreme insertion, a simple insertion method handling the integral bite block was taught according to the instruction of the manufacturer. The amount of cuff volume was determined by our preliminary study not to lengthen the insertion time by slow cuff inflation. Insertion time was measured from the point at which the participant picked up the airway device to the initiation of manual ventilation with the bag-valve-mask. Each attempt was timed with the same stopwatch. Successful ventilation was determined as volume sufficient to produce a visible chest rise.

After the five intubation attempts, participants rated the difficulty of using the devices in each of the five positions on a visual analog scale (VAS; with 0 mm indicating extremely easy to 100 mm indicating extremely difficult). Insertion time and VAS score for insertion were compared by two-way analysis of variance and Tukey's multiple comparison test, and success rate was compared by χ^2 test. Data are presented as mean ± standard deviation (SD). $P < 0.05$ was considered statistically significant.

From our preliminary study, the time taken to ventilate the lungs after successful ventilation using the Soft Seal was ~14 s, with an SD of ~5 s. With α error of 0.05 and β error of 0.2, we estimated that 20 participants would be required for two independent groups. As this study is a crossover design, we decided to enroll 19 subjects to further increase the power.

Results

The participants reported a mean clinical experience with anesthesia of 4.7 ± 3.6 months. The mean number of general anesthesia procedures was 145.0 ± 127.1.

Success rate of ventilation in each position

The success rate for each device is shown in Table 1. While evaluating the Supreme, all ventilation attempts were successful with the manikin in the supine, left-LT, and right-LT positions, but two participants failed in their attempts at ventilation in the prone and sitting positions. While evaluating the Soft Seal, three participants failed their attempts at ventilation in the supine and left-LT positions, seven failed in the right-LT position, and nine failed in the prone and sitting positions. Thus, when the manikin was in the right-LT, prone, or sitting positions, attempts at intubation and ventilation were significantly more successful with the Supreme ($P < 0.05$).

Insertion time

Insertion times are shown in Fig. 1. Insertion time was generally shorter with the Supreme device but was significantly different only when the manikin was in the sitting

Table 1 Number of successful ventilations in each position using the Soft Seal and Supreme laryngeal masks

Position	Supreme	Soft Seal	*P* value
Supine	19/19	16/19	N.S.
Left-LT	19/19	16/19	N.S.
Right-LT	19/19	12/19	<0.05
Prone	17/19	10/19	<0.05
Sitting	17/19	10/19	<0.05

Results are expressed as successful attempts/total number of attempts

N.S. not significant, *Left-LT* left lateral decubitus, *Right-LT* right lateral decubitus

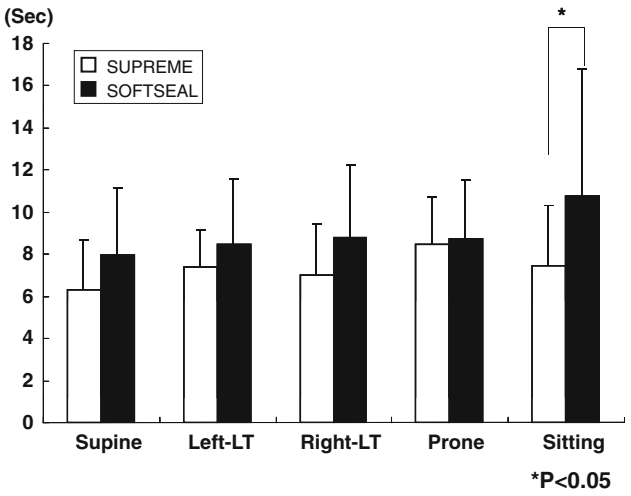

Fig. 1 Intubation time using the Soft Seal and Supreme laryngeal masks in five manikin positions (supine, left lateral decubitus, right lateral decubitus, prone, and sitting). *Left-LT*, left lateral decubitus; *right-LT*, right lateral decubitus. *$P < 0.05$

position. For each device, insertion time did not differ significantly among the five positions (Supreme: supine 6.3 ± 2.3 s, left-LT 7.3 ± 1.8 s, right-LT 7.0 ± 2.3 s, prone 8.4 ± 2.2 s, sitting 7.4 ± 2.8 s; Soft Seal: supine 7.9 ± 3.1 s, left-LT 8.4 ± 3.1 s, right-LT 8.7 ± 3.9 s, prone 8.7 ± 2.7 s, sitting 10.7 ± 6.0 s).

VAS score for difficulty of insertion

The VAS scores for difficulty of insertion are shown in Fig. 2. For both devices, the VAS score for use in the prone position was significantly higher than scores for use in the supine position (Supreme: supine 16.5 ± 17.1 mm, left-LT 22.8 ± 18.9 mm, right-LT 23.9 ± 16.6 mm, prone 33.1 ± 19.2 mm, sitting 28.6 ± 18.8 mm; Soft Seal: supine 30.7 ± 23.1 mm, left-LT 36.5 ± 21.8 mm, right-LT 40.5 ± 19.9 mm, prone 58.4 ± 31.1 mm, sitting 45.2 ± 23.6 mm). VAS scores for Supreme use were generally

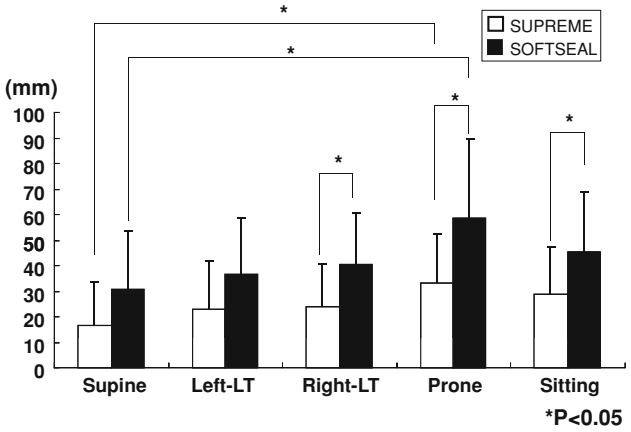

Fig. 2 Visual Analog Scale (VAS) scores of subjective difficulty using the Soft Seal and Supreme laryngeal masks in five manikin positions. *Left-LT*, left lateral decubitus; *right-LT*, right lateral decubitus. *$P < 0.05$

lower than those for Soft Seal use; these differences were significant in the right-LT, prone, and sitting positions.

Discussion

Emergent airway management can be very difficult because of the relative positions of the rescuer and patient [13]. Conventional McL is the most widely used device for tracheal intubation, but its use is considered difficult without proper patient positioning. Tracheal intubation with the McL requires axial alignment of the oral cavity, pharynx, and larynx, as well as handling of the tracheal tubes [14]. Emergent intubation with the McL is generally very difficult in the lateral, sitting, or prone positions because of the difficulty of achieving axial alignment [3].

LMAs are recommended by professionals for airway rescue in failed intubation [15]. Older models, such as the LMA-Classic®, LMA-ProSeal®, or Soft Seal have been shown to rescue the airway in a quick and safe fashion. These LMAs are easily inserted in the prone or lateral position, in contrast to tracheal tubes, and offer an easily replaceable and secure airway device in the prone position [2, 3]. Furthermore, in contrast to tracheal tube placement, insertion of the LMA does not require visualization of the glottis, so both initial training and maintenance of skills are relatively easy [16].

Compared with older LMA models, the Supreme has several beneficial features, such as the elliptical cross-sectional design of the airway tube, which facilitates reliable insertion; a rigid airway tube and reinforced tip that prevent kinking and folding; and a larger cuff and gastric access that improve airway protection [17, 18]. As a result, success rates for ventilation with the Supreme are reported

to be higher than those of previous models. In our study, all participants were successful using the Supreme in the supine, left-LT, and right-LT positions, and only two participants failed attempts at ventilation with the manikin in the prone and sitting positions. Compared with Soft Seal, the Supreme device had a high success rate, short insertion times, and low VAS score, even in the prone and sitting positions.

Because LMAs are supraglottic devices and cannot secure the trachea completely, use of these devices risks insufficient ventilation or expansion of the stomach, potentially leading to gastric fluid regurgitation and aspiration pneumonia [8]. Interestingly, the LMA Supreme promotes a patent and sealed airway, but it also permits gastric access [9]. We previously showed that ventilation with the Supreme device resulted in significantly less air in the stomach than ventilation with Soft Seal, probably because the gastric hole functions as an air release [12].

LMA is an effective supraglottic device for airway management in situations such as cardiopulmonary resuscitation [12]. In addition, LMAs may have value as backup devices in difficult airway management, especially in the "cannot intubate, cannot ventilate" situation [19]. Difficult airway management includes physical difficulties associated with the patient, such as a small jaw and restricted opening of the mouth. It also includes medical situations such as cardiopulmonary resuscitation that make airway management more difficult [20, 21]. LMA may also be useful for a situation-induced difficult airway such as that caused by a restricted body position. The advantages of higher glottic seal pressure, easy access to liquid gastric contents, and ease of insertion in the supine, lateral, and prone positions enhance its usefulness in emergent airway management [9, 10].

For airway management in positions other than supine, we previously reported the utility of the Pentax-AWS Airwayscope [11]. In emergent airway management, however, the primary concern is effective ventilation, not tracheal intubation. In our study, the time required to secure the airway and perform ventilation was generally shorter with LMAs than that demonstrated for the AWS, especially in the prone and sitting positions. The combination of ventilation with the Supreme and tracheal intubation with the AWS may be useful for emergent airway management in difficult positions.

The main limitation of this study is that it evaluated LMA insertion with a manikin rather than with real patients. The time needed to perform airway intervention with a manikin is generally shorter than that required for actual patients. Another limitation is that this study was performed with only one manikin [22]. The manikin used in our study was designed for training LMA insertion in airway management. More studies are needed to evaluate the Supreme LMA in a variety of clinical situations and patient positions.

We conclude that, in a manikin trial, Supreme performed better than the conventional Soft Seal for airway management in several positions by novice doctors.

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

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