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A comparison of ProSeal laryngeal mask airway, I-gel and endotracheal tube insertion by novices in a simulated difficult airway scenario

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Background: Insertion of supraglottic airway devices (SADs) can be technically easier to perform for novices than endotracheal intubation (ETI), particularly in a situation with difficult airway management. We evaluated the efficacy and usefulness of the ProSeal laryngeal mask airway (PLMA), I-gel, and ETI when used by novices in a simulated difficult airway scenario.
Methods: A total of 109 novices participated in a brief educational session about PLMA, I-gel and ETI. The sequence of the airway devices was randomized for each participant using a computer-generated random table, and the devices were inserted in a manikin with restricted cervical spine movement. A nasogastric (NG) tube was then inserted through each SAD. In the case of ETI, the NG tube was inserted through the manikin's nostril.
Results: The success rate at the first insertion attempt was 93.6% for the I-gel compared with 72.5% for the PLMA and 19.3% for ETI. The I-gel also enabled a significantly shorter insertion time than the PLMA (I-gel 26.3 ± 21.9 sec and PLMA 36.0 ± 35.4 sec). The novices showed high success rates for NG tube insertion using SADs (PLMA 96.3% and I-gel 98.1%) compared with ETI (24.8%).
Conclusions: We found that the I-gel provided a better first time success rate and a shorter insertion time than PLMA and ETI, which indicated that the I-gel may be preferable for difficult airway management by novices. **(Anesth Pain Med 2016; 11: 307-312)**

Key Words: Intubation, Laryngeal mask, Manikin.

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INTRODUCTION

Endotracheal intubation (ETI) is perceived as the gold standard for securing the airway in resuscitation victims. The latest European Resuscitation Council Guidelines suggest minimizing interruptions to chest compressions to protect heart and brain function [1]. Thus, ETI should be achieved as quickly as possible with the least possible interruption to chest compressions. However, ETI is a difficult skill to acquire and may be impossible in a patient with a difficult airway. Prolonged intubation times or misinserted endotracheal tubes by inexperienced personnel can lead to the life threatening deterioration of the patient's condition. A study to determine the incidence of unrecognized misplaced endotracheal tubes by paramedics found that 25% of the patients had improperly placed endotracheal tubes [2].

The supraglottic airway devices (SADs) are an alternative to ETI because SADs are technically easier to use than ETI with a conventional Macintosh laryngoscope, as shown by Lee et al. [3], who found that with novice operators who were unfamiliar with airway devices, SADs were faster and easier than ETI with a Macintosh laryngoscope in difficult airway scenarios. However, SADs also have the limitation that they do not prevent aspiration of gastric contents as reliably as ETI due to the low pressure seal. Currently, new SADs, including the ProSeal laryngeal mask airway (PLMA) and I-gel, have been developed with a better airway seal and a drainage tube to enable venting of regurgitated gastric contents and nasogastric (NG tube) tube placement. Previous studies have reported that PLMA and I-gel were superior for use in patients with a risk of aspiration [4] and provided higher leak pressures of the airway than the classic laryngeal mask airway (LMA) [5,6]. In

addition, experienced operators achieved successful insertion of a NG tube using PLMA or I-gel in all cases in trial scenarios [7,8]. Therefore, instead of ETI, the PLMA and I-gel might be ideal airway devices for novice in emergency situations, particularly for patients with difficult airways and gastric distension.

The purpose of this study was to evaluate the clinical usefulness of the PLMA and I-gel for inexperienced operators in a simulated difficult airway scenario by comparing their use with ETI via a Macintosh laryngoscope in terms of the success rate, insertion time and ease of insertion. Following each airway device insertion, we also investigated the feasibility of NG tube placement for venting of gastric contents.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board and was registered in a clinical trial registry before recruitment of the first subject. Written informed consent was obtained from medical students with no previous experience with a direct laryngoscope or any SADs. All of the participants were informed of the objective of the study and received a standardized audio-visual education session lasting 45 min that explained techniques for ETI using direct laryngoscopy and PLMA and I-gel insertion. Following the lecture, participants performed five supervised insertions of each device in a standard manikin with a normal airway setting. The novices practiced ETI using an endotracheal tube with a preloaded stylet and a Macintosh laryngoscope with a size 3 curved blade. The PLMA (Teleflex, San Diego, California, USA) was inserted using the index finger as described in the manufacturer's guidelines. The I-gel (Intersurgical Ltd., Berkshire, United Kingdom) was inserted according to the product literature provided by the manufacturer. After insertion of each device, the participants performed NG tube insertion under the guidance of the same study investigator.

A difficult airway was simulated using a manikin (SimMan^{TM}, Laerdal Medical, Stavanger, Norway) with restricted cervical spine movement. Using a laryngoscope, all study investigators identified the simulated difficult airway as Cormack-Lehane Grade 3. A 7.5 Fr endotracheal tube with a preloaded stylet and Macintosh laryngoscope with a size 3 curved blade were used. A size 4 PLMA and size 5 I-gel were used. These PLMA and I-gel sizes were selected after the investigator had inserted PLMA and I-gel devices of various sizes before starting the study to determine the best fit for each device. We confirmed that the sizes of the PLMA and I-gel were suited to the manikin through a pilot study. The sequence of the airway devices was randomized for each participant using a computer-generated random table. The devices and the manikin's palate and tongue were well lubricated before each procedure. Each novice inserted the airway device and performed inflation of the cuff and connection with a self-inflating bag. After insertion, the cuff of the PLMA was inflated with 30 ml of air [4]. Successful insertion was confirmed by inflation of the manikin's chest. In the case of an insertion attempt lasting longer than 1 min, the novices were instructed to stop the insertion attempt and perform bag-mask ventilation. If the novices recognized the misplacement of the devices, they were allowed to reinsert the device. Three failed attempts were recorded as a failure. The time of each attempt was recorded as the time taken from the point of picking up the PLMA, I-gel or laryngoscope until visible inflation of the manikin's chest. The duration of a successful insertion attempt was recorded as the total time required for successful insertion, which included the entire time that a participant spent on each attempt before success. The participant then inserted a NG tube (14 Fr for the PLMA, and 12 Fr for the I-gel) through each SAD. The 14 Fr NG tube was inserted through the manikin's nostril in the case of ETI. Successful insertion was defined as an attempt in which the NG tube passed through the manikin's esophagus within one minute, and all participants were permitted three attempts until they succeeded. The investigator opened the manikin's chest wall and checked the passage of the NG tube through esophagus. The insertion time for the NG tube was recorded as the time elapsed from the participant touching the NG tube to the time at which the tube passed through the manikin's esophagus. Following completion of the insertion of all devices, the participants recorded a level of difficulty for the procedure using a visual analogue scale (VAS 0, easiest; 100, impossible) and indicated their preferred airway device. To prevent learning effects, the participants were not allowed to watch each other during their attempts to insert the airway devices and the NG tube.

The primary endpoint of this study was the success rate of first-time insertion of each airway device. Secondary endpoints were the success rate of first-time insertion of the NG tube for each airway device, the overall rate of successful insertion for each device, the duration of successful insertion attempts for each airway device, and the difficulty of each procedure.

The sample size used for this study was calculated using G * Power 3.1. Based on a pilot study, a sample size of 105 was required to detect a difference in the success rate for first-time insertion of each airway device and assuming α = 0.05 and a power of 0.80. We recruited 115 participants to adjust for potential dropouts. The McNemar test was used to analyze the success rates of first-time insertion and the overall rate of successful insertion of ETI, the PLMA and the I-gel, as well as the success rates of NG tube insertion. The P value was adjusted with Bonferroni's correction, and $P < 0.0167$ was considered statistically significant. The duration of successful insertion attempts for each airway device was analyzed using a linear mixed model with Bonferroni's post-hoc test. The difficulty of each procedure was analyzed using a repeated measures ANOVA with Bonferroni's post-hoc test. A P value of < 0.05 was considered statistically significant. Statistical analyses were performed using SPSS 21.0 (IBM, Armonk, NY, USA).

RESULTS

Of the 115 students enrolled, 109 completed the study. Six students were excluded from the study for refusal to provide consent. There were 71 male students and 38 female students with a mean age of 28.5 ± 2.1 years. None of the students had prior experience with endotracheal tubes and SADs.

The success rate of first-time insertion was higher for the I-gel than the PLMA (I-gel 93.6% and PLMA 72.5%; P = 0.000), and ETI had the lowest success rate (19.3 %, P = 0.000, Table 1). The duration of a successful insertion attempt was also shorter for the I-gel (26.3 ± 21.9 sec) than for the other devices ($P < 0.05$, Table 1). The overall rate of successful insertion was significantly higher for the I-gel than for the PLMA and ETI, and PLMA insertion produced a higher success rate than ETI ($P < 0.0167$, Table 1). For the VAS difficulty score, the participants rated the I-gel device as easier to use than the other devices and ETI using a laryngoscope was rated as the most difficult procedure ($P < 0.05$, Table 1). Sixty nine novices preferred the I-gel, 38 preferred the PLMA and 2 preferred the ETI using the laryngoscope (Table 1).

In the scenario used for insertion of a NG tube through the airway device, the success rate of first-time insertion was higher for the I-gel than the PLMA and the endotracheal tube (I-gel 94.5%, PLMA 82.6% and ETI 7.3%; P = 0.000, Table 2). However, the difference in the overall success rate for NG tube insertion between the PLMA and I-gel was not statistically significant (PLMA 96.3% and I-gel 98.1%, Table 2). The students rated the I-gel as a less difficult technique for inserting the NG tube than the PLMA and the endotracheal tube ($P < 0.05$, Table 2).

DISCUSSION

Our results showed that novice operators were able to insert both the PLMA and I-gel with a higher success rate and faster insertion times than ETI, and the majority of the novices experienced first-time successes inserting the NG tube through both SADs. A more interesting finding of our study was that the I-gel enabled significantly greater successes and shorter insertion times than the PLMA when used by novices.

Successful and rapid tracheal intubation requires highly

Table 1. Insertion Attempt Results Using an Endotracheal Tube, ProSeal LMA and I-gel

	Endotracheal tube (n = 109)	ProSeal LMA (n = 109)	I-gel (n = 109)
Number of insertion attempts			
1	21 (19.3%)	79* (72.5%)	102*,† (93.6%)
2	40 (36.7%)	17 (15.6%)	5 (4.6%)
3	0	6 (5.5%)	2 (1.8%)
Failed insertion	48 (44.0%)	7 (6.4%)	0
Total successful insertion	61 (56.0%)	102* (93.6%)	109*,† (100%)
Time of successful insertion attempt (sec)	78.4 ± 26.4	36.0 ± 35.4‡	26.3 ± 21.9‡,§
VAS difficulty score (mm)	61.7 ± 24.5	24.4 ± 24.1†	17.7 ± 17.6†,§
Most preferred device	2	38	69

The data are expressed as the number or mean ± SD. LMA: laryngeal mask airway. VAS: visual analogue scale of airway device insertion difficulty (0 = the easiest and, 100 = impossible). *$P < 0.0167$ compared with the endotracheal tube (P value was obtained using Bonferroni's method), †$P < 0.0167$ compared with ProSeal LMA (P value was obtained using Bonferroni's method), ‡$P < 0.05$ compared with the endotracheal tube, §$P < 0.05$ compared with ProSeal LMA.

Table 2. Insertion Attempt Results Using a NG Tube in Each Airway Device

	Endotracheal tube (n = 109)	ProSeal LMA (n = 109)	I-gel (n = 109)
Number of insertion attempts of NG tube			
1	8 (7.3%)	90* (82.6%)	103*,† (94.5%)
2	11 (10.1%)	13 (11.9%)	4 (3.7%)
3	8 (7.3%)	2 (1.8%)	0
Failed insertion	82 (75.2%)	4 (3.7%)	2 (1.8%)
Total successful insertion of NG tube	27 (24.8%)	105* (96.3%)	107* (98.1%)
VAS difficulty score (mm)	78.4 ± 24.2	23.9 ± 19.9‡	18.0 ± 16.1†,§

The data are expressed as the number or mean ± SD. LMA: laryngeal mask airway. NG tube: nasogastric tube. VAS: visual analogue scale of airway device insertion difficulty (0 = the easiest and, 100 = impossible). *P < 0.0167 compared with the endotracheal tube (P value was obtained using Bonferroni's method). †P < 0.0167 compared with ProSeal LMA (P value was obtained using Bonferroni's method), ‡P < 0.05 compared with the endotracheal tube, §P < 0.05 compared with ProSeal LMA.

skilled and experienced operators who receive constant training and practice. During the initial training session, inexperienced operators successfully performed ETI in 78% of cases using a trainer manikin with a normal airway, while 3 months later the success rate was 58% [9]. ETI is particularly difficult to perform in a difficult airway such as a cervical spine injury. Even with experienced anesthetists and prehospital care providers as study practitioners, success rates of 66% and 77% have been reported for ETI in simulated difficult intubations in actual patients and in a manikin, respectively [10,11]. The novices in our study showed a success rate of 19.3% for the first attempt and an overall success rate of 56% for ETI in a manikin with restricted cervical spine movement. Lee et al. [3] also reported that the success rate for ETI by unskilled rescuers was only 47.4% in a difficult airway scenario. It is difficult to accept such a high failure rate of ETI because unsuccessful tracheal intubation in an emergency situation is associated with high rates of morbidity and mortality [12,13]. In contrast, insertion using SAD such as the LMA, PLMA, or I-gel was faster and performed with greater success than ETI in manikins by inexperienced practitioners [9,14]. Moreover, novice interns achieved successful insertion in 29 of the 30 cases in actual patients [15]. The results of our study also demonstrated that the novices achieved higher success rates (93.6% for PLMA and 100% for I-gel) and faster insertion times than ETI. Therefore, SADs such as PLMA or I-gel could be an acceptable alternative to ETI, particularly for novice practitioners or patients with an anticipated difficult airway. Paal and colleagues recommend that less experienced medical staff should ventilate with an alternative SAD [16].

The major limitation of SADs is that they do not protect the respiratory tract from regurgitated gastric contents as reliably as ETI. However, reports from the emergency department noted aspiration rates of 3.5% and 4% after urgent ETI [17,18]. The evidence to date suggests that pulmonary aspiration associated with LMA is rare, with an incidence comparable to that of outpatient anesthesia with an endotracheal tube [19]. In addition, the PLMA and I-gel, which are newly developed SADs that are intended to reduce the risk of aspiration, have a better airway seal and esophageal drainage tube that permit insertion of a NG tube and venting of gas or liquid from the upper gastrointestinal tract. Schmidbauer and colleagues demonstrated the rapid drainage of gastrointestinal fluid through the esophageal drainage tube by PLMA and I-gel without tracheal aspiration in a simulated vomiting situation [4]. Our and previous findings also showed that novices were able to insert a NG tube without difficulty through SADs [20]. Furthermore, PLMA and I-gel created higher leak pressures of the airway (29 cmH_2O for PLMA and 30 cmH_2O for I-gel) than the established 18–20 cmH_2O for the classic LMA [5,6,21,22]. This high leak pressure enabled PLMA to secure the airway as effectively as ETI during continuous chest compressions [23]. The I-gel also sealed the airway as effectively as PLMA for laparoscopic surgery [24]. Therefore, PLMA and I-gel may offer an effective alternative for novices because they allow easier insertion than ETI, improve the airway seal and have a specific design that facilitates more effective prevention of pulmonary aspiration.

Interestingly, in our study, the I-gel provided a higher first-pass success rate and more rapid insertion time for novice practitioners than the PLMA. A significant difference was also observed for the rate of overall successful insertions within three attempts between the PLMA and I-gel (93.6% vs 100%). Our results suggest that use of the I-gel is easier and requires

fewer insertion attempts than PLMA, which is consistent with previous studies showing easier and approximately 50% faster I-gel insertion than the PLMA by experienced operators [8,25]. PLMA also requires more time and attempts for successful insertion than the classic LMA [6]. In contrast, compared with classic LMA, use of the I-gel resulted in a high first-pass success rate (90.1% vs 47%) and reduced insertion time (15.2 sec vs 22.0 sec) by novices in a manikin setting [14]. The increased difficulties associated with PLMA insertion were likely caused by the large cuff impeding intraoral positioning and advancement into the pharynx, the lack of a backplate making the cuff more likely to fold over at the back of the mouth, and the need for more precise tip positioning [26,27]. By comparison, the I-gel has design features including a less flexible stem, no need for cuff inflation, and an insertion depth gauge which may simplify and facilitate insertion for inexperienced users [28]. We found that the first-pass success rate (72.5%) and insertion time (36 sec) by novices for PLMA in our study were lower and longer, respectively, than in a previous manikin study [29]. However, unlike our study, the above mentioned study used a manikin with a normal airway, and all participants had previously used the PLMA several times (average of 20 times).

Our study has several limitations. First, the difficult airway was limited to restricted cervical movement and did not include other situations such as severely a swollen tongue or restricted mouth openings. However, this situation was chosen based on the assumption that airway intervention for patients with neck immobilization could be more common in emergency situations. The Advanced Trauma Life Support guidelines also recommend that care providers should assume a cervical spine injury in any patient with multisystem trauma, and protection of the spinal cord with an immobilization device should be maintained during management of the patient's airway [30]. Second, this study was performed using a manikin rather than a real patient, and thus our results may not correlate with clinical practice. However, we chose to use a manikin (SimMan™, Laerdal Medical, Stavanger, Norway) because it can be used for SAD insertion training and provide a difficult airway scenario with a realistic anatomy [9,20]. For real patients, more than 85% of novices have successfully inserted SADs after only limited manikin training [20]. Another limitation of our study is that the efficacy of ventilation after insertion of the airway devices was assessed by only visible chest inflation. Many previous studies using an airway manikin have also mentioned this limitation [14,25,29]. More objective measurements are required to confirm successful ventilation.

In conclusion, our study showed that novice practitioners were able to insert both the PLMA and I-gel with better success rates and faster insertion times in the first attempt than ETI in a difficult airway, and the novices had a higher first-time success rate and a shorter insertion time using the I-gel than the PLMA. Additional analyses comparing the PLMA with the I-gel are needed to determine an appropriate SAD for the use of novices in emergency situations.

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