Clinical performance comparison of I-gel insertion by anesthesiology residents versus novice clinicians

Departments of Anesthesiology and Pain Medicine, *Orthopedic Surgery, Yonsei University Wonju College of Medicine, Wonju, Korea

Kwang Ho Lee, Ji-Young Lee, Ji-hyoung Park, Sangwoo Jung, Yeonggwan Jeon, John Junghun Shin*, and Hyun Kyo Lim

Background: I-gel is a recently developed supraglottic airway device with many advantages. Like laryngeal mask airway (LMA), I-gel is an easier and quicker intubation alternative to endotracheal intubation in certain situations. In this study, we assessed the ease of I-gel insertion and compared the clinical performance of anesthesiology residents (group R) experienced in endotracheal intubation versus that of interns (group I) with little intubation experience.

Methods: This prospective and randomized study included 60 patients. The ease of insertion, number of I-gel insertion attempts, presence of air leakage, and postoperative complications such as bleeding, dental trauma, hoarseness, and sore throat were evaluated in each group.

Results: Insertion was successful on the initial attempt in 29 of 30 cases in group R. In group I, 24 initial insertions were successful. The mean insertion times were 12.5 ± 4.8 and 27.9 ± 12.5 seconds for group R and group I, respectively (P < 0.001). No significant differences were observed between the two groups regarding postintubational air leakage. Regarding complications, two cases of bleeding, one case of dental trauma, and two cases of sore throat were recorded. No significant differences were observed between the two groups for any of the complications examined.

Conclusions: I-gel is a suitable alternative insertion device that enables rapid and easy intubation by physicians who are experienced with endotracheal intubation. Moreover, this device also enables efficient and safe insertion during emergent situations for novice clinicians, even those who have little experience in intubation. (Anesth Pain Med 2015; 10: 312-316)

Key Words: Airway management, I-gel.

INTRODUCTION

Improper airway management can lead to potential respiratory complications; thus, it is imperative that airway patency is maintained during anesthesia. In addition to conventional endotracheal intubation, various supraglottic airway devices such as laryngeal mask airway (LMA), the laryngeal blocker, and the pro-seal LMA have been developed to maintain airway patency. Supraglottic airway devices are a particularly safe and efficient substitute for endotracheal intubation to preserve the airway in difficult intubations or emergent situations [1]. However, endotracheal intubation requires substantial expertise. Moreover, the inflatable cuff of the LMA can cause problems such as mechanical compression, lowered airway pressure, and poor adaption to the larynx.

I-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) is the most recently developed supraglottic airway device. Unlike the LMA, it lacks an inflatable cuff. Instead, the device is composed of gel-like elastic materials. I-gel was designed to anatomically seal the area of the larynx without compressive trauma, making it easier and more convenient to maintain airway patency than with other supraglottic devices or the conventional endotracheal method [2]. In one report, I-gel was found to have a quicker insertion time and a better anatomic fit than pro-seal LMA [3].

The number of endoscopic procedures has recently increased greatly, along with the frequency of patient sedation during these procedures. This increased frequency raises the possibility of airway patency complications in sedated patients. I-gel can be used as an alternative to the LMA or endotracheal intubation to manage airway patency during these emergent conditions. However, its ease of use has not yet been fully established. Moreover, it is not yet clear whether doctors with relatively...
little experience can successfully use I-gel under emergent conditions without the help of experienced anesthesiologists. Therefore, in the present study we assessed the ease of I-gel insertion. We also compared the clinical performances of I-gel when inserted by experienced anesthesiologists versus novice clinicians.

**MATERIALS AND METHODS**

After approval of the Institutional Review Board and obtaining of written informed consent from the patients, a total of 60 patients, including both males and females, were included in the present study. The patient ages ranged from 20 to 65 years-old. Only patients who were classified as grade I or II according to the American Society of Anesthesiologists criteria were included in the present study. All patients underwent orthopedic surgeries in the supine position under general anesthesia with controlled ventilation. Patients with potential difficulties during intubation were excluded from the study. Those with illness in the throat or upper respiratory tract, a body mass index of more than 25 kg/m², cervical spine disability, surgical history of the head and neck area, an inability to open the mouth more than 2.5 cm, or the need for endotracheal intubation were also excluded from the study.

All participating patients fasted overnight before surgery. Twenty minutes before moving to the operation room, 0.2 mg of glycopyrrolate and 2 mg of midazolam were injected intramuscularly into each patient. During the operation, various parameters were monitored and recorded. These parameters included heart rate, electrocardiogram, arterial blood pressure (noninvasive), capnography readings, and oxygen saturation. After preoxygenation with 100% oxygen, anesthesia was induced with doses of 1.5 to 2.5 mg/kg of propofol and 0.1 to 1.0 μg/kg/min of remifentanil. For muscle relaxation, 0.6 mg/kg of rocuronium was given intravenously. Manual ventilation was performed using a face mask for three minutes with 100% oxygen and 2.5 vol% sevoflurane. After ventilation, the residents and interns attempted to insert the I-gel. The patients were divided into two groups during I-gel insertion.

Experienced third and fourth grade anesthesiology residents with over 200 cases of I-gel insertion and 1,000 cases of endotracheal intubation performed the insertion for the first group of patients (group R). For the second group, interns with little intubation experience attempted to insert the I-gel. Each intern was closely supervised by an experienced anesthesiologist who acted as the study evaluator in the case of an emergency (group I). Each group contained 30 patients. The appropriate I-gel size (#3 or #4) was chosen according to the manufacturer’s instructions. Similarly, I-gel insertion was carried out according to the manufacturer’s protocol. Prior to insertion, a thin layer of lubricant was applied to the back, sides, and front of the cuff. All interns watched a 10 minute video (provided by the manufacturer) describing the correct method of I-gel insertion. In addition, each intern practiced the procedure three times with an airway dummy prior to actual insertion. Interns were also taught various insertion manipulation techniques such as pushing, pulling, head extension, deep rotation, and jaw thrust for difficult insertion situations. A single observer recorded the information for all insertions performed in both group R and group I. When I-gel was inserted by an intern, the observer did not intervene in the procedure unless the insertion was not successful within a minute, oxygen saturation dropped below 95%, or the insertion failed. After each insertion, the I-gel was anchored with adhesive tape and auscultation was performed in both lung fields to confirm proper positioning of the I-gel. Successful insertion was defined as rectangular waveforms on the capnometry readouts and the lack of audible air leaks. Insertion difficulty was classified as very easy, easy, or difficult. For very easy insertions, the I-gel was situated into the larynx without any resistance on the first try. In easy insertions, the I-gel was properly situated during the first try. Some resistance could be present, but other manipulative techniques were not required. On the other hand, difficult insertions were those meeting considerable resistance during the procedure and the required more than one manipulation for proper positioning. Manipulations were performed in cases of resistant insertion, airway leakage, and device displacement. The technique used for each manipulation was recorded.

Anesthesia was maintained with an oxygen-air mixture of 50% oxygen and 2 vol% sevoflurane. Additionally, 10 mg of additional rocuronium was injected intravenously when the patient recovered from neuromuscular blockade. The time required for I-gel insertion, number of insertion attempts, presence of airway leakage, and need for further manipulation were documented for each case. Airway leakage was detected by listening under the pressure mode of 20 cmH₂O. Additional intraoperative complications such as desaturation were also noted. Other complications such as blood stains on the I-gel, tooth damage, sore throat, and hoarseness were recorded postoperatively.
**Statistical analysis**

Since this study was exploratory in nature, we selected and proceeded with 30 patients in each group for statistical analysis as a pilot study. Data are expressed according to the properties of the variables. Continuous variables are presented as means and standard deviations, whereas categorical variables are presented as frequencies and percentages. For comparisons of the two groups, the two-sample t-test or the chi-square test (Fisher’s exact test) was performed as appropriate. The two-sample t-test was used to compare the means from two independent samples, whereas the chi-square test was used to compare two binomial proportions using a contingency table. The chi-square test require that the normal approximation to the binomial distribution is valid, which is not always the case, especially for small samples. For small sample sizes, exact distributions can be used for inference rather than large-sample approximations. Thus, Fisher’s exact test was used for samples with small frequencies. P values less than 0.05 were considered statistically significant; all statistical analyses were performed using SAS ver. 9.2 (SAS Inc., Cary, NC, USA).

**RESULTS**

The demographic data of the two groups were not significantly different (Table 1). Regarding the number of insertion attempts, 29 of the first I-gel insertion attempts were successful in group R, whereas only one of the second insertion attempts was successful. In group I, 24 of the first insertion attempts were successful. The second and third attempts at insertion were successful in four cases and one case, respectively. One intern failed to achieve successful I-gel insertion. There were no significant statistical differences in the number of successful insertions between the two groups. The mean insertion times were 12.5 ± 4.8 seconds in group R and 27.9 ± 12.5 seconds in group I; this difference was significant (P < 0.05, Table 2). Group R had 23 “very easy” and seven “easy” I-gel insertions. In contrast, group I had 12 “very easy”, seven “easy”, and 10 “difficult” I-gel insertions, in addition to the one failed attempt. The degrees of insertion ease were also significantly different between the two groups (P < 0.05).

Each group exhibited one incidence of air leakage, but in both cases the leak disappeared upon controlled ventilation with the normal tidal volume. No other intraoperative complications, including desaturation, were observed. The incidences of postoperative adverse events were not significantly different between the two groups. However, group I had two cases of blood staining, two cases of sore throat, and one case of gum bleeding due to dental trauma; these events were not recorded in group R.

**DISCUSSION**

Various supraglottic airways have been designed to replace endotracheal tubes and achieve better management of airway patency. I-gel is the most recently developed gel-like thermoplastic supraglottic airway device. Compared with conventional LMA, I-gel has a shorter insertion time, is easier to position,
I-gel insertion was successful during the initial tries in both groups. In group R, the residents failed in only one case of the 30 cases in their first attempts at I-gel insertion. Novice interns also achieved successful insertion in 24 of the 30 cases during their initial attempts. Although more attempts were required and one failure was present in the second group, the two groups were not significantly different regarding the number of insertion attempts. The average resident insertion time was 12.5 seconds, whereas the average intern insertion time was 27.9 seconds; these times were significantly different. Although various mean I-gel insertion times have been reported, ranging from 8 ± 3 seconds to 27.9 seconds, initial insertion attempts have been successful in most studies and have not been associated with any complications [4-6]. In a study by Singh et al. [7] comparing I-gel with pro-seal LMA, 29 of 30 I-gel insertions were classified as “easy”, whereas only 23 LMA insertions had the same classification. Moreover, all 30 I-gel insertions had successful placement on the initial try, and the prevalence of complications was lower in the I-gel insertions. Similar results were presented by Kim et al. [8]. In this study, 49 insertion attempts out of 50 were successful on the initial effort. However, manipulation techniques were required for some of the patients in this study. Pushing was required in 12 patients, one patient required pulling, and one patient required jaw thrusting. The mean insertion time was 17.8 seconds, which is similar to our result.

Since interns with only a novice level of insertion skill performed more manipulations in our study, their I-gel insertion times longer. Moreover, insertions by interns were associated with a higher prevalence of complications such as sore throat and dental trauma compared with insertions by experienced residents, although this difference was not significant. In addition, we also found that although practitioners in both groups successfully inserted the I-gels in their first attempts, the degree of difficulty varied greatly between the two groups. The level of procedural skill of the physician was also associated with a significant degree of difference regarding insertion difficulty. For instance, the interns were more likely to hesitate and/or panic upon encountering resistance during I-gel insertion. Moreover, the interns took a much longer time to find an alternative solution for correct I-gel placement. The residents did not perform any manipulations during I-gel insertion; in contrast, 12 of the cases in the intern group required manipulation. Of these 12 cases, proper placement was achieved in two using head extension only, one with deep rotation, eight with both head extension and deep rotation, and one with head flexion movement.

Oropharyngeal leakage is a very important factor to consider when using supraglottic airway devices. A high oropharyngeal leak pressure (OLP) is beneficial when the patient is undergoing positive pressure ventilation. Most studies with I-gel have an OLP of 22 to 27 cmH2O, which is generally higher than that airway pressure under usual controlled ventilation [2,9]. We set the pressure at 20 cmH2O to investigate the presence of air leakage, and we defined the ability to provide positive ventilation as that which resulted in a successful insertion. We found that one case in each group exhibited an air leak under positive pressure controlled ventilation with 20 cmH2O. However, upon switching to ventilators with traditional settings, no air leaks were observed in any patients.

No postoperative complications were reported in the patients whose insertions had been performed by the residents. In contrast, two cases of blood staining, two cases with throat soreness, and one case with gum bleeding due to dental trauma were present in the intern group. Although the number of patients who experienced a sore throat was relatively small in our study, we suspect that more cases of sore throat would have been reported if patient-controlled analgesia had not been provided postoperatively. Since most patients received patient-controlled analgesia before moving to the recovery room, it is likely that this analgesia was effective in reducing pain and soreness, thereby reducing the number of patient complaints. Without this analgesia treatment, more patients may have complained of soreness. The potentially masking effect of analgesia on the reporting of postoperative complications is one limitation of our study. In addition, patients that were able to open their mouth less than 2.5 cm were excluded, since this would affect the success of I-gel insertion. However, a limitation of this study is that we did not compare the degree of mouth opening between the two groups.

Significant technical advances have been made recently in endoscopy. Specifically, this procedure has been developed for various new applications, resulting in an increased number of diagnostic and therapeutic endoscopic procedures. Proper patient
sedation is required to ensure an acceptable procedural environment for patients, reduce intolerance to the procedure, and increase the success rate of endoscopic procedures. Propofol or midazolam is usually used for patient sedation, either alone or in combination with other analgesics [10,11]. Although these analgesics have been proven to be safe, the increased number of endoscopies and the subsequent increase in sedation has raised concerns regarding sedation-related complications and their complication management [12]. Of these concerns, respiratory complication is a most serious problem that accounts for 0.54% of all complications associated with a mortality rate of approximately 0.05% [13,14]. Thus, it is increasingly important for physicians without much experience in intubation to be able to provide proper airway management during emergent situations outside of the operation room or emergency department, where highly trained physicians are always accessible. If physicians are not able to handle these situations appropriately, patients can suffer serious consequences. I-gel is a good device for accommodating this need. The success rate of I-gel insertion for prehospital airway management has been found to be 94%; this rate is much higher than the 90% success rate of traditional endotracheal intubation [15]. A study by Leventis et al. [16], I-gel insertion by paramedics with human dummies found a success rate of 100%. This study concluded that I-gel is a quicker and simpler method than any other technique, including endotracheal intubation and LMA, and exhibits a higher success rate.

In conclusion, I-gel is a good alternative device for achieving easy and immediate airway management. Moreover, I-gel offers considerable advantages over other methods during difficult intubations or emergent situations requiring airway management. Importantly, I-gel can also be used by physicians who are not familiar with endotracheal intubation to increase the chance of successful airway management during emergencies. Moreover, successful use of I-gel does not require assistance from other doctors who are highly skilled intubation.

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