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A comparison of i-gel™ and Laryngeal Mask Airway Supreme™ during general anesthesia in infants

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Background: The i-gel™ (i-gel) and Laryngeal Mask Airway Supreme™ (LMA Supreme) have been safely used in children. We compared the airway performance of the i-gel and LMA Supreme in infants undergoing general anesthesia.
Methods: Sixty infants with American Society of Anesthesiologists physical status I or II were randomly assigned to place either the i-gel or the LMA Supreme. The size 1 or 1.5 of each airway was selected by the weight of infants. The primary outcome variable was oropharyngeal leak pressure (OLP). We also assessed insertion success rate, insertion time, fiberoptic view of the larynx, airway quality, airway manipulations, and perioperative complications.
Results: Demographic data did not differ between the two groups. Insertion success rate was similar in both groups. OLP for the i-gel (26.0 ± 3.8 cmH_2O) was higher than for the LMA Supreme (23.7 ± 3.2 cmH_2O) (P = 0.016). Insertion time for the i-gel (16.4 ± 2.8 s) was shorter than for the LMA Supreme (18.5 ± 2.7 s) (P = 0.002). There were no differences in fiberoptic view of the larynx, airway quality, airway manipulations, and complications between the two groups.
Conclusions: This study demonstrated that the i-gel and LMA Supreme provided a similar performance of airway in infants. Compared with the LMA Supreme, the i-gel provided shorter insertion time and higher OLP in infants.

Keywords: Infant; i-gel; Laryngeal masks.

Introduction

The different types of supraglottic airway device (SAD) have been frequently used for pediatric anesthesia. Recently, the use of disposable second-generation SAD has been increasing. The i-gel™ (i-gel) is a disposable second-generation SAD that is made from a medical-grade thermoplastic elastomer. It does not require cuff inflation, reducing the complications associated with compression trauma and high cuff pressure [1]. The Laryngeal Mask Airway Supreme™ (LMA Supreme), another disposable second-generation SAD, consist of First Seal™ with the oropharynx (oropharyngeal seal) and Second Seal™ with the upper esophageal sphincter (the esophageal seal) [2].

There are many randomized studies comparing the i-gel and LMA Supreme that indicate effective clinical performance [3–7]. Several studies in adults have demonstrated similar oropharyngeal leak pressure (OLP) between both devices [3–5]. In children, the i-gel has been shown to provide higher OLP when compared with the LMA Supreme [6,7]. However, previous studies that were performed in children included a broad age

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range and various sizes of the device. The studies comparing the two devices in infants less than one year of age are lacking.

The purpose of this prospective, randomized study was to evaluate and compare the performance of i-gel and LMA Supreme in infants undergoing general anesthesia. In this study, the primary outcome measured was the oropharyngeal leak pressure (OLP), and the secondary outcomes measured were insertion success rate, insertion time, fiberoptic view of the larynx, airway quality, airway manipulations, and perioperative complications.

Materials and Methods

This study was approved by the Local Research Ethics Committee (IRB 15-064) and implemented after obtaining informed consents from the parent of infants. Children, American Society of Anesthesiologists physical status I or II, less than 12 months of age, and less than 10 kg of body weight, who were scheduled for elective surgery within two hours under general anesthesia were enrolled in the study. Infants who were accompanied by congenital airway abnormality, upper respiratory infection, or the risk of aspiration were excluded from the study.

Patients were randomly allocated to either the i-gel (i-gel™; Intersurgical Ltd., Workingham, UK) or the LMA Supreme (LMA Supreme™; Teleflex Medical, Dublin Road, Athlone, Ireland) using the sealed envelope method. An investigator, unaware of its contents, opened a sealed envelope and prepared the device. The size of each device was selected by the body weight of infant (size 1 for infants less than 5 kg and size 1.5 for those between 5 and 10 kg in weight).

When the infants arrived at the operating room, the measurements of blood pressure, pulse oximetry, and electrocardiography were monitored. Anesthesia was induced with intravenous injection of ketamine 2 mg/kg and rocuronium 0.6 mg/kg. Adequate anesthetic depth was confirmed by the lack of motor response of jaw thrust [8]. The device was inserted according to the manufacturer's recommendations. All insertions were performed by a single investigator who had experience with more than 50 prior insertions of each device in children. The investigator knew the type of device just before the insertion. The measurement of OLP and other variables were recorded by a single observer who did not participate in the study.

The inflation cuff pressure of the LMA Supreme was maintained to be 40 cmH_2O using a cuff pressure manometer (Mallinckrodt Medical, Athlone, Ireland) [9–11]. After insertion of the device, mechanical ventilation of the lung was started. Anesthesia was maintained with 3 L/min fresh gas, consisting of 2–5% sevoflurane and air in 50% oxygen. Tidal volume was set with 8 ml/kg and respiratory rate was adjusted to maintain end-tidal CO_2 between 35 and 40 mmH_2O. The ease of device placement was assessed by a subjective scale of 1–4 (1: no resistance, 2: mild resistance, 3: moderate resistance, 4: inability to place the device) [12]. Insertion was considered successful if confirmed with the bilateral chest rises, the clear lung sound with no audible leak, and the capnography of the ventilator exhibited in a square shape with no gastric insufflation. Otherwise, the device was completely removed for another attempt. Three insertion attempts were allowed. Insertion time was defined from the time of removal of the facemask to the time of the appearance of first capnography upstroke. Presence or absence of gastric insufflation by epigastric auscultation was performed during OLP assessment. Fresh gas flow was adjusted to 3 L/min, and after closing the expiratory valve, the airway pressure at which an audible leak on auscultation over neck was defined as OLP [13]. The OLP was not allowed to exceed 30 cmH_2O to avoid barotrauma. If mean airway pressure is higher than OLP or insufficient ventilation (lesser than 5 ml/kg) occurred during the airway maintenance, proper manipulations (pushing or pulling of device, extension or flexion of the head, jaw thrust) were performed. If appropriate manipulation does not solve the problem, the device should be removed and endotracheal intubation be performed.

The anatomical positions of SADs in relation to the glottis were classified into four grades by observing the fiberoptic views (grade 1: vocal cords not visible, grade 2: vocal cords and anterior epiglottis visible, grade 3: vocal cords and posterior epiglottis visible, grade 4: only vocal cords visible) [14]. We recorded heart rate, mean blood pressure, oxygen saturation, peak inspiratory pressure, inspiratory tidal volume, expiratory tidal volume, airway quality, and complications during the induction and maintenance of anesthesia. The airway quality was assessed using four grades (clear, minimal obstruction, partial obstruction, and complete obstruction) by auscultating the lung sound [6]. After the operation, sevoflurane was stopped, and patients were treated with pyridostigmine and glycopyrrolate to reverse the paralysis. When adequate movement and sufficient voluntary ventilation were observed, the device was removed. In addition, we also observed bronchospasm, desaturation (SpO_2 < 90%), coughing, blood-on device, regurgitation, aspiration, and teeth or lip injury during emergence from anesthesia.

Sample size calculation was based on our primary outcome variable, the OLP. Previous studies have demonstrated that the standard deviation (SD) of OLP of the i-gel and the LMA Supreme in children is approximated at 5 cmH_2O [7,15,16]. To detect a difference of 4 cmH_2O in OLP between the groups with a type I error of 0.05 and a power of 80%, a sample size of 25 patients in each group was required. Thirty patients in each group were included because of the possibility of dropout.

Data are presented as the mean ± SD or the number of patients. The data were analyzed using the SPSS software (version

23.0, IBM Corp., Armonk, NY, USA). Student's t-test was used for continuous data, and chi-square test or Fisher's exact test was used for categorical data. A value of $P < 0.05$ was considered significant.

Results

Sixty patients had participated in this study. The results of all sixty patients were included in the data analysis (Fig. 1). There were no significant differences between two groups in terms of demographic data, types of operation, and anesthetic time (Table 1).

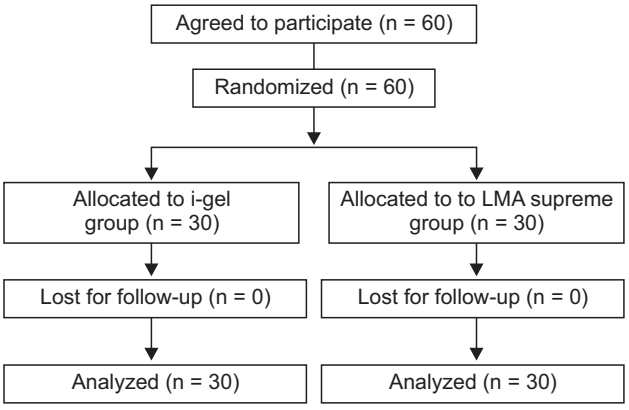

Fig. 1. CONSORT flow diagram.

The characteristics of device insertion are shown in Table 2. The distribution of device sizes, ease of insertion, and number of insertion attempts were similar between groups. The data from the i-gel group indicates shorter insertion time compared to the LMA Supreme group ($P = 0.002$). The i-gel group has also shown higher OLP compared to the LMA Supreme group ($P = 0.016$). The fiberoptic view scores were similar in both groups. The vocal cord was observed in all cases of the two groups. There was no significant difference in the initial airway quality and peak inspiratory pressure between both the groups.

Table 1. Patient Characteristics and Operation Data

	i-gel (n = 30)	LMA Supreme (n = 30)	P value
Age (month)	6.7 ± 4.2	6.2 ± 4.3	0.618
Sex (F/M)	10/20	7/23	0.567
Height (cm)	65.1 ± 14.8	67.6 ± 14.5	0.638
Weight (kg)	7.0 ± 2.5	6.8 ± 2.4	0.547
Anesthetic time (min)	57.5 ± 30.5	61.2 ± 30.5	0.642
Types of operation			0.605
Herniorrhaphy	17	21	
Laparoscopic operation	5	1	
Umbilical cystectomy	3	2	
Orchiopexy	2	2	
Lower extremity operation	2	2	
Eye operation	1	2	

Values are expressed as mean ± SD or number of patients.

Table 2. Comparative Data for the i-gel and the LMA Supreme

	i-gel (n = 30)	LMA Supreme (n = 30)	P value
Device size (1.0/1.5)	14/16	12/18	0.795
Ease of insertion (1/2/3/4)*	26/3/1/0	28/2/0/0	0.529
Number of insertion attempts (1/2)	30/0	29/1	1.000
Insertion time (sec)	16.4 ± 2.8	18.5 ± 2.7	0.002
Oropharyngeal leak pressure (cmH_2O)	26.0 ± 3.8	23.7 ± 3.2	0.016
During OLP testing on auscultation			
Audible leak over neck	24	29	0.103
Gastric insufflation	0	0	1.000
Peak inspiratory pressure (cmH_2O)	15.7 ± 2.2	16.2 ± 3.3	0.520
Fiberoptic view of larynx			0.690
Vocal cord not visible	0	0	
Vocal cord + Anterior Epiglottis	4	2	
Vocal cord + Posterior Epiglottis	12	12	
Only vocal cord visible	14	15	
Initial airway quality			0.975
Clear	20	20	
Intermittent partial obstruction	8	7	
Intermittent complete obstruction	2	2	
Complete obstruction	0	0	

Values are expressed as mean ± SD or number of patients. *Ease of insertion was graded as 1: no resistance, 2: minimal resistance, 3: moderate resistance, 4: unable to place device. OLP: oropharyngeal leak pressure.

Table 3. Manipulation of Airway Devices and Perioperative Complications

	i-gel (n = 30)	LMA Supreme (n = 30)	P value
Manipulation			0.747
Push	2	0	
Pull	1	0	
Jaw thrust	1	1	
Head extension	1	5	
Endotracheal tube change	0	1	
Perioperative complication			0.531
Audible leaks*	1	4	
Desaturation (SaO_2 < 90%)	1	1	
Gastric insufflation*	1	2	
Aspiration	0	0	
Laryngospasm	1	0	
Cough	0	1	
Blood staining	1	0	

Values are expressed as number of patients. *These complications were checked except for the period at oropharyngeal leak pressure testing.

Five patients in the i-gel group and seven patients in the LMA Supreme group underwent manipulations to maintain the airway during anesthesia (Table 3). One patient in the LMA Supreme group did not have sufficient ventilation during the operation, resulting in the LMA Supreme being removed and endotracheal intubation was performed. Initial data were recorded for this patient and therefore included in the results.

The perioperative complications occurred at period except OLP testing showed no significant difference between the two groups (Table 3). Audible leak was observed in one patient in the i-gel group and four patients in the LMA Supreme group. Gastric insufflation was observed in one patient in the i-gel group and two patients in the LMA Supreme group. Blood staining on device and postoperative airway obstruction was observed in one patient in the i-gel group. Postoperative hypoxia was observed in one patient in the i-gel group and one patient in the LMA Supreme group. Postoperative coughing was observed in one patient in the Supreme group.

Discussion

There are various studies on the safety and efficacy of airway maintenance when using SAD in children [6,7,13,14,17]. The anatomy and physiology of infants differ significantly from those of older children or adults. A younger child has a relatively big epiglottis structure. When the small SAD is inserted, the epiglottis folds and complications such as airway obstruction can occur.

There were several studies performed using SAD in infants [18–20]. The i-gel and LMA Supreme have not been compared in infants before. In a comparative study of the i-gel and LMA Classic in infants, it was reported that the first attempt insertion success rate was higher in the i-gel, but insertion time was similar in both devices [20]. In our study, the first attempt insertion was successful in all cases of the i-gel group whereas, in one case of the LMA Supreme group, the insertion was successful in the second attempt. Kim et al. [7] reported that insertion time of LMA Supreme is shorter than i-gel. However, in our study, insertion time was shorter with the i-gel group than the LMA Supreme. The i-gel was a SAD in the form of a non-inflatable cuff, but LMA Supreme was in the form of an inflatable cuff. This mechanical difference resulted in the LMA Supreme requiring more time to reach the optimal airway pressure by proper cuff inflation rather than the time needed to enter the oral cavity [21,22].

The application of intracuff pressure for pediatric LMA Supreme is important in OLP and pharyngeal mucosal pressure. Choi et al. [9] reported OLP at intracuff pressure of 60 cmH_2O is higher at 40 cmH_2O. Jagannathan et al. [10] reported OLP does not differ between intracuff pressure of 40 cmH_2O and 60 cmH_2O. The higher the intracuff pressure for the supraglottic airway device that is applied, the likelihood of postoperative pharyngolaryngeal complications can increase [11]. Therefore, in this study, intracuff pressure for LMA Supreme was maintained at 40 cmH_2O. The OLP is an important factor to maintain ventilation with the SAD. In infants, the use of SADs with a high OLP is beneficial because the high inspiratory pressure is required during positive pressure ventilation due to reduced lung compliance and increased air resistance [23]. Kim et al. [7] reported that i-gel and LMA Supreme device provide similar OLP in infants. Kayhan et al. [24] reported that there is no significant difference in terms of OLP of i-gel and Proseal LMA in infants. In our study, OLP for i-gel was higher than for LMA Supreme, which correlates with results reported in previous studies with children [6,7].

It has been shown that the i-gel group displays a better fiberoptic view of the larynx compared to other SADs [22,25]. The fiberoptic view of the larynx is not an absolute factor for evaluating whether the ventilation is performing well [24,26]. However, the rise of OLP is likely to occur in the infants as the epiglottis is folded downward, therefore confirmation of fiberoptic view of the larynx can help identify good ventilation [23]. In our study with the i-gel and the LMA Supreme, the fiberoptic views were similar in both groups.

Airway manipulation was required in five cases of the i-gel group and in seven cases of the LMA Supreme group. There was no difference in the number of infants between the two groups; however, appropriate intra-operative manipulation was done in one case of the LMA Supreme group, as the subject did not have sufficient ventilation so intubation was conducted using an endotracheal tube. In this case, due to the device not being posi-

tioned properly during the first insertion of the LMA Supreme, a second attempt was conducted, and the OLP was measured relatively low. Although proper ventilation was achieved at the beginning of anesthesia, an intra-operative audible leak had occurred causing improper ventilation despite manipulation. Therefore, an endotracheal tube intubation was conducted. The incidence of complication in our study was rare, but audible leak occurred relatively more in the LMA Supreme group. Other complications were shown to have no clinical importance.

This study had several limitations. The postoperative complications such as sore throat or hoarseness in infants could not be evaluated. We also could not perform a quantitative evaluation when airway leak occurred. Infants have normal lung function and they have no airway problems. Therefore, these results could apply to only healthy infants. This study was conducted only on Korean infants and may show differences in other races.

In conclusion, the i-gel and the LMA Supreme showed reliable performances of the airway in infants less than a year old. The i-gel displayed a faster insertion time and higher OLP when compared to the LMA Supreme. Considering that the incidence of airway leak occurred more frequently in the LMA Supreme group, the clinician will need to pay more attention during general anesthesia.

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