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Comparison of the efficacies of I-gel™ and LMA-ProSeal™ for airway management in pediatric patients

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Aim: The present study was performed to compare the performance of I-gel™ with LMA-ProSeal™ in children undergoing anesthesia.

Materials and methods: A total of 185 patients who were scheduled for elective surgery in Dicle University's hospital were randomly divided into 2 groups: the I-gel™ group (Group-I, n = 95) and the p-LMA™ group (Group-P, n = 90). Airway leakage pressure, insertion time, fiberoptic laryngeal image scores, ease of insertion, and possible complications were compared between these groups.

Results: The airway leakage pressure of Group-I was significantly higher than that of Group-P (means ± SD: 28 ± 5 vs. 20 ± 4 cmH_2O, $P < 0.01$). The duration of supraglottic airway device insertion was shorter in Group-I than Group-P (19 ± 4 vs. 28 ± 5 s, $P < 0.01$). The overall success rate was 95% for Group-I and 94% for Group-P ($P = 0.10$). The I-gel provided a better view of the glottis than the p-LMA (93% of cases in Group-I and 68% of cases in Group-P, $P = 0.03$). There were no significant differences with regard to ease of insertion ($P = 0.97$).

Conclusion: This study suggested that I-gel is an effective and safe alternative supraglottic airway device for use in children.

Key words: I-gel™, LMA-ProSeal™, supraglottic airway device

1. Introduction

The basic responsibility of an anesthesiologist is to provide adequate ventilation for patients under general anesthesia (1). However, endotracheal intubation requires special training and skill. The most serious disadvantages of intubation are laryngopharyngeal complications and lesions, especially when performed by a resident anesthetist (2).

Pediatric patients have specific characteristics that are quite different from those of adults, and their intubation therefore has a number of unique features (3). This age group is likely to be associated with higher rates of complications of laryngoscopy and intubation. Because of this, supraglottic airway devices (SADs) have been increasingly used in recent years in suitable cases (4).

In cases of elective and difficult airway management, SADs are increasingly preferred due to their confirmed efficacy and safety (5,6). Insertion of SADs causes less laryngeal trauma and may provoke less sympathetic stimulation than endotracheal intubation (7,8). The first SAD to be developed was the c-LMA (LMA-Classic™; Laryngeal Mask Company Limited, Intavent Orthofix, Maidenhead, Berkshire, UK). Although c-LMA is a practical method, the aspiration risk was reported to be around 6%–9%, as detected by observations of the esophagus via fiberoptic bronchoscopy (FOB) (9). Therefore, the p-LMA™ (LMA-ProSeal™; Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands, UK) was developed to provide gastric drainage (10). However, both the c-LMA and p-LMA have cuff-related complications (11). High cuff pressure in laryngeal mask airways (LMAs) can cause damage to the mucosae on periglottic and supraglottic structures (12). Studies in adults have shown that higher pressures in LMA cuffs are generally associated with increased morbidity, such as sore throat, hoarseness, and nerve palsies (13). Therefore, a new SAD called I-gel™ (Intersurgical Ltd., Wokingham, Berkshire, UK) was developed, which is composed of a soft gel-like thermoplastic elastomer with a noninflatable cuff and a channel for gastric suction catheter placement. The potential advantages of the I-gel are that it is compatible with anatomical structures, it can be easily inserted into

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the mouth, and there is reduced risk of pharyngeal tissue compression due to lack of high cuff pressure (14).

Although many studies on the use of I-gel in adults (15–17) have been published, there are few reports that have evaluated the pediatric I-gel, especially in small children (4,7,18,19). Such studies are particularly important because children are more vulnerable to complications related to the use of cuffed supraglottic airway devices (20). The advantages of I-gel were improved glottic view, establishment of a clear airway, and enabling of spontaneous and controlled ventilation without complications in children (21).

The aim of this prospective, randomized, controlled study was to compare the clinical performance (oropharyngeal leakage pressure, insertion time, number of trials, fiberoptic laryngeal image score, and possible complications) of I-gel and p-LMA in pediatric patients.

2. Materials and methods

This study was performed with local ethics committee approval (Dicle University Faculty of Medicine Ethics Committee, Diyarbakır, Turkey) and informed consent was obtained from the parents/guardians of all pediatric patients.

A total of 185 patients scheduled for elective surgery were included in this study. The inclusion criteria were: 1) surgical procedures of less than 1 h with no need for endotracheal intubation; 2) elective ophthalmological, lower abdominal, or urogenital operations; 3) patient age of 0–12 years; 4) American Society of Anesthesiologists (ASA) class I–II; and 5) weight of less than 30 kg. The exclusion criteria were: 1) patients with risk factors for difficult airway (mouth opening of <2 cm, Mallampati class 4, limited neck extension, history of previous difficult tracheal intubation); 2) any known pulmonary and cardiovascular diseases; and 3) risk of aspiration (gastroesophageal reflux disease, gastrointestinal stenosis or stricture, hiatal hernia).

A computer-generated randomization scheme was used to divide the patients into 2 groups: Group-I (I-gel, n = 95) and Group-P (p-LMA, n = 90). In the premedication room, a 22–24 G cannula was inserted intravenously and a 1/3 balanced electrolyte solution was started at 2 mL kg^{-1} h^{-1}. Oral or rectal midazolam was given at a dose of 0.5 mg/kg 30 min before induction of anesthesia. In the operating room, patients were monitored in the supine position. Electrocardiography, noninvasive blood pressure, heart rate, and oxygen saturation were measured as standard. All patients were preoxygenated with 100% O_2 for 3 min. Both groups were administered standard anesthetic induction with propofol (3 mg/kg) and remifentanil (1 μg/kg), and rocuronium bromide (0.3 mg/kg) after loss of eyelash reflex. Bilateral chest auscultation and capnography were used to confirm successful mask ventilation. The same anesthesiology staff performed airway management. The devices were lubricated with a water-based agent and introduced according to the manufacturer's recommendations. The appropriate SAD size was determined in accordance with the patient's weight and the manufacturer's instructions. Selected sizes were as follows: I-gel: size 1.5 for 5–11.9 kg, size 2.0 for 10–24.9 kg, size 2.5 for 25–34.9 kg; p-LMA: size 1.5 for 5–9.9 kg, size 2.0 for 10–19.9 kg, size 2.5 for 20–29.9 kg. Both I-gel and p-LMA were inserted under sufficient anesthesia depth when no response was obtained in train-of-four stimulation. The cuff of the p-LMA was completely deflated during insertion. A blind-insertion technique was used for insertion, and insertion time was measured from the moment the facemask was taken away from the patient's face until sufficient ventilation was established. Sufficient ventilation was judged clinically by the presence of symmetric chest movements, stable oxygen saturation, stable square wave capnography trace with no audible oropharyngeal leak, and a tidal volume of at least 7 mL/kg body weight (22). After successful insertion, the cuff of the p-LMA was inflated to a sufficient degree. Intracuff pressure of the p-LMA was set at 60 cmH_2O using a manometer (Rüsch GmbH, Kernen, Germany). The ease of placement was assessed using a subjective scale of 1–4 (1 = no resistance, 2 = mild resistance, 3 = moderate resistance, 4 = inability to place the device). Failure of the SAD was identified as 3 unsuccessful insertion attempts or inadequate ventilation (<7 mL/kg). When SAD insertion was unsuccessful, the device was removed from the mouth. SAD insertion was also evaluated according to the Brimacombe score using FOB (2.8 mm; Storz GmbH, Tuttlingen, Germany). The Brimacombe score was classified as follows: 4 = only vocal cords visible, 3 = vocal cords plus posterior epiglottis visible, 2 = vocal cords plus anterior epiglottis visible, and 1 = vocal cords not seen (23). A nasogastric catheter (10–14 Fr) was inserted through the gastric opening of the SAD.

To determine the airway leakage pressure, the expiratory valve was closed and a fresh gas flow of 3 L/min was set until equilibrium was reached (airway pressure was not allowed to exceed 40 cmH_2O) and then released completely. The epigastrium was then auscultated to identify gastric insufflations and recorded (18).

Anesthesia was maintained using 3 L/min fresh flow of 50/50 O_2/air mixture with sevoflurane (2 MAC) and remifentanil infusion (0.2–0.5 μg kg^{-1} min^{-1}). The volume-controlled ventilation mode was set as follows: tidal volume of 7 mL/kg, end-tidal carbon dioxide levels of 32–36 mmHg, and frequency of 14–20 breaths/min. The ventilation and hemodynamic parameters were recorded during general anesthesia. The anesthetic gas flow was terminated at the end of the operation and patients were

ventilated with 100% O_2. The anesthetist removed the SADs when spontaneous eye opening was observed. Patients were transported to the recovery room, and postoperative complications occurring during insertion, maintenance, and removal were noted for each patient. Laryngospasm or bronchospasm, blood staining, lip or dental trauma, sore throat, coughing, nausea and vomiting, aspiration, and hypoxia (SpO_2 < 90%) were evaluated and the oropharyngeal structures were examined with a light source. In addition, blood stains on the SAD were recorded during removal of the device.

2.1. Statistical analysis

All data were analyzed with SPSS (SPSS Inc., Chicago, IL, USA) and are presented as means with standard deviations or numbers and percentages. Success rates and other frequency data were compared using the chi-square test. Airway leakage pressures, insertion times, and other continuous data were analyzed by the Mann–Whitney test if the data were not normally distributed. Otherwise, the independent two-tailed Student t-test was used. In all analyses, $P < 0.05$ was taken to indicate statistical significance.

3. Results

Over a 40-week period, a total of 207 children at the Dicle University Hospital had elective day surgery with general anesthesia not necessitating tracheal intubation. Ten children were excluded due to upper respiratory tract infection, and the parents of 12 others refused consent to participate in the study. Therefore, the study population consisted of 185 pediatric patients.

There were no statistically significant differences in demographic characteristics between the groups (Table 1). Group-I showed significantly higher airway leakage pressures than Group-P (28 ± 5 vs. 20 ± 4 cmH_2O, respectively, $P < 0.01$, Table 2). SDA insertion time was shorter for Group-I than Group-P (19 ± 4 vs. 28 ± 5 s, respectively, $P = 0.01$, Table 2).

The first-attempt success rate was high for both devices (93% for Group-I and 91% for Group-P, $P = 0.40$, Table 2). The overall insertion success rate was 95% for Group-I and 94% for Group-P ($P = 0.10$, Table 2). After a failed first insertion attempt, the SAD was changed to a different size in 7 cases in Group-I and 8 in Group-P. The SAD was successfully inserted on the second attempt in 3 cases in both Group-I and Group-P. SAD insertion was considered unsuccessful in a total of 9 cases, and these patients were intubated and excluded from the study.

There were no statistically significant differences with regard to ease of insertion (93% for Group-I and 92% for Group-P, $P = 0.97$, Table 2).

The I-gel provided a better view of the glottis than did p-LMA (93% of cases in Group-I and 68% of cases in Group-P had Brimacombe scores of 3 or 4, $P = 0.03$, Table 2). The success rates of nasogastric catheter placement in both groups were similar ($P > 0.05$). Gastric fluid was aspirated using a gastric catheter in 90% of patients. There were no statistically significant differences between the 2 groups with regard to the incidence of adverse events (Table 3).

Table 1. Patient demographic characteristics.

	Group-I (n = 95)	Group-P (n = 90)	P-value
Male/female, number (%)	55/40 (58/42)	50/40 (55/45)	0.65
Age (years)	4.1 ± 3.2	4.7 ± 3.3	0.75
Weight (kg)	14.2 ± 6.3	14 ± 8.2	0.83
Height (cm)	107.2 ± 30.6	105.5 ± 26.7	0.63
ASA status I/II, number (%)	74/21 (78/22)	70/20 (78/22)	0.75
Anesthesia time (min)	110 ± 20	115 ± 16	0.65
Operation time (min)	61 ± 24	52 ± 26	0.12
Type of surgery			
Ophthalmology, number (%)	28 (30)	26 (29)	
Lower abdomen, number (%)	35 (35)	24 (27)	0.38
Urogenital, number (%)	32 (35)	40 (44)	

Values are the number (%) of the patients or mean ± SD. Group-I: I-gel™; Group-P: ProSeal™-LMA.

Table 2. Insertion of the devices.

	Group-I (n = 95)	Group-P (n = 90)	P-value
Success at first attempt	88 (93)	82 (91)	0.40
Overall success	91 (95)	85 (94)	0.50
Failed insertion	4 (4)	5 (6)	0.25
Airway leakage pressure (cmH_2O)	28 ± 5	20 ± 4	<0.01
Insertion time (s)	19 ± 4	28 ± 5	0.01
Ease of device placement 1/2/3/4*	85/4/2/0	82/1/1/0	0.97
Fiberoptic view 4/3/2/1**	75/10/6/0	39/19/14/9	0.03
Gastric catheter placement	90 (99)	85 (100)	0.10
Gastric fluid aspiration possible	81 (89)	79 (92)	0.50

Data are given mean ± SD or number (%). Group-I: I-gel™; Group-P: ProSeal™-LMA.
*1 = no resistance, 2 = minimal resistance, 3 = moderate resistance, 4 = unable to place device.
**Brimacombe score: 4 = only vocal cords visible, 3 = vocal cords plus posterior epiglottis visible, 2 = vocal cords plus anterior epiglottis visible, 1 = vocal cords not seen (35).

Table 3. Complications during mask insertion, surgery, and emergence.

	Group-I (n = 95)	Group-P (n = 90)	P-value
Laryngo- or bronchospasm	3(3)	6 (7)	0.15
Blood staining	1 (1)	3 (3)	0.10
Lip or dental trauma	1 (1)	1 (1)	0.98
Sore throat	1 (1)	3 (3)	0.10
Coughing	1 (1)	1 (1)	0.96
Nausea and vomiting	1 (1)	1 (1)	0.96
Aspiration	0	0	
Hypoxia (SpO_2 < 90%)	0	0	

Data are given as number (%). Group-I: I-gel™; Group-P: ProSeal™-LMA.

4. Discussion

The most important finding of the study was that Group-I patients had higher airway leakage pressures than Group-P. In addition, I-gel had advantages over p-LMA in terms of shorter insertion times and improved fiberoptic view of the vocal cords. However, I-gel showed similar performance to p-LMA in terms of ease of insertion in pediatric patients.

Airway leakage pressure is often used to monitor the quality of the airway seal. The effective airway leakage pressure is especially important for provision of safe and efficient ventilation with a laryngeal mask in patients with increased respiratory resistance (15). I-gel has a high leakage pressure and may provide a wide safety range for positive pressure ventilation in patients with high airway pressure. Goldmann et al. (24–26) used a similar methodology to that adopted in the present study and reported a mean leakage pressure of 23 cmH_2O for p-LMA sizes 1.5, 2.0, and 2.5. In the present study, median leakage pressure for p-LMA sizes 1.5, 2.0, and 2.5 was 20 cmH_2O. The airway leakage pressure, which was the primary outcome of the present study, in Group-I (mean: 28 cmH_2O) was significantly higher than that in Group-P (mean: 20 cmH_2O). These results indicate that I-gel may be superior to p-LMA due to its higher airway leakage pressure in children. Beylacq et al. (4) conducted the first observational study of I-gel

in children and reported adequate seal pressure (mean: 25 cmH_2O). However, the study was conducted using adult-sized I-gel SADs in a group of patients with an average age of 12 years. Theiler et al. (19) recently compared the use of pediatric-sized I-gel with Ambu AuraOnce (Ambu, Ballerup, Denmark) in pediatric patients and reported that the leakage pressure of pediatric I-gel was significantly higher than that of pediatric Ambu AuraOnce. Lee et al. (18) recently reported that pediatric-sized I-gel provided a similar leakage pressure but a shorter insertion time and improved glottic view compared with c-LMA in children.

Shorter insertion times influence the feasibility of SAD use. Lee et al. (18) reported shorter insertion times for I-gel compared with c-LMA, probably because the less flexible stem of the I-gel facilitates insertion and there is no need for cuff inflation. In our study, the insertion time of Group-I was significantly shorter than that of Group-P. Thus, I-gel is acceptable for clinical use in pediatric patients due to its short insertion time.

The insertion success rates within 3 attempts were 95% for Group-I and 94% for Group-P in the present study. In a previous study that compared c-LMA and I-gel in adult patients, the percentage of overall insertion success rate after 2 attempts was 84% in the I-gel group and 92% in the c-LMA group (17). In another study using manikin models, 8 types of SADs were compared, and the overall success rate of insertion for I-gel was 95% (27). Theiler et al. (19) recently compared the use of pediatric-sized I-gel with Ambu AuraOnce in pediatric patients and reported that both masks are suitable for ventilation of anesthetized children with high success rates. In agreement with these results, there was no significant difference in the overall success rate between the 2 devices in the present study.

The ease of insertion was graded as easy or very easy in 93% cases in the I-gel group and 92% in the p-LMA group. Other studies of pediatric I-gel and p-LMA (4,28,29) have shown similar results.

In a cadaver study in which placement of the SAD was confirmed by FOB, the I-gel was shown to effectively conform to the perilaryngeal anatomy (14). Clinical studies using FOB indicated significantly better fiberoptic scores of SAD positioning for I-gel than for other devices (15,17,18). The FOB image score was reported to be dependent on hypopharyngeal SAD position and the folding of the epiglottis. In the present study, fiberoptic examinations via the I-gel provided an acceptable view of the vocal cords (views 3 and 4) in 87% of patients. In addition, the fiberoptic view of the glottis was notably good with I-gel as compared to p-LMA. The fiberoptic imaging score confirmed that I-gel provided good visualization and anatomical localization to ensure unimpeded ventilation (15).

Both I-gel and p-LMA are more reliable than c-LMA in terms of aspiration risk because they allow gastric drainage. Previous studies indicated that nasogastric tubes (N/G) could be easily passed through the I-gel channel and gastric contents could be aspirated via the N/G (30). Many studies confirmed that N/G tubes could be easily placed through the gastric channel of I-gel and p-LMA (31–33). Similarly, gastric drainage was easier via the N/G tube in the present study.

The rates of perioperative adverse events and postoperative complaints (such as blood on the device, laryngospasm or bronchospasm, lip or dental trauma, sore throat, nausea and vomiting, and hypoxia) were low in both groups. Taken together, these observations indicate that both devices are safe for pediatric airway management.

The present study had several limitations. First, we studied only low-risk pediatric patients (ASA I–II) with normal airways. Second, both devices were inserted by a single experienced user and it may not be possible to generalize the results in pediatric patients to more inexperienced users, such as residents (34). Third, we did not compare performance with likely competitors of I-gel, such as Ambu AuraOnce and LMA-Unique.

In conclusion, the results of the present study indicated that I-gel has a higher airway leakage pressure than p-LMA in pediatric patients. I-gel can be inserted more rapidly and provides a superior fiberoptic view of the glottis than does p-LMA. Both devices are suitable for ventilation of paralyzed children, and there were no significant differences between I-gel and p-LMA in the rates of postoperative complications.

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