

Clinical performance of Ambu AuraGain™ versus i-gel™ in anesthetized children: a prospective, randomized controlled trial

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Background: Ambu AuraGain and i-gel have different characteristics in design each other. However, few reports evaluate which device has more benefits for ventilation in children undergoing paralyzed general anesthesia. This prospective, randomized controlled trial compared the clinical performance AuraGain and i-gel in anesthetized children.

Methods: Children aged between 1 month and 7 years undergoing elective surgery were randomly assigned to the AuraGain and i-gel groups. The primary outcome was initial oropharyngeal leak pressure (OLP). Secondary outcomes were OLP at 10 min post-insertion, first-attempt and total insertion success rates, number of attempts and ease of gastric suction catheter placement, peak inspiratory pressure, fiberoptic bronchoscopic view score, ventilation quality, requirement of additional manipulation post-insertion, and complications.

Results: Data of 93 patients were analyzed. The initial OLPs of the AuraGain and i-gel were 27.5 ± 7.7 and 25.0 ± 8.0 cmH₂O, respectively ($P = 0.130$). The OLP was significantly increased 10 min post-insertion in both groups. The initial success rates of the AuraGain and i-gel insertion were comparable. Suction catheter placement via the gastric port was easier ($P = 0.018$) and fiberoptic bronchoscopic view was better with the AuraGain ($P < 0.001$). The i-gel required additional manipulations post-insertion ($P = 0.038$). The incidence of complications during the emergence period was 10.8% for the i-gel and 2.2% for the AuraGain ($P = 0.1$).

Conclusions: OLP is comparable between AuraGain and i-gel. The AuraGain would be more favorable than the i-gel for use in pediatric patients under general anesthesia considering other outcomes.

Keywords: Airway management; General anesthesia; Laryngeal masks; Pediatrics.

INTRODUCTION

Appropriate airway management is critical in the pediatric population with a lower oxygen reserve. Supraglottic airway devices (SADs) have been used to secure and maintain airways in patients during surgery or emergency situations, as well as in the management of expected and unex-

pected difficult airways. Among various SADs, the i-gel™ (Inter-surgical Ltd., UK) which has a soft non-inflatable cuff and a gastric access port, has been widely used in children. According to a recent meta-analysis, the i-gel has a high oropharyngeal leak pressure (OLP) and a low risk of blood staining, compared with LMA®-Classic [1].

Another device, Ambu AuraGain™ (Ambu, Denmark), a

recently released second-generation SAD, has an inflatable cuff and a gastric port. One of the key features of the AuraGain is the 90-degree angulated shaft, following the anatomy of the upper airway, which facilitates proper insertion and is associated with a high success rate for insertion [2,3]. Although use of the AuraGain has increased, research regarding its clinical performance is limited, especially among children [4,5].

There has been some reports comparing use of the AuraGain and i-gel in pediatric patients, which concluded that the i-gel may be superior to the AuraGain in terms of OLP [5,6]. However, the incidence of additional manipulation or device failure which was defined as the abandonment of the SAD and replacement with a tracheal tube or another device was higher for the i-gel than for other SADs, which should be evaluated further in pediatric populations [1,6]. In addition, there is limited evidence in paralyzed children. Therefore, in this study, we hypothesized that the clinical performance of the AuraGain would be comparable to that of the i-gel in the pediatric populations.

The objective of this prospective, randomized trial was to compare the clinical performance of the AuraGain and i-gel in terms of OLP, successful insertion, ventilation quality, ease of suction catheter placement, additional manipulation after insertion, and complications in children under general anesthesia.

MATERIALS AND METHODS

Ethics and study population

This prospective randomized, controlled, parallel-designed trial was approved by the Institutional Review Board (no. H1704-083-846) and registered at <http://clinicaltrials.gov> (no. NCT03118245). The study was performed in accordance with the ethical standards set forth in the 1964 Declaration of Helsinki and its later amendments. One day before surgery, an anesthesiologist met with each child's parents, explained the study protocol, and obtained written informed consent from them.

Children aged between 1 month and 7 years who were scheduled for simple superficial or peripheral limb surgery within 2 h, under general anesthesia, were enrolled in this study. Children with American society of anesthesiologist physical status over than II, recent upper respiratory tract infection, any respiratory disease, a history of cervical disorder or surgery, risk factors for aspiration including insuff-

icient fasting times, difficult airways, or body mass indices $> 30 \text{ kg/m}^2$ were excluded from this study. In addition, children who were scheduled for emergency surgery, abdominal or thoracic surgeries and all laparoscopic procedures were also excluded.

Group allocation

Patients were randomly assigned to one of two groups, the i-gel group or the AuraGain group, using a stratified randomization procedure (computerized random number; <http://www.randomizer.org>). The allocation ratio was 1 : 1, and an anesthetic nurse who was not associated with the study performed the random allocation by preparing coded and sealed opaque envelopes for allocation concealment. The patients were blinded to group allocation. The bedside anesthesiologists, however, were not blinded.

Anesthesia and study protocol

Before induction of anesthesia, all pediatric patients were sedated with intravenous thiopental sodium (5 mg/kg) or propofol (2 mg/kg) and were taken to the operating room. After electrocardiographic monitoring, pulse oxygen saturation and non-invasive blood pressure measurement were initiated, and anesthesia was induced with sevoflurane 4–6 vol% in 100% oxygen. Following muscle relaxation with rocuronium (0.6 mg/kg) and mask ventilation for 90 s, the i-gel or deflated AuraGain which were lubricated with 2% lidocaine jelly was gently inserted into the oropharynx by a single experienced anesthesiologist (L.J.H), according to group allocation. The sizes of the AuraGain and i-gel were selected based on body weight, as suggested by the manufacturer as follows: size 1.5 (for 5–12 kg), 2 (10–25 kg), and 2.5 (25–35 kg) for the i-gel; size 1.5 (5–10 kg), 2 (10–20 kg), and 2.5 (20–30 kg) for the AuraGain.

After insertion, the cuff of the AuraGain was inflated to an intracuff pressure of 40 cmH₂O using a Portex[®] cuff inflator (Smiths Medical, USA). Mechanical ventilation was started, and adequate ventilation was confirmed by square-wave capnography and bilateral chest excursion. When adequate ventilation was not achieved, the SAD was removed and reinserted. Up to three insertion attempts were allowed. Tracheal intubation was planned in cases of three failed insertion attempts, and such patients were subsequently excluded from the study. During insertion of the SAD, the patient's head and neck were left in the neutral position with the

face straight up and the Frankfort plane angled at approximately 70–80 degrees to the horizontal plane of the bed, as described by Kobayashi et al. [7]. Mechanical ventilation was started in the volume-controlled mode, with a tidal volume of 8 ml/kg, and the respiratory rate was adjusted to maintain $E_t\text{CO}_2$ of 35–40 mmHg. Sevoflurane in an air-oxygen mixture, with fractional inspired O_2 at 40%, was used to maintain anesthesia at a targeted Bispectral index of 40–60.

Immediately after insertion, OLP was determined by closing the adjustable pressure limiting valve of the breathing circuit, with a fresh gas flow of 3 L/min [8,9]. While increasing the airway pressure up to 40 cmH₂O, oropharyngeal leak was assessed by placing the stethoscope over the patient's neck, immediately lateral to the thyroid cartilage. OLP was re-assessed 10 min after insertion.

After determination of the OLP, fiberoptic views were obtained by a single anesthesiologist (L.J.H) by placement of a fiberoptic bronchoscope (Olympus LF-DP, Olympus Corporation, Japan) through the SAD. The view was scored using the Okuda score as follows [10]: 1) the view was completely covered by the anterior epiglottis, but SAD function was adequate, 2) the anterior epiglottis covered more than two-thirds of the diameter of the view, 3) the anterior epiglottis covered one-third to two-thirds of the diameter of the view, and 4) the anterior epiglottis covered less than one-third of the diameter of the view.

Next, a lubricated suction catheter was inserted through the drainage port each SAD for gastric decompression. The size of suction catheter was selected according to allowable maximal catheter size, as suggested by the manufacturer as follows: 10 Fr for size 1.5, 2 and 2.5 of the i-gel; 8 Fr for size 1.5, and 10 Fr for size 2 and 2.5 of the AuraGain. The ease of placement of the suction catheter was assessed as follows: 1) easy – suction catheter enters without resistance at once, 2) difficult – suction catheter withdrawal and re-insertion are tried more than once due to resistance, and 3) suction catheter is unable to pass.

Ventilation quality was assessed by auscultating the lung sound and evaluating the waveform of capnography and bilateral chest excursion [11] as follows: 1) clear, 2) minimal obstruction, 3) partial obstruction, and 4) complete obstruction. If ventilation was inadequate, additional manipulations were performed, which included gentle pushing or pulling of the device, lifting of the chin, jaw thrusting, or head and neck re-positioning. The additional manipulation required was recorded.

The occurrence of complications during surgery and the

emergence period were recorded. These included desaturation ($\text{SpO}_2 < 90\%$), bronchospasm, laryngospasm, coughing, aspiration and bleeding or blood stain on the SAD.

Outcomes and statistical analysis

The primary outcome of this study was the OLP measured immediately after insertion. The secondary outcomes were OLP 10 min after insertion, first-attempt success rate and total success rate for insertion, number of attempts at and ease of suction catheter placement, peak inspiratory pressure, fiberoptic bronchoscopic view score, ventilation quality, requirement of additional manipulation after insertion, and complications.

The required sample size of the present study was determined based on a previous pediatric study, which compared the performance of the AuraOnce and the i-gel [12]. The mean OLP was 22 ± 5 cmH₂O with the i-gel and 19 ± 3 cmH₂O with the AuraOnce. Thus, the sample size required for the present study was determined to be approximately 41 patients per group, with an alpha error of 0.05 and a power of 0.9, using PASS 2008 software (ver. 8.0.16; NCSS statistical software, USA). A total of 98 patients were required, considering an attrition rate of about 20%.

All data were analyzed using SPSS for Windows (ver. 23.0; IBM Co., USA). Normality of data distribution was assessed using the Kolmogorov-Smirnov test. Categorical variables were expressed as numbers and percentages, and continuous variables were expressed as means \pm standard deviations (SDs) or medians and interquartile ranges. The chi-square test was used to test categorical data significance, and Fisher's exact test was used when the expected count of $> 20\%$ cells was less than five. Student's *t*-test or the Mann-Whitney rank-sum test was used to determine the significance of continuous data. A P value of < 0.05 was considered statistically significant.

RESULTS

From April 2017 to January 2018, 98 pediatric patients were screened and 4 patients who did not meet the inclusion criteria were excluded. Ninety-four pediatric patients were enrolled in the study and randomly allocated to two groups. Among them, one patient from the AuraGain group was excluded because of failure to obtain respiratory data. Thus, data from 93 children (46 in the AuraGain group and

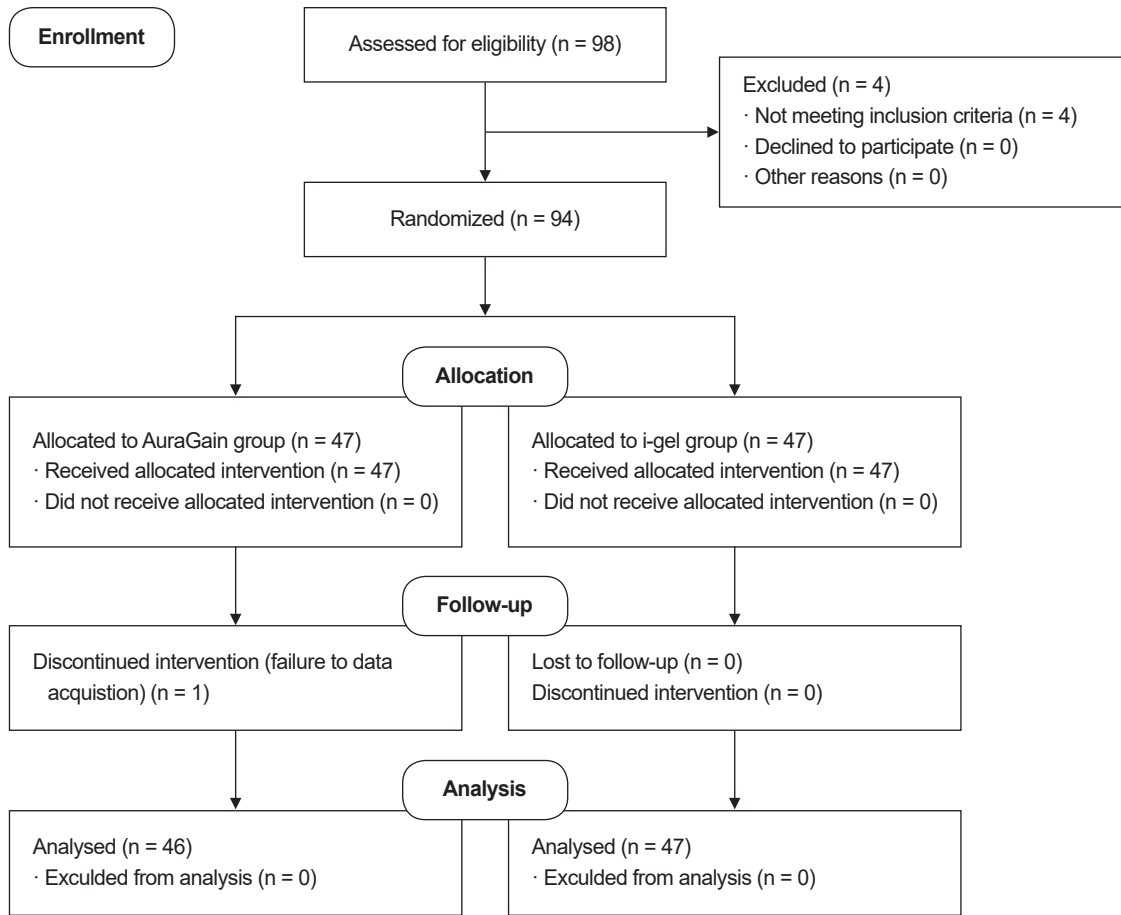


Fig. 1. Consolidated standards of reporting trials (CONSORT) diagram.

Table 1. Baseline Characteristics of Patients Undergoing Anaesthesia with the AuraGain and the i-gel

Variable	AuraGain (n = 46)	i-gel (n = 47)
Age (mo)	36 ± 26	36 ± 26
Sex (M/F)	32/14	31/16
Weight (kg)	15.7 ± 7.0	16.1 ± 7.6
Height (cm)	94.5 ± 21.0	94.9 ± 20.7
Procedure time (min)		
Anaesthesia time	64.2 ± 44.1	72.4 ± 42.6
Operation time	33.3 ± 23.9	45.4 ± 36.4
SAD size 1.5/2.0/2.5	15/16/15	16/19/12
Type of surgery		
Orthopedic surgery	4 (8.7)	10 (21.3)
Plastic surgery	9 (19.6)	11 (23.4)
Urologic surgery	25 (54.3)	22 (46.8)
Other superficial surgery	8 (17.4)	4 (8.5)

Values are presented as mean ± SD or number (percentage). SAD: supraglottic airway device.

47 in the i-gel group) were analyzed (Fig. 1, CONSORT diagram). Table 1 shows the baseline characteristics in both groups; there was no significant difference in demographics and type of surgery between the two groups.

There was no significant difference in initial OLP between the AuraGain (27.5 ± 7.7 cmH₂O) and i-gel group (25.0 ± 8.0 cmH₂O; mean difference [95% confidence interval, 95% CI], 2.5 [-0.7 to 5.8] cmH₂O; P = 0.130). In addition, post-10-min OLP did not differ statistically, between the AuraGain (30.2 ± 7.1 cmH₂O) and i-gel group (28.1 ± 7.9 cmH₂O; mean difference [95% CI], 2.2 [-1.0 to 5.4] cmH₂O; P = 0.182). The OLP was significantly increased by 10 min after insertion in both the AuraGain group (mean differences [95% CI], 2.4 [0.5 to 4.3]; P = 0.016) and the i-gel group (mean differences [95% CI], 3.4 [2.0 to 4.8]; P < 0.001) (Table 2).

We did not experience insertion failure in either group. Both the AuraGain and i-gel were inserted successfully within two attempts in all participants. The initial success

Table 2. Comparative Data for the AuraGain and the i-gel Immediately after Insertion

Variable	AuraGain (n = 46)	i-gel (n = 47)	P value
Oropharyngeal leak pressure (cmH ₂ O)			
Initial	27.5 ± 7.7	25.0 ± 8.0	0.130
After 10 min	30.2 ± 7.1	28.1 ± 7.9	0.182
No. of attempts for device placement (1st/2nd)	43/3	47/0	0.071
No. of attempts of suction catheter placement (1st/2nd)	45/1	38/6	0.039
Ease of suction catheter placement (1/2/3)*	44/1/1	35/8/1	0.018

Values are presented as mean ± SD or number. *Ease of suction catheter placement, as graded by the following subjective scale: 1 = easy (suction catheter enters without resistance at once), 2 = difficult (suction catheter withdrawal and re-insertion are tried more than once due to resistance), 3 = unable to pass.

Table 3. Comparative Data for the AuraGain and the i-gel during Anesthesia

Variable	AuraGain (n = 46)	i-gel (n = 47)	P value
Peak inspiratory pressure; cmH ₂ O	13.0 (12.0, 16.0)	14.0 (12.0, 15.0)	0.5
Fiberoptic grading* (1/2/3/4)	0/9/26/11	6/32/7/2	< 0.001
Ventilation quality [†] (1/2/3/4)	44/0/2/0	45/1/1/0	0.974
Additional manipulation required during operation [‡]	0	4 (8.5)	0.038
Complications [§]	1 (2.2)	5 (10.8)	0.1

Values are presented as median (1Q, 3Q) or number (percentage). *Fiberoptic grading: 1 = the view through the aperture bars is completely covered by the anterior epiglottis, but the supraglottic airway device (SAD) function is adequate, 2 = anterior epiglottis covering more than two-thirds of the diameter of the view, 3 = anterior epiglottis covering more than one-third, but less than two-thirds of the diameter of the view, and 4 = anterior epiglottis covering less than one-third of the diameter of the view. [†]Ventilation quality: 1 = clear, 2 = intermittent partial obstruction, 3 = intermittent complete obstruction, 4 = complete obstruction. [‡]Additional manipulation included gentle pushing or pulling of the device, lifting of the chin, jaw thrusting, or head and neck re-positioning. [§]Complications: desaturation (< 90%), bronchospasm, laryngospasm, coughing, aspiration.

rates of AuraGain and i-gel insertion were 93.5% and 100% (mean difference [95% CI], 6.5 [-2.2 to 17.5]%, $P = 0.071$), respectively. After each SAD insertion, gastric suction catheter insertion was attempted in all patients of the AuraGain group and 44 of 47 patients of i-gel group. The suction catheter was not passed in one patient from each group. Number of patients with difficult suction catheter insertion was one in the AuraGain group while eight in the i-gel group (Table 2).

Although ventilation quality did not differ significantly between the AuraGain and i-gel groups, the glottis view through the fiberoptic bronchoscope was better with the AuraGain than with the i-gel ($P < 0.001$). In six patients in the i-gel group, the laryngeal structures could not be seen owing to the epiglottis. In addition, four of the i-gel participants (8.5%) required additional intraoperative manipulation, including optimization of head position and change in the insertion depth of the SAD, as the tidal volume decreased significantly due to airway leak. In contrast, the AuraGain group did not require additional external manipulations to maintain adequate ventilation (8.5% vs. 0%; mean difference [95% CI], 8.5 [-0.7 to 20.0]%, $P = 0.038$) (Table 3).

The incidence of complications during the emergence period was higher with i-gel than with the AuraGain, but without statistical significance (2.2% vs. 10.8%; mean difference [95% CI], 8.4 [-2.6 to 20.5]%; $P = 0.1$). Complications in the i-gel group included laryngospasm, coughing, breath-holding, and desaturation (< 90%). However, none of these cases required additional management procedures such as tracheal intubation. One child had a blood stain on the AuraGain after removal.

DISCUSSION

In this study, we evaluated the clinical performance of the AuraGain and i-gel in children aged between 1 month and 7 years, who were undergoing simple surgical procedures. To compare the efficacy of the AuraGain and i-gel, OLP was measured at initial device placement and 10 min after placement. There were no significant differences in the initial or the post-10-min OLP between the two groups. In addition, ventilation quality was comparable between two SADs. However, the i-gel required more additional manipulation after insertion, provided a poorer fiberoptic bronchoscopic

view, and was associated with more difficulty in placing the suction catheter in children.

The results of the present study regarding OLP differ from that of recent, previous studies [5,6]. According Mi-hara et al. [5] and Kim et al. [6], the OLP of i-gel was about 23 cmH₂O immediately after insertion, which was similar to our results, and it was significantly higher than the OLP of the AuraGain, which was 17–18 cmH₂O [5]. However, in our trial, the OLP of the AuraGain group immediately after insertion was 27.5 cmH₂O. In addition, our previous study evaluating the performance of AuraGain at different head and neck position, the OLP in the neutral position was 26 cmH₂O [13].

There are some possible explanations for the differing results between our trial and the previous study. First, the intracuff pressure of the AuraGain in our trial was 40 cmH₂O, whereas it was 30 cmH₂O in the Mihara et al.'s study [5]. On the other hand, there was no information about an intracuff pressure for AuraGain in Kim et al.'s study [6]. The information about intracuff pressure is important to compare the OLP, because adequate cuff pressure was associated with higher OLP [14]. Second, we used a neuromuscular blocker that could relax the pharyngeal muscle and improve the airway seal by the AuraGain. In Mihara et al.'s study [5], more than half of the children maintained spontaneous ventilation or were ventilated by pressure support ventilation. In addition, no neuromuscular blockade was used in Kim et al.'s study [6]. The effect of neuromuscular blockade on OLP is different among the SADs [15,16]. However, the evidence is limited regarding OLP with AuraGain and i-gel in paralyzed children. We speculated that the AuraGain could provide adequate airway sealing pressure in paralyzed children under positive pressure ventilation.

Interestingly, the OLP of both devices improved during the early anesthesia period. This suggests that both devices have the ability to sustain a stable laryngeal seal during the initial phase of anesthetic maintenance. There are reports that there might be a chronological improvement in the OLP [17]. However, the reason for the increase in OLP is unclear. There has been some speculation about this phenomenon; it has been suggested that this might be due to the thermoplastic properties of the gel cuff [18], or that some degree of molding of the device in the posterior pharynx improves the airway seal [19]. In addition, saliva may improve the sealing due to the adhesive properties of liquids.

The overall insertion success rate within the first two at-

tempts was 100% for both the AuraGain and i-gel. The first-attempt success rates for AuraGain and i-gel insertion were 93.5% and 100%, respectively. This finding was in concordance with previous findings [4,20,21]. In this study, four patients in the i-gel group (8.3%) required additional manipulations during surgery, because the tidal volume could not be adequately achieved, whereas no patients in the AuraGain group required additional manipulations. For two patients, the i-gel had to be inserted deeper and fixed with additional tape, as it was dislodged from its initial position. Another two patients required head and neck extension to achieve an adequate tidal volume. Previously published studies indicated that the i-gel tends to slide out and requires additional manipulations [12,22,23]. According to Kim et al. [23], approximately 33% of pediatric patients required additional manipulations which was mainly further insertion of the i-gel. Hughes et al. [22] reported that the elastic characteristics of the i-gel may contribute to its instability upon insertion and cause it to slip out. We speculate that this problem occurs more commonly in children than in adults, because of the unique anatomical features of children. The pediatric i-gel is a smaller version of the adult model, but the child's upper airway anatomy is not a mere miniature version of an adult's anatomy. The key differentiating features of a child's upper airway are a larger tongue in proportion to the mouth, a smaller pharynx, a larger and more flaccid epiglottis, an anterior and superior positioned larynx, and a conical shaped larynx [24]. Even though the manufacturer claims that the i-gel is anatomically designed to seal the larynx, pediatric anatomical features may not have been taken into account in its conception. Unlike the i-gel, the AuraGain has a pronounced angulation, a feature that makes it less prone to sliding out and stabilizes its position upon insertion [2,12].

The initial success rate for gastric suction catheter insertion was significantly lower in the i-gel group than in the AuraGain group. The suction catheter placement in the i-gel was significantly more difficult than in the AuraGain, subjectively. This may be due to the relative instability of the i-gel in the hypopharyngeal space. The i-gel's tendency to rotate and slip out from the mouth may displace the gastric channel inlet away from the opening of the esophagus and make it difficult for the gastric suction catheter to pass through.

The fiberoptic bronchoscopic view score for the AuraGain was markedly better than that for the i-gel. It demonstrated a complete or partial view of the vocal cord in 87.2% of the i-gel group and 100% of the AuraGain

group. A recent study reported a similar result that regardless of size, AuraGain provided a better fiberoptic view than i-gel in pediatric patients [6]. This observation can be explained by the 90-degree tube angle of the AuraGain, which may lift up the tongue base, improving the view of the larynx and allowing the fiberoptic bronchoscope to approach closer, at a more acute angle, to the vocal cord. In contrast, the i-gel was more frequently rotated with respect to the pharyngeal structure, which makes it difficult for the observer to view the hypopharynx structures [12]. Additionally, epiglottic downfolding may be more common with the i-gel, particularly in children [22]. Ventilation quality remained the same between the AuraGain and i-gel groups. However, in terms of using SADs as an intubation conduit during difficult airway management, the poor fiberoptic view provided by the i-gel may make it a less favorable choice compared to the AuraGain.

In this study, adverse events were rare in both groups. A complication occurred in one patient (2.2%) from the AuraGain group and in four patients (10.8%) from the i-gel group. This is a much lower complication rate than that reported in previous studies (11–42%) [25–27]. Although it was not statistically significant, the complication rate was relatively higher in the i-gel group. We speculate that the additional manipulation required in the i-gel group may have irritated the upper airway and caused complications during the emergence period. Further studies are required to validate this relationship.

Several limitations of this study should be mentioned. First, the sample size was calculated from a previous study that evaluated a different SAD, the AuraOnce, which has a significantly lower OLP compared with the AuraGain in the present study and other recent studies [12,28]. Second, those measuring the outcomes were not blinded to group allocation because it was impossible to blind them to the SAD used. Third, we used a muscle relaxant in all children, which might be a limitation in generalizing our results to all anaesthetized children. However, it can provide new data for the evaluation of SADs in this specific population. Finally, we did not perform intubation through the SADs. We speculated that the AuraGain may be a better intubation conduit than the i-gel, because of the better fiberoptic view score, but further studies are required to validate this theory.

In summary, both the AuraGain and i-gel provided comparable oropharyngeal sealing and ventilation quality in children receiving neuromuscular blockers during anesthesia.

However, the i-gel required additional manipulation after insertion, which might be associated with a higher incidence of complication. In addition, the fiberoptic view score and ease of suction catheter placement through the gastric port were better with the AuraGain. Therefore, the AuraGain is more favorable than the i-gel for use in pediatric patients under general anesthesia.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

AUTHOR CONTRIBUTIONS

Conceptualization: Jin-Tae Kim. Data acquisition: Ji-Hyun Lee, Seungpyo Nam. Data analysis: Young-Eun Jang, Eun-Hee Kim. Supervision: Hee-Soo Kim. Writing: Ji-Hyun Lee, Seungpyo Nam. Writing—review & editing: Jin-Tae Kim.

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