

# A randomized comparison of the i-gel and the ProSeal laryngeal mask airway in pediatric patients: performance and fiberoptic findings

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## Abstract

**Purpose** We compared the insertion performance of the pediatric size 1.5–3 i-gel airway device with that of the ProSeal laryngeal mask airway (PLMA) in anesthetized children in a prospective, randomized, controlled manner.

**Methods** We included 134 children, aged 3 months to 15 years, scheduled for elective surgery under general anesthesia. They were randomly divided into the i-gel and the PLMA groups according to the airway device used. The primary outcome variable was oropharyngeal leak pressure. Other outcome variables were ease of insertion, required time for insertion, fiberoptic view, and first-attempt and overall success rates.

**Results** There were no differences in the ease of insertion, insertion time, or leak pressure between the devices. Fiberoptic view was significantly better with the i-gel than with the PLMA ( $P = 0.002$ ). The view was significantly better with the sizes 2, 2.5, and 3 i-gel than with the size 1.5 i-gel ( $P = 0.02, 0.004$  and  $0.002$ , respectively), and the view was significantly better with the sizes 2.5 and 3 PLMA than with the size 1.5 PLMA ( $P = 0.02$  and  $0.005$ , respectively). The first-attempt success rates were 94 and 97 % in the i-gel and the PLMA groups, respectively; the success rates including the second attempt were 100 % in both groups. No children developed side effects requiring treatment with either device.

**Conclusion** Both the pediatric i-gel and the PLMA were successfully inserted in children. The fiberoptic view was better with the i-gel than with the PLMA.

**Keywords** Airway · Device · Intubation · i-gel · ProSeal laryngeal mask airway · Pediatrics

## Introduction

The pediatric i-gel (Intersurgical, Wokingham, Berkshire, UK) is a new single-use, latex-free supraglottic airway device for children [1]. It is a smaller model of the i-gel device used in adult patients. Except that the cuff is non-inflatable, its structure with incorporated gastric channels is similar to that of the ProSeal laryngeal mask airway (PLMA; Intavent Direct, Maidenhead, UK). Because the i-gel was developed as a non-inflatable anatomical seal of the pharynx, larynx, and paralaryngeal structure, there could be several differences in its insertion performance and fiberoptic view compared with the PLMA. Although there are several studies regarding the i-gel used in children [1–5], few of them have compared the performance, including ease of insertion, fiberoptic findings, and differences in the leak pressure among various sizes (particularly the small size of the i-gel) with that of the laryngeal mask airway (LMA) with an inflatable cuff [2, 3]. The aim of this prospective randomized study was to evaluate the clinical performance of various sizes (1.5–3) of the i-gel compared with the PLMA.

## Subjects, materials, and methods

### Participants

After obtaining approval from the institutional ethics committee (No. 878) and written informed consent from the parents, we included children aged from 3 months to

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15 years with an American Society of Anesthesiologists (ASA) physical status 1 or 2 and a weight of 5–50 kg in a consecutive manner. This study has been registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000006030). All patients were scheduled for elective surgery under general anesthesia not requiring tracheal intubation at Osaka City General Hospital and Children's hospital. Exclusion criteria were: planned time for surgery more than 4 h, gastrointestinal surgery, body mass index  $>30$  kg/m<sup>2</sup>, known difficult airway (difficult mask ventilation or difficult laryngoscopy, Cormack–Lehane grade more than 2 in patient history), congenital malformation involving the respiratory tract, cervical spine disease, and refusal to participate.

### Anesthesia

Intake of food and clear fluid was allowed until 6 and 2 h before anesthesia, respectively. Oral midazolam 0.5 mg/kg (maximum 12 mg) was provided 30 min before induction to all children. The children were positioned supine with the head resting on a ring-shaped pillow to achieve optimal position and monitored according to the hospital's standard clinical operating procedures following the Japan Society of Anesthesiologists standard. Anesthesia was induced by inhalation with 8 % sevoflurane or intravenously with propofol 3–4 mg/kg, as reported previously [3] and no muscle relaxants were used. The choice of the supraglottic airway—the i-gel or the PLMA—was randomly performed by the sealed envelope method. The size of the i-gel and the PLMA was chosen according to the manufacturer's recommendations (i-gel: size 1.5 for 5–9.9 kg, size 2 for 10–24.9 kg, size 2.5 for 25–34.9 kg, size 3 for 35–50 kg; PLMA: size 1.5 for 5–9.9 kg, size 2 for 10–19.9 kg, size 2.5 for 20–29.9 kg, size 3 for 30–50 kg).

Airway management was performed by one anesthesiologist (A. F.) with experience of using the i-gel and the PLMA in more than 100 children, respectively, before starting this study. The cuff of the PLMA was fully deflated [6]. Both the i-gel and the PLMA were lubricated with a water-based agent and were inserted without an introducer after confirming disappearance of the eyelash reflex and motor response to jaw thrust [2, 4]. The cuff of the PLMA was inflated with 7–20 ml air according to its size following the manufacturer's instructions. Three failed insertion attempts of a device were defined as a failure of the device. A failed insertion attempt was defined as inability to insert the device or provide sufficient ventilation despite three minor airway interventions. A failed insertion attempt led to removal of the device from the mouth and an alternative airway device was used. After placement of the i-gel or PLMA, a 10-French gauze gastric tube, irrespective of the size of the i-gel and the PLMA,

was inserted through the esophageal drainage tube and correct placement was confirmed by auscultation of the epigastrium during injection of a small amount of air. The gastric tube was removed under suction before the devices were removed.

### Measurements

All measurements were performed by a trained unblinded observer who was not involved in the clinical procedure, as described previously. The insertion time was measured from the moment the face mask 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 6 ml/kg body weight [3]. The oropharyngeal leak pressure was determined by closing the expiratory valve of the anesthesia breathing system at a fixed gas flow of 3 l/min and noting the airway pressure (maximum allowed, 30 cmH<sub>2</sub>O) at which equilibrium was reached.

The ease of insertion of the i-gel and the PLMA was evaluated with a four-step scale (1 = very easy, 2 = easy, 3 = difficult, and 4 = very difficult) [1]. To evaluate the anatomical position of the supraglottic airway device, the breathing system was briefly disconnected and a 3-mm fiberscope (LF-DP; Olympus, Tokyo, Japan) was inserted through the airway port to evaluate the glottis view after fixation of the airway devices. The best view from the tip of the orifice of the i-gel or the PLMA was graded from 1 to 4, as proposed by Brimacombe and Berry [7] and used previously [8, 9]: score 4, only vocal cords; score 3, vocal cords plus posterior epiglottis; score 2, vocal cords plus anterior epiglottis; score 1, vocal cords not seen, but function adequately.

Adverse events, defined as suspicion of aspiration or regurgitation (gastric fluid in the ventilation tube or in the hypopharynx); hypoxia (SpO<sub>2</sub> less than 90 %); bronchospasm; airway obstruction and coughing; any visible dental, tongue, or lip trauma; and staining of blood on the removed device, were noted. The day after the surgery, the child and parents underwent a structured interview and were asked about the following postoperative symptoms: sore throat, hoarseness, dysphagia, numbness of the tongue, and postoperative nausea and vomiting. Patients, parents, and the interviewer were unaware of the airway device used.

### Statistical analysis

The null hypothesis was that there were no differences in airway leak pressure between the i-gel and the PLMA.

Based on previous studies demonstrating a mean leak pressure with the i-gel of 26 cmH<sub>2</sub>O and that of the PLMA of 23 cmH<sub>2</sub>O [5], 10 patients were required in each group for detecting a 4-cmH<sub>2</sub>O difference with a type-1 error of 0.05 and a power of 0.8. Because the number of patients for whom a size 1.5 i-gel or PLMA was suitable was lower than the number in other groups, we continued this study in a consecutive manner until 11 patients were included in both the size 1.5 i-gel and the size 1.5 PLMA groups.

Sex distribution, ASA physical status, induction medication, and type of surgery were compared between the i-gel and the PLMA groups with the  $\chi^2$  test. Differences in oropharyngeal leak pressures, times required for insertion, and other continuous data between the two groups were analyzed by Student's *t*-test if the normal distribution of data was confirmed by the Kolmogorov–Smirnov test; otherwise, the Mann–Whitney *U*-test was used. Differences in ease of insertion and the number of attempts for insertion, and differences in fiberoptic findings between the groups were analyzed by the Mann–Whitney *U*-test. Differences in the fiberoptic view among the 4 sizes of the devices within the same study groups were compared by the Kruskal–Wallis test, followed by the Steel–Dwass test for multiple comparisons. All data were analyzed with SigmaStat version 3.3 (SPSS, Chicago, IL, USA) and are presented as means with standard deviations, or as absolute numbers with the percentage (%) of the whole. A probability of  $P < 0.05$  was considered statistically significant.

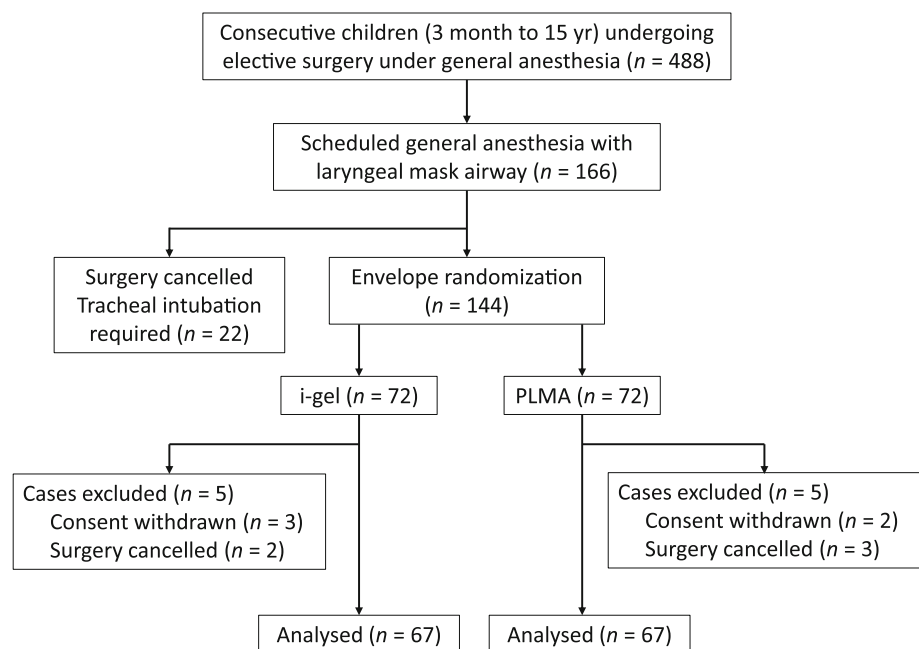
### Results

One hundred and sixty-six children scheduled for elective surgery with general anesthesia not requiring tracheal intubation were screened (Fig. 1). Of these, 22 children were excluded because the surgery was cancelled on the day before the surgery was scheduled or because the surgical procedure was changed and tracheal intubation was required; 144 children met the criteria for the study, were assigned to the i-gel or the PLMA group ( $n = 72$  each group), and were asked for informed consent. Three and 2 children and/or their parents refused to participate in the study; surgery was cancelled on the scheduled day in 2 and 3 children in the i-gel and the PLMA groups, respectively. Finally, 134 children ( $n = 67$  in each group) were included.

There were no differences between the i-gel and the PLMA groups in sex distribution, age, height, body weight, or other profiles, including induction medication (Table 1), and there were no differences between the four different subgroups regarding profile characteristics, with the exception that height and body weight in the size 2.5 i-gel group were significantly larger than the values in the corresponding PLMA group ( $P = 0.003$  and  $0.0002$ , respectively, Table 2), resulting from different body weight ranges in the two groups (i-gel: 25–34.9 kg, PLMA 20–29.9 kg).

There were no differences in ease of insertion, insertion time, or leak pressure between the i-gel and the PLMA groups (Table 3). Three children in size 2 and 1 in size 2.5 in the i-gel group, and 1 child in size 2 and 1 in size 2.5 in the PLMA group required repeated trials for insertion;

**Fig. 1** A cohort diagram of the inclusion and exclusion criteria according to the CONSORT (Consolidated Standards of Reporting Trials) statement



**Table 1** Baseline characteristics and data on surgery of the study groups

	i-gel ( <i>n</i> = 67)	PLMA ( <i>n</i> = 67)	<i>P</i> value
Male/female	34/33	31/36	0.60
Age (months)	83 ± 55	77 ± 54	0.50
Height (cm)	114 ± 30	110 ± 31	0.42
Body weight (kg)	24 ± 13	22 ± 13	0.42
ASA status 1/2	58/9	56/11	0.62
Induction			
Inhalational/propofol	44/23	48/19	0.46
Duration of anesthesia (min)	69 ± 26	67 ± 28	0.64
Duration of surgery (min)	39 ± 21	37 ± 22	0.64
Type of surgery			0.47
Ophthalmic	41	43	
Inguinal hernia	20	18	
Urological	6	4	
Plastic surgery	0	2	

Data are presented as absolute numbers of patients or means ± SD. There were no differences between the i-gel and the ProSeal laryngeal mask airway (PLMA) groups

however, there were no differences in the success rate at first attempt between the two groups ( $P = 0.68$ ). All of these devices were successfully inserted the second time, and the overall success rate was 100 %. In one child, a size 2 i-gel came away from the mouth after a successful insertion at the first attempt and after the confirmation of adequate ventilation, and required reinsertion. Following successful device insertion, all children had adequate chest movement and stable oxygen saturation with an expired tidal volume of more than 6 ml/kg, except for one child in whom a size 1.5 i-gel was inserted, who developed breathhold for approximately 10 s without a decrease of SpO<sub>2</sub>.

The fiberoptic view was better in the i-gel group than in the PLMA group including all sizes, and for only size 2 and only size 2.5 ( $P = 0.002$ , 0.03, and 0.04, respectively, Table 4). There were significant differences in the fiberoptic view among the 4 sizes of the i-gel and the 4 sizes of the PLMA ( $P < 0.001$  and 0.003, respectively). The fiberoptic view of the size 2, 2.5, and size 3 i-gel was significantly better than that of the size 1.5 i-gel ( $P = 0.02$ , 0.004, and 0.002, respectively), and the fiberoptic view of the size 2.5 and size 3 PLMA was significantly better than that of the size 1.5 PLMA ( $P = 0.02$  and 0.005, respectively).

During removal of the i-gel and the PLMA after surgery, blood was detected on the surface of the cuff of the i-gel

**Table 2** Subgroup analysis of the baseline characteristics according to the size of devices

	i-gel ( <i>n</i> = 67)	PLMA ( <i>n</i> = 67)	<i>P</i> value
Male/female			
Size 1.5	7/4	4/7	0.20
Size 2	14/9	13/10	0.76
Size 2.5	5/10	7/8	0.46
Size 3	8/10	7/11	0.46
Age (months)			
Size 1.5	10 ± 4	9 ± 5	0.69
Size 2	50 ± 21	43 ± 20	0.30
Size 2.5	105 ± 18	93 ± 19	0.11
Size 3	153 ± 20	143 ± 21	0.61
Height (cm)			
Size 1.5	69 ± 5	68 ± 7	0.60
Size 2	97 ± 12	92 ± 13	0.16
Size 2.5	129 ± 6	120 ± 8	0.003
Size 3	149 ± 10	149 ± 8	0.81
Body weight (kg)			
Size 1.5	8 ± 1	8 ± 1	0.18
Size 2	15 ± 4	14 ± 3	0.08
Size 2.5	27 ± 2	23 ± 3	0.0002
Size 3	42 ± 6	41 ± 7	0.66

Data are presented as absolute numbers of patients or means ± SD. Sizes 1.5, 2, 2.5, and 3 of the i-gel were used for patients with body weights between 5 and 9.9, 10 and 24.9, 25 and 34.9, and 35 and 50 kg, respectively; sizes 1.5, 2, 2.5, and 3 of the ProSeal laryngeal mask airway (PLMA) were used for patients with body weights between 5 and 9.9, 10 and 19.9, 20 and 29.9, and 30 and 50 kg, respectively

and PLMA in 1 and 3 children, respectively; however, other complications such as loss of airway and laryngospasm were not detected. Two children in the i-gel group and 3 in the PLMA group developed adverse effects such as bleeding and breathhold (3.0 and 4.5 %, respectively), and postoperative nausea and vomiting (PONV), which disappeared spontaneously and required no medication, occurred in 4 children in the i-gel group and 5 children in the PLMA group (6.0 and 7.5 %, respectively).

## Discussion

In the present study, both the i-gel and the PLMA were successfully inserted in children from 3 months to 15 years old. These results are consistent with those reported recently by Lee et al. [2], comparing the size 1.5–2.5 i-gel and the LMA Classic in children weighing between 5 and 30 kg. Goyal et al. [5] also reported that the ease of insertion and its success rate of the i-gel was comparable with that of the PLMA, although this comparison was

**Table 3** Insertion performance of all sizes and of each size of the i-gel and the Proseal laryngeal mask airway (PLMA)

	i-gel (n = 67)	PLMA (n = 67)	P value
Ease of insertion: scale 1/2/3/4			
All sizes	52/13/2/0	57/9/1/0	0.26
Size 1.5	10/1/0/0	11/0/0/0	
Size 2	18/4/1/0	21/2/0/0	
Size 2.5	10/4/1/0	10/4/1/0	
Size 3	14/4/0/0	15/3/0/0	
Insertion time (s)			
All sizes	13 ± 4	13 ± 3	0.90
Size 1.5	10 ± 3	11 ± 4	
Size 2	13 ± 5	12 ± 3	
Size 2.5	14 ± 6	14 ± 4	
Size 3	13 ± 2	14 ± 2	
Leak pressure (mmHg)			
All sizes	24 ± 6	24 ± 5	0.96
Size 1.5	25 ± 7	23 ± 6	
Size 2	23 ± 6	22 ± 4	
Size 2.5	24 ± 6	26 ± 4	
Size 3	25 ± 6	27 ± 5	
Success at first attempt: number (%)			
All sizes	63/67 (94)	65/67 (97)	0.68
Size 1.5	11/11 (100)	11/11 (100)	
Size 2	20/23 (87)	22/23 (96)	
Size 2.5	14/15 (93)	14/15 (93)	
Size 3	18/18 (100)	18/18 (100)	

Data are presented as absolute numbers for ease of insertion, as means ± SD for insertion time and leak pressure, and as absolute numbers [with the percentage (%) of the whole] for success rate for insertion. Ease of insertion was evaluated with a four-step scale (1 = very easy, 2 = easy, 3 = difficult and 4 = very difficult). There were no differences in ease of insertion, insertion time, leak pressure, or success rate between the i-gel and the PLMA groups

performed only for size 2 and there were no data for other sizes of those devices.

The insertion time, defined in our study as the duration from removal of the face mask from the patient’s face until confirmation of sufficient ventilation, was comparable with that reported previously [10] and there were no differences between the i-gel and the PLMA. In contrast to our study, Theiler et al. [3] reported that the i-gel required a longer time for insertion than the Ambu AuraOnce (Ambu, Ballerup, Denmark), a single-use supraglottic airway device. In that study, however, the time required for fixation was also included in the insertion time. The shape of the Ambu AuraOnce, with the cuff and the tube forming a single item with a 90° tube angle, designed to reduce stress on the upper jaw and lacking epiglottic bars [11], in contrast to the non-pronounced airway angle of the i-gel and the PLMA, may also have influenced the shorter insertion time.

**Table 4** Fiberoptic scores of the i-gel and the ProSeal laryngeal mask airway (PLMA)

	i-gel (n = 67)	PLMA (n = 67)	P value
Score 1/2/3/4			
All sizes	4/15/6/42	12/15/18/22	0.002
Size 1.5	3/6/0/2	7/1/2/1	0.26
Size 2	1/4/5/13*	5/5/7/6	0.03
Size 2.5	0/2/1/12**	0/5/4/6*	0.04
Size 3	0/3/0/15**	0/4/5/9**	0.08

Data are presented as absolute numbers of cases. Fiberoptic view was classified as: score 1 = vocal cords not visible but normal ventilation; score 2 = vocal cords and anterior epiglottis; score 3 = vocal cords and posterior epiglottis; score 4 = only vocal cords. There were significant differences in the fiberoptic scores between the i-gel and the PLMA groups ( $P = 0.002$ ), among the 4 sizes of the i-gel, and among the 4 sizes of the PLMA ( $P < 0.001$  and  $0.003$ , respectively) \*  $P < 0.05$  and \*\*  $P < 0.01$  compared with size 1.5 within the same study group

The leak pressure is one of the characteristics that determine the efficacy of a supraglottic airway device [2]. Higher leak pressure may be an advantage in positive-pressure ventilation, such as in obesity, the lithotomy/head down position, pneumoperitoneum, or restrictive pulmonary pathology [6]. In the present study, the leak pressure of the i-gel and that of the PLMA were comparable to those reported previously [1, 2, 4, 5, 12] and there were no differences between these two devices, consistent with studies comparing the i-gel and the LMA Classic [2]. Of importance, there were no differences in the leak pressure between the size 1.5 i-gel and the size 1.5 PLMA. Combined with the paucity of data regarding the performance of the size 1.5 i-gel [2–4], our results have shown the safe and easy insertion of the size 1.5 i-gel, facilitating its use in children with body weight less than 10 kg.

On the other hand, Theiler et al. [3] have shown that the leak pressure of the i-gel was significantly higher than that of the Ambu AuraOnce. Because the leak pressure of the i-gel in their report was comparable to that in studies by us and by others [4, 5], this difference could have resulted from the lower leak pressure of the size 1.5–3 Ambu AuraOnce used for children with body weight lower than 30 kg. Importantly, the leak pressure of the size 1.5 Ambu AuraOnce was much lower than that of the comparable sized i-gel (median value, 15 and 27 mmHg, respectively). Goyal et al. [5] also showed that the leak pressure of the size 2 i-gel was significantly higher than that of the size 2 PLMA. These results seem to show better fitting of the i-gel to the airway than the PLMA.

Despite the better fiberoptic view achieved with the i-gel than with the PLMA, the leak pressure of these devices was comparable. These results would suggest that the anatomical location of the i-gel was better than that of the PLMA

due to the shape of the cuff, although the difference in location does not affect airway resistance. Previous studies comparing the leak pressure and fiberoptic view between the i-gel and the LMA Classic in children [2], and comparing these factors between the i-gel and the LMA-Supreme in adults [13] have also shown that the fiberoptic view was better with the i-gel than with the other devices, although there were no differences in the airway leak pressure between them. Besides differences between devices, our study showed that the fiberoptic view improved with the increase of sizes of both the i-gel and the PLMA; this improvement with increasing size could have resulted from the relatively longer epiglottis easily being caught and folded down or it could have been a result of the anterior and cranial position of the pediatric larynx in younger children [14]. Although several studies have examined the fiberoptic view in airway devices of various sizes in children [2–4, 6], none of them have shown age-related differences in the fiberoptic view.

In our study, no children required changes of the device or developed side effects requiring treatments. Concerning adverse effects, one child developed breathhold for a short time after the insertion of a size 1.5 i-gel; however, there were no children with bronchospasm or laryngospasm, and the rate of complications such as trauma, hoarseness, or PONV was low, suggesting that both devices were safely used. In one child, a size 2 i-gel slipped out of the mouth after successful insertion. The i-gel device, particularly if it is a small size, but not the PLMA, should be taped in place to achieve sufficient seal to allow ventilation, as reported previously [3].

There are several limitations of our study. First of all, gastric insufflations were not evaluated despite the placement of a gastric tube. Secondly, the anesthetics used for induction were not controlled, and anesthetic depth was not equal in all children. Third, despite significant differences in the fiberoptic view between the i-gel and the PLMA, there were no differences in the leak pressure, suggesting that only small differences would exist between these two devices in clinical use. The performance of a smaller size of the i-gel (size 1), designed for neonates weighing between 2.0 and 5.0 kg, was not evaluated. Finally, a single practitioner conducted all trials and another single observer evaluated all performances. The results, thus, could have been significantly influenced by personal bias and could be difficult to generalize.

In conclusion, both the i-gel and the PLMA were successfully inserted in pediatric patients. Although the fiberoptic view was better with the i-gel than with the PLMA, neither the leak pressure nor the time for insertion was different between these devices.

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