

Performance of the Pediatric-sized i-gel Compared with the Ambu AuraOnce Laryngeal Mask in Anesthetized and Ventilated Children

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ABSTRACT

Background: This prospective, randomized, controlled trial compares the performance of the pediatric i-gel (Intersurgical Ltd., Wokingham, United Kingdom) with the Ambu AuraOnce laryngeal mask (Ambu A/S, Ballerup, Denmark) in anesthetized and ventilated children.

Methods: With ethics committee approval and written informed consent, the authors included 208 children, aged 0–17 yr, scheduled for elective day-surgery under general anesthesia. The primary outcome variable was oropharyngeal

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What We Already Know about This Topic

- A variety of new supraglottic airway devices for both children and adults are emerging. In children, the clinical usefulness of the Ambu AuraOnce is well established, but no information is available for the i-gel.

What This Article Tells Us That Is New

- This randomized controlled trial (n = 208, 0–17 yr old) demonstrated equal clinical performance with high leak pressures and success rates for both devices, but the i-gel needed to be secured more frequently by being taped in place (44% vs. 0%).

leak pressure. Other outcome variables were first-attempt and overall success, time to sufficient ventilation, and adverse events.

Results: Demographic data did not differ between groups. The leak pressure of the i-gel was significantly higher than the leak pressure of the Ambu (mean \pm SD: 22 ± 5 cm H₂O vs. 19 ± 3 , $P < 0.01$). First-attempt success was 91% for the i-gel and 93% for the Ambu ($P = 0.50$). Overall success was 93% for the i-gel versus 98% for the Ambu ($P = 0.10$). Successfully inserted i-gels needed to be secured by taping in place to ensure the seal in 44% (0% with the Ambu, $P < 0.01$). Insertion was faster with the Ambu (24 ± 8 s vs. 27 ± 11 , $P = 0.02$). There were no major side effects with either device.

Conclusions: The leak pressure of the i-gel was statistically but not clinically significantly higher than the leak pressure of the Ambu. Time to insertion was longer with the i-gel. Both airway devices are suitable for positive pressure ventilation with high success rates in infants and children. Because the i-gel is prone to sliding out, it must be taped in place to avoid loss of the airway.

THE pediatric i-gel (Intersurgical Ltd., Wokingham, Berkshire, United Kingdom) is a new disposable supraglottic airway device for children. It is a smaller model of the well known i-gel used in adult patients; it is made of a soft, gel-like elastomer with a noninflatable cuff and a channel for gastric catheter placement, except for size 1.¹ Studies in adults have been promising, showing an easy insertion, high airway leak pressures, and low complication rates with few postoperative complaints.^{2–8} In children, only one observa-

tional study has been published analyzing clinical performance of the i-gel size 3 in children weighing more than 30 kg.⁹ For the smaller pediatric i-gel, no data are available.

The Ambu AuraOnce (Ambu A/S, Ballerup, Denmark) is a supraglottic airway device with an inflatable cuff.¹⁰ The cuff and tube form a single item with a 90-degree tube angle.¹¹ It is a disposable device as well, but unlike the i-gel, it does not feature a gastric channel. Its clinical use is well established in adults and children, and several studies have shown the device's safety and effectiveness and patients' tolerance to it.^{11–16}

The aim of this prospective, randomized, controlled trial was to compare clinical performance of the newly developed pediatric i-gel and the well-established Ambu AuraOnce in children. Our null hypothesis was that the difference in leak pressure between the two devices is less than 10% of the device leak pressures.

Materials and Methods

Participants

With local ethics committee approval (Kantonale Ethikkommission, Bern, Switzerland, approval number 018/09, ISRCTN64997093) and written informed consent, we included in the study 208 children (boys and girls) aged 0–17 yr with an American Society of Anesthesiologists Physical Status 1 or 2 and a weight of 5–50 kg. All were scheduled at the University Hospital of Bern for elective day-surgery under general anesthesia not requiring tracheal intubation. Exclusion criteria were planned operation time more than 4 h,¹ risk of aspiration (nonfasted, gastroesophageal reflux disease, gastrointestinal stenosis or stricture), known difficult airway (difficult mask ventilation or difficult laryngoscopy, Cormack-Lehane grade more than 2 in patient history), congenital malformations involving the respiratory tract, cervical spine disease, preoperative sore throat or clinically relevant upper respiratory tract infection, and refusal to participate.

Anesthesia

Oral or rectal premedication with midazolam 0.5 mg/kg (maximum 10 mg) was provided 30 min before induction. The patients were positioned supine with the head resting on a ring-shaped pillow (“donut”) to achieve optimal position and monitored according to the hospital's standard clinical operating procedures following American Society of Anesthesiologists standard.**

The supraglottic airway devices were intended to provide a patent airway for controlled mechanical ventilation during deep anesthesia. Anesthesia was induced by inhalation with sevoflurane or intravenously with propofol. The method was chosen according to the patient's age and compliance by the

attending anesthesiologist. In the case of sevoflurane induction, inspiratory concentrations of 8% sevoflurane in 50% nitrous oxide and 50% oxygen were applied until an age-corrected, end-tidal concentration of twice the minimal alveolar concentration was achieved. After adequate anesthetic depth (*vide infra*) was verified, the laryngeal mask was inserted and the inspired concentration of sevoflurane was reduced to 6%. For intravenous induction, 4 mg/kg propofol and 20 µg/kg alfentanil were used. Intraoperative opioids were given unless regional anesthesia was sufficient for pain therapy (*e.g.*, penile block for circumcision). No muscle relaxant was used. After the patients lost eyelash reflex, bag-mask ventilation was provided. If bag-mask ventilation was adequate (oxygenation SaO₂ more than 96% and capnography indicating stable gas exchange), the patient was randomly assigned to receive either the i-gel or the Ambu AuraOnce. By computer randomization,†† multiple blocks of 10 were generated, with 5 children in the Ambu and 5 children in the i-gel group. Each block was assigned to weight groups of 5 kg (5–<10 kg, 10–<15 kg, and so forth to 45–50 kg). Randomization was secured by the use of opaque envelopes. After induction of anesthesia, the next envelope that corresponded to the child's weight subgroup was opened and the assigned device was used. The children and the parents were unaware of the device. When 10 children of one weight group were included in the study, randomization was continued with the next block of 10 envelopes that was assigned to that weight group. Absence of motor and cardiovascular response to the jaw thrust maneuver verified adequate depth of anesthesia. The jaw thrust maneuver also facilitated insertion of the device.

Insertion of the Device

The laryngeal mask size 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; Ambu: 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 the anesthesiology staff of the Pediatric Anesthesia Division of the Department of Anesthesiology at the University Hospital Bern and supervised by one of the study authors. The devices were lubricated with K-Y Lubricating Jelly (Johnson & Johnson Medical Limited, Gargrave, Skipton, United Kingdom) and introduced according to the manufacturer's recommendations.^{1,10} Intra-cuff pressure of the Ambu was set at 60 cm H₂O using a digital manometer (VBM GmbH, Sulz, Germany, or Rüsch GmbH, Kernen, Germany).

Definition of Device Failure and Secondary Strategies for Failed Attempts

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 (6 ml/kg) despite three minor airway interventions. A failed

** Available at: <http://www.asahq.org/publicationsAndServices/sgstoc.htm>. Accessed February 17, 2011.

†† Available at: <http://www.randomization.com>. Accessed February 17, 2011.

insertion attempt led to removal of the device from the mouth. Minor airway interventions were defined as adjusting head/neck position, changing depth of insertion, or holding the device in place by tape. After at least one failed insertion attempt, the anesthesiologist was free to choose a different size mask of the same device for the second or third insertion attempt. In the event of failure to insert a device, the alternative device was used to provide a patent airway, again allowing three insertion attempts and three minor airway interventions.¹⁷ If insertion of both devices failed, the airway was secured according to the decision of the attending anesthesiologist.

Measurements

All measurements were performed by a trained unblinded observer who was not involved in the clinical procedure. The number of insertion attempts needed to establish a patent airway with either laryngeal mask was recorded (first-attempt success rate and overall success rate with a maximum of three insertion attempts). After positioning and fixation of the device, oropharyngeal leak pressure was assessed by closing the expiratory valve of the circle system to 30 cm H₂O at a fixed gas flow of 3 l/min, and noting the airway pressure at which a steady state of airway pressure was reached.¹⁸ Thus, the digital readout of the anesthesia machine defined the leak pressure. Airway pressure as measured on a visual pressure gauge included in the anesthesia machine was not permitted to exceed 30 cm H₂O.¹⁹ Oropharyngeal leak pressure was defined as the primary outcome variable.

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.^{17,20} Minor airway interventions were recorded.

To evaluate the anatomic position of the supraglottic airway device, the breathing system was briefly disconnected and a 3-mm fiberscope (ACUTRONIC Medical Systems AG, Hirzel, Switzerland) was inserted through the airway port to evaluate glottic view. The best view from the tip of the orifice of the i-gel or the Ambu was graded from 1 to 4, as recommended by Cook²¹ and proposed previously²² (grade 1: full view of the glottis; grade 2: partial view of the glottis; grade 3: only epiglottic structures seen; grade 4: no glottic/epiglottic structures visible). In addition, epiglottic downfolding and rotation of the device were noted.

For the i-gel device, a gastric catheter (Charriere 8 or Charriere 10, depending on the size of the device) was placed through the gastric vent tube. Aspiration of gastric fluid or air was noted.

Adverse events, defined as suspicion of aspiration or regurgitation (gastric fluid in the ventilation tube or in the hypopharynx); hypoxia (SpO₂ less than 90%)²³; broncho-

spasm; airway obstruction and coughing; any visible dental, tongue, or lip trauma; and staining of blood on the removed device, were noted.

The day after surgery, the patient or the patient's parents underwent a structured telephone interview and 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

We based our sample size calculation on our primary outcome variable, oropharyngeal leak pressure.¹⁷ No data about the performance of the pediatric-sized i-gel were available for a reliable sample size calculation. However, previous studies had revealed airway leak pressures of 19–24 cm H₂O for the Ambu.^{11,12,14,15} We defined equality as not more than 10% difference in leak pressures between the two masks. This difference of 1.9–2.4 cm H₂O in leak pressure probably would be of no clinical relevance and is less than previous airway studies in adults suggest.^{8,17} Assuming a leak pressure of 19–24 cm H₂O for the Ambu and a difference of 10% for the i-gel, given a type I error of 0.05 and a power of 0.9, we expected a necessary sample size of 100 children in each group to detect a difference of 10% in airway leak pressure between the two devices.

In a first step, we compared the overall performance of both masks, and in a second step, we evaluated differences of the performance in subgroups for each device (predefined subgroup analysis). Subgroups according to weight were: (1) 5–9.9 kg, (2) 10–19.9 kg, (3) 20–29.9 kg, (4) 30–50 kg.

The devices were evaluated as intention-to-treat according to randomization. Success rates and other frequency data were compared with chi-square test. Oropharyngeal leak pressures, insertion times, and other continuous data were analyzed by Mann–Whitney test if the data were not normally distributed; otherwise the independent two-tailed Student *t* test was used. Subgroup analysis was performed by a one-way ANOVA if continuous data were normally distributed, by Kruskal–Wallis test if continuous data were not normally distributed, and by chi-square test for frequency data. A Bonferroni correction for multiple testing was applied for subgroup testing by multiplying *P* values with the number of comparisons. All data were analyzed with SPSS version 15 (SPSS Inc., Chicago, IL) and are presented as mean with standard deviations or number and percentage. Effect sizes (with 95% CI) are reported as Cohen's *d* for interval data and as odds ratio for proportions. A probability of *P* < 0.05 was considered statistically significant.

Results

Participants and Demographics

On 79 days of day case surgery during a 46-week period, 381 children scheduled at the University Hospital of Bern for

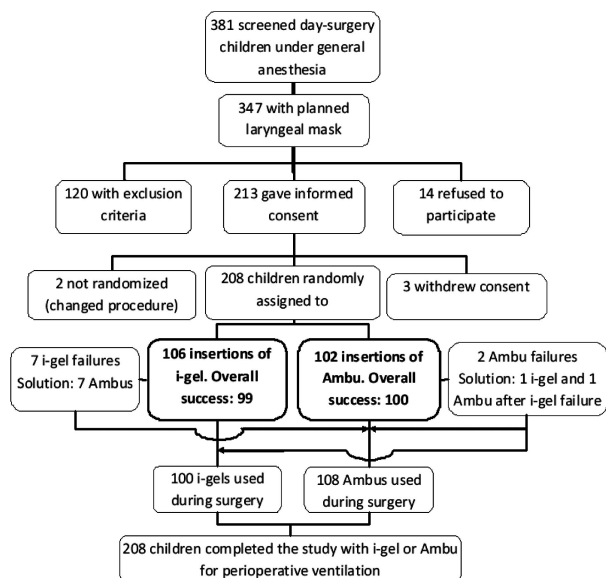


Fig. 1. Study flowchart.

elective day-surgery with general anesthesia not requiring tracheal intubation were screened (fig. 1). Of these, 227 patients qualified for the study and were asked for informed consent. Fourteen patients and/or the patient’s parents refused to participate in the study, 3 withdrew consent before induction of anesthesia, and 2 had to be excluded before randomization because of changed anesthetic procedure (decision for an endotracheal tube). Finally, 208 children were studied. Statistical analysis showed no significant differences in patient characteristics between the groups. More boys than girls were included because of the high number of circumcisions. Between the groups, the male/female ratio was equal. There was no difference in induction medication used between devices, and there was no difference in the ratio of i-gel to Ambu within the four age subgroups. All demographic data, data about drugs used for induction, and anesthesia times are displayed in table 1. There was no statistically significant difference in i-gel and Ambu in assignment to the four different subgroups regarding distribution to subgroups ($P = 0.94$), age ($P = 0.73$), or weight ($P = 0.98$, table 2).

According to the randomization in blocks of 5-kg body weight, 102 children were assigned to the Ambu and 106 children to the i-gel.

Primary Outcome Variable: Oropharyngeal Leak Pressure.

The i-gel showed statistically significant higher airway leak pressures than did the Ambu (22 ± 5 cm H₂O vs. 19 ± 3 cm H₂O, $P < 0.001$), as displayed in table 3. The 95% CI of the difference of the airway leak pressures was 1.4–3.8 cm H₂O.

Secondary Outcome Variables during Anesthesia

There was a high first-attempt success rate for both devices: 93% for the Ambu and 91% for the i-gel ($P = 0.50$). The 95% CI of the difference in first-attempt success rates between the two masks was -0.10 to 0.05 .

Table 1. Demographic Data of the Patients

Patients	i-gel n = 106	Ambu n = 102	P Value
Males/females, number (%)	73/33 (69/31)	79/23 (78/23)	0.16
Age (yr)	6.3 ± 3.7	6.2 ± 4.0	0.80
Weight (kg)	24.7 ± 11.2	24.7 ± 11.6	0.98
Height (cm)	121 ± 24	119 ± 23	0.54
ASA status 1/2, number (%)	87/19 (82/18)	82/20 (80/20)	0.76
Induction inhalative/propofol, number (%)	60/46 (57/43)	66/36 (65/35)	0.23
Anesthesia time (min)	97 ± 32	94 ± 25	0.78
Operation time (min)	36 ± 24	34 ± 20	0.80
Time of masks in place (min)	73 ± 31	71 ± 26	0.56
Type of surgery			0.32
Urology, number (%)	56 (53)	42 (41)	—
Orthopedics, number (%)	35 (33)	38 (37)	—
Visceral, number (%)	13 (12)	20 (20)	—
Dermatology, number (%)	2 (2)	2 (2)	—

Data are given as mean ± SD or number (%). ASA status = American Society of Anesthesiologists Physical Status.

The overall insertion success rate was 98% for the Ambu and 93% for the i-gel ($P = 0.10$). All insertion failures were attributable to inadequate ventilation caused by insufficient airway seal, rather than by failure of the actual insertion. In these cases, the devices did not seal, there was absence of chest movements, absence of capnography trace, and no measurable tidal volume. The seven i-gel insertion failures were backed up by insertion of seven Ambu devices; and one of the two Ambu insertion failures was backed up by an i-gel insertion. In the other Ambu insertion failure, insertion of the alternative device, an i-gel, also failed. The attending anesthesiologist chose a different size Ambu (size 2 changed to size 2.5) with subsequent insertion success. Although the airway was secured with an Ambu in the end, this case did not meet the criteria of a successful mask insertion as defined in the study protocol and thus was rated as an insertion failure.

After a failed first insertion attempt (insertion possible, but ventilation not possible because of oropharyngeal leak), four Ambus were changed to a larger size. These four Ambus were then successfully inserted at the second or third attempt. None of the i-gels was changed to a different size.

Insertion time for the Ambu was shorter than for the i-gel (24 ± 8 s vs. 27 ± 11 s, $P = 0.02$). More minor airway interventions had to be performed when inserting an i-gel (49% for the i-gel vs. 8% for the Ambu, $P < 0.01$, table 3). Most of these interventions were attributable to the necessity

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Table 2. Subgroup Analysis According to Body Weight for Each Device

		Group 1 (5–9.9 kg)	Group 2 (10–19.9 kg)	Group 3 (20–29.9 kg)	Group 4 (30–50 kg)	P Value*
i-gel	Number of patients (%)	3 (3)	38 (36)	34 (32)	31 (29)	—
	Age (yr)	13 (8–17)†	3 ± 1.6	7 ± 1.5	11 ± 2.0	—
	Weight (kg)	9 (8.8–9.5)†	15 ± 2.8	23 ± 2.9	40 ± 6.5	—
	Success at first attempt, number (%)	2 (67)	33 (87)	32 (94)	29 (94)	0.33
	Overall success rate, number (%)	2 (67)	36 (95)	32 (94)	29 (94)	0.31
	Leak pressure (cm H ₂ O)	27 (23–30)†	20 ± 4	22 ± 4	23 ± 6	0.05
	Insertion time (s)	22 (20–24)†	30 ± 11	29 ± 12	21 ± 8	0.01‡
	Taping necessary, number (%)	2 (100)	24 (73)	15 (47)	3 (10)	<0.01§
Ambu	Number of patients (%)	3 (3)	40 (39)	29 (28)	30 (29)	—
	Age (yr)	14 (12–16)†	3 ± 1.6	6 ± 1.6	11 ± 2.2	—
	Weight (kg)	9 (7.8–9.7)†	15 ± 2.7	24 ± 3.0	40 ± 6.2	—
	Success at first attempt, number (%)	3 (100)	35 (88)	28 (97)	29 (97)	0.34
	Overall success rate, number (%)	3 (100)	38 (95)	29 (100)	30 (100)	0.37
	Leak pressure (cm H ₂ O)	15 (12–18)†	18 ± 3	19 ± 3	21 ± 3	<0.01
	Insertion time (s)	15 (14–34)†	26 ± 8	24 ± 9	21 ± 6	0.02#
P values** i-gel vs. Ambu	Success at first attempt	0.27	0.93	0.65	0.57	—
	Overall success rate	0.27	0.96	0.18	0.16	—
	Leak pressure (cm H ₂ O)	0.08	0.01	0.01	0.10	—
	Insertion time (s)	0.56	0.09	0.08	0.72	—

Data are given as mean ± SD, median (range), or number (%).

* Comparing all four groups. Kruskal-Wallis or chi-square test. † Age in subgroup 1 given as median and range in months. Weight, leak pressure, and insertion time given as median and range. ‡ *Post hoc* analysis revealed differences between subgroup 2 vs. 4 ($P = 0.01$) and subgroup 3 vs. 4 ($P = 0.03$). § *Post hoc* analysis revealed differences between subgroups 2 vs. 4 ($P < 0.01$) and subgroup 3 vs. 4 ($P = 0.03$). || *Post hoc* analysis revealed differences between subgroups 1 vs. 4 ($P < 0.01$) and subgroup 2 vs. 4 ($P < 0.01$). # *Post hoc* analysis revealed differences between subgroups 2 vs. 4 ($P = 0.04$). ** Within subgroup comparison.

of taping the device to hold it in place. In 44 of the 99 successfully inserted i-gels (44%), the device had the tendency to slide out again and needed to be secured by taping in place to maintain sufficient airway seal. This was not necessary in any of the 100 successful Ambu mask insertions ($P < 0.01$, table 3). The fiber-optic view was evaluated in 196 of the 199 children with successful mask placement (fiber-optic view not available in 3 cases with Ambu randomization). The fiber-optic laryngeal view ($P = 0.99$) and epiglottic downfolding ($P = 0.93$) were similar for both devices without a statistically significant difference. Fiber-optic control through the airway port of the successfully placed devices revealed that some of the masks lay rotated compared with pharyngeal and laryngeal structures (i-gel 16%, Ambu 6%, $P = 0.03$, table 3). Placement of a gastric catheter through the i-gel was possible in 96 of 97 attempted insertions (99%). Gastric fluid was aspirated in 76% of these successfully inserted gastric catheters.

On-treatment Analysis

The successfully inserted masks used as a rescue device when insertion of the randomly assigned mask failed were not included in the main statistical analysis (intention-to-treat analysis). However, performing an on-treatment analysis (including all randomly assigned and all rescue masks) gave no different results compared with the intention-to-treat analysis, except there was no statistically significant difference in rotation of the device in the on-treatment analysis.

Subgroup Analysis

Children were divided into four subgroups according to their weight to assess differences in mask performance between smaller and bigger children. Table 2 summarizes the subgroup analysis. For the i-gel, statistically significant differences were found in insertion time and the need to tape the mask in place. For the Ambu, statistically significant differences were found in leak pressure and insertion time. Oropharyngeal leak pressure tended to be higher in older children, whereas insertion time tended to be shorter in older children. In younger children, the i-gel needed to be taped in place more often than in older children.

Adverse Events

There were no serious adverse events with either device (table 4). Of the 14 laryngo- or bronchospasms, 1 occurred at induction, 4 during surgery, and 9 after removal of the device; 5 resulted in brief episodes of hypoxia (1 during surgery and 4 after mask removal). In the single case of intraoperative laryngospasm with hypoxia, the attending anesthesiologist decided to remove the Ambu mask and intubate the trachea. All other spasms were resolved immediately maintaining ventilation without invasive airway maneuvers. In one i-gel case, a new airway leak occurred during surgery and the device had to be removed and reinserted to maintain sufficient ventilation. The 24-h follow-up revealed an uneventful anesthesia outcome in all cases. No statistically significant difference was found between the two groups with regard to incidence of adverse events.

Table 3. Insertion of the Devices

	i-gel (n = 106)	Ambu (n = 102)	P Value	Effect Size (95% CI)
Success at first attempt	96 (91)	95 (93)	0.50	0.71 (0.26–1.94)*
Overall success	99 (93)	100 (98)	0.10	0.28 (0.06–1.40)*
Successful Supraglottic Airways				
	i-gel (n = 99)	Ambu (n = 100)		
Leak pressure (cm H ₂ O)	22 ± 5	19 ± 3	<0.01	0.60 (0.32–0.89)†
Insertion time (s)	27 ± 11	24 ± 8	0.02	0.33 (0.05–0.61)†
Minor intervention necessary	48 (49)	8 (8)	<0.01	10.71 (4.70–24.39)*
Taping the mask in place necessary	44 (44)	0 (0)	<0.01	NA
Fiber-optic view 1/2/3/4/5‡	88/9/2/0/0 (89/9/2/0/0)	87/8/2/0/3 (87/8/2/0/3)	0.98	0.92 (0.37–2.28)§
Device rotated	16 (16)	6 (6)	0.03	3.02 (1.13–8.08)*
Epiglottic downfolding	9 (9)	7 (7)	0.63	1.33 (0.47–3.72)*
Gastric catheter placement possible: yes/no/missing	96/1/2 (97/1/2)	Not possible	NA	NA
Gastric fluid aspiration possible	75 (76)	Not possible	NA	NA

Data are given as mean ± SD or number (%).

* Effect size for proportions given as odds ratio. † Effect size for interval data given as Cohen’s d. ‡ Fiber-optic view graded as 1: full view of the glottis, 2: partial view of the glottis, 3: only epiglottic structures seen, 4: no glottic/epiglottic structures visible,^{21,22} 5: missing data. § Effect size given as odds ratio. Fiber-optic view dichotomized as 1 or less than 1.

NA = not applicable.

One failed i-gel insertion resulted in tongue trauma with blood staining, and one Ambu that could not be inserted was blood-stained at removal of the mask. No other complications were observed in the failed masks.

Postoperative Complaints

Postoperative complaints were all rare and without statistically significant differences between the two devices. Of the 208 children who participated in the study, 193 were avail-

able for the postoperative interview, and 15 were lost to follow-up (8 successful i-gel and 7 successful Ambu placements). There was no difference in reported complaints for the i-gel and the Ambu, respectively: Sore throat occurred in n = 0 (0%) versus n = 3 (3%), P = 0.25; dysphagia and hoarseness in n = 0 (0%) versus n = 1 (1%), P = 1.00; and postoperative nausea and vomiting in n = 10 (11%) versus n = 15 (15%), P = 0.41. Numbness of the tongue was not reported. In 193 cases (100%), parents would have chosen the same mask again, although they were unaware of the treatment groups.

Table 4. Complications during Mask Insertion, Surgery, and Emergence

	i-gel (n = 92)	Ambu (n = 100)	P Value
Laryngo- or bronchospasm	4 (4)	10 (10)	0.10
Blood on the device	1 (1)	5 (5)	0.10
Hypoxia SpO ₂ <90%	1 (1)	4 (4)	0.18
Coughing	4 (4)	7 (7)	0.36
Hiccup	2 (2)	2 (2)	0.99
Dental trauma	0 (0)	0 (0)	NA
Aspiration	0 (0)	0 (0)	NA
Retching/vomiting	1 (1)	1 (1)	0.96
New airway leak during surgery	1 (1)	0 (0)	0.30
Intraoperative airway maneuver	3 (3)	1 (1)	0.28
Intraoperative removal of mask	1 (1)	1 (1)	0.96

Data are given as number and percentage of all successfully inserted masks. Data on taping down of the masks given in table 3. NA = Not applicable.

Discussion

For our primary outcome variable, airway leak pressure, we found a statistically significant difference in favor of the i-gel. The 95% CI of the difference between the airway leak pressures (1.4–3.8 cm H₂O) showed that the real difference between the leak pressures could exceed the previously defined 10% (calculated as 1.9 cm H₂O). But even so, the difference in airway leak pressure would not be of clinical importance.

For the first-attempt success rate, we did not detect a statistically significant difference between the devices. The 95% CI of the difference in success rates includes 0 and was calculated to be from –0.1 to 0.05. Therefore, with a probability of 95%, the real difference in success rates is maximally 10%, and it is safe to say that first-attempt success rates between the Ambu and the i-gel are similar.

On the other hand, overall success trended toward a better performance of the Ambu without a statistical difference. This could be explained partly by the higher number of insertion attempts for the Ambu: Of the seven Ambus that failed on first-attempt insertion, four (57%) were inserted a second time and two (29%) a third time, resulting in five (71%) of them successfully being inserted. Of the 10 i-gel devices that failed on first-attempt insertion, 5 (50%) were inserted a second time and 1 (10%) a third time, and 3 (30%) succeeded. Only one (14%) Ambu was rated as a definitive failure after only one insertion attempt, whereas the same occurred with four (40%) of the i-gel devices. Furthermore, no change of mask size was attempted with the i-gels, but the same was attempted with 4 Ambus. This may explain the tendency for a better performance of the Ambu with respect to overall success. No data about success rates in children weighing less than 30 kg existed for the i-gel. The study Beylacq *et al.* performed with the i-gel size 3 in 50 children weighing more than 30 kg showed a 100% success rate at first attempt.⁹ With 91% success at first attempt and 93% overall success, the current study showed a high success rate for the i-gel even in smaller children, but the rate did not reach 100%. Success rates of the Ambu were in concordance with previous findings.^{12,14,16} The longer insertion times seen for the i-gel in the current study are in accordance with a previous study by the authors comparing the i-gel and the LMA Supreme™ (Laryngeal Mask Company Limited, San Diego, CA) in adults.⁸ The 95% CI of the difference in insertion times (0.5–5.8 s) showed that the maximal difference is less than 6 s and thus probably of low clinical importance.

Once inserted, the i-gel was prone to slide out and often needed to be taped in place to achieve sufficient seal to allow ventilation; this was not necessary for the Ambu. Previously published studies have demonstrated the easy insertion and placement of the Ambu and attributed this characteristic to the shape of the device, with its 90-degree tube angle, which seems to fit laryngeal anatomy very well.^{11,14,24} Comparing the angle of both devices used in our study, the Ambu indeed shows a more pronounced airway angle (fig. 2), which might fit anatomically better into the hypopharynx and onto the laryngeal inlet. The pediatric i-gel is a smaller version of the adult model. The more straight design of the i-gel might explain that observation: the i-gel often slid out of the mouth, especially in very small children. The longer insertion time and the fact that the i-gel was subjectively found to be more difficult to insert correlates with this tendency for the device to slide out and the necessity to secure it with tape. However, once in place, the i-gel performed with great success. Sliding out of the mouth was rarely seen when the adhesive tape was released from the mask at the end of surgery. Because muscle tone increases at this time, we speculate that a high muscle tone is not responsible for the i-gel sliding from the mouth.

The fiber-optic view was remarkably good through both devices, and epiglottic downfolding was rarely observed. The



Fig. 2. Lateral view of the i-gel #2 (Intersurgical Ltd., Wokingham, Berkshire, United Kingdom) and the Ambu AuraOnce #2 (Ambu A/S, Ballerup, Denmark). The more pronounced airway angle of the Ambu AuraOnce compared with the i-gel is clearly visible.

i-gel was found to be more frequently rotated compared with pharyngeal structures. Again, this could be caused by the lack of angulations in the i-gel. As was shown in previous studies, no correlation was found between fiber-optic view and successful ventilation.^{6,8,14} The good view of the larynx provided by both laryngeal masks might encourage attempts to intubate with fiber-optic guidance. As was recently recommended for pediatric airway management, supraglottic airway devices may be used as an alternative “plan B” after failed laryngoscopy.²⁵

It was not surprising that gastric access was successful in all but one patient (99%); this confirms our previous findings in adults.⁸ However, it is noteworthy that in nearly 80% of the pediatric patients we could aspirate gastric fluid although patients were fasted for fluids for 4 h. Some of the aspirate contained the premedication (midazolam, given orally 30 min before induction), as indicated by the red color of the raspberry syrup it was given with. Our study was not powered to detect a reduction in pulmonary aspiration of gastric content, so we can only speculate about the benefits of easy gastric content aspiration. Insertion of a gastric catheter next to a supraglottic airway device without integrated esophageal access conduit is possible but cumbersome. To our knowledge, there are no data about the increased risk of mucosal tissue injury in doing so. Because mask ventilation may easily lead to air insufflation and subsequent gastric extension, it may be of advantage to have an easy access for gastric fluid and air aspiration with the i-gel.

Adverse events and postoperative complaints were rare in both groups. The number of laryngo- or bronchospasms was comparable with results of previously published work.²⁶ One

might assume that the number of postoperative complaints rises with increasing anesthesia time or with the necessity of taping the device (possible tissue trauma). However, no relationship was seen between the times a mask stayed in place and postoperative complaints or between the necessity of taping a mask and postoperative complaints. We consider both devices to be safe for pediatric airway management.

We carried out subgroup analysis on the performance of the devices to detect relevant differences in younger and in older children. Because of the relatively small numbers in some of the subgroups, the power of that analysis is low. Because the sample size of infants smaller than 10 kg (subgroup 1) included only three children in each group, we analyzed whether exclusion of this small subgroup changed our outcome. There were no changes in *P* values for leak pressure, insertion time, or fiber-optic view. There was no statistically significant difference in the frequency of the rotation of the devices when the small subgroup of infants weighing less than 10 kg was excluded from the analysis (i-gel 14%, Ambu 6%, *P* = 0.07). The *P* value changed only insignificantly for evaluation of success at first attempt (without the data: i-gel 91% vs. Ambu 93%, *P* = 0.66 instead of *P* = 0.50), overall success rate (94% vs. 98%, *P* = 0.17 instead of *P* = 0.10) and epiglottic downfolding (7% vs. 6%, *P* = 0.82 instead of *P* = 0.63). Regardless of inclusion of the data of infants weighing less than 10 kg, the subgroup analysis showed a statistically significant difference in the Ambu airway seal pressure: the smaller the child, the lower was airway seal pressure. This is in contrast to the findings of Monclus *et al.*,¹¹ who found no statistical difference between the sizes. For the i-gel, more minor interventions and longer insertion times were necessary in the small sizes, which might indicate differences in mask performance according to children's age and weight. The question arises whether the shape of the pediatric i-gel, which is a smaller version of the adult model, fully acknowledges the relatively anterior and cranial position of the pediatric larynx.²⁷ We suggest that, especially in the small sizes, the pediatric i-gel might perform better and might need to be taped in place less often if it featured a preformed angle.

This study was limited by the fact that the power calculation was based on vague figures because no data were available for the pediatric i-gel. We had to base the sample size calculation for our study plan on known leak pressures of the Ambu and deduced a difference in leak pressure of 10% for the i-gel. However, we included 208 children to be sure to achieve high power and robust results for this pediatric study.

Another limitation is related to the choice of induction anesthetics being influenced by the individual patient. For example, smaller children usually have anesthesia induced *via* inhalation without previous intravenous access, whereas older children undergo intravenous induction with propofol. To assure that this did not introduce any bias to the insertion of the supraglottic airway devices, we adhered to a rigorous induction protocol, as described in Materials and Methods. The measurement of anesthetic depth in pediatric anesthesia

practice relies on clinically obtained data. All our clinical data were the same for inhalational and intravenous induction, but we cannot prove that anesthetic depth was equal in all children. There was no difference between study participants anesthetized with propofol *versus* sevoflurane regarding leak pressure (21 ± 5 vs. 20 ± 4 cm H₂O, *P* = 0.15), success rate (96% vs. 95%, *P* = 0.70), or minor airway interventions needed (23% vs. 29%, *P* = 0.30). The time necessary for insertion was statistically longer for the sevoflurane induction group with both the i-gel (28.9 vs. 24.1 s, *P* = 0.03, Cohen's *d* = 0.45, 95% CI 0.04–0.84) and the Ambu (24.9 vs. 21.6 s, *P* = 0.04, Cohen's *d* = 0.43, 95% CI 0.01–0.84). The airway devices in the current study were inserted by all six members of the pediatric anesthesiology staff of our pediatric anesthesia division. Therefore, our results reflect the performance of the masks in daily routine practice, rather than their best possible performance in the hands of designated airway specialists. Across the participating staff members, there was no difference regarding leak pressure or time required to insert the device.

Obviously, this study was single-blinded because the anesthesia personnel were aware of the airway device used. However, our primary outcome variable, airway leak pressure, was an objective measurement obtained by the anesthesia machine, without influence of the study personnel. All other data were obtained by a trained member of the research group who was not otherwise involved in the clinical procedure and according to previously defined criteria and procedures. Because all measurements were taken in deeply anesthetized and ventilated children, our results are not necessarily the same for spontaneously breathing and less deeply anesthetized patients.

Conclusion

The leak pressure of the pediatric i-gel is statistically significantly higher than that of the pediatric Ambu. Both masks are suitable for ventilation of anesthetized children with a high rate of success. Of advantage for the i-gel may be that it offers the possibility of gastric access. An advantage of the Ambu AuraOnce is a slightly faster insertion, despite the necessity to cuff the device. Especially in small children, the i-gel is prone to sliding out and often needs to be held in place by tape. Both devices performed well and were associated with only a few adverse events. The clinician has to choose which device fits best for the specific necessities and probably should use the device he knows best.

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