A Clinical Evaluation of the Intubating Laryngeal Airway as a Conduit for Tracheal Intubation in Children

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BACKGROUND: The air-Q™ Intubating Laryngeal Airway (ILA) (Cookgas LLC, Mercury Medical, Clearwater, FL) is a supraglottic airway device available in pediatric sizes, with design features to facilitate passage of cuffed tracheal tubes when used to guide tracheal intubation. We designed this prospective observational study of the ILA to assess the ease of its placement in paralyzed pediatric patients, determine its position and alignment to the larynx using a fiberoptic bronchoscope, gauge its efficacy as a conduit for fiberoptic intubation with cuffed tracheal tubes, and evaluate the ability to remove the ILA without dislodgement of the tracheal tube after successful tracheal intubation.

METHODS: One hundred healthy children, aged 6 months to 8 years, ASA physical status I to II, and scheduled for elective surgery requiring general endotracheal anesthesia were enrolled in this prospective study. Based on the manufacturer’s guidelines, each patient received either a size 1.5 or 2.0 ILA according to their weight. The number of attempts for successful insertion, leak pressures, fiberoptic grade of view, number of attempts and time for tracheal intubation, time for ILA removal, and complications were recorded.

RESULTS: ILA placement, fiberoptic tracheal intubation, and ILA removal were successful in all patients. The size 1.5 ILA cohort had significantly higher rates of epiglottic downfolding compared with the size 2.0 ILA cohort (P < 0.001), despite adequate ventilation variables. When comparing fiberoptic grade of view to weight, a moderate negative correlation was found (r = −0.41, P < 0.001), indicating that larger patients tended to have better fiberoptic grades of view. The size 1.5 ILA cohort had a significantly longer time to intubation (P = 0.04) compared with the size 2.0 ILA cohort. However, this difference may not be clinically significant because there was a large overlap of confidence bounds in the average times of the size 1.5 ILA (27.0 ± 13.0 seconds) and size 2.0 ILA cohorts (22.7 ± 6.9 seconds). When comparing weight to time to tracheal intubation, a weak correlation that was not statistically significant was found (r = −0.17, P = 0.09), showing that time to intubation did not differ significantly according to weight, despite higher fiberoptic grades in smaller patients.

CONCLUSIONS: The ILA was easy to place and provided an effective conduit for tracheal intubation with cuffed tracheal tubes in children with normal airways. Additionally, removal of the ILA after successful intubation could be achieved quickly and without dislodgement of the tracheal tube. Because of the higher incidence of epiglottic downfolding in smaller patients, the use of fiberoptic bronchoscopy is recommended to assist with tracheal intubation through this device. (Anesth Analg 2011;112:176–82)
There were 4 main objectives for this prospective observational study of the ILA: first, to assess the ease of placement; second, to determine the position of the ventilating orifice in relation to the larynx using a fiberoptic bronchoscope, indicating the feasibility of blind tracheal intubation by grading the quality of airway alignment; third, to test its efficacy as a conduit for fiberoptic intubation with cuffed tracheal tubes in paralyzed pediatric patients; and fourth, to evaluate the ability to remove the ILA without dislodgement of the tracheal tube after successful tracheal intubation.

**METHODS**

This study was approved by the IRB, and written informed consent was obtained from the parents of all patients. One hundred eligible pediatric patients scheduled for elective surgery to receive general endotracheal anesthesia were enrolled in this study over a 6-week period. Inclusion criteria were patients with ASA physical status I and II, ages 6 months to 8 years, weighing 7 to 30 kg. Patients were excluded if they had a history of cardiopulmonary disease, severe gastrointestinal reflux, or abnormal airway anatomy, which was assessed by the following: passive mouth opening, microglossia, thyromental distance, and submental compliance. Four study investigators (NJ, LES, IIM, and AGR) who were experienced with fiberoptic intubations through the ILA performed all of the intubations in this study. Before this study, all study investigators had used the ILA for tracheal intubation in at least 25 patients including both normal and difficult airway patients and were considered experienced for the purposes of this study.

After placement of standard monitors, inhaled anesthesia was induced using 8% sevoflurane in 70% nitrous oxide and 30% oxygen. An IV cannula was placed, and 0.6 mg/kg rocuronium was administered to provide neuromuscular blockade. Nitrous oxide was discontinued and an end-tidal rocuronium was administered to provide neuromuscular blockade. The ILA was then inserted after application of jaw thrust, using the standard midline technique, and the cuff of the ILA was inflated following manufacturer recommendations. Successful placement was determined by the ability to achieve at least 5 mL/kg tidal volume and bilateral chest excursion with the presence of a square wave capnogram upon delivery of a positive pressure breath. The airway leak pressure was measured while observing the pressure gauge with the expiratory valve closed and a fresh gas flow of 5 L/min until an audible noise was heard over the patient’s mouth. Airway pressures were not allowed to exceed 40 cm H2O.

A fiberoptic bronchoscope (LF-P outer diameter 2.2 mm, LF-DP outer diameter 3.1 mm, LF-2 outer diameter 3.8 mm, LF-V outer diameter 4.1 mm; Olympus America, Inc., Melville, NY) was loaded with the appropriately sized cuffed tracheal tube (Mallinckrodt Inc., St Louis, MO) based on the age of the patient, and inserted through the lumen of the ILA with the 15-mm connector removed. A view of the glottic opening was recorded from the airway tube of the ILA just proximal to the ventilating orifice. Video images of the fiberoptic view were obtained using a digital camera and stored on a personal computer for analysis and grading by an independent observer (SS). The images were graded according to a score of 1 to 5 defined as follows: grade 1 = only larynx seen; grade 2 = larynx and epiglottis posterior surface seen; grade 3 = larynx and epiglottis tip of anterior surface seen, <50% visual obstruction of epiglottis to larynx; grade 4 = epiglottis downfolded and its anterior surface seen, >50% visual obstruction of epiglottis to larynx; and grade 5 = epiglottis downfolded and larynx cannot be seen directly. Images of all 5 grades of glottic view through the ILA are shown in Figure 2. According to the discretion of the anesthesiologist, maneuvers were allowed if the view was grade 2 or worse, in an attempt to optimize the laryngeal view and facilitate fiberoptic navigation past the epiglottis. The following manipulations were allowed: neck extension or flexion, jaw thrust, and gentle advancement or withdrawal of the device. Scores were recorded before and after the manipulations to see whether these maneuvers improved the laryngeal view. Once the carina was visualized with the bronchoscope, the tracheal tube was passed through the ILA and into the trachea. An independent observer (RJK) measured the time for successful tracheal intubation from the time the fiberoptic bronchoscope entered the ILA until reconnection of.

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**Figure 1.** The air-Q Intubating Laryngeal Airway (ILA). A, Lateral view of the size 1.5 (top) and 2.0 (middle) ILA, and removal stylet (bottom). The airway tube is wide, short, and hyper-curved (large arrows), and the 15-mm adapter (small arrows) is removed before tracheal intubation, effectually increasing the internal diameter of the airway tube and allowing for passage of auffed tracheal tube. The removal stylet is used to stabilize the tracheal tube upon removal of the ILA. B, The mask bowl of the size 2.0 ILA. The elevated keyhole-shaped ventilating orifice (large arrow) is designed to prevent occlusion by the epiglottis, and its mask ridges (small arrow) form a seal against the posterior larynx with isolation of the upper esophagus.

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the anesthesia circuit to the tracheal tube. Successful tracheal intubation was confirmed with auscultation of bilateral breath sounds and end-tidal carbon dioxide.

After successful tracheal intubation, the ILA cuff was deflated and removed using the manufacturer’s removal stylet (Fig. 1A) to stabilize the tracheal tube. The time for removal of the ILA started with the disconnection of the breathing circuit from the tracheal tube and ended at the time of reconnection. End-tidal carbon dioxide was verified to ensure that the tracheal tube had not been dislodged during ILA removal. The patient was ventilated with 100% oxygen throughout the intubation process to minimize the risk of oxygen desaturation.

The intubation was recorded as a failure and the patient was intubated by direct laryngoscopy if correct placement of the ILA was not achieved after 3 attempts, fiberoptic bronchoscopy was not successful in intubating the trachea after 2 attempts, the tracheal tube was dislodged during ILA removal, or there were 2 clinically significant instances of oxygen desaturation ($\text{SpO}_2 < 90\%$). At the end of the surgical procedure, the tracheal tube was removed after reversal of muscle relaxant and when standard extubation criteria were met. Complications such as traumatic placement as evidenced by blood staining of the ILA, aspiration, bronchospasm, laryngospasm, oxygen desaturation ($\text{SpO}_2 < 90\%$), and postextubation stridor were also recorded. Data collection regarding postoperative sore throat was not included in this study, because many of the children were too young to objectively report this complication. Patient follow-up was conducted according to standard postoperative protocols at our institution.

Based on previous experience with this device, we anticipated that the time to intubation in the ILA 1.5 group would be approximately $30 \pm 15$ seconds and that time to intubation in the ILA 2.0 group would be approximately $20 \pm 15$ seconds. Using an $\alpha$ of 0.05 and desired power of $90\%$, we estimated that 48 patients would be needed in each group to demonstrate a statistically significant difference. The study was designed with 50 patients in each group to account for possible failed intubation or exclusion from the study for any reason.

Data were recorded intraoperatively using a standardized data collection sheet and analyzed using Microsoft Excel Spreadsheet and the statistical software PASW Statistics 18 (SPSS Inc., Chicago, IL). Statistical comparisons between cohorts were made using Student $t$ tests for continuous data, $\chi^2$ tests for categorical data, and Mann-Whitney $U$ for ordinal data. A Spearman $\rho$ correlation coefficient was calculated for the relationship between a patient’s weight and fiberoptic grade of view and fiberoptic view to time to intubation. A Pearson correlation coefficient was calculated for the relationship between patient’s weight and time to tracheal intubation.

**RESULTS**

We studied 72 male and 28 female pediatric patients, with a mean weight of $17 \pm 5.5$ kg, and a mean age of 4.2 $\pm$ 2.1 years, who were divided into 2 cohorts of 50 according to the size of ILA placed. Patients underwent a variety of procedures including urological ($n = 31$), otolaryngological ($n = 29$), orthopedic ($n = 10$), general ($n = 9$), ophthalmological ($n = 9$), plastic ($n = 5$), and dental ($n = 5$) surgery, as well as medical imaging ($n = 2$). Demographic information and summary of results for both cohorts are presented in Table 1. No patients were excluded after enrollment for protocol violation or refusal to participate.

Insertion of the ILA with subsequent ventilation was successful in all 100 patients. In 99 patients, this was achieved on the first attempt. One case required a second attempt because the mask tip folded back upon itself during insertion as verified by fiberoptic bronchoscopy. There was no clinical evidence of airway obstruction or oxygen desaturation in any of the patients. The mean airway leak pressure for all patients was $16.6 \pm 5.5$ cm H$_2$O. There was no statistically significant difference in leak pressures between the 2 ILA sizes ($P = 0.08$).

Overall, 31% had a grade 1 view, 21% a grade 2 view, 12% a grade 3 view, 9% a grade 4 view, and 27% a grade 5 view. Details of fiberoptic grading for both cohorts are presented in Table 1. Of the 27 patients with a grade 5 view, 22 (81.5%) had a size 1.5 ILA placed. Of the 6 patients weighing $<10$ kg, all had grade 5 views. The grade of view was significantly better in the size 2.0 ILA cohort ($P < 0.001$).

When comparing the patient’s weight and the fiberoptic grade of view, a moderate negative correlation that was
A moderate positive correlation was found for the relationship between the fiberoptic grade of view and time to intubation ($r = 0.31, P = 0.01$), indicating shorter intubation times with better fiberoptic view.

Table 1. Demographic and Descriptive Statistics Regarding Placement and Tracheal Intubation Through the Intubating Laryngeal Airway (ILA)

<table>
<thead>
<tr>
<th></th>
<th>All patients</th>
<th>Size 1.5 ILA ($n = 50$)</th>
<th>Size 2.0 ILA ($n = 50$)</th>
<th>$P$ value</th>
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</thead>
<tbody>
<tr>
<td>Gender, male:female</td>
<td>72:28</td>
<td>38:12</td>
<td>34:16</td>
<td>0.37</td>
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<tr>
<td>Age, y</td>
<td>4.2 ± 2.1 (0.5–8.9)</td>
<td>2.6 ± 1.1 (0.5–5.2)</td>
<td>5.8 ± 1.7 (3.3–8.9)</td>
<td>&lt;0.001*</td>
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<tr>
<td>Weight, kg</td>
<td>17.0 ± 5.5 (8.0–30.0)</td>
<td>12.7 ± 2.0 (8.0–16.2)</td>
<td>21.2 ± 4.0 (17.0–30.0)</td>
<td>&lt;0.001*</td>
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<tr>
<td>ILA insertion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st attempt</td>
<td>99 (99%)</td>
<td>50 (100%)</td>
<td>49 (98%)</td>
<td></td>
</tr>
<tr>
<td>2nd attempt</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>ILA leak pressure, cm H$_2$O</td>
<td>16.6 ± 5.5 (8–36)</td>
<td>17.5 ± 6.4 (8–36)</td>
<td>15.7 ± 4.3 (8–30)</td>
<td>0.09</td>
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<td>Fiberoptic laryngeal view*</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Grade 1</td>
<td>31 (31%)</td>
<td>13 (26%)</td>
<td>18 (36%)</td>
<td>&lt;0.001*</td>
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<tr>
<td>Grade 2</td>
<td>21 (21%)</td>
<td>4 (8%)</td>
<td>17 (34%)</td>
<td></td>
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<tr>
<td>Grade 3</td>
<td>12 (12%)</td>
<td>7 (14%)</td>
<td>5 (10%)</td>
<td></td>
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<tr>
<td>Grade 4</td>
<td>9 (9%)</td>
<td>4 (8%)</td>
<td>5 (10%)</td>
<td></td>
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<tr>
<td>Grade 5</td>
<td>27 (27%)</td>
<td>22 (44%)</td>
<td>15 (10%)</td>
<td></td>
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<tr>
<td>Tracheal tube insertion</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>1st attempt</td>
<td>97 (97%)</td>
<td>48 (96%)</td>
<td>49 (98%)</td>
<td></td>
</tr>
<tr>
<td>2nd attempt</td>
<td>3 (3%)</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Time for intubation, s</td>
<td>24.8 ± 10.6 (11.6–84.9)</td>
<td>27.0 ± 13.0 (11.6–84.9)</td>
<td>22.7 ± 6.9 (12.1–45.2)</td>
<td>0.04*</td>
</tr>
<tr>
<td>Time for ILA removal, s</td>
<td>11.2 ± 4.6 (5.3–29.4)</td>
<td>10.8 ± 4.6 (5.3–29.4)</td>
<td>11.6 ± 4.5 (5.6–24.4)</td>
<td>0.36</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD (range).

* Fiberoptic grade was defined as follows: grade 1 = only larynx seen; grade 2 = larynx and epiglottis posterior surface seen; grade 3 = larynx and epiglottis tip of anterior surface seen, <50% visual obstruction of epiglottis to larynx; grade 4 = epiglottis downfolded and its anterior surface seen, >50% visual obstruction of epiglottis to larynx; and grade 5 = epiglottis downfolded and larynx cannot be seen directly.

* $P < 0.05$ designates a significant difference between cohorts.

Figure 3. Fiberoptic grade of view through the Intubating Laryngeal Airway in relation to weight of patient. A moderate negative correlation that was statistically significant was found ($r = -0.41$, $P < 0.001$), showing that larger patients tended to have better fiberoptic grades of view, indicating a better epiglottic isolation. ○ = statistical outliers; * = sample maximum.

statistically significant was found ($r = -0.41$, $P < 0.001$), indicating that larger patients had better fiberoptic grades of view (Fig. 3). A moderate positive correlation was found for the relationship between the fiberoptic grade of view and time to intubation ($r = 0.31$, $P = 0.01$), indicating shorter intubation times with better fiberoptic view.

Tracheal intubation was successful in all patients. Insertion was successful on the first attempt in 97 patients and on the second attempt in 3 patients. In these patients, a second attempt was necessary because of secretions obscuring the fiberoptic view. Successful intubation took an average of 24.8 ± 10.6 seconds across all 100 patients. Intubation times ranged from 11.6 to 84.9 seconds, and there were no instances of oxygen desaturation from patients’ baselines. In the size 1.5 ILA cohort, intubation took an average of 27.0 ± 13.0 seconds. The time to intubation in the size 2.0 cohort, 22.7 ± 6.9 seconds, was significantly faster ($P = 0.04$), but may not be clinically significant. The relationship between the time to intubation and the child’s weight across all patients (Fig. 4) showed a weak correlation that was not statistically significant ($r = -0.17$, $P = 0.09$).
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Figure 4. Time to tracheal intubation in relation to weight of patient. A weak correlation that was not statistically significant was found ($r = -0.17$, $P = 0.09$). This shows that time to intubation did not differ significantly according to weight, despite higher fiberoptic grades in smaller patients. × = size 1.5 Intubating Laryngeal Airway; + = size 2.0 Intubating Laryngeal Airway.

Of the 69 patients with a grade 2 view or worse, 41 (59.0%) received a maneuver in an attempt to optimize the view that resulted in an improvement by ≥1 grade in 39 cases (95.1%). The maneuvers performed were jaw thrust on 34 patients, head extension on 5 patients, and gentle advancement of the ILA in 2 patients.

The ILA was successfully removed while keeping the tracheal tube in place in all 100 patients. The mean time for removal was 11.2 ± 4.6 seconds. The time for removal did not differ significantly between cohorts ($P = 0.355$).

There were no cases recorded as failures, and no instances of blood staining of the ILA, aspiration, bronchospasm, laryngospasm, oxygen desaturation ($\text{SpO}_2 < 90$), or postextubation stridor reported in any patients.

**DISCUSSION**

The ILA is currently the only available supraglottic device in pediatric patients designed to act as a conduit for tracheal intubation with cuffed tracheal tubes. The traditional LMA has been used for this purpose with success, but a series of modifications to the tracheal tube or LMA may be required for optimal results and can be impractical in the difficult airway.4–7 In this study, the ILA was successfully inserted in all patients, and leak pressures were consistent with earlier studies using the LMA in children.8–11 Even in cases of complete epiglottic downfolding, ventilation was adequate. This is consistent with previous studies that compared LMA positioning with airway patency.12,13 Additionally, fiberoptic-guided tracheal intubation and subsequent removal of the ILA while leaving the tracheal tube in place were completed quickly without complications in all patients.

Our observation of a frequent incidence of partial or complete obstruction by the epiglottis upon fiberoptic examination is consistent with earlier literature regarding pediatric LMAs.10,12,14,15 Indeed, our findings show that smaller sized patients exhibited greater obstruction of the glottic opening compared with larger patients. A potential explanation for this is the combination of a large, floppy epiglottis in smaller children with the use of neuromuscular blockade. This may have predisposed the epiglottis to be pushed downward by the front end of the ILA when using the standard midline insertion technique as recommended by the manufacturer. We may have found lower rates of epiglottic downfolding by using the rotational method of ILA insertion, a technique that was shown to obtain an optimal glottic view in a previously published case series.16 With the rotational method of insertion, the LMA has also been shown to have a higher rate of success in smaller patients versus standard insertion technique.17–19 However, even in cases of complete visual obstruction of the larynx through the ILA by the epiglottis, the anesthesiologist was able to bypass the epiglottis to gain a full view of the vocal cords in all patients. Additionally, the use of airway manipulations while attempting to intubate through the ILA improved the laryngeal view by raising the epiglottis anteriorly to open the laryngeal inlet.20 Although studies have shown high success rates of blind intubation with the Intubating LMA in adult patients,21 the high rates of epiglottic obstruction observed in our study lead us to advise against blind intubations through the ILA in children. Similarly, blind intubations through the LMA have also been cautioned against for pediatric patients because of the risk of laryngeal trauma or esophageal intubation.22,23

During intubation through the ILA, there is a period when the patient is disconnected from the breathing circuit. Although these intubation times reflect an apneic period when the patient is at potential risk for oxygen desaturation, our longest intubation times were still within acceptable clinical limits.24,25 This correlates with our findings that none of the patients exhibited oxygen desaturation after adequate oxygen administration. Of note, as part of the study, the investigators briefly paused advancement of the fiberoptic bronchoscope within the lumen of the ILA to optimize the laryngeal view for subsequent grading. Also, the size 2.0 ILA had shorter intubation times when compared with the smaller size. However, this difference may not be clinically significant given the large overlap of confidence bounds, the nonsignificant correlation coefficient that compared tracheal intubation times to weight across all patients, and the absence of oxygen desaturation. Fiberoptic intubation through the ILA may be clinically acceptable in patients with normal cardiopulmonary reserve, but larger-scale studies are indicated to further confirm these findings.

When attempting to remove the LMA after tracheal intubation with a cuffed tracheal tube, there is a potential risk of accidental dislodgement of the tracheal tube or pilot balloon rupture. This might lead the clinician to leave the supraglottic airway in place until extubation. However, when using the ILA, the shorter and wider airway tube allows smoother passage of the pilot balloon. Furthermore,
the ability to stabilize the tracheal tube with the removal stylet allows the clinician greater control of the tracheal tube during removal of the ILA. Given these features, removal of the ILA after tracheal intubation was performed expeditiously without any oxygen desaturation, pilot balloon breakage, or dislodgement of the tracheal tube in all patients. This may be particularly useful in clinical practice as the paradigm is shifting toward the use of cuffed tracheal tubes in children.26 In addition to the use of the ILA removal stylet, several other methods of stabilizing the tracheal tube during removal of the ILA have also been described. This includes the use of a second tracheal tube,27 laryngeal forceps,28 a fiberoptic bronchoscope,29 or an airway exchange catheter.30 The removal stylet may be the most user friendly, but alternative modalities are an option if the removal stylet is not available or the clinician is not comfortable with its use.

This study had several limitations. First, only low-risk patients with normal airways were enrolled; second, there was no performance comparison with an established supraglottic device; third, our patients received muscle relaxants and our results may be less applicable to patients who are spontaneously breathing; fourth, the ILA intracuff pressures were not checked after cuff inflation; and fifth, airway manipulations to facilitate tracheal intubation were not standardized in all patients. Finally, this study was a pilot evaluation of the use of the ILA as a conduit for tracheal intubation in healthy patients. Further prospective comparison trials with a larger number of patients, particularly infants weighing <10 kg who are at higher risk for airway difficulty, are required to more fully judge both the safety of this device and the feasibility of blind tracheal intubation.

In summary, the ILA was easy to place and provided an effective conduit for tracheal intubation with cuffed tracheal tubes in children with normal airways. Additionally, removal of the ILA after successful intubation could be achieved quickly and without dislodgement of the tracheal tube. Because of the higher incidence of epiglottic down-folding in smaller patients, the use of fiberoptic bronchoscopy is recommended to assist with tracheal intubation through this device.

**AUTHOR CONTRIBUTIONS**

NJ helped design and conduct the study, analyze the data, and write the manuscript. This author has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files. RJK helped conduct the study, analyze the data, and write the manuscript. This author approved the final manuscript. LES helped design and conduct the study, analyze the data, and write the manuscript. This author approved the final manuscript. SS helped design and conduct the study, analyze the data, and write the manuscript. This author approved the final manuscript.

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