Prospective evaluation of the self-pressurized air-Q intubating laryngeal airway in children

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Introduction

The air-Q™ ILA intubating laryngeal airway (ILA) (Cookgas LLC, Mercury Medical, Clearwater, FL, USA) has been designed for tracheal intubation and routine airway management during maintenance of anesthesia in both children and adults. A newer version of the ILA, the self-pressurized air-Q™ ILA (ILA-SP), has recently been introduced into our practice for routine airway maintenance in children. This supraglottic airway device shares structural similarities with the original ILA, including the ability to provide a reliable conduit for tracheal intubation (1,2). Two main features distinguish the ILA-SP from the original ILA: (i) the absence of a pilot balloon and (ii) continuity between the airway tube and the cuff through an inner aperture at their junction.

Keywords

Children; airway devices; intubating laryngeal airway; laryngeal mask airway; air-Q

Summary

Objectives: To assess the clinical efficacy of the self-pressurized air-Q ILA™ (ILA-SP).

Aim: The purpose of this prospective audit was to evaluate the feasibility of the ILA-SP in clinical practice and generate data for future comparison trials.

Background: The ILA-SP is a new first-generation supraglottic airway for children with a self-adjusting cuff and lack of a pilot balloon.

Methods: Over a 4-month period, 352 children with an ASA physical status of I–III, newborn to 18 years of age, undergoing various procedures were studied. Data points assessed included insertion success rates, airway leak pressures, quality of ventilation, and perioperative complications associated with the use of this device.

Results: In 349 of the 352 patients in this study, the ILA-SP was used successfully as a primary supraglottic airway device in a variety of patients. Three patients required conversion to a standard laryngeal mask airway or a tracheal tube. The mean initial airway leak pressure for all patients was $17.8 \pm 5.4 \text{ cm H}_2\text{O}$, and $20.4 \pm 5.5 \text{ cm H}_2\text{O}$ when re-checked at 10 min, which was statistically significant ($P < 0.001$). Complications were limited to 14 patients and related to reflex activation of the airway (coughing, laryngospasm, and bronchospasm) ($n = 10$), sore throat ($n = 3$), and blood staining on removal of the device ($n = 1$). There were no episodes of regurgitation, aspiration, or hoarseness.

Conclusions: Acceptable clinical performance was demonstrated with the ILA-SP for a variety of procedures in infants and children with spontaneous and positive pressure ventilation. Future studies comparing this device to other supraglottic airways may provide useful information regarding the safety of the ILA-SP in pediatric clinical practice.
These features may allow for several clinical benefits when compared with other cuffed supraglottic airways: First, intra-cuff pressures are determined by the airway pressures, because of the equalization of pressures with the movement of gas between the cuff and airway tube. Second, lower intra-cuff pressures are maintained overall as a result of being limited by the peak airway pressures, with the highest pressures exerted during inspiration. Third, by not exceeding peak airway pressures, the balance between intra-cuff pressures and the airway seal of the device may be optimized at lower pressure. Therefore, the risk of sore throat, neuropraxic injury, and gastric insufflation seen with overinflation (3,4) of traditional cuffed supraglottic devices may be reduced. Figure 1 highlights the structural features of the ILA-SP.

The purpose of this study was to evaluate the clinical efficacy of this device assessing: (i) insertion success rates, (ii) airway leak pressures, (iii) quality of ventilation, and (iv) perioperative complications. The results obtained from this study will allow us to determine the feasibility of this device in clinical practice and generate data for future comparison trials.

Methods

This quality assurance study was approved by the IRB. The need for written parental consent was deemed unnecessary because the device was FDA approved and licensed for use in the USA. The ILA-SP was already in use in other pediatric institutions and a part of our standard practice for airway management with supraglottic airways and therefore not considered experimental. Over a 4-month period, 352 patients with an ASA physical status of I–III, newborn to 18 years of age, and scheduled to undergo an elective procedure requiring general anesthesia with a supraglottic airway device were consecutively included in this study. Exclusion criteria were ASA physical status II–IV, active respiratory tract infection (presence of rhinorrhea, cough, and temperature >38°C on the day of surgery), clinically significant pulmonary disease, severe gastrointestinal reflux, features or syndromes suggestive of a difficult airway, emergent surgery, or surgery requiring placement of a tracheal tube.

Four study investigators (NJ, LES, AGR, KEL) who were subspecialized in pediatric anesthesia performed all insertions of the ILA-SP in this study. Prior to this study, they were experienced in placing the original ILA in at least 25 pediatric patients.

After placement of standard monitors, we recorded the type of induction, size of ILA-SP inserted, and number of attempts required for successful insertion. Prior to insertion of the ILA-SP, adequate depth of anesthesia was confirmed by the lack of a motor response to jaw thrust (5). The ILA-SP was inserted using either a standard midline approach or a rotational method (6) depending on the study investigator’s preferred technique. A disposable ILA-SP was used in

![Figure 1](image_url)

Figure 1 The self-pressurized intubating laryngeal airway (ILA-SP) size 2.5. (a) ILA-SP mask bowl showing the inner orifice communicating with the airway tube at the proximal portion of the cuff that allows for self-pressurization. Arrows show direction of air entry into mask bowl. Note that the proximal portion of the mask bowl was cut to reveal this orifice. (b) Lateral view of the standard ILA (bottom) versus ILA-SP (top). Note that the ILA-SP lacks a pilot balloon for its cuff. (c) View of airway tube of the ILA-SP. Two horizontal line markings are present as a guide for the suggested position of upper incisor/gums of the patient, indicating appropriate fit. Upsizing of ILA-SP may be required if the upper incisor of the patient rests above upper horizontal line. Downsizing of ILA may be required if upper incisor rests below bottom horizontal line.
all patients; those weighing between 0 and 7 kg received a size 1.0 ILA, 7 and 17 kg received a size 1.5 ILA, 17 and 30 kg received a size 2.0 ILA, and patients between 30 and 50 kg received a size 2.5 ILA, according to the manufacturer’s guidelines, while allowing for adjustments based on the study investigator’s clinical judgment. Guideline markings on the airway tube in relation to the patient’s upper gums/incisors were also used as a confirmatory measure for determining the appropriately sized ILA-SP (Figure 1). If resistance or difficulty with the insertion was encountered, an alternative method of insertion was allowed to achieve successful placement and considered a second attempt. If the airway leak pressures were not clinically acceptable, a change in size was permitted, and this event was also recorded as an additional attempt. Successful device placement and adequate ventilation was evidenced by bilateral chest excursion, tidal volumes of at least 7 ml·kg⁻¹·min⁻¹, square-wave capnogram tracing with positive pressure ventilation, and the absence of an airway obstruction or dislodgement of the device. Once the ILA-SP was properly secured, the airway leak pressure was observed with the head in neutral position. The airway leak pressure was determined when an audible noise was heard over the patient’s mouth by closing the expiratory valve of the breathing circuit with a fresh gas flow of 3 l·min⁻¹ (7).

The expiratory valve was immediately released when the leak pressure was determined by the onset of audible noise or if airway pressure reached 40 cm H₂O without an audible leak. A second airway leak pressure was taken at least 10 min later to observe whether there was a change in the airway seal. The mode of ventilation whether spontaneous, mechanical, or pressure support was noted and based on the study investigator’s preference. None of the patients in this study received neuromuscular blockade to facilitate mechanical ventilation. At the end of the procedure, the ILA-SP was removed under a deep plane of anesthesia in all patients. Standard institutional protocols were used to evaluate all patients postoperatively assessing the patients’ pain and sore throat.

Complications such as regurgitation of gastric contents, pulmonary aspiration, laryngospasm, bronchospasm, oxygen desaturation (SpO₂ < 90%), hoarseness of voice, blood on the ILA-SP after removal, or sore throat in children able to objectively report complaints (5 years and older) were also recorded. Failure of the ILA-SP in this study was defined as (i) the inability to achieve correct placement within three attempts, (ii) dislodgement of the device, (iii) inadequate ventilation as evidenced by obstructive chest wall movements, poor capnogram morphology, or an inability to achieve tidal volumes of at least 5 ml·kg⁻¹, or (iv) the need to convert to an alternative airway.

Previously, data on the original ILA size 1.5 and 2.0 described airway leak pressures to be 16.6 ± 5.5 cm H₂O (2). Our study was designed to detect a difference of 5 cm H₂O between the ILA-SP sizes. Assuming a similar variance in leak pressure with the ILA-SP and the original ILA, an alpha of 0.05, and a power of 90%, we calculated that a minimum of 26 patients would be required per group. Enrollment of eligible patients was performed continuously until this quantity was achieved in each group, recognizing this would lead to a greater number of patients being included in the cohorts of the ILA-SP sizes used most commonly.

Data were recorded intra-operatively using a standardized data collection sheet and analyzed using Microsoft EXCEL Spreadsheet and PASW Statistics 18 (SPSS Inc., Chicago, IL, USA). Data are expressed as mean ± sd. Statistical comparisons between the ILA-SP size cohorts were made using chi-square tests for categorical data, and ANOVA with Bonferroni’s multiple comparison tests for continuous data. A P value less than 0.05 was considered statistically significant.

Results

A total of 352 patients were included in this study. There were 221 male, and 131 female pediatric patients with a mean weight of 19.3 ± 11.2 kg and a mean age of 5.0 ± 4.0 years, who were divided into four cohorts according to the size of ILA-SP placed. Demographic information and the summary of results for all cohorts are presented in Table 1. Results for infants (under 10 kg) were also analyzed separately and are included in Table 2. Patients in this study underwent a variety of procedures: urological (n = 106), medical imaging (n = 83), general surgery (n = 49), orthopedic (n = 47), ophthalmological (n = 47), and otolaryngological (n = 20). Of the 352 patients studied, 298 received an inhalational induction with sevoflurane, six received an intravenous induction with propofol, and 48 received supplemental propofol after a sevoflurane induction.

The ILA-SP was inserted using the standard midline technique (n = 236) or rotational method (n = 115), with subsequent successful ventilation in 351 patients. In one patient, the ILA-SP could not be placed adequately, necessitating the conversion to a laryngeal mask airway (LMA) (LMA North America, San Diego, CA, USA). Placement of the ILA-SP was achieved on the first attempt in 336 patients, while 13 cases required a second attempt without a change in the insertion technique. Of the 13 needing a second
attempt, seven required a change in the ILA-SP size as determined by the study investigator. Upsizing of the ILA-SP occurred in six of the seven size changes owing to low airway leak pressures. Five of the six reports involved changing from size 1.5 to 2.0, and the other was from size 2.0 to 2.5. The one instance of ILA-SP downsizing was from size 2.0 to 1.5. The remaining six cases requiring a second placement attempt involved removal of the device secondary to increased resistance from light anesthesia upon initial placement followed by reinsertion of the same-size ILA-SP after increasing anesthetic depth. Three cases were recorded as failures: two required conversion to a tracheal tube because of laryngospasm and desaturation during maintenance of anesthesia and one required the use of a LMA size 2.0 because an adequate seal could not be achieved with the ILA-SP size 2.0 after two attempts. The mean initial airway leak pressure for all patients was 17.8 ± 5.4 cm H2O, and 20.4 ± 5.5 cm H2O when re-checked at 10 min, and this difference was statistically significant (P < 0.001) (Figure 2). There were statistically significant differences in initial airway leak pressures between size 1.0 and 2.0 (P = 0.034), 1.5 and 2.5 (P = 0.004), and 2.0 and 2.5 (P < 0.001). At 10 min, there were statistically significant differences in airway leak pressures between size 1.0 and 2.0 (P = 0.031), 1.5 and 2.5 (P = 0.028), and 2.0 and 2.5 (P < 0.001). Spontaneous ventilation was reported in 203 patients, mechanical ventilation in 144, and 5 received pressure support ventilation. The mean peak airway pressures recorded were 15.28 ± 2.37 cm H2O when positive pressure ventilation modes were utilized. Ventilation parameters were acceptable in all patients.

Table 1 Demographic and descriptive statistics regarding use of the self-pressurized intubating laryngeal airway (ILA-SP)

<table>
<thead>
<tr>
<th>Size weight recommendation (kg)</th>
<th>ILA 1.0</th>
<th>ILA 1.5</th>
<th>ILA 2.0</th>
<th>ILA 2.5</th>
<th>Total</th>
<th>Test/P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>27</td>
<td>143</td>
<td>121</td>
<td>61</td>
<td>352</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>0.49 ± 0.61</td>
<td>2.1 ± 1.3</td>
<td>6.1 ± 2.3</td>
<td>11.2 ± 3.0</td>
<td>5.0 ± 4.0</td>
<td>ANOVA P &lt; 0.001</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>6.3 ± 2.4</td>
<td>11.7 ± 2.3</td>
<td>21.2 ± 3.9</td>
<td>39.1 ± 8.4</td>
<td>19.3 ± 11.2</td>
<td>ANOVA P &lt; 0.001</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>47</td>
<td>45</td>
<td>27</td>
<td>131</td>
<td>(37.2%) Paulson $\chi^2$ P = 0.383</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>96</td>
<td>76</td>
<td>34</td>
<td>221</td>
<td>(62.8%)</td>
</tr>
<tr>
<td>ASA physical status (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>13</td>
<td>91</td>
<td>68</td>
<td>38</td>
<td>210</td>
<td>(59.7%) Paulson $\chi^2$ P = 0.475</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>32</td>
<td>38</td>
<td>13</td>
<td>93</td>
<td>(26.4%)</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>20</td>
<td>15</td>
<td>10</td>
<td>49</td>
<td>(13.9%)</td>
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<tr>
<td>Placement success (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First attempt</td>
<td>24</td>
<td>141</td>
<td>112</td>
<td>59</td>
<td>336</td>
<td>(95.5%)</td>
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<tr>
<td>Second attempt</td>
<td>2</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Failed*</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Overall success</td>
<td>26</td>
<td>143</td>
<td>119</td>
<td>61</td>
<td>351</td>
<td>(99.7%)</td>
</tr>
<tr>
<td>Initial leak pressure (cm water)</td>
<td>19.9 ± 6.1</td>
<td>17.4 ± 5.1</td>
<td>16.8 ± 4.9</td>
<td>20.1 ± 5.9</td>
<td>17.8 ± 5.4</td>
<td>ANOVA P &lt; 0.001 (failed cases excluded)</td>
</tr>
<tr>
<td>Leak at 10 min (cm water)</td>
<td>22.1 ± 6.7</td>
<td>20.3 ± 5.2</td>
<td>18.9 ± 5.1</td>
<td>22.7 ± 5.8</td>
<td>20.4 ± 5.5</td>
<td>ANOVA P &lt; 0.01 (failed cases excluded)</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD (range).
*P < 0.05 designates a statistically significant difference between cohorts; however, a clinical significance may not exist.
*There were a total of three failed airways. In one patient, the ILA-SP could not be placed adequately necessitating the conversion to a laryngeal mask airway. In the two other patients, ILA-SP placement was successful; however, these were considered failures as tracheal intubation was required secondary to airway complications during maintenance of anesthesia.

The mean initial airway leak pressure for all patients was 17.8 ± 5.4 cm H2O, and 20.4 ± 5.5 cm H2O when re-checked at 10 min, and this difference was statistically significant (P < 0.001) (Figure 2). There were statistically significant differences in initial airway leak pressures between size 1.0 and 2.0 (P = 0.034), 1.5 and 2.5 (P = 0.004), and 2.0 and 2.5 (P < 0.001). At 10 min, there were statistically significant differences in airway leak pressures between size 1.0 and 2.0 (P = 0.031), 1.5 and 2.5 (P = 0.028), and 2.0 and 2.5 (P < 0.001). Spontaneous ventilation was reported in 203 patients, mechanical ventilation in 144, and 5 received pressure support ventilation. The mean peak airway pressures recorded were 15.28 ± 2.37 cm H2O when positive pressure ventilation modes were utilized. Ventilation parameters were acceptable in all patients.
A total of 14 complications were noted. Airway complications occurred in ten patients and involved laryngospasm without desaturation (n = 5), laryngospasm with desaturation (n = 2), bronchospasm without desaturation (n = 2), and bronchospasm with desaturation (n = 1). Of these, three were associated with the placement of the ILA-SP. In the remaining six patients, these events occurred either on induction or during the maintenance of anesthesia and were not related to the insertion of the device. Tracheal intubation was required in one patient for persistent desaturation from bronchospasm. In four patients, clinical evidence of potential mucosal trauma included sore throat (n = 3) and blood staining of the ILA-SP (n = 1). There were no cases of gastric regurgitation, aspiration, or hoarseness reported. A summary of airway-related complications and interventions is shown in Table 3.

Discussion

The concept of a self-pressurized cuff is new to supraglottic airways. This simple design modification may have some clinical advantages. Insertion techniques are similar to other supraglottic airway devices but without the need for cuff manipulation. The pressure in the cuff is self-regulated and no longer a closed air space. The success rates of insertion in this study were similar to those found in the literature on the use of traditional LMAs with reported first-attempt insertion rates of 90% (8,9), and overall insertion rates of 99–100% (8,10–14). Both the standard midline technique and the rotational method of insertion were found to be effective for the ILA-SP and may be a reflection of the study investigators’ prior experience with the device rather than the insertion technique itself. These results demonstrate an overall ease of placement on the first attempt, similar to reports on the original ILA (2) and LMA (8,9,13,15). Additionally, in infants, the ILA-SP may allow for a better anatomic fit when compared with the corresponding-size LMA. The wider mask bowl of the ILA-SP and its curved airway tube may improve approximation with oropharyngeal anatomy, providing greater lateral stability and better seating in the hypopharynx. This was evidenced by the lack of dislodgement or obstruction of the ILA-SP in infants.

In this study, the ranges of leak pressures are consistent with current evidence on the use of the original ILA (2) and LMA in children (8,11–13,16–18) although there were statistically significant differences in airway leak pressures between both sizes 1 and 2.5 when compared with the size 2.0, it is likely to be clinically insignificant, as all patients were adequately ven-
tilated through the ILA-SP regardless of patient size and the mode of ventilation. In some LMA studies, airway leak pressures in infants were lower than in larger children (11,17,19) and raised concerns regarding the safety and effectiveness of positive pressure ventilation in smaller patients. In contrast, this study demonstrated airway leak pressures with the ILA-SP in infants that were comparable to those of the larger children. By increasing the range of pressures at which mechanical ventilation may be delivered, the ILA-SP may improve the applicability of supraglottic airway devices for the anesthetic management of smaller children. This may be of particular importance when dynamic changes in ventilatory pressures occur during surgical procedures. These findings require further study to evaluate the use of this device for positive pressure ventilation in infants.

An improvement in airway leak pressures was seen in the 10-min leak pressure testing, potentially indicating an improvement in airway seal across all cohorts. This may be secondary to the increased pliability of the cuff because of the warmth from body temperature and potential self-adjustment of the ILA-SP, with better alignment of the ventilating orifice to the laryngeal inlet. Additional studies are needed to verify this anatomic relationship. As a result of the ILA-SP design, airway seals may also have been optimized at lower intra-cuff pressures. This may be analogous to studies with the LMA showing an improvement in the mask seal when lower intra-cuff pressures are maintained (20,21).

Of the complications reported, the low rates of mucosal trauma in this study may be secondary to the high first-attempt success rates and soft PVC material of the cuff and airway tube. Additionally, by eliminating the closed airspace in the cuff, the risk of overinflation is decreased, and the overall pressure exerted on the posterior pharyngeal wall and the risk for postoperative airway morbidities (3,22) are potentially minimized. This is of particular interest in the pediatric population where mucosal perfusion pressure is typically lower than in adults (21). Other complications were related to reflex activation of the airway (coughing, bronchospasm, laryngospasm), infrequent, promptly resolved with increased depth of anesthesia and/or bronchodilator therapy, and did not lead to patient morbidity. The overall complication rate in this study was lower (4%) when compared with larger LMA studies (11 %) (8,15) and was limited to reflex activation of the airway and mucosal trauma. Some studies suggest that the smaller-sized LMAs, in particular sizes 1 and 1.5, may be associated with more frequent airway complications such as airway obstruction.
during maintenance in infants (8,15,19,23). The findings in this study did not indicate an increased complication rate in the smaller-sized ILA-SP’s when compared with the larger sizes. A larger number of patients are needed to provide more definitive conclusions in regard to the overall safety of this device in clinical practice.

There are several limitations to this study as a result of its observational nature and because validated clinical signs in our routine practice were used to assess the clinical efficacy of the ILA-SP. First, the induction and insertion techniques were not standardized. Second, a fiberoptic examination was not performed to determine the anatomic alignment of the ILA-SP in relation to the vocal cords. Third, there was no control with an established supraglottic device. Fourth, postoperative complications should be interpreted within the constraints that smaller children were not able to report subjective complaints such as a sore throat or may have been masked by postoperative pain medications. Fifth, our results may not be applicable to those who receive neuromuscular blockade. These limitations were inevitable because of the study design and thought to be acceptable for the purposes of this study.

The ILA-SP was inserted with a high degree of success on the first attempt. The airway leak pressures and ventilation parameters achieved for a variety of procedures were clinically acceptable throughout all patient sizes, even with the use of positive pressure ventilation. This study may serve as an initial assessment of the feasibility of the ILA-SP in clinical practice. Randomized comparison studies regarding this device are now needed to further assess the features of the ILA-SP in comparison with other supraglottic airway devices with traditionally designed cuffs for airway management in children.

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Conflict of interest
None.

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Disclaimers
The devices used in this study was provided by the manufacturer.

References
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