A New Supraglottic Airway, the Elisha Airway Device: A Preliminary Study

Sonia J. Vaida, MD*, Diana Gaitini, MD†, Bruce Ben-David, MD‡, Mostafa Somri, MD*, Carin A. Hagberg, MD§, and Luis A. Gaitini, MD*

*Department of Anesthesiology, Bnai-Zion Medical Center, Haifa, Israel; †Department of Radiology, Rambam Medical Center, Haifa, Israel; ‡Department of Anesthesiology, University of Pittsburgh Medical Centers, Pittsburgh, Pennsylvania; and §Department of Anesthesiology, University of Texas-Houston Medical School, Houston, Texas

We describe the Elisha Airway Device (EAD), a new reusable supraglottic ventilatory device. Its uniqueness consists of its ability to combine three functions in a single device: ventilation, blind and/or fiberoptic-aided intubation without interruption of ventilation, and gastric tube insertion. This study was performed in 70 ASA status I–II, Mallampati class I–II patients undergoing elective knee arthroscopy and receiving general anesthesia with mechanical ventilation. Anesthesia was induced with fentanyl and propofol and was maintained with isoflurane in N2O/oxygen. Neuromuscular blockade was achieved with vecuronium. Blind insertion of the device was successful in 96% of patients, with a mean insertion time of 20 ± 4 s. In these patients it was possible to maintain oxygenation and ventilation throughout the surgical procedure. Gastric tube insertion was successful in all cases. Endotracheal intubation via the EAD was attempted in 20 patients. Blind intubation was possible during the first and second attempts in 15 and 2 patients, respectively. Fiberoptic intubation was then successful in two of the remaining three patients. The EAD is a new alternative in the evolution of supraglottic ventilatory devices; however, further clinical studies are necessary to evaluate its efficacy.

Accepted for publication February 6, 2004.
Address correspondence and reprint requests to Luis A. Gaitini, MD, Department of Anesthesiology, Bnai-Zion Medical Center, 31048, 47 Golomb St., Haifa, Israel. Address e-mail to sonia@netvision.net.il.
DOI: 10.1213/01.ANE.0000123492.26499.63
©2004 by the International Anesthesia Research Society

In recent years, supraglottic ventilatory devices have come to play an important role in airway management. Despite the plethora of new devices, none combines ventilation, endotracheal intubation, and gastric tube placement in one device. We describe a new supraglottic airway, the Elisha Airway Device (EAD) (Elisha Medical Technologies, Ltd., Katzrin, Israel), whose uniqueness consists of its ability to combine three functions in a single device: ventilation, intubation (blind and/or fiberoptic aided) without interruption of ventilation, and gastric tube insertion.

Methods

The shape of the EAD was based on spiral computed tomographs of the oropharyngeal cavity in subjects weighing 50–70 kg, followed by postprocessing with multiplanar reconstruction (1,2). The EAD is constructed of latex-free medical-grade silicone and has three separate channels for ventilation, intubation, and gastric tube insertion (Fig. 1). The ventilation channel (VC) and the intubation channel (IC) are side by side, whereas the gastric tube channel (GTC) has an outlet located in the distal end of the device. The VC and the IC have a partitioning wall between them, but they join at the ventilation outlet situated in front of the laryngeal inlet. The VC has a standard 15-mm connector located on the proximal end of the device: ventilation, intubation (blind and/or fiberoptic aided) without interruption of ventilation, and gastric tube insertion.

© International Anesthesia Research Society. Unauthorized Use Prohibited.
and gastroesophageal reflux. Two attending anesthesiologists experienced in the use of supraglottic airway devices inserted the EAD; they trained by inserting the device more than 100 times in the Laerdal Airway Simulator and 20 times in patients before the performance of this study.

Anesthesia was induced with up to 3 μg/kg of fentanyl and 2–3 mg/kg of propofol and maintained with 70% N₂O/30% oxygen and isoflurane. Neur muscular blockade was obtained with vecuronium 0.1 mg/kg. After confirmation of neuromuscular blockade (zero of four twitches on train-of-four), the EAD was inserted blindly with the patient’s head in neutral position. The number of attempts (a maximum of two attempts was allowed) and the time taken to insert the EAD were noted.

The balloons were inflated to a pressure of 70 cm H₂O by using an aneroid manometer (VBM Medizintechnik GmbH), and the device was connected to an anesthesia breathing circuit. The criteria for an effective airway included a minimal expired tidal volume of 7 mL/kg. Oropharyngeal leak pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and noting when the airway pressure reached equilibrium. The alignment of the ventilatory hole with the laryngeal aperture was then graded fiberoptically according to the grading scale of Brimacombe and Berry (3): 4, only vocal cords; 3, vocal cords plus posterior epiglottis; 2, vocal cords plus anterior epiglottis; 1, cords not seen but function adequately; and 0, cords not seen and failure of EAD to function adequately.

During maintenance of anesthesia, patients were ventilated with volume-controlled mechanical ventilation and a respiratory rate of 12 breaths/min. Breath-by-breath spirometry values were obtained by using a sidestream spirometry device (D-lite™ flow sensor; Datex Ohmeda, Helsinki, Finland). Data were recorded at 5-min intervals and included airway pressures, inspiratory and expiratory minute volumes, and the ratio of passively exhaled volume during the first second to the total expiratory tidal volume.

A lubricated 18F gastric tube was inserted through the GTC in all patients. The gastric tube was left in situ for the duration of the procedure.

Insertion of an armored ET (RUCHELIT®; Willy Rüsch AG, Kernen, Germany) (7.5-mm inner diameter in women and 8.0-mm inner diameter in men) through the IC was attempted in a subset of 20 patients. A maximum of two attempts at blind intubation was allowed. If the second blind intubation failed, a fiberoptic bronchoscope was used to guide endotracheal intubation. At the end of the procedure, anesthesia was discontinued, the patient awakened, and the device was removed upon return of the patient’s laryngeal reflexes and following verbal commands.

Upper airway trauma was assessed in all patients by checking for the presence of blood on the EAD after its removal (0 = no blood and 1 = blood stains present). Patients were examined for sore throat and hoarseness at 2 and 24 h after surgery.

Results

Patient demographics are shown in Table 1. Blind insertion of the device was successful in 96% of patients, with an insertion time of 20 ± 4 s (mean ± sd). First and second attempt rates were 76% and 20%, respectively. In all of these patients, it was possible to maintain oxygenation (SpO₂ 97.4 ± 5 mm Hg) and ventilation (ETCO₂ 37.5 ± 7 mm Hg) during the surgical procedure. Three patients were excluded from further study after two unsuccessful attempts to insert the device.

The spirometry data are depicted in Table 2. The average oropharyngeal leak pressure was 27 ± 5 cm H₂O. The fiberoptic scoring results are presented in Table 3. Gastric tube insertion was successful in all cases.

Blind insertion of an ET through the IC of the device was successful in 17 (85%) of 20 patients. In 15 of 20 patients, blind intubation was successful on the first attempt, and in 2 of the remaining 5 patients, it was successful on the second attempt. After a second failure of blind endotracheal intubation, fiberoptic-aided intubation was successful in two of the remaining

![Figure 1. Elisha Airway Device.](image-url)
Table 2. Spirometry Data

<table>
<thead>
<tr>
<th>Inspiratory MV (L/min)</th>
<th>Expiratory MV (L/min)</th>
<th>V1.0% (L/min)</th>
<th>Ppeak (cm H$_2$O)</th>
<th>Pplat (cm H$_2$O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.7 ± 4.6 (4.7–10.5)</td>
<td>5.3 ± 5.7 (3.6–9.9)</td>
<td>68.2 ± 14.5</td>
<td>33.4 ± 6.6</td>
<td>21.4 ± 7.6</td>
</tr>
</tbody>
</table>

Data are presented as mean ± sd (range).

MV = minute volume; V1.0% = the ratio of passively exhaled volume during the first second to the total expiratory tidal volume; Ppeak = maximum airway pressure; Pplat = end-expiratory pressure after inspiratory pause.

Table 3. Fiberoptic Score

<table>
<thead>
<tr>
<th>Fiberoptic Score</th>
<th>No. Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>33</td>
<td>49.3</td>
</tr>
<tr>
<td>3</td>
<td>17</td>
<td>25.4</td>
</tr>
<tr>
<td>2</td>
<td>11</td>
<td>16.4</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>8.9</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
<td>100</td>
</tr>
</tbody>
</table>

Scores are as follows: 4 = only vocal cords; 3 = vocal cords plus posterior epiglottis; 2 = vocal cords plus anterior epiglottis; 1 = cords not seen but function adequately; 0 = cords not seen and failure of Elisha Airway Device to function adequately (2).

Discussion

This preliminary evaluation demonstrates the following: 1) the EAD was easily inserted with frequent success; 2) in most cases, the device afforded good alignment of the ventilation hole with the larynx, as confirmed by fiberoptic assessment; 3) the mean airway sealing pressures were similar to those of other supraglottic ventilatory devices (4,5); 4) it was possible to ventilate the patients with controlled ventilation through the VC, perform endotracheal intubation through the IC, and place a gastric tube through the GTC; and 5) the EAD caused minimal complications, including minor airway trauma and sore throat.

The supraglottic ventilatory devices, especially the Laryngeal Mask Airway (LMA) (Laryngeal Mask Co., Henley-on-Thames, UK), have a well established role in management of the airway. Four variations of the LMA (the LMA-Classic™, the LMA-Fastrach™, the LMA-ProSeal™, and the LMA-Unique™) have separate capabilities of ventilation, intubation, and gastric tube placement (5–7). The Esophageal Tracheal Combitube (Tyco-Kendall-Sheridan, Mansfield, MA) has a role in emergency airway management combining the possibility of ventilation and gastric tube placement (8). The Laryngeal Tube™ (VBM Medizintechnik GmbH, Sulz a.N, Germany) is strictly a device for ventilation (9), yet the new Laryngeal Tube Suction™ allows for both ventilation and drainage of gastric contents (10). None of the existing supraglottic ventilatory devices combines all three functions of ventilation, blind or fiberoptic-assisted endotracheal intubation, and gastric tube placement in one device. One of the most important features of the EAD is that the VC and the IC are side by side, and this unique design allows endotracheal intubation without interruption of ventilation.

The importance of drainage of stomach contents during mechanical ventilation when supraglottic ventilatory devices are used has been well established (11,12). It is likely that the upper esophageal sphincter becomes incompetent after the administration of muscle relaxants (13), thereby further increasing the possibility of gastric contents passing into the larynx. The GTC of EAD offers the possibility of drainage of gastric contents. Furthermore, both the proximal and esophageal balloons are intended to offer protection against aspiration.

Nevertheless, this study has a number of limitations. First, it was an observational study, and further investigation is necessary to compare the EAD with other supraglottic ventilatory devices. Second, all patients had Mallampati class I and II airways; thus, the performance of this device in patients with difficult airways is undetermined. Third, this study demonstrated the use of the EAD only in paralyzed and mechanically ventilated patients, so its use in spontaneous ventilation was not validated. Fourth, only one size of the device was evaluated.

In conclusion, this preliminary study suggests that the EAD successfully performs multiple functions and achieves a useful compromise between effectiveness, safety, and simplicity of a supraglottic ventilatory device. Further investigation of this device is warranted.

References