An Evaluation of the Laryngeal Tube® During General Anesthesia Using Mechanical Ventilation

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The Laryngeal Tube® is a new supraglottic ventilatory device for airway management. It has been developed to secure a patent airway during either spontaneous or mechanical ventilation. In this study, we sought to determine the effectiveness of the Laryngeal Tube for primary airway management during routine surgery with mechanical ventilation. One hundred-seventy-five subjects classified as ASA physical status I and II, scheduled for elective surgery, were included in the study. After the induction of general anesthesia and insertion of a Size 4 Laryngeal Tube, measurements of oxygen saturation, end-tidal CO₂ and isoflurane concentration, and breath-by-breath spirometry data were obtained every 5 min throughout surgery. The lungs were ventilated with volume-controlled mechanical ventilation. The number of attempts taken to insert the Laryngeal Tube and the insertion time were recorded. In 96.6% of patients, it was possible to maintain oxygenation, ventilation, and respiratory mechanics by using mechanical ventilation throughout the surgical procedure. The results of this study suggest that the Laryngeal Tube is an effective and safe airway device for airway management in mechanically ventilated patients during elective surgery.

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The Laryngeal Tube® (VBM Medizintechnik GmbH, Sulz a.N, Germany) is a new supraglottic ventilatory device for airway management. It consists of an airway tube with an approximate angle of 130° and average diameter of 1.5 cm (1) and two low-pressure cuffs (proximal and distal), with an oval aperture placed between them that allows ventilation (Fig. 1). The Laryngeal Tube is usually inserted blindly, although a laryngoscope may be used to facilitate placement. Insertion requires a mouth opening of at least 23 mm (2). The distal balloon (esophageal balloon) seals the airway distally and protects against regurgitation. The proximal balloon (oropharyngeal balloon) seals both the oral and nasal cavity. The two balloons are inflated sequentially via a unique connector at a pressure of 60 cm H₂O by using a manometer. When the Laryngeal Tube is inserted, it lies along the length of the tongue, and the distal tip is positioned in the upper esophagus. During ventilation, air passes into the pharynx and from there over the epiglottis into the trachea, because the mouth, nose, and esophagus are blocked by the balloons. There are six sizes, suitable for neonates up to large adults, designated 0 through 5. The aim of this study was to determine the effectiveness of the Laryngeal Tube for primary airway management during routine surgery with mechanical ventilation in adults.

Methods

The Local Human Ethics Committee approved the study, and written, informed consent was obtained. Subjects were 175 patients classified as ASA physical status I and II, 18–75 yr old, 155–180 cm in height, and 50–90 kg in weight, scheduled for elective surgery during general anesthesia (orthopedic, urologic, and gynecologic surgery). Preoperative airway evaluation was performed by using the Samsoon and Young (3) modification of the Mallampati airway classification, and only patients with a score of I or II were included in the study. Exclusion criteria included known esophageal disease, pulmonary disease, or cardiovascular disease.

Three attending anesthesiologists used the Laryngeal Tube during the study. Each had performed at least 10 Laryngeal Tube insertions before the implementation of the study.

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All patients received premedication with oral diazepam 10–20 mg. After 3 min of preoxygenation, anesthesia was induced with up to 3 μg/kg of fentanyl and 2–3 mg/kg of propofol and was maintained with 70% N2O in 30% (remainder) oxygen and isoflurane. Neuromuscular blockade was obtained with vecuronium 0.1 mg/kg and maintained throughout the surgery to train-of-four count of 1/4, as assessed by using a peripheral nerve stimulator with electrodes placed over the ulnar nerve. After confirmation of complete neuromuscular blockade, a Size 4 Laryngeal Tube was inserted in accordance with the manufacturer’s recommendations. The patients were positioned in sniffing position.

Both balloons were sequentially inflated with air by using a manometer (Cuff Pressure Gauge; VBM Medizintechnik GmbH) until intraballoon pressure reached 80 cm H2O, and then the deflate valve was pressed to adjust the pressure to 60 cm H2O. Proper positioning of the Laryngeal Tube was confirmed by bilateral chest movement and auscultation, absence of gastric insufflation, and partial pressure of end-tidal CO2 (ETco2).

The lungs were ventilated with volume-controlled mechanical ventilation by using a ventilator of an AS/3™ anesthesia delivery unit (Datex-Ohmeda, Helsinki, Finland) with a semiclosed circuit incorporating a CO2 absorber. Ventilatory settings included an inspiratory/expiratory ratio of 1:2 and an average tidal volume of 12 mL/kg. The initial inspiratory rate was 12 breaths/min and was adjusted to obtain an ETco2 of 40 mm Hg. The fresh gas flow was 3 L/min. Blood pressure, heart rate, oxygen saturation (SpO2), ETco2, and end-tidal isoflurane concentration were measured with the AS/3 monitor. Breath-by-breath spirometry data were obtained by using a sidestream spirometry device (D-lite™ flow sensor; Datex-Ohmeda) attached between the proximal end of the Laryngeal Tube and the Y-piece. Data measured included airway pressures (peak, plateau, and positive end-expiratory pressure), lung volumes (minute and tidal volume), graphically displayed loops (pressure volume and flow volume) and curves (pressure and flow), airway resistance, and dynamic compliance. Data were recorded at 5-min intervals after the introduction of the Laryngeal Tube.

Gas leak was determined by auscultation with a stethoscope placed on the neck region and/or as a nonclosing flow-volume loop. Upper airway trauma was assessed by checking for the presence of blood on the Laryngeal Tube after its removal (0 = no blood and 1 = blood stains present) and by examining the patients for sore throat and hoarseness 24 h after surgery.

The number of attempts taken to insert the Laryngeal Tube was recorded. The insertion time was noted from removal of the face mask to attachment of the breathing system to the Laryngeal Tube after inflation of the cuffs.

Intraballoon pressures (proximal and distal) were measured by using the manometer connected to the pilot tube of the pharyngeal cuff of the Laryngeal Tube and were recorded at 10-min intervals, beginning after the introduction of the Laryngeal Tube, for 30 min of anesthesia. The intraballoon pressure was measured during the expiratory phase of the ventilatory cycle to prevent changes in airway pressure from affecting intraballoon pressure. After 30 min of anesthesia, the intraballoon pressure was released to the initial value of 60 cm H2O.

The study was terminated immediately if ventilation of the patient’s lungs was clinically unacceptable, peak airway pressure exceeded 40 cm H2O, or SpO2 decreased to <90%. At the end of the procedure, anesthesia was discontinued and the device was removed as the patient’s reflexes returned, in accordance with the manufacturer’s recommendations.

Statistical process control (X control charts) was used to determine the stability of the spirometry data. The data were considered stable if they were within the limits of the mean value ± 3 σ and in the absence of a “run” or a “trend.” Warning limits were fixed.

Figure 1. Laryngeal Tube®.
within the mean value ± 2 sd. A “run” was defined as at least seven successive points on the same side of the mean value. A “trend” was defined as a succession of seven values that were increasing or decreasing (4).

Data were also analyzed with the Friedman analysis of variance test, followed by Wilcoxon’s matched pairs signed rank tests with an appropriate correction analysis of variance for repeated measurements. A P value of <0.05 was considered significant.

Results
Demographic data and duration of surgery are displayed in Table 1. In 96.6% of patients, the Laryngeal Tube was successfully used to maintain respiratory mechanics during mechanical ventilation, as reflected by spirometry data during the entire duration of surgery (Table 2). Mean SpO₂, ETCO₂, and end-tidal isoflurane concentrations were 98.4% ± 3%, 39.8 ± 6 mm Hg, and 0.7% ± 5%, respectively. Insertion was possible on the first, second, and third attempt in 159 (94%), 5 (3%), and 5 (3%) patients, respectively. The median insertion time was 21 s (range, 8–40 s).

The Laryngeal Tube was unsuccessful in 6 patients (3.4%): 3 because of airway pressures more than 40 cm H₂O and 3 because of clinically unacceptable ventilation. Evidence of upper airway trauma occurred in four patients (Grade 1). No blood (Grade 0) was visualized in 171 cases. Twelve patients complained of sore throat in the postanesthesia care unit after surgery. Sore throat disappeared after 24 h, and no patient required treatment. No patient complained of hoarseness.

A gas leak was detected at a ventilation pressure of 25 cm H₂O in 10 patients; the leak disappeared after overinflation of the balloon with an additional 10 mL of air. Gastric insufflation was not detected by epiglottic auscultation in any patient. The pharyngeal balloon pressure was noted to increase progressively during the procedure, with a mean increase of 14.1 ± 4 cm H₂O at 30 min.

Statistical process control charts showed stable systems for all data. Examples of x-charts are presented in Figures 2–4. No significant statistical differences were observed by the Friedman analysis of variance test for different time points of recording for all data.

Discussion
The results of this study show that the Laryngeal Tube is an efficient and reliable device for airway management during elective surgery with mechanical ventilation. The remarkable features of this device, as reflected by this study, are its ease of insertion, requiring only a minimal mouth opening, and the maintenance of effective mechanical ventilation with standard ventilatory settings. Successful mechanical ventilation confirms alignment of the ventilation orifice of the Laryngeal Tube with the laryngeal aperture.

One of the advantages of the Laryngeal Tube is its small intraballoonal pressure (60 cm H₂O). Inflation with the maximum recommended cuff volume produces intraballoonal pressures more than 100 cm H₂O in other supraglottic ventilatory devices (4–9). The incidence and degree of mucosal trauma caused by the pressure exerted by the pharyngeal balloon of the Laryngeal Tube are unknown. Although there is no clear correlation between the intracuff pressure of the supraglottic ventilatory devices and the pressure exerted on the pharyngeal mucosa (5,6,10), it is obvious that decreased intraballoonal pressure is a desirable feature in these devices.

With volume-controlled mechanical ventilation, the mean peak respiratory pressure (22 cm H₂O) was close to the values obtained with the laryngeal mask airway (LMA) in similar conditions (11,12). We believe that monitoring the cuff pressure of the Laryngeal Tube with the aid of a manometer and readjusting the pressure to its initial values may help avoid excessive pressure on the surrounding tissues. The cuff pressure increase can be explained by the fact that nitrous oxide diffuses more rapidly into the cuff than nitrogen diffuses out of it (13).

The leak fraction calculated by subtracting expired from inspired tidal volume was 10%; however, by auscultation with a stethoscope placed on the neck

Table 1. Patient Demographic Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± sd (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>49 ± 14 (19–75)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>76.9 ± 12.1 (54–90)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>170 ± 13 (159–180)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>26.5 ± 5 (19–44)</td>
</tr>
<tr>
<td>Sex ratio (M:F)</td>
<td>46:54</td>
</tr>
<tr>
<td>ASA I-II</td>
<td>64:36</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>63 ± 23 (15–140)</td>
</tr>
</tbody>
</table>

These data are for all patients for all times.

MV = minute volume; V 1.0% = the ratio of passively exhaled volume during the first second to the total expiratory tidal volume; Ppeak = maximum airflow pressure; Pplat = end-expiratory pressure after inspiratory pause; PEEP = positive end-expiratory pressure.

Table 2. Spirometry Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± sd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspiratory MV</td>
<td>7.0 ± 21/min</td>
</tr>
<tr>
<td>Expiratory MV</td>
<td>6.3 ± 21/min</td>
</tr>
<tr>
<td>V 1.0%</td>
<td>71.5 ± 91/min</td>
</tr>
<tr>
<td>PEEP</td>
<td>3.0 ± 0.5 cm H₂O</td>
</tr>
<tr>
<td>Ppeak</td>
<td>21.9 ± 1.9 cm H₂O</td>
</tr>
<tr>
<td>Pplat</td>
<td>16.5 ± 5 cm H₂O</td>
</tr>
<tr>
<td>Dynamic compliance</td>
<td>44.1 ± 14 mL/cm H₂O</td>
</tr>
</tbody>
</table>

Inspiratory MV = minute volume; V 1.0% = the ratio of passively exhaled volume during the first second to the total expiratory tidal volume; PEEP = positive end-expiratory pressure.
region, no significant air leak was detected at a peak respiratory pressure of 22 cm H2O with an intra-balloon pressure of 60–70 cm H2O. This finding is in agreement with a report of Doerges et al. (14), who found that airway pressures even up to 40 cm H2O would have been possible without gastric insufflation, although an intra-balloon pressure of 90 cm H2O was required.

In this study, the Laryngeal Tube proved to be remarkably atraumatic. The small percentage of cases with upper airway trauma (2.3%), evaluated by checking for the presence of blood on the Laryngeal Tube after removal and by the presence of sore throat (6.8%), is probably due to its design and its low-pressure, high-volume oropharyngeal balloons. Comparative sore throat percentages for the LMA and Combitube® are 5.8%–18% (15,16) and 25%–48% (10,17), respectively.

Previous studies used the first version of the Laryngeal Tube with two separate pilot tubes for inflation of the two balloons (1,14,18). The improved version of the Laryngeal Tube used in this study has a unique connector to inflate both balloons, minimizing the possibility of overinflation of the distal balloon and, consequently, the risk of esophageal trauma. One of the disadvantages of the Laryngeal Tube is that it is impossible to empty the gastric contents, because the esophagus is blocked.

Recently, Miller et al. (19) reported a frequent failure rate of the Laryngeal Tube during spontaneous ventilation, possibly because of an obstruction of the

**Figure 2.** Example of statistical process control for peak pressure in a typical patient. Control p-chart analyzed by statistical process control: M = mean; UCL = upper control limit (mean + 3 sd); LCL = lower control limit (mean – 3 sd); UWL = upper warning limit (mean + 2 sd); LWL = lower warning limit (mean – 2 sd). UCL and UWL are mean values for the whole study population.

**Figure 3.** Example of statistical process control for end-tidal CO2 in a typical patient. Control p-chart analyzed by statistical process control: M = mean; UCL = upper control limit (mean + 3 sd); LCL = lower control limit (mean – 3 sd); UWL = upper warning limit (mean + 2 sd); LWL = lower warning limit (mean – 2 sd). UCL and UWL are mean values for the whole study population.
single ventilation hole by the epiglottis, which occupies a considerable part of its area. This form of obstruction could be more easily overcome by the ventilator during positive pressure mechanical ventilation than by the spontaneously breathing patient’s efforts.

The improved version of the Laryngeal Tube used in this study has two additional small lateral holes in addition to the principal ventilation hole (2 mm long and 7 mm wide). These additional holes are intended to improve the ventilation by offering an additional route for air passage into the larynx.

This is an observational study, and further comparative studies are needed to compare the Laryngeal Tube with other supraglottic airway devices. However, the frequent rate of successful use (96.6%) of the Laryngeal Tube in mechanical ventilation makes it comparable to the LMA and the Combitube® (12,20).

The Laryngeal Tube is a promising device in the evolution of supraglottic devices and might be an important alternative for airway management. We believe that it is suitable for airway management with mechanical ventilation during general anesthesia of at least moderate duration.

References


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