A randomised comparison between Cobra PLA and classic laryngeal mask airway and laryngeal tube during mechanical ventilation for general anaesthesia

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Abstract

Background. The aim of this study was to compare ventilation parameters during mechanical ventilation using Laryngeal Mask Airway (LMA), Laryngeal Tube (LT), and Peri-Laryngeal Airway Cobra (PLA).

Methods. In a prospective, randomised controlled trial, 90 patients undergoing general anaesthesia for elective surgery were divided into three subgroups. The settings of controlled ventilation were: oxygen 50%, air 50%, sevoflurane 1.5–2.0%, TV 7 mL kg⁻¹, RR 10 breath min⁻¹, inspiratory/expiratory ratio 1:2 and FGF 3 L min⁻¹. The number of attempts, time taken to insert the device, airway pressure (peak airway pressure, plateau airway pressure), air leak (inspiratory and expiratory volume difference), and dynamic compliance were measured. The timepoints for collecting data were after successful insertion of the device, and after ten, 20, 30 and 50 mins of ventilation. The presence of visible blood traces, patients' assessment of their throat soreness, dysphonia and dysphagia were noted postoperatively.

Results. The success rates at first insertion were 90% and 80% and 90%, while time for insertion was 5 sec and 21.94 sec and 5.24 sec in the Cobra PLA, LMA and LT groups respectively. Ventilation pressures during procedure were highest in the LT group, where compliance was lowest compared to the Cobra PLA and LMA groups. The air leak was similar in all the groups. 30% vs. 40% vs. 10% of devices had positive blood traces; 20% vs. 40% vs. 30% of patients suffered from a sore throat; and 30% vs. 30% and 30% of patients suffered from dysphagia in the Cobra PLA, LMA and LT groups respectively.

Conclusion. The differences were small, but Cobra PLA seemed to be slightly superior in terms of the measured parameters.

Key words: airways, artificial, extraglottic devices, ventilation, mechanical

Establishing the airway is the primary aim during general anaesthesia as well as in emergency situations. While tracheal intubation is considered the gold standard, it requires adequate skill to secure the airway. The laryngeal mask airway (LMA®, Laryngeal Mask Company, Henley-on-Thames, UK) and the laryngeal tube (LT®; VBM Medizintechnik, Sulz, Germany) are two of the most popular, safe methods of tracheal intubation for airway maintenance during general anaesthesia in selected patients and surgical procedures. The perilaryngeal airway Cobra PLA (PLA®; Engineered Medical Systems, Indianapolis, IN, USA) is a relatively new extraglottic airway device.

The aim of this study was to assess the efficacy of the Cobra PLA, LMA and LT during controlled mechanical ventilation in paralysed patients during surgical procedures.

METHODS

After Ethics Committee approval and informed written consent had been obtained, 90 ASA I-II patients, with Mallampati 1 and 2, BMI under 30, at minimal risk of pulmonary aspiration, and scheduled for surgical procedures lasting about 60 minutes, were included in the study and randomly assigned to one of the three subgroups: LMA, LT, or Cobra PLA. Standard monitoring was used throughout the study:
ECG, HR, SpO₂, non-invasive MAP, Et CO₂, airway pressures, tidal volumes and compliance.

The patients’ lungs were ventilated with volume-controlled mechanical ventilation using an AS/3™ anaesthesia delivery unit (Datex-Ohmeda, Helsinki, Finland). Mechanical ventilation was performed with tidal volume of 7 mL kg⁻¹, respiratory rate of 10 breath min⁻¹, inspiratory/expiratory ratio of 1:2 and a fresh gas flow of 3 L min⁻¹.

The number of attempts, the time taken to insert the device, airway pressures (peak and plateau), air leak (inspiratory and expiratory tidal volume difference) and any unwanted effects were recorded. Also recorded (in patients in whom it was possible to ventilate the lung) was the time taken to insert the airway measured from the time that the airway was blinded, attaching it to the breathing system after inflating the cuffs.

Breath to breath spirometry data was obtained using a sidestream spirometry device (D-lite™ flow sensor, Datex-Ohmeda) attached between the proximal end of devices and the Y-piece of the anaesthetic breathing system. Data measured was recorded immediately after insertion of the device (T₀) and again after ten min (T₁₀), 20 min (T₂₀), 30 min (T₃₀) and 50 min (T₅₀) of ventilation.

The following intraoperative complications were documented: aspiration/regurgitation, hypoxia (SpO₂ < 90%), bronchospasm, airway obstruction, gastric insufflations, oropharyngeal leak, coughing/gagging/hiccup. At the end of surgery, the devices were removed and examined for the presence of visible blood traces. Patients were asked to rate their throat soreness, dysphonia (difficulty/pain on speaking), and dysphagia (difficulty/pain on swallowing) one, six and 24 h postoperatively using a visual analogue score (VAS).

Statistical analysis was performed between groups using ANOVA test and post-hoc analysis. P < 0.05 was considered as significant.

### RESULTS

There was no difference in terms of demographic data between the groups (Tab. 1). The success rates at first insertion were 90% and 80% and 90%, and the time taken to insert was 5, 21.94 and 5.24 sec in the Cobra PLA, LMA and LT groups respectively.

Ventilation pressures during the whole procedure were highest in the LT group, where compliance was lowest compared to the Cobra PLA and LMA groups (Tab. 2).

When comparing ventilatory parameters at measurement points, there were no significant differences between the Cobra PLA group and the LMA group. However, between the Cobra PLA group and the LT group, and between the LMA group and the LT group, there were differences in every measurement point in terms of dynamic lung compliance (Fig. 1).

Inspiratory peak pressure was significantly higher in the Cobra PLA group compared to the LMA group at T₀, T₁₀ and T₂₀. When comparing the Cobra PLA and LT groups, the inspiratory peak pressure increased significantly in LT only at T₃₀ (Fig. 2). In the LT group, plateau pressure increased at T₂₀, T₃₀ and T₅₀ compared to the Cobra PLA group. There were also significant differences in this parameter between the LT group and the LMA and PLA groups (Fig. 3).

The air leak was significantly higher in the Cobra PLA group compared to the LMA group at T₀, T₁₀ and T₂₀. When comparing the Cobra PLA and LT groups, the inspiratory peak pressure increased significantly in LT only at T₃₀ (Fig. 2). In the LT group, plateau pressure increased at T₂₀, T₃₀ and T₅₀ compared to the Cobra PLA group. There were also significant differences in this parameter between the LT group and the LMA and PLA groups (Fig. 3).

Dynamic lung compliance decreased when all evaluated devices were in use. Peak inspiratory pressure increased over time, but for LT this tendency was more expressed than for other devices. The same observation was made for plateau pressure. Air leak was highest at the beginning in the LT group, but decreased and was comparable to other devices. For all evaluated parameters at measurement points, the LMA

### Table 1. Demographic characteristics of patients (x ± SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cobra PLA</th>
<th>LMA</th>
<th>LT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>45.7 ± 19.5</td>
<td>46.04 ± 18.75</td>
<td>46.16 ± 14.21</td>
</tr>
<tr>
<td>BMI (kg m⁻²)</td>
<td>24.04 ± 2.9</td>
<td>23.97 ± 2.81</td>
<td>24.64 ± 2.74</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>13/17</td>
<td>15/15</td>
<td>14/16</td>
</tr>
</tbody>
</table>

### Table 2. Mean ventilation parameters during procedures (x ± SD)

<table>
<thead>
<tr>
<th>Group</th>
<th>Peak pressure (cm H₂O)</th>
<th>Plateau pressure (cm H₂O)</th>
<th>Compliance (mL cm H₂O⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobra PLA</td>
<td>16.2 ± 3.8*</td>
<td>14.4 ± 3.5</td>
<td>61.7 ± 19.4 #</td>
</tr>
<tr>
<td>LMA</td>
<td>14 ± 1.1</td>
<td>13.5 ± 0.9</td>
<td>62.1 ± 8.7</td>
</tr>
<tr>
<td>LT</td>
<td>18.8 ± 3.3</td>
<td>16 ± 3.4</td>
<td>50.5 ± 4.5</td>
</tr>
</tbody>
</table>

* P < 0.05 compared to LMA; # P < 0.05 compared to LT
Figure 1. Plateau inspiratory pressure (cm H$_2$O). Means and 95% CI of means

Figure 2. Peak inspiratory pressure (cm H$_2$O). Means and 95% CI of means

Table 3. Air leak at measurement points ($\bar{x} \pm SD$)

<table>
<thead>
<tr>
<th>Time-points</th>
<th>Cobra PLA (%)</th>
<th>LMA (%)</th>
<th>LT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>7.16 ± 1.61</td>
<td>5.23 ± 1.73</td>
<td>9.11 ± 3.32</td>
</tr>
<tr>
<td>T10</td>
<td>7.02 ± 1.72</td>
<td>4.37 ± 2.09</td>
<td>7.72 ± 1.81</td>
</tr>
<tr>
<td>T20</td>
<td>7.53 ± 2.07</td>
<td>4.76 ± 2.83</td>
<td>7.19 ± 2.22</td>
</tr>
<tr>
<td>T30</td>
<td>7.82 ± 0.12</td>
<td>4.54 ± 2.05</td>
<td>6.99 ± 2.47</td>
</tr>
<tr>
<td>T50</td>
<td>7.14 ± 2.36</td>
<td>4.74 ± 1.7</td>
<td>6.6 ± 1.69</td>
</tr>
</tbody>
</table>
group had the best results: lowest peak inspiratory and plateau pressures, smallest air leak, and highest dynamic lung compliance.

After completion of surgery in the Cobra PLA, LMA and LT groups respectively, 30% vs. 40% vs. 10% of devices had positive blood traces, 20% vs. 40% vs. 30% of patients suffered from a sore throat, and 30% vs. 30% and 30% of patients suffered from dysphagia.

**DISCUSSION**

In this study, the success rates for first insertion attempts were higher for Cobra PLA and LT than for LMA. The mean insertion times of the Cobra PLA and LT were comparable to and lower than the LMA. Lower insertion success rates and longer insertion times in the LMA group were observed, confirming previous findings [1]. Air leaks to the mouth and to the stomach were not recorded, probably because the peak airway pressures in our study in all groups were lower than airway sealing pressures, as described by others [1, 2, 3]. The Cobra PLA device generates a sealing pressure of above 20 cm H2O [4, 5]. In the case of LT, this pressure is higher: about 36 ± 3 cm H2O [7]. It has also been shown that the airway sealing pressure is about 5 cm H2O greater with Cobra PLA than LMA [4, 8].

In our study, during the whole procedure, the ventilation pressures were highest and compliance lowest in the LT group compared to the Cobra PLA and LMA groups, and similar to those found by other investigators [6, 7, 8]. At any measurement points, there were no significant differences either between the PLA and the LMA group or between the PLA and the LT group according to dynamic lung compliance. Our findings did not demonstrate any differences in air leak between the Cobra PLA and LT groups. However, the differences between Cobra PLA and LMA were significant, except at T0. A higher leak pressure for Cobra PLA compared to LMA has also been observed by other investigators [9].

During our study, the incidences of sore throat using Cobra PLA were lower than using LT and LMA, and were lower than previously reported [1]. The incidence of sore throat after using LMA was higher than with Cobra PLA and similar to that registered by Brimacombe [10] and lower than reported by others [1, 11, 12]. The occurrence of sore throat following LT use was consistent with the results of similar reports [2, 13, 14, 15]. The blood traces were detected...
tied on LT devices upon removal similarly to those reported by other authors [2, 13, 14, 15, 16] and were less common than when using Cobra PLA and LMA. The mucosal trauma determined by incidence of sore throat and blood traces was more frequent in the case of LMA. According to some published data, this complication is more common following Cobra PLA use, which results from the construction of this device and its rigid head. However, the LT construction is more rigid than LMA and the mucosal trauma determined by this device is less frequent than LMA [1].

In our study, we have not observed such complications as aspiration/regurgitation, hypoxia, bronchospasm or airway obstruction. The incidences of dysphagia were similar in all groups of patients; when LMA and LT were used, it was higher than has been reported by others [17, 18].

CONCLUSIONS
1. Cobra PLA, LMA and LT all provide adequate airway maintenance during general anaesthesia for surgical procedures.
2. A comparison between the ventilator parameters during procedures in all time-points was generally similar between the PLA, LT and LMA groups. There were slight advantages in favour of the PLA. The LT group performed the most poorly.

References:

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