Comparison of the laryngeal mask (LMA™) and laryngeal tube (LT®) with the perilaryngeal airway (CobraPLA®) in brief paediatric surgical procedures

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SUMMARY
We compared the laryngeal mask airway (LMA™) and the laryngeal tube (LT®) with the perilaryngeal airway (CobraPLA®, PLA) in anaesthetised, paralysed children having brief surgical procedures.

After obtaining informed consent, 90 paediatric ASA Status I to II patients awaiting short surgical procedures were randomised to have their airways managed with an LMA, LT or PLA. Anaesthesia was induced with sevoflurane (2.5 to 4%) and muscle paralysis with mivacurium (0.2 mg/kg intravenously). The number of insertion attempts, time taken to insert the device, haemodynamic responses to insertion (mean arterial blood pressure, heart rate, pulse oximetry and end-tidal CO₂), clinical performance and occurrence of postoperative sore throat were recorded.

When the airway device was removed, it was examined for visible blood. Patients and parents were asked about the occurrence of sore throat, dysphonia and dysphagia 24 hours postoperatively.

Heart rate, mean arterial blood pressure, pulse oximetry and end tidal CO₂ did not differ among the groups. Insertion times for the devices were similar (LMA: 19±11 seconds, LT: 21±12 seconds, PLA: 18±12 seconds), as were the rates of successful insertion at first attempt (LMA 66.7%; LT 70.0%; PLA 73.3%). The number and type of airway interventions to achieve an effective airway were comparable. When the airways were removed, positive blood traces were noted on 20% of the LMAs, 20% of the PLAs and 10% of the LTs.

Haemodynamic, ventilation and oxygenation variables throughout the surgery were similar with LMA, LT and PLA and there were no significant differences in insertion time or signs or symptoms of mucosal trauma when these devices were used in paralysed children.

Key Words: anaesthesia, general, intubation intratracheal, laryngeal masks
search found no reports of comparison of these three devices in paediatric patient population. At our institution, the anaesthesia for these procedures includes the use of muscle relaxants.

Our hypothesis was that there would be no difference between airways with regard to the primary study end-points: haemodynamic responses induced by airway insertion, clinical performance, insertion time, oxygen saturation, end-tidal carbon dioxide and side-effects.

METHODS

After ethics committee approval, informed consent was obtained from the parents of all subjects and assent obtained from children aged six to 13 years. All participants were American Society of Anesthesiologists physical status I or II, free of underlying airway disease and scheduled to undergo elective surgery lasting less than one hour under general anaesthesia using airway management. Exclusion criteria were upper respiratory infection, craniofacial malformation, patients assessed as Mallampati class 3 or 4, intracranial hypertension, risk of aspiration and emergency surgery.

Randomisation was based on computer-generated codes that were maintained in opaque envelopes. Patients were randomised to LMA (LMA™ Classic, Henley on Thames, U.K.), LT (Laryngeal tube®, VBM, Sulz, Germany), or PLA (Cobra PLA®, Engineered Medical Systems, IN, U.S.A.) (Figure 1) airway devices. Standard monitoring was used throughout the study and included electrocardiography, heart rate (HR), pulse oximetry (SpO₂), non-invasive mean arterial blood pressure (MAP) and end-tidal CO₂ (ETCO₂). Anaesthetic management was standardised according to the following protocol. After breathing oxygen for three minutes via a facemask, anaesthesia was induced in the patient using sevoflurane 2.5 to 4% in oxygen and air (1:1). Neuromuscular blockade was achieved with mivacurium, 0.2 mg/kg initially and maintained with 0.05 mg/kg boluses intravenously. The airway device was placed two minutes after mivacurium administration, after the loss of eyelash reflex and complete relaxation of the jaw had been observed. All the anaesthesiologists that participated in the trial were experienced with the insertion of all the devices. Two trained observers (not blinded to the airway device) collected data during anaesthesia and trained observers, blinded to the airway device used, collected the data after surgery.

The patients in the LMA group (n=30) received an LMA size 2 for a body weight of 10 to 20 kg, size 2.5 for 20 to 30 kg and size 3 for 30 to 50 kg. In the LT group (n=30), LT size 1 was used in patients weighing 6 to 15 kg, size 2 for those weighing 15 to 30 kg and size 3 for those weighing 30 to 60 kg. In patients allocated to the PLA group (n=30), size 1 1/2 was used for patients weighing 10 up to 15 kg, size 2 for those weighing 15 to 30 kg and...
size 3 for those weighing more than 35 kg. A clear, water-based gel without local anaesthesia was used for lubrication. Devices were inserted and fixed according to the manufacturers’ instructions.

The number of attempts and time for insertion for the device (starting when the anaesthesiologist picked up the prepared airway until delivery of the first tidal lung volume) were recorded. The need for adjusting airway position to achieve an adequate airway control was graded as minor (adjusting head/neck position or changing depth of insertion) or major (applying jaw lift/changing device size/reinserting the device) was recorded, as well as the occurrence of coughing at insertion or any other unwanted effect. If an air leak was detected at an inflation pressure of less than 20 cmH\textsubscript{2}O, we adjusted either the head position or repositioned the device. Mechanical ventilation (fraction of inspired oxygen=0.5 fraction of inspired air=0.5) was performed with controlled positive pressure ventilation, at a respiratory rate of 12 to 18 breaths per minute (Cato Dräger, Lübeck, Germany). If more than 20% of the inspiratory gas volume was lost to the expiratory limb (proportion of leak), we evaluated the position of the device and checked for gastric insufflation.

Mean arterial blood pressure, HR, SpO\textsubscript{2} and ETCO\textsubscript{2} were recorded immediately before airway placement, immediately after and at one, two and four minutes after airway insertion and following the removal of the airway. Other data collected throughout the procedure were complications such as gastric insufflation (determined by epigastric auscultation), regurgitation (after removal of the device, the mouth was inspected for secretions and gastric fluid), coughing, bronchospasm, ETCO\textsubscript{2} >45 mmHg and pulse oximeter saturation <95%.

After three failed attempts at airway insertion, an alternative airway device was to be inserted if the patient could be ventilated and the pulse oximeter saturation was ≥95%; otherwise, an endotracheal tube was to be inserted to secure the airway.

Anaesthesia was discontinued after completion of surgery, the cuff of the device was immediately deflated and the airway device was removed when the patient was able to open his or her mouth on command. The device was examined and the presence of visible blood was noted. Parents and those patients able to answer were questioned as to whether the patient had hoarseness, sore throat or problems swallowing.

Sample size was based on success rate data from previous studies\textsuperscript{3,5} and a pilot study of 20 paediatric patients with the CobraPLA. The sample size was selected to detect a projected difference of 15% or more between the groups for a type I error of 0.05 and a power of 0.9. For multiple comparisons the variance analysis test with a Bonferroni correction were used. For non-parametric data the chi-square test and Kruskal-Wallis tests were used, as appropriate, followed by Mann Whitney tests when indicated. Kolmogorov-Smirnov and t-tests were also used for in-group comparisons. All analyses were done with Statistica AXA software, number AXA 507775506FAN. A \textit{P} value of <0.05 was considered statistically significant.

**RESULTS**

From January 1, 2005 to August 1, 2006, 108 patients were evaluated for study eligibility (four patients failed to meet the inclusion criteria and 12 patients/families chose not to participate in the study). There was a protocol violation in two patients causing the data from those patients to be excluded from analysis. The remaining 90 patients completed the entire study and their data were included in the final analyses.

The patients’ demographic, surgical and anaesthetic data are presented in Table 1. There were no significant differences between the groups with respect to age, weight, duration of anaesthesia or duration of surgery. Facemask ventilation before the device insertion was easy in all patients; however, five patients in the LMA group, seven in the LT group and four in CobraPLA group needed an oral (Guedel) airway to maintain airway patency prior to insertion of the device.

<table>
<thead>
<tr>
<th>Types of surgery</th>
<th>Laryngeal mask airway (n=30)</th>
<th>Laryngeal tube (n=30)</th>
<th>Perilaryngeal airway (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernia repair</td>
<td>22</td>
<td>51</td>
<td>23</td>
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<tr>
<td>Circumcision</td>
<td>6</td>
<td>5</td>
<td>4</td>
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<tr>
<td>Orchidopexy</td>
<td>2</td>
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</table>

Values are shown as number of patients or mean ± SD.

No significant differences were found among the groups.
There were no differences in HR, MAP, SpO₂ and ETCO₂ at the times analysed (Table 2). The time required for insertion of the device did not significantly differ between the groups (LMA: 19±11 seconds, LT: 21±12 seconds, PLA: 18±12 seconds). The number of minor and major airway interventions required for achieving an effective airway were similar in the three groups (Table 3). All patients had satisfactory airways and maintained them (tidal volume of 4 to 8 ml/kg);
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Consequently, none of the patients required tracheal intubation. There was no difference in the rate of successful insertion at the first attempt: LMA=67% with 95% CI (50 to 84), LT=70% with 95% CI (54 to 87) and PLA=73% with 95% CI (57 to 89). The number of attempts required to place the airways did not differ significantly among the groups (Table 3).

When the airways were removed, 20% of the PLA and LMA devices showed blood traces, while only 10% of the LT devices had blood traces on them (P >0.05, Table 3). Five (16.7%) patients suffered sore throat in the PLA group and two (6.6%) in the LMA and LT groups each (P >0.05). None of the patients suffered from dysphonia or dysphagia at one and 24 hours after surgery. The most common side-effect was coughing (14 patients out of 90; 15.5%), but there were no significant differences between the groups in coughing or any other side-effects (Table 3).

With the observed common standard deviation of approximately 12 seconds for insertion time and 30 patients per treatment group, our study achieves 80% power to detect a difference of 9 seconds between devices and 90% power to detect a difference of 11 seconds between devices. As for the success rate for insertion on the first attempt, 30 patients per groups allows for estimating these success rates with a 95% confidence interval within ±17%.

DISCUSSION

In this study, we demonstrated that LMA, LT and PLA all provided an adequate airway and similar clinical performance for short surgical procedures in children. There were no significant differences in times to establish the airway, number of attempts or side-effects related to device use.

Since its introduction, the LMA has gained broad popularity in adult and paediatric anaesthesia. When the LMA was introduced to the market, it was used as an alternative to the facemask but currently it is used for almost all short anaesthesia cases. Advantages of supraglottic devices over the endotracheal tube are improved haemodynamic stability during induction and emergence, lower incidence of coughing and sore throat, reduced anaesthetic requirement for airway tolerance and no requirement for muscle relaxants (though we elected to use relaxants in our patients).

In our study, we were surprised that the insertion success rate with the LMA, with which our investigators had years of experience, was similar to that of the CobraPLA and LT, which they had inserted approximately 20 times in children. The CobraPLA head is rigid enough to permit easy insertion without the device kinking. One comparative study of LMA and LT in children found a rate of failure to provide adequate ventilation of 25% with the LT; the authors concluded that the LT is less effective than the LMA for ventilation in children younger than 10 years. Genzweker et al10 showed an overall success rate of 96.3% for LT insertion after two attempts in children. Another trial demonstrated a cumulative success rate of 95.7% after two attempts in children. In our study, the LT also demonstrated a high success rate, 96.7%.

Previous findings in adult patients found a higher incidence of blood traces and sore throat with the CobraPLA compared with other devices. In the present study we could not demonstrate any statistically significant difference (LMA with 10% vs. LT and CobraPLA with 20%) in the incidence of blood trace or sore throat with the three devices. Our findings were similar to previously reported ranges: between 7% to 30%, 28.5% and up to 42%. It is possible that this variation may relate variation in the methods of questioning the children and families about sore throat.

Placement of the supraglottic devices and inflation of the cuff stimulates the pharyngeal wall to produce clinically relevant increases in BP and HR, as reported in previous investigations comparing cardiovascular changes induced by placement of either LMA or LT airways. We could not find any significant differences in cardiovascular response between the airways.

Our study has a number of limitations. The investigators were more experienced with the LMA than with the LT or CobraPLA. All investigators had used the LT and CobraPLA approximately 20 times before the trial, the placement success rates were high with all devices and we did not detect any evidence of an ongoing operator “learning curve” with any of the devices during the trial. The evaluation of trauma associated with the use of airway devices usually involves a standard physical laryngeal examination, which we did not perform but relied on the indirect measures of blood on the device, hoarseness, dysphonia or sore throat. Our results were obtained with patients initially paralysed, so coughing and laryngospasm in response to device insertion, which are important complications in unparalysed patients, would not be likely to occur. Generalising this aspect of our results to patients breathing spontaneously would not be appropriate.

In conclusion, the three devices studied provided adequate ventilation and oxygenation while showing no difference in haemodynamic variables at insertion. The incidence of side-effects was similar. These results suggest that it would be reasonable to proceed with further use and evaluation of the devices in paediatric practice.

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REFERENCES