RESPIRATION AND THE AIRWAY

A randomized non-crossover study comparing the ProSeal™ and Classic™ laryngeal mask airway in anaesthetized children

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Background. We tested the hypothesis that ease of insertion, oropharyngeal leak pressure, fibreoptic position, gastric insufflation, and the frequency of mucosal trauma differ between the ProSeal laryngeal mask airway (PLMA) and the classic laryngeal mask airway (cLMA) in anaesthetized children. For the PLMA, we also assessed the ease of gastric tube placement via the PLMA drain tube and measure residual gastric volume.

Methods. 240 consecutive ASA I–III children aged 1–16 yr were randomized for airway management with the ProSeal or cLMA.

Results. The time taken to provide an effective airway, the number of insertion attempts, fibreoptic position of the airway tube and frequency of mucosal trauma were similar, but oropharyngeal leak pressure was higher (33 vs 26 cm H₂O, P < 0.0001) and gastric insufflation less common (0 vs 6%, P < 0.01) for the PLMA. Gastric tube insertion was successful at the first attempt in 106 of 120, and at the second attempt in 14 of 120. The mean (SD; range) value for residual gastric volume was 2.2 (5.9; 0–30) ml. There were no differences in performance among sizes for the PLMA and the cLMA.

Conclusions. We conclude that ease of insertion, fibreoptic position, and frequency of mucosal trauma are similar for the PLMA and cLMA in children, but oropharyngeal leak pressure is higher and gastric insufflation less common for the PLMA. Gastric tube insertion has a high success rate, provided the PLMA is correctly positioned.


Keywords: airway, technique, complications; children; equipment, ProSeal laryngeal mask airway

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The ProSeal™ laryngeal mask airway (PLMA, Laryngeal Mask Company, Henley-on-Thames, UK) is a relatively new laryngeal mask device with a modified cuff to improve the seal and a drain tube to: (i) prevent gastric aspiration; (ii) prevent gastric insufflation; (iii) facilitate gastric tube insertion; and (iv) provide information about position.1,2 Recently, it has been shown that the drain tube can also function as a highly effective guide to insertion.3 Adult studies have shown that compared with the classic™ laryngeal mask airway (cLMA) the PLMA forms a better seal with both the respiratory1,4 and gastrointestinal tracts,5 provides easier access to the gastrointestinal tract,6 and exerts lower mucosal pressures for a given seal pressure,7 but is more difficult to insert at the first attempt.4,5 The paediatric sizes vary slightly from the adult sizes in that they lack a dorsal cuff and the drain tube is proportionally larger, but this does not appear to interfere with the performance.8 There are two studies comparing the ProSeal and cLMA in children. Shimbori and colleagues,9 in a non-crossover study of 60 children, showed that PLMA offered no advantages over the cLMA, other than a lower frequency of mucosal trauma, and that gastric tube insertion was possible in 90%. In contrast, Goldmann and Jakob,10 in a crossover study of 30 children, showed that the PLMA was a better

¹Declaration of interest. Dr Brimacombe has worked as a consultant for the Laryngeal Mask Company, who manufacture the ProSeal™ laryngeal mask airway.
ventilatory device and had a lower frequency of gastric insufflation than the cLMA, and gastric tube placement was possible in 100%. In the present non-crossover randomized study of 240 children, we have tested the hypothesis that ease of insertion, oropharyngeal leak pressure, fibreoptic position, gastric insufflation and the frequency of mucosal trauma differ between the PLMA and the cLMA in anaesthetized children. For the PLMA, we also assessed the ease of gastric tube placement and residual gastric volume.

Methods

Ethical committee approval and written parental consent were obtained for all the patients. 240 consecutive ASA I, II, III children aged 1–16 yr undergoing minor surgery (excluding head and neck surgery) in the supine position were randomized for airway management with the PLMA or cLMA by opening an opaque envelope containing the computer-generated random assignments. Patients were excluded if they were at risk of aspiration.

Patients were fasted for at least 6 h for solids and 4 h for liquids. Pre-medication, midazolam 0.5 mg kg\(^{-1}\) by mouth, was given 30 min before induction of anaesthesia. A standard anaesthesia protocol was followed and routine monitoring applied, including an ECG, pulse oximeter, gas analyser, non-invasive arterial pressure monitor, tidal volume monitor, and airway pressure monitor. Patients were given atropine 0.01 mg kg\(^{-1}\) i.v. and pre-oxygenated for 2 min. Anaesthesia was then induced with remifentanil 0.1 \(\mu\)g kg\(^{-1}\) min\(^{-1}\) and propofol 3 mg kg\(^{-1}\) along with lidocaine 0.5 mg kg\(^{-1}\) given over 1 min. Facemask ventilation was performed until conditions were suitable for insertion of the laryngeal mask (loss of eyelash reflex, jaw relaxation, absence of movement). Additional boluses of propofol 1 mg kg\(^{-1}\) were given as required until an adequate level of anaesthesia was achieved for placement. The devices were inserted according to manufacturer’s instructions with the cuff fully deflated using either the digital or introducer tool techniques, according to the preference of the clinician. The size 2, 2.5, and 3 were used in children weighing 10–20, greater than 20–30, and greater than 30 kg, respectively.

All insertions were carried out by three experienced users of the cLMA and PLMA. Once inserted into the pharynx, the cuff was inflated with air until effective ventilation was established or the maximum recommended inflation volume reached. Fixation was according to the manufacturer’s instructions.\(^{11}\) Effective ventilation was judged by observation of chest wall movement and a square wave capnograph trace. Three attempts were allowed before insertion was considered a failure. A failed attempt was defined as removal of the device from the mouth. Between attempts, the lungs were ventilated using the facemask. If insertion failed after three attempts, the alternative device was used.

The time between picking up the laryngeal mask device and obtaining an effective airway was recorded. Once insertion was successful, the intra-cuff pressure was set at 60 cm H\(_2\)O using a digital manometer (Mallinckrodt Medical, Athlone, Ireland) and the oropharyngeal leak pressure was determined by closing the expiratory valve of the anaesthesia breathing system at a fixed gas flow of 3 litre min\(^{-1}\) and noting the airway pressure (maximum allowed, 40 cm H\(_2\)O) at which equilibrium was reached.\(^{12}\) Gastric insufflation was assessed by listening with a stethoscope over the epigastrium during oropharyngeal seal pressure testing.\(^{13}\) Anatomic position of the airway tube was determined by passing a fibreoptic scope to a position just proximal to the end of the airway tube and scoring the view.\(^{14}\) Anatomic position of the drain tube was determined by passing a fibreoptic scope to the end of the drain tube and scoring the position, as described previously.\(^{4}\)

A well-lubricated gastric tube (size 2 PLMA, Fr 10; size 2.5, Fr 10; size 3 PLMA, Fr 12) was inserted through the drain if there was no air leak up the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy. Two attempts were allowed before gastric tube insertion was considered a failure. The volume of gastric fluid was noted. Any episodes of hypoxia (\(Sp_{\text{O}_2}<90\%\)), airway reflex activation (coughing, gagging, retching, laryngospasm, bronchospasm) or aspiration/regurgitation/vomiting were documented. At the end of the procedure, the laryngeal mask device was inspected for any stains of blood. Data were collected by a second anaesthesiologist.

Sample size was selected for a type I error of 0.05 and a power of 0.95 and was based on a pilot study of 10 patients with a measured difference in oropharyngeal leak pressure of 10% between the groups. Statistical evaluation was with Student’s \(t\)-test and \(\chi^2\)-test. Significance was taken as \(P<0.05\).

Results

Data are presented in Table 1. There were no differences between the groups regarding patient characteristics. The digital technique was used in 64 children and the introducer tool technique in 56 children. The time taken to provide an effective airway, the number of insertion attempts, fibreoptic position of the airway tube and frequency of mucosal trauma were similar, but oropharyngeal leak pressure was higher (\(P<0.0001\)) and gastric insufflation less common (\(P<0.01\)) for the PLMA. Gastric tube insertion was successful at the first attempt in 106/120 and at the second attempt in 14/120. The mean (sd; range) value for residual gastric volume was 2.2 (5.9; 0–30) ml. There were no differences in performance among the sizes 2, 2.5, and 3 of either PLMAs or cLMAs. There were no differences in performance between the digital and introducer tool techniques. There were no differences in performance among users.

Discussion

The time taken to provide an effective airway, the number of insertion attempts, and fibreoptic position were similar
between the devices. This is a similar finding to the studies in children by Shimbori and colleagues and Goldmann and Jakob, but contrasts with the studies in adult patients which show that PLMA insertion is more difficult and fibreoptic position inferior. Perhaps the PLMA is better suited to the paediatric airway. Oropharyngeal leak pressure was higher for the PLMA. This is a similar finding to the studies in adults and the crossover study in children by Shimbori and colleagues.

We found that gastric tube insertion was successful in all patients after two attempts. The first attempt failures were related to the distal cuff being folded over or inadequate lubrication.

We found that gastric insufflation was more common with the cLMA. This supports the findings of Goldmann and Jakob. The risk of gastric insufflation should be higher with the cLMA, as the seal with the hypopharynx is less effective, and malposition, which predisposes to gastric insufflation by exposing the upper oesophageal sphincter to positive pressure ventilation, is less easy to detect. We found that the upper oesophageal sphincter was open in 9% of children with the PLMA, a similar finding to our previous study in children and the studies in adults. The clinical importance of this finding is unknown.

Our study has three limitations. First, the number of patients managed with each size was different between devices, particularly for the size 3; however, we found no differences in performance among subgroups and a previous study suggested there were no differences in performance between the size 2 and 3. Secondly, all the devices were inserted by experienced personnel, and our data may not be applicable to those with less experience. Thirdly, there was no blinding in the data collection, a possible source of bias.

We conclude that ease of insertion, fibreoptic position, and frequency of mucosal trauma are similar for the ProSeal and cLMA in children, but oropharyngeal leak pressure is higher and gastric insufflation is less common with the PLMA. Gastric tube insertion has a high success rate, provided the PLMA is correctly positioned.

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