



COMPARISON OF LMA-PROSEAL WITH LMA CLASSIC IN ANAESTHETISED PARALYSED CHILDREN

Anaesthesiology

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ABSTRACT

The classic laryngeal mask airway (cLMA), though popular in anaesthesia practice provides low oropharyngeal seal pressure and there are concerns with its use during positive pressure ventilation for fear of gastric distension with subsequent gastric regurgitation and pulmonary aspiration. The ProSeal laryngeal mask airway (PLMA) is a modified LMA with a larger, wedge shaped cuff and a drain tube. This modification improves the seal around glottis when compared to a cLMA and its drain tube prevents gastric distension and offers protection against aspiration when properly placed. We compared PLMA and cLMA in 100 anaesthetized, paralysed children with 50 patients in each group with respect to ease of insertion, oropharyngeal seal pressure and pharyngolaryngeal morbidity. Gastric tube insertion was also assessed for the PLMA. The ease of insertion and the number of attempts at insertion were found to be comparable in the two groups while the oropharyngeal seal pressure was significantly higher in the PLMA group ($P < 0.001$). The pharyngolaryngeal morbidity was comparable in both the groups. There was no incidence of regurgitation or aspiration in either group. The PLMA offered high reliability of gastric tube placement and significantly increased oropharyngeal seal pressure over the cLMA. This might have an important implication for use of this device for positive pressure ventilation in children.

KEYWORDS

Anaesthesia, Paediatric, Equipment, Laryngeal mask airway monitoring, Oropharyngeal seal pressure.

INTRODUCTION

Positive pressure ventilation (PPV) is a limitation of the classic laryngeal mask airway (cLMA), in paediatric patients as it forms a less effective glottic seal in children than in adults^{1,2}. The ProSeal™ laryngeal mask airway (PLMA, Laryngeal Mask Company, Hanley on Thames, UK) is a LMA device with a modified cuff and a double tube that has been especially designed for controlled ventilation and protection against aspiration. In addition to the airway tube, it has a drain tube to provide a bypass channel for regurgitated gastric contents and prevent gastric insufflation, thereby, prevents gastric regurgitation and pulmonary aspiration. It also allows easy placement of gastric tube and detects malposition of the device.³ The paediatric versions (sizes 1, 1.5, 2, 2.5) were made available after the introduction of the adult PLMAs. The paediatric PLMA lacks the dorsal cuff of the adult version and has a proportionately larger drain tube. However, these modifications do not appear to interfere with its performance.⁴ The drain tube acts as a conduit to monitoring of gastric pH and volume, cardiac output and core temperature.^{5,6} Recently, it has been shown that the drain tube can also function as a highly effective guide to insertion of the device, oesophageal dilatation and instrumentation in children.⁶⁻⁹ There is paucity of data of the use of PLMA and cLMA in paralysed children. In the present study, we compared the ease of insertion, oropharyngeal seal pressure and pharyngolaryngeal morbidity between the PLMA and the cLMA in anaesthetized, paralysed children. The ease of gastric tube placement through the drain tube of the PLMA was also assessed.

METHODS

Following institutional ethics committee approval and written informed consent from the parents, 100 children of either sex, aged 1-8 yrs, weighing 10-30 kg of ASA physical status I-II were enrolled for this prospective study. These patients were scheduled for elective lower abdominal or inguinal surgical procedures lasting more than 30 minutes. Children were allocated to either PLMA or cLMA group as per computer generated random numbers. Patients with upper respiratory tract infection, anticipated difficult airway, hiatus hernia, gastro-oesophageal reflux disease, non-fasting status and lung diseases were excluded from the study.

All children were premedicated with 0.3 mg.kg⁻¹ nasal midazolam, 30 min prior to surgery. Standard monitoring included pulse oximetry, non-invasive arterial pressure, electrocardiography and capnography. The patient's head was kept in a neutral position. Anaesthesia was induced with 50% nitrous oxide in oxygen and sevoflurane (6-8%) and maintained with sevoflurane (1-2%) with 66% nitrous oxide in oxygen. Neuromuscular blockade was achieved with atracurium besylate 0.5 mg.kg⁻¹ and boluses of 0.1 mg.kg⁻¹ were given for maintenance of neuromuscular blockade. The patient's lungs were

ventilated with a face mask for three minutes to allow for full relaxation of the jaw before placing the device. The investigators were experienced anaesthesiologists who had performed more than 20 PLMA and 300 cLMA insertions. A size 1.5, 2, or 2.5 PLMA / cLMA was chosen depending on the weight of the patient. The cuff was fully deflated prior to insertion. A clear water based gel (KY jelly) was used for lubricating the posterior aspect of the cuff. Both devices were inserted and fixed according to the manufacturer's instructions. The PLMA was inserted using the introducer tool. The PLMA or cLMA was connected to a circle breathing system and the cuff was inflated to a pressure of 60 cm H₂O using a cuff pressure monitor (Mallinckrodt Medical, Athlone, Ireland) and maintained at this pressure throughout the procedure. The closed circle breathing system with soda lime was used (Penlon, Abingdon, Made in UK, CE 0473). The number of insertion attempts to effective ventilation were recorded. Effective ventilation of the device was defined as a square wave capnograph trace and bilateral chest movements on manual ventilation.

In the event of partial or complete airway obstruction or a significant air leak, the device was removed and reinsertion attempted. A maximum of three insertion attempts were allowed before the device was considered a failure. An alternative device; a cLMA or a tracheal tube was used in such a situation and the number of attempts to secure the airway were noted. The time interval between picking up the PLMA/cLMA and obtaining an effective airway was recorded. The ease of insertion was judged by time taken and number of attempts to provide an effective airway.

After obtaining an effective airway, the oropharyngeal seal pressure (OSP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 5 liters.min⁻¹ and recording the airway pressure (maximum allowed was 40 cm H₂O) at which equilibrium was reached. In the case of PLMA, gel displacement test and successful placement of gastric tube as confirmed by aspiration of gastric contents or detection of injected air by epigastric auscultation were also carried out.³ The number of insertion attempts were recorded. Gastric tube placement was not attempted with cLMA. The patient's lungs were ventilated with a tidal volume of 5-7 ml.kg⁻¹, the respiratory rate adjusted to maintain EtCO₂ of 35-40 mm of Hg with inspiratory: expiratory ratio of 1:2.

Fibreoptic grading of the airway tube was carried out for both the masks. In the PLMA group the drain tube view was also evaluated. A flexible fibreoptic scope (Olympus BF type XP40, CE 0197, with distal end outer diameter of 2.8 mm) was introduced into the airway and the drain tubes for viewing and scoring the laryngeal and oesophageal structures. The fibreoptic position was graded as: 1 = vocal cords not seen; 2 = vocal cords and anterior epiglottis visible; 3 = vocal cords and

posterior epiglottis visible; 4= only vocal cords visible.¹⁰ The view from the drain tube was catalogued as: hypopharynx (mucosal); oesophageal sphincter open (clear view down the oesophagus); others (glottis, epiglottis, arytenoids).¹¹

Intraoperative analgesia was achieved with either intravenous fentanyl citrate 1-2 mcg.kg-1 or caudal epidural block with 0.5 ml.kg-1 of 0.25% bupivacaine hydrochloride. The following complications were documented: failed use, intraoperative displacement, gastric insufflation, regurgitation - aspiration, laryngospasm, bronchospasm and airway obstruction. After the completion of procedure, anaesthesia was discontinued and residual neuromuscular blockade was reversed with neostigmine methyl sulfate 0.05 mg.kg-1 and atropine sulfate 0.02 mg kg⁻¹. The device was then removed and any blood staining of the device, tongue-lip-dental trauma and duration of anaesthesia were recorded. Pharyngolaryngeal morbidity was assessed as hoarseness of voice in the post anaesthesia care unit and 24 hours subsequently. Two unblinded trained observers collected the intraoperative data while postoperative data was collected by two blinded trained observers.

Statistical Analysis

The primary variable tested was the OSP in the two devices. We considered a 30% increase in OSP to be clinically significant. The sample size allowed a projected difference of 30% to be detected for the primary variables for a type I error of 0.05 and a power of 0.9. Secondary variables tested were PLMATM device insertion success rates and times, fiberoptically anatomic position, orogastric tube insertion success rates and total intraoperative respiratory complications. The data was analysed using SPSS software, (10.0 version; SPSS Inc., Chicago, IL, USA). Kolmogorov-Smirnov test indicated that data was normally distributed, hence parametric tests; Chi-square, and Mann-Whitney tests were applied as appropriate. Significance was taken as $P < 0.05$.

RESULTS

The patient characteristics as shown in Table 1, were comparable in both the groups. The number of patients subjected for herniotomy, orchidopexy and hypospadias repair were 50, 30, and 20 respectively. Ease of insertion was similar for both devices. The mean (range) time taken to obtain an effective airway were comparable in the two groups. All devices were placed within two attempts. First attempt success rate was similar between PLMA and cLMA (94% and 98% respectively). Three cases in PLMA group and one case in cLMA group required a second attempt.

There was statistically significant difference ($P < 0.001$) between the two groups with respect to OSP, with PLMA group exhibiting higher OSP [18.72 cm of H₂O (12-28)] than cLMA group [15.43 cm of H₂O (11-22)]. (Table 1)

Table 1 Comparative Data for the PLMA and cLMA.

Variables	PLMA	cLMA	P Value
1. No. of Patients(n)	50	50	NS
2. Patient characteristics			
• Age (month)	49.26 (30.91;12-98)	39.82 (21.49;12.98)	NS
• Male : Female (n)	48:2	46:4	NS
• Weight (kg)	16.60 (6.20;10-30)	14.44 (4.82;10-30)	NS
3. Ease of insertion			
• Attempts 1/2/3(n)	47/3/0	49/1/0	NS
• Time taken for effective airway(sec)	23.52 (3.68;20-37)	22.54 (2.67;19-34)	NS
4. Oropharyngeal Seal Pressure (cm of H ₂ O)	18.72 (3.28;12-28)	15.84 (2.94;11-12)	< 0.001
5. Fiberoptic grading			
• Airway tube(1/2/3/4 (n)	2/1/8/39	0/3/15/32	NS
• Drain tube			
Hypopharyngeal Mucosa/UOS/others (n)	42/5/3	-	-
6. Complications			
• Nausea/vomiting	0	0	NS
• Laryngospasm/ Bronchospasm	0	0	NS
• Regurgitation/Aspiration	0	0	NS
• Blood on mask	4	4	NS
• Hoarseness in PACU/after 24 hrs	0/0	0/0	NS

Values are given as mean (SD; range) and number (n). The fiberoptic grading of airway tube: 1=vocal cords not seen; 2= vocal cords and anterior epiglottis visible; 3= vocal cords and posterior epiglottis visible; 4= only vocal cords visible. The view from the drain tube was catalogued as: hypopharynx (mucosal); oesophageal sphincter open (clear view down the oesophagus); others (glottis, epiglottis, arytenoids).

Fiberoptic grading of airway tube revealed a grade 4 in 39 and 32 patients in PLMA and CLMA groups respectively, but there was no statistically significant difference in the fiberoptic grading between the two groups ($P = 0.121$). In 2 patients in PLMA group, the fiberoptic grade was I. There was medial in folding of cuff of PLMA in these cases. Fiberoptic view through the drain tube in PLMA group revealed hypopharyngeal mucosa, upper oesophageal sphincter and others in 42, 5 and 3 patients respectively.

A gastric tube was successfully placed through the drain tube without any difficulty in 48 patients in group PLMA group at the first attempt. In two patients these were posterior folding of the cuff of PLMA and gastric tube could not be inserted and could be successfully placed only after reinsertion of the PLMA. Gastric fluid was aspirated in 3 patients, the volume of which was 2,3 and 8 ml respectively. All the patients in both groups had SpO₂ > 95% and EtCO₂ < 45mm of Hg. There was no case of airway obstruction or intraoperative displacement of the mask. There was no case of laryngospasm, bronchospasm, nausea, vomiting, gastric insufflation, regurgitation - aspiration and or pulmonary aspiration in our study. Blood on mask was found in 8% children with both devices, and was comparable in the two groups. No patient had sore throat or hoarseness of voice in either group in post anaesthesia care unit or 24 hours thereafter.

DISCUSSION

We found the PLMA to be as effective as cLMA in providing a patent airway during controlled ventilation of the lungs. Higher sealing pressures were provided by PLMA than the cLMA.

The ease of insertion was found to be similar in both the groups. This is in contrast to studies conducted in adults, where placement of PLMA has been found to be more difficult.^{8,9} The paediatric PLMA lacks the large dorsal cuff and thus making it less bulky, in addition to not just being a scaled down version of the adult PLMA. This may account for its placement to be as easy as that of the cLMA.

The OSP achieved with PLMA was greater than with the cLMA ($P < 0.001$) and is supported by previous studies in adults and paediatric patients.^{4,11-20} The improved seal is because of modified cuff, which is wider proximally, and larger distally thereby forming a more effective plug in the proximal and the distal pharynx, thus preventing air leaking into the gastrointestinal tract. In addition, the parallel arrangement of the airway and drain tubes allows the tongue to fall more efficiently over the wider proximal cuff.⁷ However, a lower OSP (as compared to adults) is unlikely to have major implications in children due to the high compliance of their lungs.¹⁹

Studies comparing PLMA and cLMA in children have been conducted earlier with inconclusive results. While Shimbori et al concluded that airway seal pressure is similar,¹⁴ other workers have concluded that the oropharyngeal seal pressure is significantly increased with PLMA.¹⁵⁻¹⁸

Sinha and colleagues have used PLMA successfully for laparoscopic procedures in children where there are concerns of raised intraabdominal and intrathoracic pressures resulting from carbon dioxide.²⁰ The use of PLMA has also been reported for neonatal resuscitation.²¹

We found that the first attempt success rate of gastric tube insertion was 96%. In the two cases (4%) with posterior folding of the cuffs, we were able to place the gastric tube only on reinsertion of the device. Similar results have been reported by Mellisa.¹³ Gastric tube placement may be useful in cases when gastric insufflation accompanies face mask ventilation or during laparoscopic procedures. The successful placement of the gastric tube also aids in correct positioning of the PLMA in the event of intraoperative displacement. Keller et al reported a case wherein the drain tube of the size 2 PLMA successfully diverted gastric contents away from the respiratory tree.²²

The fiberoptic view of the airway was grade 4 with PLMA in 39(78%)

patients as compared to 32(64%) in cLMA group, but was statistically not significant. There was medial in folding of cuff in two patients in PLMA group with grade I airway view, although ventilation and oxygenation were well maintained. The fiberoptic grading of drain tube revealed hypopharyngeal mucosa in 84% of children while upper oesophageal sphincter was visible in 10%. Similar results have been reported by other workers in children and adults.^{4,23}

There was no case of nausea, vomiting, laryngospasm, bronchospasm, regurgitation or pulmonary aspiration in our study. The incidence of mucosal injury as revealed by blood on the mask was similar in both groups. Though the cuff of the PLMA is larger, the intracuff pressure gets distributed over a large area. None of the children had hoarseness of voice in post anaesthesia care unit or 24 hours thereafter in either group.

Our study has a few limitations. The intraoperative data was collected by unblinded observers and all three different sizes of the mask have not been compared separately. However, the difference in the OSP between the two groups was found to be highly significant.

We conclude that the PLMA is easy to insert in the paediatric population. Fiberoptic position and frequency of mucosal trauma are similar for PLMA and cLMA in children. The high reliability of gastric tube placement, greater OSP, adequate ventilation and oxygenation without any gastric distension with the PLMA, might have important implications for the use of this device as an alternative to tracheal intubation for positive pressure ventilation in paediatric population.

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