Original Article

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Efficacy of the LMA-Classic™ and LMA Proseal™ in Children Undergoing Elective Surgery under General Anaesthesia

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Abstract

Background: The LMA-Proseal™ is a second generation supraglottic airway device with modified cuff and a drainage tube, designed for better seal with both the respiratory and gastrointestinal tracts, notwithstanding the access to the alimentary tract. The present study is planned to compare efficacy of the LMA-Classic™ and LMA Proseal™ in children undergoing elective surgery under general anaesthesia. **Subjects and Methods:** 120 children belonging to American Society of Anesthesiologists Physical Status 1 and 2, aged 3 to 15 years and weighing 5 to 45 kg undergoing elective surgery in the supine position were randomized for airway management with the LMA-Classic™ or LMAProseal™ by computer-generated random assignments. **Results:** There was no difference between LMA Classic™ and LMA Proseal™ with regard to ease of insertion, number of attempts for insertion, device positional stability, airway trauma and hemodynamic changes. **Conclusion:** The LMA-ProsealTM has advantages over LMA-Classic™ like the placement of gastric tube, adequate ventilation and oxygenation without any gastric distension. The complications of usage of the LMA are minimal and similar in both the devices.

Keywords: LMA Classic, LMA Proseal, Children.

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Introduction

The Laryngeal Mask Airway (LMA) is a supraglottic airway device designed to maintain a clear airway, which sits outside of and creates a seal around the larynx.[1] It is relatively non-invasive as compared to endotracheal intubation and in scenarios where endotracheal intubation is not mandatory; LMA has emerged as a formidable choice over endotracheal intubation. Compared with the face mask, the LMA allows for a more "hands-free approach" to airway management.[2,3]

In difficult airway management, LMA can bypass obstruction at supraglottic level and allow rescue oxygenation and ventilation, provided that mouth opening is sufficient. The LMA-Classic™ is a first generation supraglottic airway device, with largest evidence base for efficacy and safety, and is considered benchmark against which newer LMA are judged. However, use of positive pressure ventilation and the associated gastric insufflations is a limitation to its use.[2,4]

The LMA-Proseal™ is a second generation supraglottic airway device with modified cuff and a drainage tube, designed for better seal with both the respiratory and gastrointestinal tracts, notwithstanding the access to the alimentary tract.[5] The present study is planned to compare efficacy of the LMA-Classic™ and LMAProseal™ in children undergoing elective surgery under general anaesthesia.

Subjects and Methods

After obtaining the Institutional Ethical Committee's approval, the study was carried out in the Department of Anesthesiology and Critical Care. Written informed consent from the parent / guardian was taken for all the subjects participating in the study. 120 children belonging to American Society of Anesthesiologists Physical Status 1 and 2, aged 3 to 15 years and weighing 5 to 45 kg undergoing elective surgery in the supine position were randomized for airway management with the LMA-Classic™ or LMAProseal™ by computer-generated random assignments.

Exclusion criteria were: Refusal by the parent / guardian for the consent for study; American Society of Anesthesiologists Physical Status III and above; Patient at specific risk of aspiration and anticipated difficult airway; and head and neck procedures. Anesthesia Protocol A thorough preanaesthetic evaluation was performed before the day of procedure. Patients were fasted based on standard guidelines for age for solids and liquids type of diet.

A standard general anaesthesia protocol was followed and routine monitoring was applied in all patients, including an electrocardiogram, precordial stethoscope, pulse oximeter, non-invasive arterial blood pressure monitor. Atropine 15

mcg/kg i.v. was given and pre-oxygenated for 3 minutes. Anaesthesia was induced with fentanyl 2 mcg/kg i.v. and propofol 2 mg/kg i.v. and maintained with propofol infusion 100 mcg/kg/min, nitrous oxide 66% in oxygen, and sevoflurane 0.5% to 1%.

The LMAClassic™ or the LMA-Proseal™ was inserted by the standard index finger insertion technique. The size of LMA-Classic™ / LMA-Proseal™ was chosen depending on the weight of the patient. The cuff was fully deflated prior to insertion. A clear water based gel was used for lubricating the posterior aspect of the cuff. Both devices were inserted and fixed according to the manufacturer's instructions. The gastric tube was inserted in the LMA-Proseal™ Group and gastric decompression was done, if indicated.

The propofol infusion was terminated before the start of skin suture. The LMA was removed after completion of procedure with the patient fully awake. Further, the patients received oxygen supplementation as needed. The ease of insertion, number of insertion attempts, displacement of the device and associated oropharyngeal leak, oesophageal regurgitation, pulmonary aspiration, bronchospasm, and airway obstruction were observed. Other complications including laryngospasm, oropharyngeal trauma, if any, were also recorded. A failed attempt was defined as removal of the device from the mouth.

The ease of insertion was judged as: 'No difficulty' – able to insert the LMA in first attempt with adequate seal; 'Moderate difficulty' – able to insert the LMA in second attempt with adequate seal More than two attempts for LMA insertion was considered as Insertion failure. Device positional stability was defined as non-displacement of the LMA during the maintenance of anaesthesia. All the observations were recorded in a pilot-tested proforma.

Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t-test and categorical variables were analysed with the Chi-Square Test.

Results

The two groups were formed in the present study: group 1:LMA classic and group 2:LMA Proseal groups. Total of 48 males and 12 females were in LMA Classic group and LMA Proseal group consist of 50 males and 10 females. The average age in group 1 and group 2 was found to be 4.5 years.

The surgical procedures done in both the groups were similar. Inguinal herniotomy was done in 58. Other procedures included inguinal cyst excision, hypospadiasis repair, orchidopexy, cystoscopy. When the number of insertion was compared between the two group, in 42 patients it was inserted in the first attempt in group 1, where as for group 2 it was in 40 patients. In 9 patients in group 1 it was inserted in 2nd attempt, where as in 20 patients it was inserted in 2nd attempt in group 2. When the comparison of the oropharyngeal trauma was done between the two groups, it was found negative for both the groups. In most of the patients the device was found to be stable.

Table 1: Sex distribution in both the groups

Group	Male	Female
LMA-Classic	48	12
LMA-Proseal	50	10

Table 2: Age distribution in both the groups

Group	Mean
LMA-Classic	4
LMA-Proseal	4.5

Table 3: Number of attempts for LMA insertion

Group	1	2
LMA-Classic	42	18
LMA-Proseal	40	20

Table 4: Comparison of LMA ease of insertion

Group	No difficulty	Moderately difficult
LMA-Classic	46	14
LMA-Proseal	38	22

Table 5: Oropharyngeal trauma in both the groups

Oropharyngeal Trauma	Yes	No
LMA-Classic	10	50
LMA-Proseal	10	50

Discussion

The best evidence requires a randomized controlled trial comparing a new device against an established alternative, properly powered to detect clinically relevant differences in clinically important outcomes. Such studies in children are very rare.[6] Safety data is even harder to establish particularly for rare events such as aspiration. Therefore, most safety data comes from extended use rather than high quality evidence which inevitably biases against newer devices. For reason of these factors, claims of efficacy and particularly safety must be interpreted cautiously.

LMA-Classic™ is a first generation supraglottic airway device, whose usage in children is well established in both routine and difficult airway management. It has the largest evidence base for efficacy and safety and are the benchmark by which other supraglottic airway devices are evaluated. 5LMA-Proseal™ is a second generation supraglottic airway device designed for controlled ventilation and increased airway protection. The modifications in the LMA-Proseal™ are a modified cuff to better seal with both respiratory and gastroesophageal tract; and a drain tube to (a) prevent gastric aspiration; (b) prevent gastric insufflation; (c) facilitate gastric tube insertion; and (d) provide information about position.[7]

There was no difference between LMA-Classic™ and LMA-Proseal™ with regard to ease of insertion, number of attempts for insertion, device positional stability, airway trauma and hemodynamic changes.[5] Various randomized controlled trials comparing LMA-Classic™ and LMA-Proseal™ in children have demonstrated no differences in ease of LMA insertion, and number of attempts of LMA insertion.

Kai Goldmann et al found placement of the pediatric LMA-Proseal™ was as easy as the LMA-Classic™ and suggested that the LMA-Proseal™ might be a more suitable device for positive pressure ventilation in pediatric patients because it

avoids gastric insufflation and facilitates emptying of the stomach.[8] Lopez-Gil et al found the time taken to provide an effective airway, the number of insertion attempts, and fibreoptic position were similar between the devices. LMAProseal™ had a improved seal because of wider proximal end of the device.[9]

Conclusion

The LMA-ProsealTM has advantages over LMA-ClassicTM like the placement of gastric tube, adequate ventilation and oxygenation without any gastric distension.

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