Original Article

A prospective, randomized, Single-blinded, comparative study of Classic Laryngeal Mask Airway and ProSeal Laryngeal Mask Airway in pediatric patients

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Abstract

Context: ProSeal Laryngeal Mask Airway (PLMA) is extensively being used in pediatric anesthesia.
Aims: To evaluate the efficacy of PLMA as compared to Classic Laryngeal Mask Airway (CLMA) for airway maintenance in pediatric patients.
Settings and Design: A prospective, randomized, Single-blinded study was conducted in a tertiary care teaching hospital.
Materials and Methods: Sixty ASA I and II children were included. Patients were randomized to either size 2 PLMA or size 2 CLMA groups. Parameters noted were time for insertion, number of attempts, airway sealing pressure, blood pressures (systolic, diastolic, and mean), pulse rate, end-tidal carbon dioxide ($EtCO_2$), peripheral oxygen saturation (SpO_2), and postoperative change in abdominal circumference, and airway trauma.
Statistical analysis used: Parametric data were analyzed with the unpaired *t*-test and non-parametric data were analyzed with the chi-square (χ^2) test. Unless otherwise stated, data are presented as mean (SD). Significance was taken as $P < 0.05$.
Results: There was no statistical difference between the two groups for the success rates at the first attempt of insertion, airway sealing pressure, hemodynamic responses, SpO_2, $EtCO_2$ and postoperative changes in abdominal circumference. Patients in the PLMA group had longer time of insertion and higher incidence of airway trauma.
Conclusions: The PLMA and the CLMA were comparable for hemodynamic and ventilatory parameters and change in abdominal circumference; however, the time taken for insertion and airway trauma was more with PLMA.

Key words: Classic laryngeal mask airway, pediatric patients, ProSeal laryngeal mask airway

Introduction

The first prototype of the Laryngeal Mask Airway (LMA) was used clinically in the summer of 1981 at Ashford, Kent, United Kingdom, by Dr. Archie Brain. Half-sizes (1.5 and 2.5) were developed subsequently as the original range of pediatric LMAs was inadequate to address all children sizes.[1] As in adult practice, the LMA and other supraglottic airway devices have radically changed pediatric anesthesia practice. The limitations of the Classic LMA (CLMA) (lack of protection from aspiration, airway leak, and risk of gastric distension with positive pressure ventilation) led to the development of the ProSeal LMA (PLMA), which is available in sizes of 1.5 (5–10 kg) and bigger.[2] The PLMA has a better anatomic fit and is more suitable for positive pressure ventilation. These features are of great benefit for pediatric anesthesia.[3] The pediatric PLMA lacks the dorsal cuff of the adult version and has a proportionately larger drain tube.[4] The drain tube can also function as an effective guide to insertion of the device.

We hypothesized that the absence of dorsal cuff in size 2 PLMA may not produce a significant difference in quality of insertion, hemodynamic parameters, and airway seal pressure. We therefore compared PLMA to CLMA in children in respect of ease of insertion, hemodynamic and ventilatory parameters, and postoperative complications.

Materials and Methods

After getting approval from the Local Ethical Committee and parental consent, 60 ASA physical status I and II children

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(aged 1–6 years, weight 10–20 kg) undergoing general anesthesia for elective lower abdominal, inguinal, and upper extremity procedures were included. Patients with upper respiratory tract infection, known airway problems, hiatus hernia, gastroesophageal reflux disease, non-fasting status, lung diseases, and known contraindications to the use of LMA were excluded from the study.

After enrolment, the patients were randomly allocated to either a size 2 CLMA group or a size 2 PLMA group for airway management, using the sealed envelope method.

All patients were administered midazolam 0.05 mg/kg intravenous (IV) before the induction of anesthesia. After standard monitoring devices had been applied, anesthesia was induced by inhalation oxygen and sevoflurane. Once an adequate depth of anesthesia had been achieved, each device was inserted by an experienced anesthesiologist who had used the CLMA more than 100 times and a PLMA more than 25 times, with the index finger insertion technique, as per manufacturer's instructions.

Both devices were fixed by taping the tube over the chin and the cuff was inflated with air to 60 cm H_2O using an ergonomic pressure gauge (Hi-Lo Hand Pressure Gauge; Mallinckrodt Medical GmbH, Hennef, Germany). An effective airway was judged by square wave capnograph trace, normal thoraco-abdominal movement, and inaudibility of inspiratory leak. If an effective airway could not be achieved, the device was removed and three attempts were permitted before failure of insertion was recorded. The trachea was intubated in case of three unsuccessful attempts. The numbers of insertion attempts were recorded.

Five minutes after establishment of a patent airway with the LMAs, intracuff pressure was rechecked as set at exactly 60 cm H_2O using the pressure gauge. The airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min, noting the airway pressure (maximum allowed was 40 cm H_2O) at which equilibrium was reached. Gas leakage was determined at the mouth (audible) and the stomach (epigastric auscultation).

Basal values of pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), end-tidal carbon dioxide ($EtCO_2$), and peripheral oxygen saturation (SpO_2) were recorded just prior to induction. Further values were recorded at intervals of 0, 3, and 5 min after placement of the airway devices. At the end of the surgical procedure, anesthesia was discontinued and the device was removed. Postoperative abdominal circumference was measured and blood staining of the device was recorded.

Sample size was based on a crossover pilot study of 10 patients and was selected to detect a projected difference of 30% between the groups for airway sealing pressure for a type 1 error of 0.05 and a power of 0.8. Parametric data were analyzed with the unpaired *t*-test and non-parametric data were analyzed with the chi-square (χ^2) test. Unless otherwise stated, data are presented as mean (SD). Significance was taken as $P < 0.05$.

Results

There was no difference between the two groups with respect to demographic and surgical details [Table 1]. The average time of insertion was 10.1 seconds in the CLMA group and 12.6 seconds in the PLMA group, which was statistically significant. Correct positioning of CLMA after the first attempt was seen in 100% of patients, while correct positioning of PLMA after the first attempt was seen in 93.33% of patients, and in the remaining patients (6.67%), PLMA was properly positioned in the second attempt. Airway sealing pressure was similar for the two devices [Table 2]. Gas leakage at airway sealing pressure occurred only from the mouth, and gas leakage from the other locations was not detected in all cases.

The change in pulse rate, SBP, DBP, and MAP was comparable in both the groups, with no patient having an increase of more than 10% from baseline in either group [Table 3]. Normocapnia was maintained throughout the intraoperative period in both the groups. There was no significant difference in the rise of $EtCO_2$ recordings in between the groups. There was no desaturation in any patient in either group.

At removal, incidence of traces of blood on the airway device was noted in 1 patient (3.33%) in the CLMA group and 4 patients (13.33%) in the PLMA group [Table 2]. Mean abdominal circumference was 46.6 cm in the CLMA group and 47.1 cm in the PLMA group postoperatively, which was statistically insignificant ($P > 0.05$).

Table 1: Patient characteristics

	LMA Classic (n = 30)	LMA ProSeal (n = 30)
Age (Years)	4.7 (1.4)	5.1 (1.6)
Gender (Male:female)	22:8	23:7
Weight (Kg)	16.6 (2.2)	15.4 (3.1)
Types of surgery		
Lower abdominal	17	13
Inguinal	6	9
Upper extremity	7	8

Data are mean (SD)

Table 2: Comparison between the LMA Classic and the LMA ProSeal

	LMA Classic (*n* = 30)	LMA ProSeal (*n* =30)	*P* value
Attempts at insertion (*n*)			
1	30	28	
2 or 3		2	
Time for insertion (seconds)	10.1 (1.21)	12.6 (3.19)	0.0002
Seal pressure (cm H_2O)	18.5 (2.18)	19.27 (2.20)	0.86
Abdominal circumference			
1. Preoperative (cm)	45.88 (1.52)	46.18 (1.28)	0.68
2. Postoperative (cm)	46.6 (1.4)	47.1 (1.4)	0.91
Airway trauma	1	4	

Data are mean (SD), LMA: Laryngeal Mask Airway

Table 3: Hemodynamic parameters immediate post-insertion

	LMA Classic (*n* =30)	LMA ProSeal (*n* = 30)	*P* value
Pulse rate (bpm)	116.6 (9.2)	125.7 (20.7)	0.97
SBP (mm Hg)	119.4 (9.2)	122.3 (7.6)	0.84
DBP (mm Hg)	75.6 (6.4)	73.7 (3.9)	0.86
MAP (mm Hg)	89.7 (7.2)	89.5 (4.1)	0.36

Data are mean (SD), LMA: Laryngeal Mask Airway

Discussion

Our study was designed to compare the insertion qualities, hemodynamic changes, ventilatory parameters, and postoperative complications of CLMA and PLMA in children. PLMA was placed successfully in the first attempt in 28 out of 30 (93.33%) patients. Two patients (6.67%) required second attempt for correct positioning of PLMA. Whereas, correct positioning of CLMA after the first attempt was seen in 30 out of 30 (100%) patients. Similar success rates have been shown by previous studies.[5-7]

The average insertion time of PLMA (12.6 seconds) was longer than the average time of insertion of CLMA (10.1 seconds), and this increment in time was statistically significant. This observation of our study can be supported by the study of others.[8,9] These studies attributed the longer time of PLMA insertion to the larger, deeper, softer bowl, and the nonlinear leading edge formed by the drain tube.

We compared the hemodynamic responses at insertion of these devices and found no significant difference in pulse rate, SBP, DBP, and MAP. This was possibly due to the absence of dorsal cuff in size 2 PLMA, which results in lesser hemodynamic response. Others have found similar lower hemodynamic response during PLMA insertion.[10-12]

Although it has been reported that the PLMA provides a better airway seal than the CLMA in adults, there was no difference between the two devices in our study in the pediatric age group. Better sealing pressure in the PLMA is mainly due to the dorsal cuff.[8,9,13] PLMA could not form a better seal than the CLMA possibly because of the lack of a dorsal cuff in size 2 PLMA. The prototype of the PLMA for the children studied had a rear cuff and the sealing pressure was kept over 40 cm H_2O, confirming the importance of the rear cuff in airway seal.[14]

In our study, the sealing pressure was measured by closing the expiratory valve of the circle system at a fixed fresh gas flow of 3 l/min until airway pressure reached a steady value. Lopez-Gil *et al*, compared four kinds of measurements of the airway sealing pressure,[15] i.e. detection of an audible noise by listening over the mouth, detection of exhaled carbon dioxide by placing a gas sampling line of the capnograph inside the mouth, detection of a steady value airway pressure while occluding the expiratory valve of the circle system, and detection of an audible noise using a stethoscope placed just lateral to the thyroid cartilage. They concluded that all the four tests were excellent.

Change in abdominal circumference postoperatively in the PLMA group compared to the CLMA group was not significant. Gastric inflation in the PLMA group was equal to that in the CLMA group, and thus PLMA was not superior to CLMA in preventing gases from going to the stomach, as shown in earlier studies.[9]

A limitation of our study was that the data were collected by an unblinded observer.

To conclude, PLMA and CLMA were comparable for hemodynamic and ventilatory parameters and change in abdominal circumference; however, time taken for insertion and airway trauma was more with PLMA. PLMA was not found to be superior to CLMA in the pediatric age group.

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