A prospective, randomized comparative study for use of proseal laryngeal mask airway as an alternative to endotracheal intubation for airway management in children under general anesthesia

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Abstract

Introduction: Proseal laryngeal mask airway (PLMA) which is an upgraded modification of classic LMA, incorporating a gastric drainage tube lateral to the main airway tube which permits the regurgitated liquid gastric contents to bypass the glottis and prevents pulmonary aspiration. A prospective randomized interventional comparative study was performed to compare the efficiency of PLMA with a tracheal tube (TT) in pediatric patients with respect to number of attempts to placement of devices, hemodynamic responses and perioperative complications.

Material and Methods: Sixty children, ASA physical status I and II weighing 10-20 kg between 2 and 8 years of age group of either sex undergoing elective infraumblical surgeries of 30-60 minutes duration, randomly divided into two group of 30 patients each. All patients were premedicated with IV midazolam and glycopyrrolate. General anesthesia with caudal epidural analgesia was given in all cases. IV propofal and sevoflurane was used for inducing general anesthesia. PLMA was inserted in group I and tracheal tube (TT) in patients of group II. In all cases after PLMA / TT insertion; caudal epidural analgesia was given and general anesthesia (GA) was maintained with O2, N2O and sevoflurane.

Results: Ease of insertion was comparable in both the groups. There were no significant differences in mean oxygen saturation SpO2 (%) and end tidal carbon dioxide (ETCO2)) levels recorded at different time intervals between the two groups. However, highly significant changes in hemodynamic parameters were observed in the TT group. Complications such as nausea and vomiting (3.33%), sore throat (2%) and coughing (26.66%) were observed in the TT group.

Conclusion: We concluded that PLMA could be used as an effective and safe airway device in children alternative to TT undergoing general anesthesia.

Keywords: General anesthesia, Hemodynamic response, Paediatric, Proseal laryngeal mask airway, Tracheal tube.

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Introduction

Airway management is an essential skill in the field of anesthesiology. Before 1983, facemask and tracheal tube (TT) were available devices. Tracheal tube is considered an ideal device for managing the airway as it has an inbuilt capability for providing positive pressure ventilation and preventing gastric distension, thereby preventing pulmonary aspiration, but is associated with problems of intubation failure and damage to structures of oropharynx and laryngoph-arynx. The first supraglottic airway tool, the Laryngeal Mask Airway (LMA) was conceptualized by Brains in 1983.[1] This is relatively noninvasive when compared to tracheal intubation and is reported to result in nominal variations in the cardiovascular and respiratory systems[2]. It has minimal potential to cause injuries to the airway during the post operative period.[3,4] This laryngeal mask airway is now known as the classic laryngeal mask airway (CLMA). The pediatric CLMA forms a less efficient glottis seal around the glottis and has the risk of gastric insufflations and reflux of liquid gastric contents due to escape of gas from the stomach which often leads to pulmonary aspiration.

An alteration of CLMA was introduced by Brain et.al.[5] in 2000 known as Proseal Laryngeal Mask Airway (PLMA). Proseal LMA has a gastric drainage tube, placed together with the main airway tube till the tip end of the mask. This drainage tube separates the food and airway tracts. It allows access to or evacuation of gastric fluids and reduces the risk of gastric distension and its potential to lead to pulmonary aspiration. A gastric tube can be inserted through a drain tube and can identify whether PLMA is properly positioned or not. Pediatric PLMA was made available in 2004 and is unlike adult PLMA as it doesn't have a dorsal cuff.[6] Its available in different sizes.

Here in our prospective randomized study we plan to evaluate and compare the PLMA with tracheal tube (TT) in the management of airway in children under general anesthesia for infraumblical surgical procedures.

Material and Method

After obtaining approval from the Institutional Ethics Committee and written informed consent from the parents, a prospective randomized interventional comparative study was performed. The study comprised of 60 children belonging to American Society of Anesthesiologists (ASA) grade I and II, in the age group of 2 to 8 years, posted for infraumblical surgeries of short duration (30-60 minutes) such as congenital hydrocele, hypospadias, circumcision, colostomy closure, congenital hernia and appendectomy etc. Children with gastro-esophageal reflux, infection of respiratory tract, hiatus hernia, and with anticipated difficultly in airway management were not included in the study. Children were randomly separated into two groups.

Group I comprised of 30 children in whom PLMA was inserted.

Group II comprised of 30 children in whom tracheal tube (TT) was inserted.

After conforming fasting status, all patients received premedication with oral midazolam 0.5mg /kg 30 minutes before induction. All children were monitored with precordial stethoscope, pulse oximeter, electrocardiography and non-invasive blood pressure (NIBP) and capnograph. Intravenous glycopyrrolate) 0.004mg/kg, ondansetron 0.1mg/kg, and dexamatha-sone 0.2 mg/kg given 5 minutes prior to induction. Following preoxygenation, anesthesia was induced with intravenous propofol 2-3 mg/kg and sevoflurane (7-8%) with N_2O and O_2 (50:50) using Jackson Rees modification of Ayre's T piece. Loss of eyelash reflex was taken as endpoint for completion of induction. Induction time was noted i.e. time taken from the beginning of induction of anesthesia to loss of eyelash reflex. After this jaw relaxation was assessed as full, partial or difficult. Next, PLMA size 2 was selected for group I children, the cuff was fully deflated and 2% Lignocaine jelly was applied on its posterior surface. The child's head was held in the sniffing position while the PLMA was inserted through the oral cavity using the index finger technique. The cuff was inflated with 7-10 ml of air. Effective airway time (the time taken between picking up the device i.e. PLMA/TT and obtaining the effective airway seal) was also recorded in all children. The positioning of the PLMA was confirmed by gel displacement test, observation of bilateral chest movements and square wave capnography. In group II patients, tracheal intubation was done using appropriately sized cuffed or uncuffed tracheal tubes. Proper placement of the TT was determined by auscultation bilateral equal air entry, observing rising of the chest on ventilation and the normal rectangular shape of the capnograph tracking. The total number of attempts for PLMA insertion / TT intubation was recorded in both groups. Ryle's tube was passed in all patients. Caudal epidural analgesia was given with 1ml/kg Bupivacaine (0.25%) and Fentanyl (1µg/kg) for intra and postoperative analgesia while the child was in lateral position. Subsequently the patient was placed in supine position and bilateral equal air entry was reconfirmed. Anesthesia was maintained with N_2O, O_2 and sevoflurane in all cases without use of any muscle relaxant. $ETCO_2$ was maintained between 35 to 40 mm of Hg. All patients were manually ventilated throughout the surgical procedure. Intravenous Ringer-lactate solution was used as maintenance according to the Holliday Segar formula.

Hemodynamic parameters such as heart rate, systolic blood pressure, diastolic blood pressure, SpO_2 and $ETCO_2$ were recorded before induction, during induction, during PLMA/TT insertion and later every 5, 10, 15, 20, 25 and 30 minutes during the course of surgery, during removal of airway device i.e. PLMA/TT and in the postoperative period. Following surgery, anesthetic agents were discontinued and patients were kept on 100 % oxygen for at least 5 minutes. PLMA/ TT was removed when the child awakened by observing facial grimace, adequate tidal volume and the ability to open eyes. After PLMA/TT removal 100 % O_2 was administered via face mask for 10 minutes. Any airway related complications such as coughing, aspiration, hypoxemia, nausea, vomiting and sore throat, were recorded. All qualitative data was analyzed using the chi square test and the quantitative data using students unpaired t test. The results were expressed as mean ± SD. P value <0.05 was taken as statistically significant.

Results

Demographic data such as age, sex, weight, ASA physical status were comparable in both groups; males were dominant in both groups (Table I).

Table I: Demographic data in both groups.

Variable	PLMA group	ET group	P value
Age (in years)	4.39 ± 1.75	4.46 ± 1.63	p>0.05
Weight (kgs)	14.70 ± 2.54	15.5 ± 2.62	p>0.05
Sex (M/F)	26 / 4	27 / 3	p>0.05
ASA status (1/11)	28 / 2	29 / 1	P0.05

Induction time (time to loss of eyelash reflex) in PLMA group (209.96 ± 33.25 seconds) and TT group (219.73 ± 21.71 seconds) were comparable in both groups. Effective airway time (time between picking up the device and

obtaining airway seal) in PLMA group (30.5 ± 7.04 seconds) and TT group (33.8 ± 3.72 seconds) were comparable (P >.05) in both the groups. PLMA was inserted in one attempt whereas TT tube was inserted in second attempt in two of the cases. Ryle's tube was passed in one attempt in both groups (Table II).

Table II: Induction characteristics in both groups.

Parameters	PLMA	TT	P value
Induction time (seconds)	209.96 ± 33.25	219.73 ± 21.71	>0.05
Effective Airway Time (seconds)	30.5 ± 7.04	33.8 ± 3.72	>0.05
No of attempts for PLMA /ETT insertion	1/30*	2/2*, 1/28*	>0.05
No of attempts at Ryles tube insertion	1/30*	1/30*	>0.05

*No. of patients

Insertion conditions were comparable in both the groups. Complete jaw relaxation was achieved in 93.33% of PLMA group and 90 % of TT group. Jaw relaxation was partial in remaining 6.66 % of the PLMA group and 10 % of the TT group. There was no coughing, gagging or laryngospasm during insertion in both the groups. Child's limb movements were moderate in 2 of the cases in TT group while there was no limb movement in the PLMA group (Table III).

Table III: Analysis of ease of insertion conditions for PLMA insertion and Endotracheal intubation.

Parameters	PLMA	TT	P value
Jaw opening Full / Partial / Difficult	28 / 2 / 0	27 / 3 / 0	>.05
Ease of insertion Easy / Difficult	30 / 0	30 / 0	>.05
Coughing / gagging / Laryngospasm	No	No	>.05
Patient movements (Nil / Moderate)	30 / 0	28 / 2	>.05

There was no change in hemodynamic parameters (Heart rate and Blood Pressure) in group 1 (PLMA) during insertion and at the time of removal. However in group II (TT) there was a rise in both heart rate and blood pressure during insertion and also at the time of extubation. The change was statistically significant ($p< 0.05$). There was a gradual decrease in heart rate and Blood Pressure in both the groups after induction at 5, 10, 15, 20, 25 and 30 minute interval (Figure1,2). There were no significant differences in SpO_2 and $ETCO_2$ levels in both study groups.

As seen in table IV, post operatively 1(3.33%) of the patients in TT group had post operative nausea and vomiting while none of the patients in PLMA group had nausea and vomiting. There was no incidence of sore throat in the PLMA group whereas sore throat was observed in 6 patients (20%) of TT group which was statistically significant. There was one incidence of coughing in PLMA group (3.33%) whereas 8 of the patients had coughing in TT group (26.66%) which was statistically significant. There was no aspiration or drop in saturation (hypoxemia) in patients of both the study groups (Table IV).

Table IV: Complication in both groups.

Complications	PLMA		TT		P Value
	Yes	No	Yes	No	
Nausea and vomiting	0	30	1	29	<0.05
Sore Throat	0	30	6	24	>0.05
Coughing	1	29	8	22	>.05
Aspiration	0	30	0	30	-----
Hypoxemia	0	30	0	30	-----

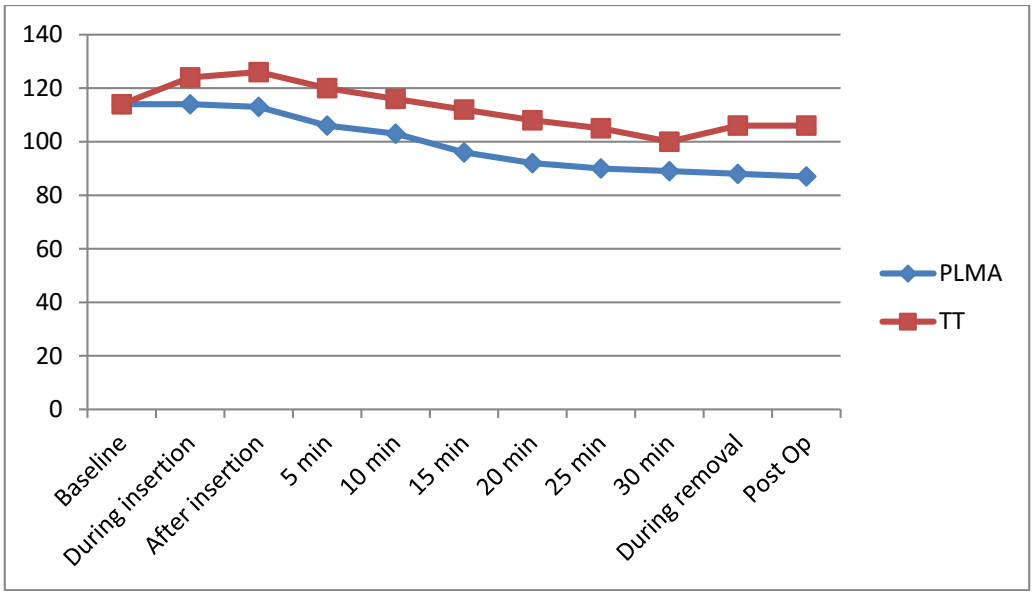

Fig. 1: Showing changes in Heart Rate in both groups

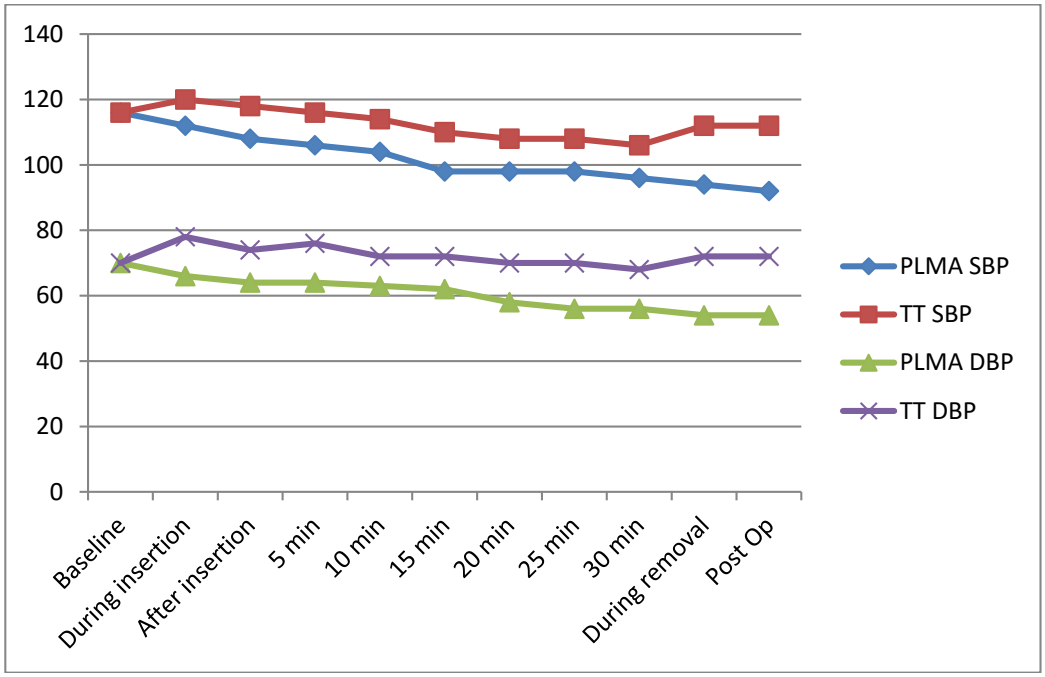

Fig. 2: Showing changes in Systolic Blood Pressure and Diastolic Blood Pressure in both groups

Discussion

The LMA and other supraglottic airways have drastically changed the practice of pediatric anesthesia and have become a key element for managing the airway in children. CLMA has gained wide recognition in pediatric anesthesia since its introduction in to clinical practice. Although at first it was used only as a replacement for the face mask, it is now used as an alternative to TT.[7]

In this study we have compared the influences of airway devices i.e. PLMA and TT used for infraumblical abdominal surgeries in children on efficacy and safety. There was no significant difference in induction characteristics. Both devices appeared equal in induction and effective airway time. In evaluation of ease of insertion, PLMA was inserted in one attempt where as TT tube was inserted in second attempt in two of the cases. Lim Y et al [8] have compared PLMA with tracheal tube in gynecological laparoscopies. They reported that the number of attempts for successful insertion was similar between the two groups but effective airway time was shorter for the PLMA and that all the devices were successfully inserted within three attempts. In contrast to them, we were able to insert the PLMA device in all patients in a single attempt. Our results are similar to Piper SN et

al[9] who on comparing PLMA with tracheal tube in gynecological laparoscopy found that the insertion of the former was easier than the latter and that insertion times were similar with both devices.

Many studies on PLMA conclude that the hemodynamic stress response to insertion and removal of airway devices are greater for the tracheal tube than the PLMA.[8,10], However two non-randomized studies involving 335 patients with different anesthetic techniques reported that hemo-dynamic variables change less than 10% at PLMA insertion.[11,12] A study in the past that compared the hemo-dynamic changes at c-LMA and tracheal tube insertion has reported minimal hemo-dynamic responses to c-LMA insertion with a 0 - 20% increase in HR and MAP.[13] Fujii Y and co-workers[14] have found a rise in HR and MAP during both LMA and TT insertion and that it was more pronounced in the latter. This correlated with a significant rise in plasma adrenaline and nor-adrenaline concentrations. One study reports that the hemo-dynamic changes are similar between PLMA and c-LMA insertion.[15] Our study results indicate that there is significant change in heart rate, systolic and diastolic blood pressures in TT group, both during insertion and extubation as compared to PLMA group.

In this study there were more post operative complications in TT group than PLMA. Incidence of coughing was significantly higher in TT group. Postoperative complications were less with PLMA than with TT group. Similarly in a study reported by Hohlrieder et. al[16] reported that PLMA reduced the risk of postoperative nausea and vomiting by 40%. We observed that the frequency of postoperative nausea, vomiting and airway morbidity is lower for PLMA than for tracheal tube.

Conclusions

Proseal Laryngeal mask airway (PLMA) is a safe and suitable alternative device as judged by ease of insertion, stable hemodynamic parameters, good oxygenation, adequate ventilation and absence of post operative complication when compared to tracheal intubation (TT) for routine pediatric infraumblical surgical procedures of short duration.

Conflict of Interest: None
Source of Support: Nil

Bibilography

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