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Research Article

Pro-Seal Laryngeal Mask Airway versus Endotracheal Intubation in Paediatric Patients

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Abstract

Background: *The management of airway in a paediatric patient is an important concern of anesthesiologist. Endotracheal tube (ET) is always considered a gold standard but it has several demerits. Recently ProSeal LMA (PLMA) was introduced to clinical practice with additional advantages over ET and LMA. Hence the present study was undertaken to compare PLMA with ET for airway management in paediatric patients requiring elective surgery under general anaesthesia in terms of attempts of insertion, haemodynamic parameters and perioperative complications.*

Method: *A total 90 patients of either sex, of ASA grade I/II, age between 2-10 years were enrolled and randomly allocated to Group P (n=45)- PLMA used to establish airway (Size 2) and Group E (n=45)- Endotracheal intubation done to establish airway.*

Results: *The 1st attempt success rate for placement of airway device was 95.56% in group P and 97.78% in group E, (p>0.05). In group P, the first attempt success rate for insertion of feeding tube was found to be 91.11%, it was not tried in group E. Haemodynamic changes were comparable and found no significant difference between two groups. SpO2 and ETCO2 in both groups were comparable and clinically acceptable. The incidence of coughing, sore throat, hoarseness and vomiting was more in group E than group P whereas the incidence of trauma was more in group P.*

Conclusion: *Proseal LMA is a safe and suitable alternative airway device to ETT in pediatric patients as judged by comparable success rate of insertion, stable hemodynamics, good oxygenation, adequate ventilation and lesser incidence of postoperative complications.*

Keywords: *Paediatric, Endotracheal tube, ProSeal LMA, Anaesthesia, Haemodynamic.*

Introduction

Children have been the earliest patrons of anaesthesiology from its earliest clinical applications of surgical anaesthesia[1]. Endotracheal intubation (ETT) is always considered as the gold standard[2,3] for airway management due to its ability to provide positive pressure ventilation under high airway pressures.

It offers protection against gastric distension and pulmonary aspiration[3]. It also facilitates the delivery of anaesthetic drugs via the endotracheal tube as well as allows suctioning of the tracheobronchial tree. Even though it is a time tested and familiar way of securing an airway, it has several disadvantages. Haemodynamic responses, situations of failed intubation and damage to the oropharyngeal structures[3] during intubation are also a serious concern.

Dr. Archie Brain designed the first laryngeal mask airway, which was called LMA classic (cLMA) in 1981 at the Royal London Hospital. It combined the advantage of a non-invasive face mask and more invasive endotracheal tube. This invention changed the scenario from “cannot intubate, cannot ventilate” to “cannot intubate, can ventilate.”[4]. The other advantages offered by LMA over ETT include ease of placement even by inexperienced personnel, improved hemodynamic stability at induction and during emergence, minimal increase in intraocular pressure following insertion, reduced anaesthetic requirements for airway tolerance, lower frequency of coughing during emergence, improved oxygen saturation (SpO2) during emergence and lower incidence of sore throat in adults[4]. The paediatric Classic LMA forms a less effective glottic seal[5] with the subsequent risk of gastric distension and regurgitation due to leakage of gas in the stomach which can lead to pulmonary aspiration.

Proseal LMA (PLMA) was introduced by Dr. Archie brain in the year 2000. PLMA is a second-generation supraglottic device which permits peak airway pressure > 30 cm H2O without a leak. It has a drain tube, parallel to the ventilation tube, which allows the drainage of passively regurgitated gastric fluid away from the airway to prevent aspiration and avoidance of gastric insufflation during positive pressure ventilation[6]. The paediatric PLMA lacks the dorsal cuff[5]. With this background, the present study was conducted to compare PLMA with the ET for airway management in paediatric patients requiring elective surgery under general anaesthesia in terms of attempts of insertion, haemodynamic parameters and perioperative complications and clarify the safety of either technique for the purpose of anaesthesia.

Materials and Methods

After obtaining Institutional Ethical Committee approval, this prospective, randomized controlled, single blind, unicentric study was carried out in Department of Anaesthesiologist at Tertiary Care Centre in Maharashtra during a period from December 2017 to December 2019. Total 90 children of ASA grade I/II, of either sex, age between 2-10 years, weight 10 – 20 kg posted for elective surgery under general anaethesia. Children with difficult airway, URI, hiatus hernia, full stomach, and cardiovascular, neurological, respiratory, renal or endocrinal disease, children posted for emergency surgery and lack of written informed consent from parents were excluded from the study. All the patients were randomly allocated into two equal groups by computerized randomization method. In group P- PLMA used to establish airway (Size 2) n=45 and in group E- Endotracheal intubation done to establish airway n=45.

A thorough pre-anaesthetic evaluation and all relevant investigations were done. All patients were kept nil per oral (NPO) as per fasting guideline. On the morning of surgery intravenous access was secured in preoperative room in presence of parents and ringer lactate was started slowly. Patients were premedicated with injection glycopyrrolate 4 mcg/ kg IV, ketamine: 0.5 mg/ kg IV and midazolam 0.03 mg/ kg IV. Once the patient was sedated, was shifted inside the operation theatre. Standard monitoring cables of pulse oximeter, electrocardiography, capnography (attached after intubation / PLMA), automated noninvasive blood pressure (NIBP) and temperature probe were attached and baseline vital parameters i.e. Heart rate, SpO2, systolic blood pressure (SBP), diastolic blood pressure (DBP) and temperature were noted. Injection fentanyl 2mcg/kg was given for analgesia. Patients were preoxygenated with 100 % O2 for 3 minutes. Induction was done with inj. propofol- 2 mg/ kg + sevoflurane 3%. After ensuring that mask ventilation was possible, injection atracurium 0.5mg/ kg IV was administered; after 3 minutes of inj. atracurium and IPPV; as per the group under study, the appropriate size PLMA or endotracheal tube was inserted after proper lubrication.

In Group P, PLMA size 2 was inserted after proper lubrication using the index finger technique. The cuff was inflated with 7-10 ml air as per recommendation. Three attempts were allowed for placement of PLMA before it was considered a failure and the device was replaced with ETT and vice versa. . In all patients, intubation or placement of PLMA was done by anaesthetist having 2 or more years of experience in the field of anaesthesia.

After confirmation of proper placement, judged by adequate chest inflation, bilateral equal breath sound on auscultation and a regular waveform on capnograph, fixation of PLMA or endotracheal tube was done. In group P, feeding tube 8/10Fr was inserted through drain tube. Two attempts were allowed for placement of feeding tube after which it was labeled a failure. Number of insertion attempts of PLMA/ETT/feeding tube was noted. In Group E, endotracheal intubation was done using appropriate size cuffed or uncuffed ETT. Maintenance of anaesthesia was done with oxygen + nitrous oxide (40%:60%) + sevoflurane (2-3%) + injection atracurium 0.1 mg/kg as intermittent muscle relaxant and controlled ventilation. Diclofenac sodium 1.5 mg/ kg suppository was inserted per rectally.

Intraoperatively, haemodynamic parameters (HR, SBP, DBP, MAP), SpO2, temperature, ETCO2 were recorded immediately after intubation, then on 3 min, 5 min, 10 min after insertion of airway device and thereafter at the interval of 10 min throughout the surgery. Reversal was done using Inj. glycopyrrolate 8mcg kg IV + Inj. Neostigmine 0.05mg/ kg IV. Subsequently on regaining consciousness, adequate spontaneous respiration and skeletal motor tone of patient, gentle removal of PLMA or endotracheal tube was done after oral suction. Presence or absence of blood on the device was noted. This was labeled as trauma due to the device. The occurrence of any complications like coughing, vomiting, laryngospasm, bronchospasm, regurgitation, aspiration etc. during emergence was noted.

After extubation, patient was shifted to Post Anaesthesia Care Unit (PACU) and monitored for a period of 2 hour. The patients were followed for next 24 hours for development of sore throat and hoarseness.

Statistical Analysis

The continuous variables were presented as Mean ± SD. Categorical variables were expressed in frequency and percentages. Continuous variables (age, haemodynamic parameters) were compared between 2 groups by performing independent t-test. Categorical variables were compared by performing chi-square test. For small number, fisher exact test was used wherever applicable. $p<0.05$ was considered as statistical significance. Statistical software STATA version 14.0 was used for data analysis.

Observations and Results

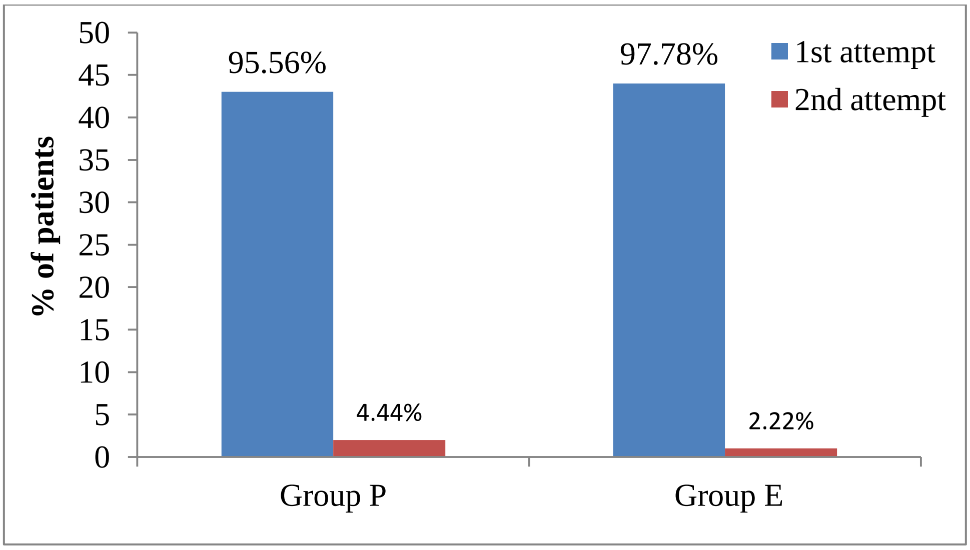
A total of 90 children were enrolled in the study and divided into two equal groups. The maximum number of patients was between the age group of 2-4 years (Group P= 44.44% Vs Group E= 42.22%) followed by 4-6 years (Group P= 37.78% Vs Group E= 42.22%). In both the groups, male preponderance was observed and most of the children (60%) were seen in 15-20 kg weight category. Herniotomy was most performed surgery in both the groups. The demographic profile of the patients, type and duration of surgery was comparable and found no significant difference between two groups as shown in table 1.

Table 1: Demographic profile, Type and Duration of surgery

Parameters	Group P	Group E	P- value
Age in years	5.02 ± 2.31	4.84 ± 1.57	0.6681
Weight in Kg	15.65 ± 2.76	16.15 ± 2.43	0.3657
Male/Female	43 (95.56%)/2(4.44%)	43 (95.56%)/2(4.44%)	>0.05
Duration of Surgery	30.48±5.55	30.06±4.47	0.6922
Type of surgery	**No. of patients (%)**	**No. of patients (%)**	**P value**
Orchedopexy	6 (13.33%)	4 (8.88%)	>0.05
Circumcision	14 (31.11%)	9 (20%)	
Herniotomy	22 (48.89%)	27 (60%)	
Cornial Suture Removal	0 (0.0%)	3 (6.67%)	
Urethroplasty	1 (2.22%)	1 (2.22%)	
Exci.Cyst/Sebacious Cyst	2(4.44%)	1(2.22%)	

The 1st attempt success rate for placement of airway device was 95.56% in group p and 97.78% in group E, (Figure 1). In group P, feeding tube insertion was successful in 91.11% cases in 1st attempt and 8.89% in 2nd attempt, there was no case of a failed attempt in current study.

Figure 1: Distribution of Study Population According to Attempt of Insertion



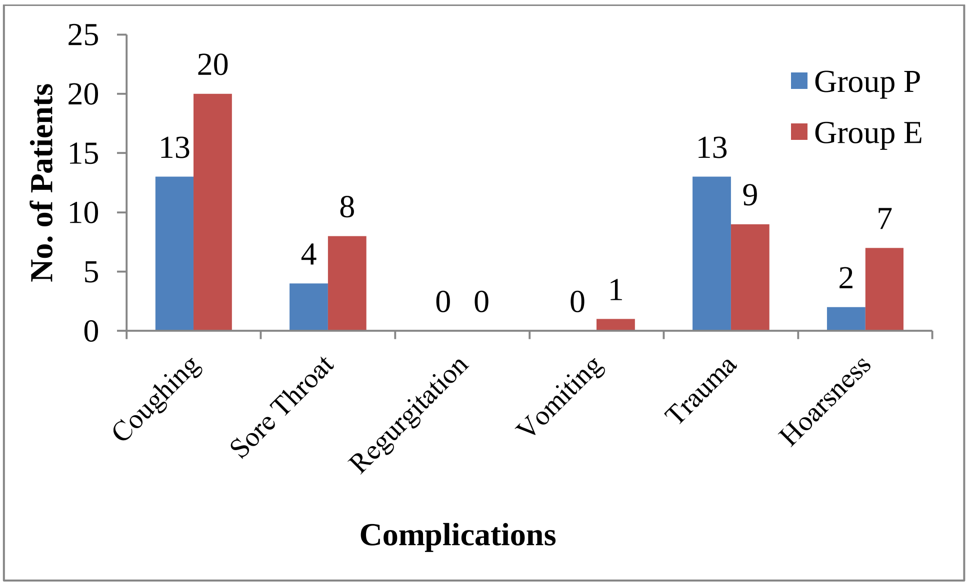
After insertion of airway device baseline mean values of PR, SBP and DBP were increased in both the groups but more in Group E than Group P. (p>0.05). There was a statistically significant difference in haemodynamic parameters (PR, SBP and DBP) between two groups at 3minute, 5minute after insertion and after removal of device, as depicted in Table 2. SpO2 and ETCO2 in both groups were comparable (P >0.05) and clinically acceptable.

Table 2: Comparison of haemodynamic parameters between two groups

Time	Pulse Rate			SBP			DBP		
	Group P	Group E	p value	Group P	Group E	P value	Group P	Group E	P value
Pre-op	104.73±14.81	106.93±10.09	0.4125	96.88±7.38	96.17±6.38	0.6264	52.82±4.92	53.38±5.69	0.6216
After Induction	109.82±12.95	111.22±9.88	0.5657	95.62±6.84	93.55±5.73	0.1244	51.18±5.66	51.60±5.31	0.7161
After Insersion	118.26±11.73	126.55±9.14	0.0003	104.86±8.43	108.55±5.69	0.0171	56.13±5.09	58.76±5.59	0.0223
3 min	115.51±12.36	120.40±8.65	0.0324	103.04±8.06	106.75±5.56	0.0128	54.93±4.97	57.18±5.12	0.0376
5 min	111.27±12.10	117.16±8.86	0.0100	100.75±7.44	104.35±5.45	0.0104	53.51±4.89	55.91±4.98	0.0234
10 min	107.49±10.79	110.62±8.01	0.1216	99.02±7.32	100.53±4.78	0.2498	52.51±5.19	54.42±4.98	0.0783
20 min	106.17±10.28	110.06±9.06	0.0604	98.46±7.07	99.00±4.77	0.6761	52.08±5.01	53.28±5.30	0.2732
30 min	103.4±9.87	109.82±10.85	0.0918	96.62±6.27	98.17±4.72	0.4263	51.05±4.80	52.11±5.91	0.7451
Removal of airwaydevice	116.62±11.13	121.0±8.88	0.0422	103.86±7.26	107.33±5.98	0.0154	55.53±4.94	58.42±5.26	0.0087

The incidence of coughing, sore throat, hoarseness, vomiting was noted more in group E than in group P whereas the incidence of trauma was more in group P as shown in figure 2. There were no incidence of regurgitation and aspiration in either group.

Figure 2: Distribution of Patients According to Postoperative Complications



Discussion

One of the most fundamental and key skill of an anaesthesiologist is management of airway. Maintenance of a patent airway is vital for adequate oxygenation and ventilation and failure to do so, even for a short duration, can be life threatening. The airway of the paediatric patients is different from adult airway in various aspects and presents some unique challenges. To be successful at securing an airway, it is important for an anaesthetist to have knowledge of the anatomical, physiological differences and important pathological conditions related to paediatric airway. It is also important for an anaesthetist to be acquainted with the various tools and techniques developed for this purpose. The reported incidence of difficult intubation in infants is 0.24%-4.7% and 0.07%-0.7% in older children[8]. However, compared to adults, the consequences of mismanagement of paediatric airway are far more serious and could lead to increased incidence of morbidity and mortality. This is probably because of narrow margin of safety resulting from the unique anatomical components of the paediatric airway, as well as physiological differences such as high oxygen consumption and reduced functional residual capacity[9].

In the present study, we compared PLMA with ETT in paediatric patients for general anaesthesia. The 95.56% of patients had easy insertion of ProSeal LMA while 4.44% patients required a second attempt which is correlated with the study done by Dave et al (93.33%)[2]. The success rate of placement of Proseal LMA in the first attempt was 83% in the study conducted by Lalwani et al[10], 100% in Dar et al[11] and 100% in Patel et al[12]. Sinha et al[13] and Misra et al[3] reported that the PLMA was placed in 88% patients at first attempt in paediatric and adult laparoscopic surgeries, respectively. The higher success rate of present study in comparison to other studies[3, 10 and 13] may be due to frequent use of PLMA in our institute. In group E, the first attempt success rate was found to be 97.78% and 2.22% patient required second attempt; this finding is comparable with the study done by Lalwani et al[10]. Laryngoscopy and endotracheal intubations are main forte of anaesthetist this explains the higher success rate of endotracheal intubation in comparison to PLMA. In group P, the first attempt success rate for insertion of feeding tube was found to be 91.11% and 8.89% patient required second attempt. Insertion of feeding tube was not tried in group E. Patel et al[12] reported 100% success rate of feeding tube in first attempt via PLMA in paediatric patients.

Endotracheal intubation being more invasive cause's profound hemodynamic changes than the placement of PLMA as latter does not invade the trachea. In the current study, there was increase in mean PR, SBP, DBP and MAP after placement of airway device in both the groups and this increase in mean values was found to be more in group E than in group P which was statistically significant (p value>0.05). The variation in haemodynamic parameters was also present at 3 minutes and 5 minutes after insertion of airway device, after which it was not statistically significant throughout the procedure. At the time of removal of airway device the increase in mean values was more with ETT than PLMA, which was statistically significant (p-value->0.05). These results are correlated well with the previous studies[10-12, 14]. SpO2 was found to be in the range of 98-100% while ETCO2 was between 35-44 mmHg in both groups. No active interventions were needed as the values were in normal ranges. There were no significant differences in mean SpO2 (%) and EtCO2 levels recorded at different time intervals between the two groups.

Supraglottic airway devices could be less irritating to the airway and associated with less laryngeal stimulation thus causing minimum post-operative complications. There was no incidence of aspiration and regurgitation in either group during induction of anaesthesia, in intraoperative period or after the removal of the respective airway device. Similar finding was observed by Lalwani et al[10] and Dar et al[11]. The incidence of cough and sore throat was comparatively more in group E than group P, this finding coincides with Patodi et al[15] and Saraswat et al[16]. The lower incidence of cough and sore throat with PLMA could be due to the fact that it exerts less mucosal pressure and does not hamper the pharyngeal perfusion pressures. The cuff of PLMA is less stimulating to pharyngeal mucosa as compared to ETT cuff in trachea which may be the cause of reduced incidence of postoperative nausea and vomiting in these patients[15]. We found no incidence of vomiting in PLMA group and only 1 patient had episode of vomiting in group E (2.22%) which is comparable with the study done by Patel et al[12]. Trauma found in 13 (28.89%) patients in group P and 9 (20%) in group E (p value=0.327) whereas hoarseness of voice in 4.44% in group P and 15.56% in group E. These findings are correlated with the previous studies[6, 10, and 16].

Conclusion

From the results of present study, it can be concluded that Proseal LMA is a safe and suitable alternative airway device to ETT in paediatric patients as judged by comparable success rate of insertion, stable hemodynamics, good oxygenation, adequate ventilation and lesser incidence of postoperative complications.

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