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Comparison of Proseal Laryngeal Mask Airway versus Endotracheal tube in Anaethetized Adult Patients

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Abstract

Background: Endotracheal intubation is the gold standard for maintenance of airway patency. But it is not without complications. Objectives: We therefore aimed at comparing Proseal LMA with endotracheal tube for insertion characteristics, cardiovascular responses, and efficacy of oxygenation, ventilation and complications. **Methods**: 60 patients of ASA I and II between 18 to 60 years of either sex posted for elective surgery under general anaesthesia were randomly divided into two equal groups. Group A (30) – PLMA Insertion, Group B (30) – ETT Insertion **Results:** Easy insertion was noted with Proseal LMA 24 (80%) v/s 21(70%) with endotracheal tube. Insertion in first attempt was seen in 24(80%) for Proseal v/s 23(76.7%) for endotracheal tube. Both groups were comparable with number of attempts at insertion. The mean insertion time with Proseal LMA was 36.87±16.19 v/s 42.2±17.42 seconds with endotracheal tube. Haemodynamic parameters were maintained better with Proseal LMA. Ventilation, oxygenation, intraoperative and postoperative complications were comparable in both the groups. **Conclusion:** Placement of Proseal LMA is relatively easy, simple, rapid and is as good as endotracheal tube in providing general anaesthesia.

Keywords: Ease of Insertion, Endotracheal Intubation, Haemodynamics, Proseal Lma

INTRODUCTION

Despite major advances in contemporary anaesthesia practice, maintenance of patent airway still remains a primary concern for anaesthetist. Cuffed endotracheal tube is considered as the gold standard to maintain airway patency because of its ability to provide positive pressure ventilation under high airway pressures without risk of gastric distension and pulmonary aspiration with added benefit of suctioning and delivery of anaesthetic gases.[1] However, its usage is not without demerits. These demerits can be seen during insertion, after insertion and during extubation and include airway trauma, physiological reflexes like hypoxia, tachycardia and hypertension, malposition, laryngospasm as well as negative pressure pulmonary edema.[1,2] Post-operative sore

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throat is another major concern associated with the use of endotracheal tube.These drawbacks prevent the global utility of the endotracheal tube and calls for a better alternative.[3] Classical Laryngeal mask airway was used initially to combat drawbacks of endotracheal tube. However, risk of gastric distension and inadequate ventilation with classic LMA remained until the discovery of ProSeal LMA (PLMA) in early 2000.[4] PLMA has a dorsal cuff, in addition to the peripheral cuff which pushes the mask anterior to provide a better seal around the glottic aperture and thereby permits use of high airway pressures without leak.[5] The drain tube parallel to the ventilation tube permits passive drainage of regurgitated gastric fluid away from the airway and serves as a passage for gastric tube.[6] The PLMA is therefore, more suitable than the classical LMA in patients with decreased total lung compliance and in surgeries in which intra-operative gastric drainage or decompression is desirable. The PLMA is a relatively new airway device in developing countries. This study was therefore undertaken to compare PLMA with standard endotracheal tube for the ease of insertion, number of attempts and time taken for insertion, haemodynamic changes, oxygenation, ventilation and intraoperative and postoperative complications occurring during general anaesthesia.

MATERIALS AND METHODS

After obtaining the Ethics committee approval and written informed consent, this prospective randomised study was carried out in 60 adult patients undergoing elective surgery under general anaesthesia.

Inclusion Criteria

- ASA Grade I and II
- 18 to 60 years of age
- Mallampatti grade I and II
- Weight 40 – 70 Kg

Exclusion Criteria

- Patients with known difficult airway
- Cervical spine disease
- Obese patient BMI > 25 Kg/M^2
- Mouth opening < 2.5 cm
- Risk of aspiration (full stomach, hiatus hernia, GERD)
- Oral pathology
- Upper respiratory tract infections

All the patients were randomly divided into two groups.

Group A (n=30) – PLMA Insertion
Group B (n=30) – ETT Insertion.

All patients were kept nil orally for 6 hours prior to surgery. All patients received tab. Alprazolam 0.25 mg and tab ranitidine 150 mg orally the night before surgery and on the morning of surgery.

After shifting the patient to the OT, an intravenous line was secured under aseptic precautions and routine monitoring including three lead surface electrocardiogram (ECG), pulse oximetry (SpO_2) and non invasive blood pressure monitoring were established and baseline parameters recorded. All patients were premedicated with Injection midazolam 30 mcg/kg, Injection glycopyrolate 0.004 mg/kg, injection Ondansetron 4 mg and injection butorphenol 30 mcg/kg 5 minutes before induction. After preoxygenation with 100% O2 for 3-5 minutes, anaesthesia was induced with injection propofol 2-2.5 mg/kg till the loss of verbal commands. Bag and mask ventilation checked and intravenous succinylcholine 1-2 mg/kg given to facilitate placement of device. In group A ,

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size 3 or 4 PLMA (according to weight) was used. The cuff of PLMA was fully deflated prior to insertion. Posterior surface of PLMA was lubricated with 2% lignocaine jelly. PLMA was inserted through the oral cavity using index finger technique. In group B, endotracheal intubation (7.5 in females and 8 in males) was performed in standard manner. After placement in case of PLMA cuff was inflated and in case of ETT cuff was also inflated via pilot balloon. Anaesthesia was maintained by mechanical ventilation with FiO2=0.33%,Tidal volume of 8 ml/kg , respiratory rate of 12 per minute and I:E ratio of 1:2 with oxygen(50%), nitrous oxide(50%) + isoflurane (0.5-1%) and intermitant boluses of intravenous vecuronium 0.02 mg/kg was given as required. At the end of the surgery, anaesthetic agents were discontinued and patients were reversed with intravenous glycopyrrolate 0.01 mg/kg with neostigmine 0.05 mg/kg .All the patients were extubated by deflating the cuff of the device when patient was fully awake and criteria of extubation were fulfilled.

Parameters to Be Observed:

1. Prior to insertion of device
2.

a)Insertion Time**:** The time interval between holding the airway device to confirmation of correct placement . Correct placement of the devices was confirmed by:

- Adequate chest movement on manual ventilation
- Square wave capnography
- Expired tidal volume of more than 8 ml/kg
- No audible leak from the drain tube with peak airway pressure (PAP) less than 20 cm H_2O. A leak below 20 cm H_2O was taken as significant and suggested a malposition.

The last test was specific for group A

b)Number of Attempts: In the event of partial or complete airway obstruction and significant leak, the devices were removed and re- inserted. Maximum number of attempts to secure the device were noted.
c)Ease of Insertion: Insertion were graded as easy or difficult .

Easy insertion – insertion at first attempt with no resistance.
Difficult insertion –insertion with resistance or at second attempt or use of a manoeuvre;
Failed insertion – insertion not possible.
ETT and PLMA insertions were performed by the same anaesthetist.

2. After insertion of device

a) Haemodynamic responses (SBP, DBP, MAP and HR were recorded at induction; and at 1 , 3 and 5 minutes after insertion of device.
b) Oxygen saturation (SpO2), end-tidal carbon dioxide (EtCO2), peak airway pressure and tidal volume were recorded at the 1st, 5th, 15th, 30th and 45th minutes after the insertion of airway device at a tidal volume of 8 ml/kg, fraction of inspired oxygen (FiO2) 0.33, respiratory rate of 12/min and I/E of 1:2 .

SpO_2 fluctuating between 94- 90% was graded as suboptimal and failed if it was <90%.

c) Complications like presence of leak, gastric insufflations or regurgitation were noted.

During emergence the occurrence of any complication like coughing, bronchospasm

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and laryngospasm were noted in both groups. After removal of airway devices blood staining of Endotracheal and posterior aspect of the PLMA, tongue-lip-dental trauma and hoarseness of voice were noted. Post operatively incidence of vomiting, sore throat, dysphagia, dysphonia and dysarthria were noted.

STATISTICAL ANALYSIS

The sample size was calculated to be 30 patients in each group showing a significant difference between the two groups with regard to different study parameters and based on previous studies, with type 1 error of 0.05 and a power of 0.9. Statistical analysis was done using Chi-Square test, Fisher's Exact test and Student's paired and unpaired t test. Null hypothesis was assumed. Data were analyzed using the statistical software (SPSS version 17.0, Chicago, IL, USA). Data were expressed as Mean±SD and percentage. P value of >0.05 was considered to be statistically not significant, a P value of <0.05 was statistically significant and a P value of <0.001 was highly significant.

RESULTS

Table 1: Comparison of demographic profile

Demographic Profile	Group A	Group B	P Value
AGE(MEAN±SD)(Years)	47.00 ±10.028	44.03± 9.978	0.255(NS)
WEIGHT (MEAN±SD)(Kg)	66.33±8.462	66.10±7.971	0.913(NS)
SEX(MALE/FEMALE)%	40/60	46.7/53.3	0.6(NS)
ASA STATUS(I/II)(%)	86.7/13.3	83.3/16.7	0.718(NS)
MP GRADING(I/II)(%)	70/30	66.1/7.971	0.559(NS)
OT TIME (MEAN±SD)(Mins)	48.56±11.26	46.43±13.75	0.5141(NS)

In group A, PLMA was inserted without resistance in 24(80.0%) patients which was graded as easy insertion. While insertion was graded as difficult in 6 (20.0%) patients in which there was leak after device placement. Device was taken out and repositioned. In group B, in 21 (70%) patients the insertion was easy and in 9 patients (30%) it was found to be difficult. Both the groups were comparable regarding ease of insertion. In group A, the insertion of PLMA in first attempt was seen in 24 (80.0%) patients as compared to 23 (76.7%) patients in group B. In group A, the insertion in second attempt was seen in 6 (20.0%) patients as compared to 7 (23.3%) in group B. The two groups were comparable with respect to number of attempts required for insertion. Third attempt was not required in either of the groups. Neither any failed attempt at insertion was reported in both the groups. The mean insertion time in group A was 36.87±16.19 seconds and in group B it was 42.2±17.42 seconds. Statistically no significant difference was found between the two (p=0.22).(table 2).

Table 2: Comparison of airway characterstics between the two groups

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	PLMA	ETT	p value
Ease of insertion (Easy/Difficult)	24/6	21/9	0.371(NS)
Attempts at insertion (1,2,3,failed)	24,6,0,0	23,7,0,0	0.754(NS)
Time required for insertion (Mean±SD) (secs)	36.87±16.19	42.2±17.42	0.22(NS)

Changes in haemodynamic parameters (SBP,DBP,MAP,HR) from baseline were stastically non significant at all times in Group A(PLMA). In group B (ETT) , stastically significant increase in SBP and DBP were observed at 3 and 5 minutes after intubation, while stastically significant increase in MAP and HR were observed at 1,3 and 5 minutes after intubation. On comparison between the two groups ,stastically significant increase in SBP and HR were observed at 1,3 and 5 minutes after insertion of device in group B (ETT Group) as compared to group A (PLMA group) . Also stastically significant increase in DBP and SBP was observed at 1 and 3 minutes after insertion of device when group B(ETT group) was compared with group A (PLMA group)(Table 3,4,5,6).

Table 3 Comparison of SBP mmHg at different time intervals

	PLMA(Mean±SD) beats/min	Intragroup p va	ETT(Mean±SD) beats/min	Intragroup p value	Intergroup p value
Baseline	119.97± 9.87		119.93± 10.94		0.99(NS)
Induction	121.23± 7.35	0.523(NS)	121.23± 7.35	0.263(NS)	0.259(NS)
1 min	124.20± 8.05	0.074(NS)	125.20± 8.05	0.086(NS)	<0.001(HS)
3 min	117.9 ±7.02	0.319(NS)	139.1± 6.98	0.000(HS)	<0.001(HS)
5 min	119.3± 7.87	0.774(NS)	126.87± 6.56	0.021(SS)	<0.001(HS)

Table 4 Comparison of DBP mmHg at different time intervals

	PLMA(Mean±SD) beats/min	Intragroup p va	ETT(Mean±SD) beats/min	Intragroup p value	Intergroup p va

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Baseline	80.70± 8.247		78.87 ± 7.683		0.375(NS)
Induction	81.9 ± 5.517	0.513(NS)	79.0± 6.229	0.9429(NS)	0.0612(NS)
1 min	83.63± 3.643	0.080(NS)	77.23± 6.564	0.386(NS)	<0.001(HS)
3 min	84.20± 6.451	0.0723(NS)	90.40± 7.137	.000(HS)	0.0008(HS)
5 min	84.17 ± 5.471	0.059(NS)	82.90± 5.268	0.044(SS)	0.3635(NS)

Table 5 Comparison of MAP mmHg at different time intervals

	PLMA(Mean±SD) beats/min	Intragroup p value	ETT(Mean±SD) beats/min	Intragroup p value	Intergroup p value
Baseline	92.63± 7.407		88.77± 10.769		0.111(NS)
Induction	92.87± 5.8	0.762(NS)	88.10± 6.779	0.757(NS)	0.225(NS)
1 min	94.00± 5.038	0.263(NS)	84.97± 7.117	0.047(SS)	<0.001(HS)
3 min	90.77± 4.281	0.130(NS)	101.1± 7.208	<0.0001(HS)	<0.001(HS)
5 min	94.17± 6.487	0.304(NS)	94.03± 7.156	0.029(SS)	0.94(NS)

Table 6 Comparison of HR(bpm) at different time intervals

	PLMA(Mean±SD) beats/min	Intra group p value	ETT (Mean±SD) beats/min	Intra group p value	Intergroup p value
Baseline	72.93 ± 14.12		77.10 ± 15.59		0.280(NS)
Induction	67.37 ± 10.912	0.0933(NS)	72.73 ± 13.133	0.2451(NS)	0.0966(NS)
1 min	69.63 ± 9.076	0.2860(NS)	84.97 ±10.88	0.0388(SS)	<0.0001(HS)
3 min	68.00 ± 7.516	0.0968(NS)	81.50 ± 10.461	0.0015(HS)	<0.0001(HS)
5 min	69.53 ± 11.041	0.3031(NS)	85.2 ± 11.784	0.0269(SS)	<0.0001(HS)

The EtCO2, SPO2, peak pressures and tidal volume were comparable in both groups throughout the surgery (P>0.05).(Figures 1, 2 and 3)

Figure 1: Comparison of peak pressure (PLMA PEAK VS ETT PEAK) and ETCO2

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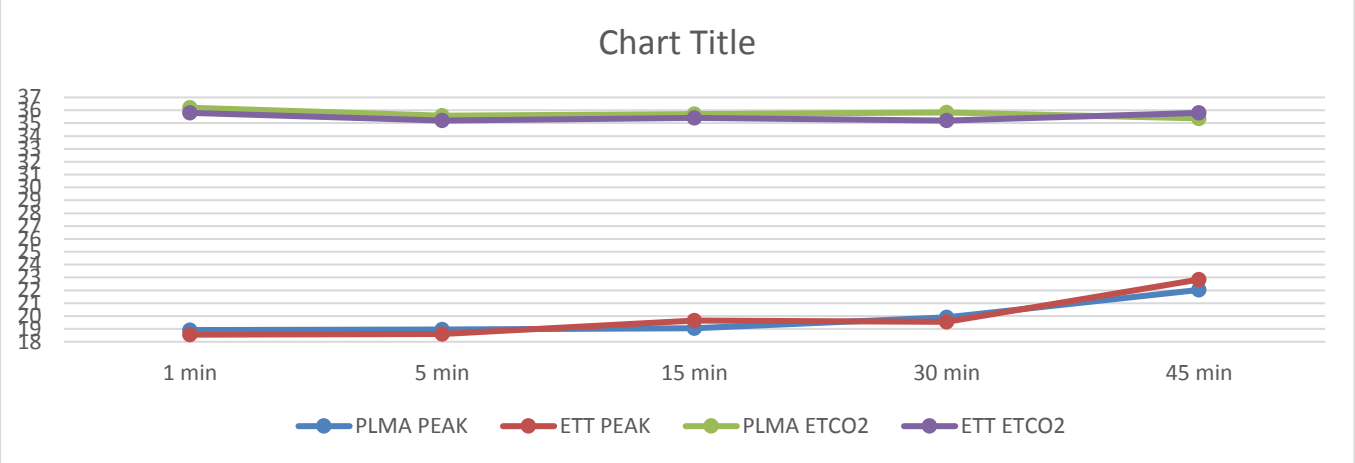

Figure 2: Comparison of tidal volume (ml) between PLMA and ETT

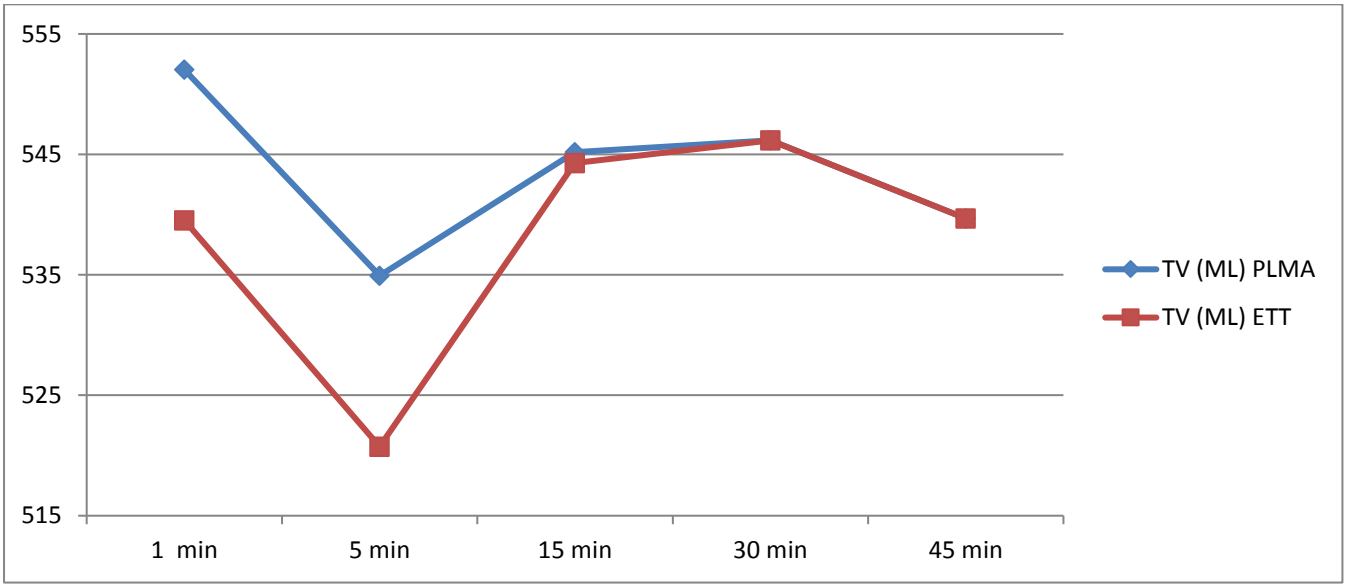

Figure 3: Comparison of SPO_2 between PLMA and ETT

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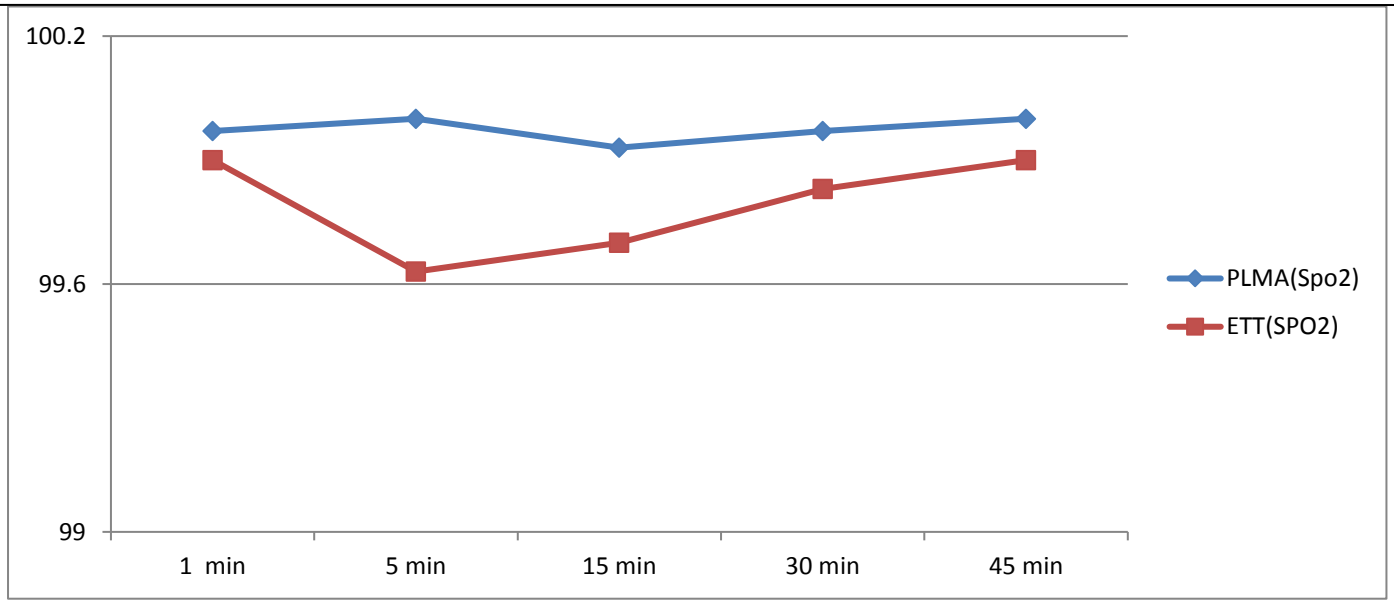

Statically non-significant differences were observed in complications like air leak and gastric distension between the two groups. Regurgitation was not observed in either of the groups. (table7)

Table 7 :Showing incidence of mal positioning of device in both the groups

Incidence	Group A	Group B	p value	Significant
Leak	3(10%)	0	0.2373	NS
Regurgitation	0	0		
Gastric Distension	4(13.3%)	0	0.1124	NS

Incidence of complications like airway trauma, cough, bronchospasm, sore throat were comparable in both the groups. Laryngospasm was not observed in either group. Vomiting, dysphagia, dysphonia, dysarthria were not observed in any patient of other the groups. (Table8).

Table no. 8: Complications observed in both the groups

Complications	Group A	Group B	p value	Significance
Blood shown on device	3(10%)	5(16.6%)	0.4461	NS

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Trauma to lip,teeth,tongue	4(13.3%)	1(3.33%)	0.353	NS
Cough	3 (10%)	10(33.3%)	0.575	NS
Laryngospasm	0	0		
Bronchospasm	1 (3.3%)	2 (6.7%)	1	NS
Sore throat	2(6.6%)	6(20%)	0.2542	NS
Vomiting	0	0		
Dysphagia, dysphonia, dysarthria	0	0		

DISCUSSION

Endotracheal intubation has a long history of one of the most widely accepted techniques for maintainence of airway patency in anaesthesia practise. But it is not without complications, most of which arise from the need to visualize and penetrate the glottis. These complications can be observed during insertion, after insertion and during extubation and include pressor response, airway trauma, laryngospasm, negative pressure pulmonary edema and sore throat.[1,2] Continous attempts have been made over a period of time to overcome these drawbacks with a variety of new airway devices. The PLMA is one such device. The PLMA belongs to the second generation LMA with some additional advantages over the classic LMA.[5] The cuff of PLMA is designed to provide a better glottis seal at lower mucosal pressure and the drain tube isolates the alimentary tract from respiratory tract.[5,6] This study was therefore conducted to compare insertion characterstics, cardiovascular responses, efficacy of ventilation, airway dynamics and complications of PLMA insertion and endotracheal intubation.

In our study we found that although PLMA was relatively easier to insert with higher success rate (80.0%) in the first attempt than the ETT(76.7%), the difference was statistically non-significant. Second attempt in insertion was required in 6 (20.0%) patients with PLMA v/s 7 (23.3%) patients with ETT. Third attempt was not required in either of the groups. Neither any failed attempt at insertion was reported in both the groups. This is similar to finding of Saraswat et al,[7] Carron et al.[8] However Misra et al[9], Patodi et al,[10] Kanan et al[11], Shah et al,[12] reported easier insertion with ETT as compared to PMLA and also time taken for insertion with ETT was lesser. In our study, the mean insertion time for PLMA was lesser as compared to ETT (36.87±16.19 and 42.2±17.42 seconds respectively) but it was statistically non-significant (p=0.22). This is similar to findings of Saraswat et al.[7] But the time taken for insertion by Saraswat et al in both the groups was lesser than our study. This could be due to the fact that their study

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was conducted by more experienced anaesthetist.

That laryngoscopy and tracheal intubation cause stress response in the form of significant rise in HR, SBP, DBP, MAP is an established phenomenon. This has been established by numerous studies in the past. Our experience with respect to this haemodynamic response on endotracheal intubation is similar to the previous studies. In our study we found that changes in haemodynamic parameters from baseline were stasticallynon significant at all times in PLMA group. However in ETT group, stastically significant increase in SBP and DBP were observed at 3 and 5 minutes after intubation, while statically significant increase in MAP and HR were observed at 1,3 and 5 minutes after intubation. On comparison between the two groups, stastically significant increase in SBP and HR were observed at 1,3 and 5 minutes after insertion of ETTas compared to PLMA . Also stastically significant increase in DBP and HR was observed at 1 and 3 minutes after insertion of ETT as compared to PLMA. Thus in our study we found that haemodynamic parameters were maintained with PLMA insertion as compared to ETT insertion. Similar results were obtained by Carron et al,[8] Patodi et al,[10] Kanon et al,[11] Shah et al,[12] Idrees and Khan et al.[13] Similar to our study Sharma B et al,[14] reported no significant haemodynamic change at 1 and 5 minutes after PLMA insertion.
Mishra et al,[9] Parikh et al,[15] Kanchi et al,[16] Takahashi et al,[17] reported both PLMA and ETT produced haemodynamic response but response was greater with ETT than PLMA insertion. Saraswat et al,[7] reported statistically significant increase in heart rate and the mean blood pressure at 10 seconds after intubation which persisted till 3 minutes after intubation and during the time of extubation in the ETT group. However, statistically significant increase in the heart rate and mean blood pressure in PLMA group was seen only 10 seconds after insertion. This difference in observation could be due to the fact that response was noted as early as 10 seconds after device insertion. However, Lalwani et al,[18] and Dave et al,[19] found that heart rate was increased significantly in both ETT and PLMA group whereas in our study, HR is increased significantly in ETT group only. This difference could be due to the paediatric age group being used as sample population. Direct laryngoscopy and intubation is almost always associated with hemodynamic changesand these changes are due to reflex sympathetic discharge caused by epipharyngeal and laryngopharyngeal stimulation. PLMA being a supraglottic device does not require airway stimulation and thereby probably does not evoke a significant haemodynamic response.[20,21]

Respiratory parameters such as EtCO2, SPO2, peak pressures and tidal volume were comparable in both groups throughout the surgery (P>0.05) in our study. Similar results were observed by Saraswatet al,[7] Shah et al,[12] Sharma et al,[14] Lalwani et al,[18] and Sinha et al.[22]

In our study, the incidence of sore throat was comparatively more in group B(ETT) (20%) then in group A(PLMA) (6.6%).[23] Saraswat et al,[7] Higgins et al[23] and Shroff et al,[24] also found the greatest incidence of sore throat with endotracheal intubation than PLMA. This could be explained by study of Murphy et al,[25] who found that in a supraglottic device mucosal pressures achieved are usually well below pharyngeal perfusion pressures. Hohlrieder et al,[26]

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noted The ProSeal LMA reduced the absolute risk of postoperative sore throat and dysphagia by 26% and 12% respectively. Our findings were in close collaboration with these studies.

There was no incidence of laryngospasm, regurgitation or aspiration in either group in our study. Similar results have been reported by Saraswat et al,[7] Sharma B et al[14] & Higgins et al.[23]

Evans et al,[21] and Keller et al,[27] researched whether PLMA could prevent the aspiration of regurgitated fluid or not. They found that a correctly placed PLMA allowed fluid in the esophagus to bypass the pharynx and mouth when the drainage tube was open and thus provided a safe airway management.

In our study, blood staining of devices on removal was seen in 3% patients in group A(PLMA) and in 5% patients in group B(ETT). Although blood staining of ET tube was found to be higher as compared to PLMA, it was not statistically significant (P=0.4461). These findings are similar to findings of Saraswat et al,[7] who found that blood staining of device on removal was seen in 10% patients in group PLMA and in 16.67% patients in group ETT but the comparison was stastically non significant.

In our study, cough was seen in 3(10%) patients in group A as compared to 10(33.3%) patients in group B and the difference was non significant (p=0.575). Carron et al,[8] and Patodi et al,[10] also reported a higher incidence of cough and sore throat after intubation in ETT group. 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 cough, sore throat, postoperative nausea and vomiting also in these patients.[28]

There are several reports of gastric inflation during PLMA use from one author group (stix MS et al).[29] But in our study no case of gastric insufflations was noted in both the groups. Minor trauma to the lip and gums and other oral cavity structures was seen in 4 patients (13.33%) in group A(PLMA) while 1(3.33%) in group B(ETT). Findings were similar to study by Saraswat et al.[7]

Although cuffed endotracheal tube is considered as the gold standard for maintaining airway in surgeries under general anaesthesia, it is concluded from our study that performance of PLMA is as good as the conventional ETT in providing general anaesthesia in terms of adequate oxygenation, ventilation and airway patency. The added advantage of PLMA is

- It is better over large variables as ease of insertion, leak, insertion time, attempts at insertion
- No hemodynamic stress response to insertion
- Minimal intraoperative and post operative complications.

CONCLSUION

Placement of Proseal LMA is relatively easy, simple, rapid and is as good as endotracheal tube in providing general anaesthesia.

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