Original Research Paper

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"COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY VERSUS ENDOTRACHEAL TUBE IN ANAESTHETIZED ADULT PATIENTS."

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ABSTRACT BACKGROUND AND OBJECTIVES: Endotracheal tube is always considered as the gold as it provide positive				

ABSTRACT BACKGROUND AND OBJECTIVES: Endotracheal tube is always considered as the gold as it provide positive pressure ventilation under high airway pressures, avoid gastric distension, pulmonary aspiration, facilitation of successfully as a rescue device during failed rapid sequence induction in obstetric, paediatrics, and geriatric patients. MATERIALAND METHODS: 60 adult patients of ASA I and II, age group of 18 to 70 years of either sex randomly selected and divided in

group A and group B undergone general anaesthesia at Maharishi Markandeshwar institute of medical science and research, Mullana (Ambala).

RESULTS: Monitored intra-operatively for HR, NIBP, $ETCO_2$, SPO_2 , at 1, 3 and 5 minutes of interval. Change in hemodynamic parameters significantly seen in group A (PLMA) HR, SBP, DBP, MAP significantly decreased at the time of induction and upto 5 minutes (p<0.05). In group B(ETT) HR, SBP, DBP, MAP significantly increased at the time of induction and upto 5 minutes (p>0.05).

CONCLUSION: It is concluded from our study that placement of PLMA is relatively easy, simple, and rapid for insertion and performance of PLMA is as good as the conventional ETT in providing general anaesthesia in selected conditions.

KEYWORDS:

INTRODUCTION

Endotracheal tube is always considered as the gold standard due to its ability to provide positive pressure ventilation under high airway pressures, to avoid gastric distension, pulmonary aspiration, facilitation of suctioning, delivery of anaesthetic and other drugs via the Endotracheal tube.¹ On the other hand disadvantages of tracheal intubation in terms of concomitant hemodynamic responses, situations of failed intubation and damage to the oropharyngel structures at insertion², It alters neuro-humoral, immunological and metabolic systems which attribute to surgical stress response.³ In clinical practice these activations in biochemical measurements like noradrenaline, adrenaline and cortisol levels.⁴

With the advent of newer supraglotic devices these drawbacks are avoided. The laryngeal mask airway(LMA) is a supraglotic device developed by the British anaesthesiologist Dr. Archi Brain. It's in use since 1988.⁵ LMA has more recently come into use in the emergency setting as an important accessory device for management of the difficult airway.⁶

LMA is shaped like large endotracheal tube on the proximal end that connects to an elliptical mask on the distal end. It is designed to sit in the patient's hypopharynx and cover the supraglotic structures, thereby allowing relative isolation from the trachea.⁷ LMA is a good airway device in many settings, including the operating room, emergency. One of the major benefits of LMA is that we don't require muscle relaxants to achieve adequate relaxation and laryngoscope is not needed for LMA insertion whereas drawbacks of LMA are that it cannot isolate the respiratory tract from alimentary tract.8 Therefore placement of LMA is always have a risk of aspiration of the gastric content. In the scenario of the difficult airway, the establishment of an airway and provision of oxygen and ventilation must be weighed against the risk of aspiration. So, in a hypoxic or anoxic patient, the providing of oxygen far outweighs the risk of aspiration of stomach contents.⁹Objective of the study was to compare the effects of insertion of PLMA and ETT on hemodynamic response, ease of placement and to evaluate the safety and efficacy of PLMA as an airway device in anesthetised patients.

MATERIALAND METHODS

60 adult patients of ASA I and II between the age group of 18 to 70

years of either sex, weighing 20-70 kg with Mallampatti grade I and II, randomly grouped in two were studied Maharishi Markandeshwar institute of medical science and research, Mullana (Ambala). Patients with mouth opening less than 2.5 cm, full stomach and upper respiratory tract infections were excluded from the study. Preoperative assessment: with history, examination, vital parameters and investigations were done. Pre-operatively patients were kept fasting nil orally for overnight. All patients received tab. Alprazolam 0.25 mg and tab ranitidine 150 mg orally night before anaesthesia i.e. three hours before anaesthesia and on the morning of surgery with 1-2 sips of H₂O and Premedicated with Injection midazolam 30 mcg/kg + Injection glycopyrolate 0.004 mg/kg intravenous 10 minutes before anaesthesia.

In Operation Theatre BP, Pulse, SPO2 ECG and non-invasive blood pressure were recorded Intravenous line was secured with 18G cannula and 0.9% normal saline was started. Anaesthesia was induced with injection butorphenol 30 mcg/kg, injection propofol2 mg/kg intravenously mixed with preservative free injection lignocaine + intravenous succinylcholine 1-2 mg/kg were given with oxygen, nitrous oxide(50:50) was provided via face mask and adequacy of ventilation was confirmed. On adequate relaxation of jaw appropriate size of PLMA or ETT were chosen as per group allocation and the patient. The cuff of PLMA was fully deflated prior to insertion. Posterior surface of PLMA was lubricated with 2% lignocaine jelly. PLMA was inserted via standard technique in group A patients. In group B patient was intubated with ETT and appropriate size by standard technique. Both the devices in both groups were then fixed properly and were then connected to the Bain's circuit with anaesthesia machine and manual ventilation were started in both the groups. The position of devices were confirmed by ETCO₂, capnograph waveforms, bilateral chest movements on gentle ventilation and auscultation of epigastrium and larynx. Anaesthesia was maintained by controlled ventilation with oxygen (50%), nitrous oxide (50%) +isoflurane (0.5-1%) and intermittent boluses of intravenous vecuronium 0.02 mg/kg was given as required. Intra-operatively the patients were monitored for HR, NIBP, ETCO₂, SPO₂ and these were recorded at 1, 3 and 5 minutes of interval. 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. After checking criteria's for extubation PLMA in group A or Endotracheal in group B. During emergence the occurrence of any

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complication like coughing, bronchospasm 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 was recorded. Patients were monitored throughout the perioperative period till their stay in post anaesthesia care unit (PACU).

Parameters observed:

- 1. Insertion Time:
- 2. Number of Attempts:
- 3. Ease of Insertion:

Insertion were graded as, moderate or difficult and can be defined as A) GRADE I (EASY) and **B**) GRADE II (DIFFICULT). If device were placed without resistance or no manoeuvre required, it was graded as 'easy' (Grade I). If single manoeuvre was used it was graded as moderate (Grade II) and if more than one manoeuvres were required then it was graded as difficult.

4. Malposition of device. Leak test or Quality of Airway: was judged on manual ventilation

- a) Excellent-No audible Leak
- b) Good Audible leak with lode air but sufficient leak as indicated by ETCO₂<40.
- c) Poor clinical lode of air and insufficient ventilation requiring repositioning of device.

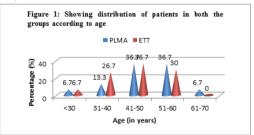
Observation and results

In group A, 6.7% of patients were between the age group of 21- 30 years, 13.3 were in the age group of 31- 40 years, 36.7% patients were in the age group of 41-50 years, similarly 36.7% were in the age group of 51-60 years and 6.7% patients were in the age group of 61-70 years. The mean age of the patients in the group was 4700 ± 10.028 years.

In group B, in this age group 6.7% patients were in the age group of 21-30 years. 26.7% in the age group of 31-40 years, 36.7% patients were in the age group of 41-50 years while 30% patients were between the age group of 51- 60 years but there was no patient between the ages of 61-70 years. Mean age of the patients in this age group was 44.03±9.978 years.

The two groups were comparable with respect to age. Difference in the age between the groups was not significant (0.255).

Table no.2 and fig no.2 shows the distribution of patients according to sex in both the groups. In group A number of male patients is 12(40%) and female 18 (60%). This shows that the number of female patients in group A is outnumbered the male patients. In group B the number of male patients is 14 (46.7%) and the number of female patients is 16 (53.3%). Similarly the number of female patients is more in group B. In both the groups female patients outnumbered the male patients (60%) and 53%)



Age distribution of patients in two study groups

Age (in years)	PLMA	ETT	P value	Significance
21-30	2 (6.7)	2 (6.7)	p-value	NS
31-40	4 (13.3)	8 (26.7)	0.255	
41-50	11 (36.7)	11 (36.7)		
51-60	11 (36.7)	9 (30.0)		
61-70	2 (6.7)	0 (0)		
Mean Age+ SD	47.00 +10.028	44.03+ 9.978		
Total	30 (100.0)	30 (100.0)		

(Figures in parenthesis indicate percentage)

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Table no.1 and Fig no.1 shows age distribution of the patients in both the groups (0% and 53%)

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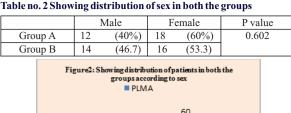




Figure no.2

The mean weight of patients in group A was 66.33 ± 8.462 while in group B it was 66.10 ± 7.971 . The two groups were comparable with respect to weight. Statistically the difference in two groups was non-significant (p>0.913).

Table No. 4 shows the distribution of patients according to ASA grading in both the groups

ASA Grading	Group A (PLMA)	Group B (ETT)	p Value	Significance	
1	26 (86.7)	25 (83.3)	0.718	NS	
2	4 (13.3)	5 (16.7)			
Total	30 (100.0)	30 (100.0)			
P value= 0.718, Non-Significant					

Table No. 5	shows the distribution of patients according to
Mallampatti Gi	rading in both the groups

Mallampatti	Group	Group	PValue	Significance
Grading	A(PLMA)	B(ETT)		_
Grade I	21 (70.0)	23 (77.7)	0.559	NS
Grade II	9 (30.0)	7 (23.3)		
Total	30 (100.0)	30 (100.0)		

(Figures in parenthesis indicate percentage)

Figure 6. Shows the distribution of patients in two groups according to the ease of insertion. **In group A**, PLMA was inserted without resistance in 24(80.0%) which was graded as easy 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%) of patients the insertion was easy and in 9 patients (30%) it was found to be difficult and no second attempt was made. No failed insertion was reported in both the groups. Both the groups were comparable regarding ease of insertion. Statistically no significant difference was found (p > 0.371).

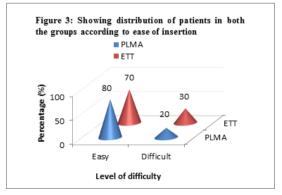


Table No. 7 shows the distribution of patients according to No. of attempts required for insertion of device.

No. Of Attempts	Group A (PLMA)	Group B (ETT)	P value	Significance
1 attempt	24 (80.0%)	23 (76.7%)	P= 0.754	NS
2 attempt	6 (20.0%)	7 (23.3%)		
Total	30(100.0%)	30 (100.0%)		

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Table No 8. Showing time required for insertion of device

Time taken (in secs)	Group A (PLMA)	Group B (ETT)	p value	Significance
Mean	36.87±16.19 secs	42.2 ± 17.42	0.224	NS
Std. Deviation	16.19	17.42		

Table No. 9. Shows the change in Systolic blood pressure (SBP) during the procedure in two groups

Systolic	Group A	Group B	t- test	p-	Significance
BP	(PLMA)	(ETT)mmHg		value	Ũ
	mmHg				
Baseline	119.97+9.87	119.93+ 10.94	0.012	0.99	NS
Before	116.73+7.99	121.23+7.35	2.269	0.259	NS
induction					
After	115.63+9.62	125.20+ 8.05	4.177	< 0.001	HS
(1 min)					
induction					
3 min	117.9 +7.02	139.1+6.98	-11.735	< 0.001	HS
5min	119.3+7.87	126.87+6.56	-4.045	< 0.001	HS

Table no. 10 Showing Change in Systolic blood (SBP) pressure at different time interval in group A

Systolic Blood	Range	Mean	t- test	p-	Significance
Pressure	_			value	_
Baseline	107-134	119.97+9.87			
Before induction	102-132	121.23+7.35	-0.647	0.523	NS
After induction	113-147	125.20+ 8.05	-2.443	0.021	S
(1 min)					
3 min	112-134	117.9 +7.02	1.013	0.319	NS
5min	109-138	119.3+7.87	.289	0.774	NS

Table no. 11 Change in Systolic Blood Pressure (SBP) at different time interval in group B

Systolic Blood	Range	Mean	t- test	p-	Significance
Pressure				value	
Baseline	100-136	119.93+ 10.94			
Before induction	106-130	116.73+7.99	1.140	0.263	NS
After induction (1min)	104-136	115.63+9.62	1.775	0.086	NS
(111111)					
3 min	123-151	139.1+6.98	-7.128	0.000	HS
5min	112-138	126.87+6.56	-2.436	0.021	S

Table no. 12 showing change in Diastolic blood pressure (DBP) at different time intervals in both groups

Diastolic	PLMA	ETT	t- test	p-	Significance
Blood				value	
Pressure					
Baseline	87.70+ 8.247	78.87 + 7.683	4.293	< 0.001	Highly
					significant
Before	83.9 + 5.517	76.57+ 6.229	4.427	< 0.001	Highly
induction					significant
After	87.63+ 3.643	77.23+ 6.564	7.588	< 0.001	Highly
induction					significant
(1min)					
3 min	84.63+ 6.451	90.40+ 7.137	-3.283	0.002	Significant
5min	84.17 + 5.471	82.90+ 5.268	0.913	0.913	NS

Table no. 13 shows the change in Diastolic blood pressure (DBP) at different time intervals in group A

Diastolic Blood	Range	Mean	t- test	p-	Significance
Pressure				value	
Baseline	76-101	87.70+ 8.247			
Before induction	74-96	83.9 + 5.517	2.385	0.024	S
After induction	82-98	87.63+ 3.643	0.041	0.968	NS
(1min)					
3 min	74-98	84.63+ 6.451	1.605	0.119	NS
5min	71-93	84.17 + 5.471	2.204	0.036	S

Table no. 14 and showing the change in Diastolic Blood Pressure (DBP) at different time intervals in group B

Diastolic Blood	Range	Mean	t- test	p-	Significance
Pressure				value	
Baseline	62-89	78.87 + 7.683			
Before induction	68-88	76.57+ 6.229	-16.415	.000	HS
After induction	62-92	77.23+ 6.564	0.879	0.386	NS
(1min)					

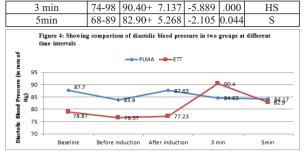


Table no. 16 shows the Change in mean arterial pressure (MAP) at different time interval in Group A

MAP	Range	Mean	t- test	p-	Significance
				value	
Baseline	82-111	92.63+7.407			
Before induction	78-103	92.87+ 5.8	-0.306	0.762	NS
After induction (1min)	84-106	94.00+ 5.038	-1.142	0.263	NS
3 min	82-97	90.77+4.281	1.558	0.130	NS
5min	84-108	94.17+ 6.487	-1.047	0.304	NS

Table no. 17 shows the change in Mean arterial pressure (MAP) at different time intervals in group B

MAP	Range	Mean	t- test	p-	Significance
				value	
Baseline	68-106	88.77+10.769			
Before induction	77-103	88.10+6.779	0.312	0.757	NS
After induction (1 min)	73-102	84.97+7.117	2.077	0.047	S
3 min	84-110	101.1+7.208	-4.559	.00	HS
5min	68-106	94.03+7.156	-2.290	0.029	S

Table no. 18 shows the change in Heart Rate (HR) in two groups at different intervals

Heart	PLMA	ETT	t- test	p-	Significance
Rate				value	
Baseline	72.93 + 14.12	77.10 + 15.59	-1.085	0.282	NS
Before	67.37 + 10.912	72.73 + 13.133	-1.722	0.090	NS
induction					
After	69.63 + 9.076	69.97 + 10.88	-0.129	0.898	NS
induction					
(1 min)					
3 min	67.00 + 7.516	93.50 + 10.461	-11.268	< 0.001	HS
5min	69.53 + 11.041	77.2 + 11.784	-2.6	0.012	Significant

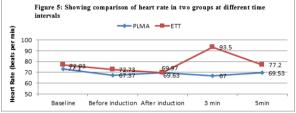


Table no 19 shows the change in SPO2 at different time interval in both the groups

SPO2	PLMA	ETT	t- test	p-	Significance
				value	
Baseline	99.97+ 0.183	99.9+ 0.960	11.589	0.527	Highly
					significant
Before	100.0 + 00	99.63+1.033	7.244	0.623	Highly
induction					significant
After	99.93+ 0.254	99.4 +0.814	3.427	0.001	Significant
induction					_
(1 min)					
3 min	99.97+ 0.183	99.83+ 0.592	1.179	0.243	NS
5min	100.0+00	99.87+ 0.346	2.112	0.039	Significant

Table no. 20 showing change in ETCO2 at different time intervals in both the groups

[ETCO2	PLMA	ETT	t- test	p-value	Significance
	Baseline	36.20 +1.540	35.8+ 0.961	1.207	0.232	NS
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Before induction	35.57+ 0.817	35.8+ 0.961	-1.013	0.315	NS
After	35.7+0.466	35.27+ 0.740	2.715	0.009	Significant
induction					
(1 min)					
3 min	35.03+0.183	36.20+ 1.883	-3.378	0.001	Significant
5min	35.37+ 0.490	35.8+ 0.925	-2.268	0.027	Significant

Table no. 21 showing incidence of mal-positioning of device in both the groups

Incidence	Group A	Group B	p value	Significant
Leak	6 (20.0%)	3 (10.0%)	0.076	NS
Regurgitation	0 (0%)	5 (16.7%)	0.019	NS
Gastric Distension	6 (20.0%)	7 (23.3%)	0.754	NS

Table no. 22 showing complications observed in both the groups

•	-			•
Complications	Group A	Group B	p value	Significance
Trauma	5(16.7%)	11(36.7%)	0.079	NS
(blood shown on device				
Sore throat	2(6.7%)	15(50.0%)	< 0.001	HS
Cough	3(10.0%)	18(60%)	< 0.001	HS
Laryngospasm	1(3.3%)	7(23.3%)	0.023	S
Bronchospasm	1(3.3%)	2(6.7%)	0.554	NS

DISCUSSION

The anaesthesiologist must ensure a patent airway and adequate ventilation. Till date the cuffed tracheal tube was considered as ideal for providing a safe glottis seal especially for laparoscopic procedures under general anaesthesia.

Our study on patients revealed, ease of insertion and 1st successful attempt in group A over group B similarly reported by saraswat et al.¹ the mean time of the insertion was 36.8 sec and 42.0 sec in group A & B was statistically lesser in PLMA (p=0.224). Liu Y et al.¹¹ also noted shorter effective time of PLMA 20±0.2 vs 37±3 secs.(p=0.001).

Heart rate. After induction and placement of device there was 13.8% decrease in HR in group A and 17.2% increase in HR in group B at 3 minutes. The increase in HR after intubation was due to sympathetic stimulation during laryngoscopy and passage of tube through the vocal cords. The fact that PLMA has relatively simple characteristic to insert and does not require laryngoscopy. Evans et al. 12 and Shroff et al. 13 differ in their opinion.

Systolic blood pressure and diastolic blood pressure shows a significant (p<0.001) fall at 3 minutes in group where as Mean arterial pressure in group A showed a maximum rise 3 min which was 101.1±7.208(12.8%). It was statistically highly significant (p<0.001). Regarding hemodynamic changes to insertion, studies by Lim Y et al.¹¹, Piper SN et al.¹⁴ and EL-Ganzouri et al.¹⁵ on PLMA have observed that the hemodynamic stress responses to insertion were greater for the tracheal tube than the PLMA. Fujii Y et al.¹⁶ have observed a rise in HR and MAP during both LMA and TT insertion and that it was more pronounced in TT group. This was correlated with a significant increase in plasma adrenaline and nor-adrenaline concentrations. Lalwani J et al.¹⁷ evaluated PLMA as an alternative to ETT in paediatric patients for short duration surgical procedures. They found hemodynamic responses to insertion of PLMA to be lower than ETT.

Ventilator parameters Like Oxygen saturation and end tidal carbon dioxide changes were not statically significant similar to Maltby et al.¹⁸ and Sharma et al.

COMPLICATIONS.

Higgins et al²⁰, Shroff et al.¹³ Murphy PG Rabey et al.²¹ and Cook et al.22 Reported higher incidence of sore throat in patients undergoing intubation comparative to PLMA. Hohlrieder et al²³ noted that the ProSeal LMA reduced the absolute risk of postoperative sore throat and dysphagia by 26% and 12% respectively.

Evans et al.¹² and Keller et al.⁷ 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.

Mucosal injury, recognized by blood on the PLMA after removal range from 3 to 28%: mean 10.2% (Cook et al.²³) similar with our findings.

Piper et al.¹⁴ found the incidence of coughing was 24% in group E while 0% in ProSeal group. In our study post extubation coughing were also lesser probably because of short duration of procedure and use of relatively small size ET tube in group E.

CONCLUSION

It is concluded from our study that placement of PLMA is relatively easy, simple, and rapid for insertion and performance of PLMA is as good as the conventional ETT in providing general anaesthesia.

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