Original Research Paper

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COMPARATIVE EVALUATION OF PROPOFOL VERSUS ETOMIDATE FOR PROSEAL LARYNGEAL MASK AIRWAY INSERTION

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KEYWORDS :

INTRODUCTION

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between the face mask and tracheal tube [1]. The increased speed and reliability of placement, improved hemodynamic stability at induction, reduced anaesthesia requirement for airway tolerance, lower frequency of coughing during insertion and lower incidence of sore throat are the main advantage of LMA over endotracheal tube. Successful insertion of the LMA requires adequate mouth opening and sufficient depth of anaesthesia to suppress the upper airway reflexes to prevent untoward events such as coughing, gagging, and laryngeal spasm [2]. The ProSeal laryngeal mask airway (Proseal LMA) is a modified laryngeal mask device with a modified cuff to improve seal and a drainage tube to provide a channel for regurgitated fluid and gastric tube placement [3]

In this study we compared the insertion conditions of Proseal laryngeal mask airway with propofol or etomidate as an induction agents.

MATERIAL AND METHODS

This prospective, randomized double blind study was carried out in the Department of Anaesthesia and Intensive Care, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi after approval by the institutional ethical committee.

PATIENT SELECTION

This prospective randomized double blind study was conducted in 80 patients of either sex in the age group of 18-65 years of ASA grade I or II scheduled for elective surgery with Proseal LMA insertion under general anaesthesia. Patients were randomly divided into two groups of 40 patients each

Group I : Propofol (P) (n=40)
Group II : Etomidate (E) (n=40).

EXCLUSION CRITERIA:

1. Anticipated difficult airway.
2. H/o recent upper respiratory tract infection.
3. H/o any systemic and metabolic disorders.
4. Patients who are at increased risk of regurgitation and aspiration.eg hiatus hernia, GERD, pregnancy etc.
5. H/o epilepsy/seizures.
6. Allergic to drugs used in the study.
7. Smokers.
8. BMI > 25kg/m^2.
9. Mouth opening < 2.5 cm.

PREOPERATIVE PREPARATION

After a detailed pre-anesthetic check-up, an informed written consent was taken from the selected patients. Patients were then randomized by the sealed envelope method into two groups. All patients were fasted overnight and received oral alprazolam 0.25 mg the night before the surgery.

In the pre-operative room standard monitoring was applied, which included non-invasive blood pressure(NIBP), oxygen saturation (SpO2), heart rate(HR), ECG and the parameters were monitored. An IV access was secured with 18G intravenous cannula and Ringer's lactate was administered along with addition of inj. ranitidine (50 mg) and metoclopramide (10 mg) and infused at 10ml/kg/hr. Premedication was given with inj. midazolam (0.03mg/kg) intravenously 30 minutes before induction. Baseline hemodynamic parameters were noted 5 minutes after giving inj. midazolam.

ANAESTHETIC TECHNIQUE

In the operation theatre, the monitors were reattached and, HR, NIBP, SpO_2 and ECG were monitored. Inj. fentanyl (2µg/kg) was given intravenously. Anaesthesia was induced with propofol or etomidate. The induction agent was prepared by another anaesthesiologist not involved in the study and the IV syringe was wrapped in paper so that the anaesthesiologist; who inserted the Proseal LMA and assessed the inserting conditions was blinded to the IV induction agent being used. Group I (P) (n=40) received inj. Propofol (2.5mg/kg) intravenously over 30 secs. 10 ml of propofol 1% was mixed with 10mg lignocaine (preservative free). Group II (E) (n=40) received inj. Etomidate(0.3mg/kg) intravenously over 30 secs.

An appropriate sized face mask was placed with 50% oxygen and 50% nitrous oxide with spontaneous respiration on a circle breathing system and $EtCO_2$ was also monitored. If the patient had apnoea (defined as no respiration for 30 secs), then assisted ventilation was given maintaining SpO_2>95% and $EtCO_2$ between 30-40 mmHg. The duration of apnoea was noted. Loss of consciousness was determined by loss of verbal response and loss of eyelash reflex.

After 60 seconds, an appropriate sized Proseal LMA was inserted using the standard technique and cuff of Proseal LMA was inflated with air to 60 cm H_2O pressure. The insertion time started from picking up of Proseal LMA till effective airway was achieved. It was noted by an independent observer. The effective airway was considered by achieving bilateral synchronized chest movement, square waveform capnograph, no audible leak, and ease of gastric tube insertion.

The number of attempts of Proseal LMA insertion was noted as 1 or > 1. An insertion attempt was defined as placement of Proseal LMA in mouth. A failed attempt was defined as removal of Proseal LMA from the mouth. A maximum of 2 attempts was allowed before failure of insertion was recorded. In that event an appropriate endotracheal tube was inserted for securing the airway.

After placement of Proseal LMA anaesthesia was maintained with 0.6% isoflurane and 66% N_2O in oxygen.

Assessment of Insertion Conditions

The Proseal laryngeal mask airway insertion characteristics were assessed using a 6 variable, 3 point score:-

	1	2	3
1.Jaw Relaxation:	full	partial	nil
2.Coughing/Gagging:	nil	mild	severe
3.Swallowing	nil	slight	gross
4.Head and Limb Movements	nil	moderate	severe
5.Laryngospasm		partial	complete
6.Ease of LMA Insertion	nil	dificult	impossible

The condition of PLMA insertion was graded as:-

1. Excellent if all the qualities are graded as 1.
2. Satisfactory if all the qualities are graded as 1 or 2.
3. Unsatisfactory if there is presence of even a single grading as 3.

Statistical analysis

Assuming the minimum difference of 15% for insertion conditions in

group I and group II, with α=0.05 and power=80%, the minimum sample size required for the study is approximately 36 patients in each group. We included 40 patients in each group to compensate for potential dropouts.

The data will be presented in terms of Mean ± SD for quantitative variables (age, height, heart rate, B.P) and counts (percentage) for category variables.

The significance between the two groups for quantitative variables were carried out by ANOVA test/Non parametric Krushkal Wallis test and for categorical variables using Chi-Square/Fisher Exact test.

The level of significance was set as p ≤0.05. The data was analyzed by SPSS Statistical Software version 16.0.

RESULTS

The results of the study entitled "COMPARATIVE EVALUATION OF PROPOFOL VERSUS ETOMIDATE FOR PROSEAL LARYNGEAL MASK AIRWAY INSERTION" in which 80 adult patients in the age group of 18-65years, belonging to ASA physical status I and II scheduled for elective surgeries were included in the study. They were randomly allocated to Group P (Propofol) and Group E (Etomidate) with 40 patients in each group.

Table 1: Demographic Data of the patients

Variables	Group P Mean±SD	Group E Mean±SD	p value
Age (years)	33.75±9.44	33.95±5.96	0.91
Gender (M/F)	24/16	17/33	0.12
Weight (kgs)	58.75±5.66	60±6.46	0.45
Height (cms)	160.55±7.77	160.35±5.66	0.89
BMI (kg/m^2)	22.69±1.72	23.28±1.67	0.12

No statistically significant difference (p>0.05) was present between two groups for demographic data of the patients.

Jaw relaxation

Table 2: Jaw relaxation

Jaw Relaxation	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Full	35	87.5%	27	67.5%	0.059
Partial	5	12.5%	13	32.5%	
Nil	0	0%	0	0%	
Total	40	100%	40	100%	

In 35 patients of group P and 27 patients of groups E, jaw relaxation was full. Jaw relaxation was partial in 5 and 13 patients in group P and group E respectively. Nil jaw relaxation was not present in both the groups. There was no statistically significant difference of Jaw relaxation in both the groups (p=0.059).

Table 3: Incidence of Coughing/Gagging

Coughing/ Gagging	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Nil	40	100%	34	85%	0.026
Mild	0	0%	6	15%	
Severe	0	0%	0	0%	
Total	40	100%	40	100%	

There were 40 patients in group P and 34 patients in group E in which no incidence of coughing was present. There were 6 patients in group E in which mild coughing was present. Incidence of severe coughing/gagging was absent in both the groups. Incidence of coughing/gagging was statistically significant in group E in which mild coughing/gagging was present (p=0.026).

Table 4:Incidence of swallowing

Swallowing	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Nil	40	100%	40	100%	1.00
Slight	0	0%	0	0%	
Gross	0	0%	0	0%	
Total	40	100%	40	100%	

Incidence of swallowing was absent in all 40 patients in both the groups.

Table 5: Incidence of myoclonus

Myoclonus	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Nil	38	95%	24	60%	0.001
Slight	2	5%	15	37.5%	
Gross	0	0%	1	2.5%	
Total	40	100%	40	100%	

Myoclonus were absent in 38 patients of group P and 24 patients in group E. 2 patients of group P and 15 patients of group E had slight myoclonus. 1 patient of group E had severe myoclonus. Statistically significant difference was present between two groups for myoclonus (p=0.001).

Table 6:Incidence of laryngospasm

Laryngospasm	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Nil	39	97.5%	38	95%	1.00
Partial	1	2.5%	2	5%	
Complete	0	0%	0	0%	
Total	40	100%	40	100%	

Incidence of laryngospasm was absent in 39 patients of group P and 38 patients of group E. 1 patient of group P and 2 patients of group E had partial laryngospasm. Incidence of severe laryngospasm was absent in both the groups. There was no statistically significant difference between the two groups (p=1.00).

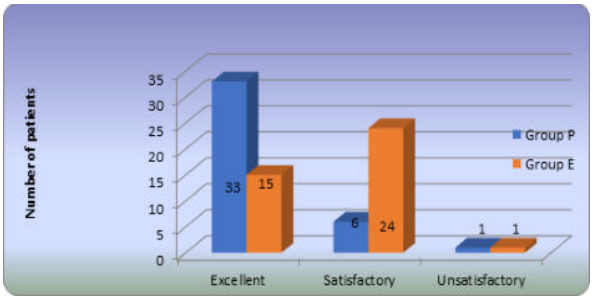
Table 7:Ease of proseal LMA insertion

Ease of PLMA Insertion	Group p		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Easy	37	92.5%	30	75%	0.075
Difficult	2	5%	9	22.5%	
Impossible	1	2.5%	1	2.5%	
Total	40	100%	40	100%	

Proseal LMA insertion was easy in 37 patients of group P and 30 patients of group E. Difficult insertion was present in 2 patients of group P and 9 patients of group E. Proseal LMA insertion was impossible at first attempt in 1 patient in both the groups. There was no statistically significant difference between two groups (p=0.075).

Table 8: Proseal LMA Insertion Conditions

Proseal LMA Insertion Conditions	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
Excellent	33	82.5%	15	37.5%	<0.0001
Satisfactory	6	15%	24	60%	
Unsatisfactory	1	2.5%	1	2.5%	
Total	40	100%	40	100%	



Statistically significant difference was present between two groups. Proseal LMA insertion conditions were Excellent in 33 patients of group P and 15 patients of group E. Proseal LMA insertion conditions was satisfactory in 6 patients of group P and 24 patients of group E; and Proseal LMA insertion conditions was unsatisfactory in 1 patient of both the groups (p<0.0001).

Table 9:Proseal LMA insertion attempts

Number of Proseal LMA Insertion Attempts	Group P		Group E		p value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	
1	37	92.5%	31	77.5%	0.127
2	3	7.5%	9	22.5%	
Failure	0	0%	0	0%	
Total	40	100%	40	100%	

Proseal LMA was inserted in first attempt in 37 patients of group P and 31 patients of group E. Proseal LMA was inserted in second attempt in 2 patients of group P and 8 patients of group E. There was no statistically significant difference between the two groups (p=0.127).

Table 10: Proseal LMA Mean Insertion Time

	Group P (secs) Mean±SD	Group E (secs) Mean±SD	p value
Mean Insertion Time	25.64±9.18	31.17±9.71	0.012

Means insertion time of groups P was 25.64±9.18 secs whereas it was 31.17±9.71 secs for group E. The difference of Proseal LMA Mean insertion time was statistically significant (p=0.012).

DISCUSSION

In our study Proseal LMA insertion conditions such as jaw relaxation, coughing/gagging, swallowing, myoclonus, laryngospasm and ease of PLMA insertion were studied.

Jaw relaxation was graded as full, partial and nil. 87.5% patients of propofol group and 67.5% patients of etomidate group had full jaw relaxation. Jaw relaxation was partial in 12.5% patients of propofol group and 32.5% patients of etomidate group. Jaw relaxation was comparable between the two groups (p=0.059). Uzun et al conducted a study where they found that full jaw relaxation was present in 72% patients of propofol group and 52% patients of etomidate group. Partial jaw relaxation was present in 28% patients in propofol group and 44% patients of etomidate group. The difference was statistically not significant between the two groups. Results of our study are comparable to Uzun et al study. [4]

Coughing/Gagging was graded as nil, mild and severe. 85% patients of etomidate group had mild coughing/gagging whereas no incidence of coughing/gagging was observed in propofol group. 15% patients of etomidate group had mild coughing/gagging. The incidence of coughing/gagging was statistically significant between the two groups (p=0.026). in the study by Uzun et al gagging was present in 8% patients of propofol group and 32% patients of etomidate group (p=0.03). Coughing was present in only 1(4%) patient of propofol group and 5 (20%) patients of etomidate group (p>0.05). Incidence of gagging was statistically significant between the two groups. The lower incidence of coughing/gagging observed in our study is probably because we had used intravenous midazolam 0.03mg/kg (as premedication) and also fentanyl 2mcg/kg in our study.[4]

Swallowing was graded as nil, slight and gross. None of the patients had incidence of swallowing in both the groups. The incidence of swallowing was found to be statistically insignificant between the two groups (p=1.000).

Myoclonus was graded as nil, slight and gross. 95% patients of propofol group and 60% patients of etomidate group had nil incidence of myoclonus. 5% patients of propofol group and 37.5% patients of etomidate group had slight myoclonus. 2.5% patient of etomidate group had gross myoclonus. None of the patients in propofol group had severe myoclonus. The incidence of myoclonus was statistically significant between the two groups (p=0.001. Jitesh kumar et al found the incidence of myoclonus was 33% in etomidate group and 0% in propofol group. The results were comparable with our study.[5]

Laryngospasm was graded as nil, partial and complete. 97.5% patients of propofol group and 95% patients of etomidate group had no incidence of laryngospasm. 2.5% patients in propofol group and 5% patients of etomidate group had partial laryngospasm. None of the patients in either of the group had complete laryngospasm. The incidence of laryngospasm was statistically insignificant between the two groups (p=1.000).

Ease of Proseal LMA insertion was graded as easy, difficult and impossible. Easy Proseal LMA insertion was observed in 92.5% patients of propofol group and 75% patients of etomidate group. 5% patients of propofol group and 22.5% patients of etomidate group had difficult Proseal LMA insertion and 2.5% patients in both the groups had impossible Proseal LMA insertion at first attempt. Ease of Proseal LMA insertion was found to be statistically insignificant between the two groups (p=0.075). Uzun et al also observed that ease of LMA insertion was good in 64% patients of propofol group and 24% patients of etomidate group (p=0.004). Ease of LMA insertion was poor in 36% patients of propofol group and 76% patients of etomidate group. Ease of LMA insertion was statistically significant between the two groups. In our study ease of Proseal LMA insertion was comparable between the two groups. This is probably because we had used intravenous midazolam 0.03mg/kg (as premedication) and fentanyl 2mcg/kg in our study.[4]

Proseal LMA insertion conditions were graded as excellent, satisfactory and unsatisfactory. Overall Proseal LMA insertion conditions were excellent in 82.5% patients of propofol group and 37.5% patients of etomidate group whereas 15% patients of propofol group and 60% patients of etomidate group had satisfactory Proseal LMA insertion conditions. 2.5% patients in each group had unsatisfactory insertion conditions at first attempt. Statistically significant difference was present with respect to Proseal LMA insertion conditions between the two groups (p=0.0001).

Ghafoor et al compared etomidate and propofol and found that Proseal LMA was inserted in first attempt in 93.3% patients in propofol group and 36.7% patients in etomidate group whereas Proseal LMA was inserted in second attempt in 6.7% patients of propofol group and 63.3% patients of etomidate group. Statistical significant difference was found between two groups (p<0.001). In contrast in our study there was no statistically significant difference with regard to number of Proseal LMA insertion attempts. This was probably because we used intravenous midazolam 0.03mg/kg as premedication while their patients were not premedicated with iv midazolam. Also, LMA was inserted in 30 seconds after giving induction agents in their study whereas in our study Proseal LMA was inserted in 60 seconds after giving induction agents.[6]

Insertion time of Proseal LMA in propofol group was 25.64±9.18 seconds and etomidate group was 31.17±9.71 seconds in our study. Statistically significant difference was found between the two groups.

CONCLUSION

Based on the results of our study we conclude that propofol 2.5mg/kg in combination with midazolam 0.03mg/kg and fentanyl 2mcg/kg provided better conditions for Proseal LMA insertion compared with etomidate 0.3mg/kg in combination with midazolam and fentanyl. Though jaw relaxation, ease of Proseal LMA insertion and number of attempts were comparable in both the groups there was a significantly increased incidence of coughing/gagging, head and limb movements in the etomidate group.

Propofol is recommended as an induction agent in combination with midazolam and fentanyl for Proseal LMA insertion as it provides better quality of insertion conditions.

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