

Original research article

The Comparison of Ease of Insertion of Proseal Laryngeal Mask Airway and Endotracheal Tube in Patients Undergoing Laparoscopic Surgeries Under General Anaesthesia

Adlene Rodrigues ¹, Sheeila Rani Imanual ², Rehana B ^{3*}

¹ Resident, Department of Anaesthesiology, Government Medical College, Thiruvananthapuram, Kerala, India

² Additional Professor, Department of Anaesthesiology, Government Medical College, Thiruvananthapuram, Kerala, India

³ Associate Professor(CAP), Department of Anaesthesiology, Government Medical College, Kollam, Kerala, India

Corresponding Author: Rehana B

E-mail: rehana_babu@hotmail.com

Abstract

Background: The cuffed endo tracheal tube was considered as the gold standard for provision of a safe glottic seal, especially for laparoscopic procedures under general anaesthesia. Proseal laryngeal mask airway (PLMA) has a dorsal cuff, in addition to the peripheral cuff of LMA, pushing the mask anterior providing a better seal around the glottic aperture and permitting high airway pressures without leak. The drain tube which lies parallel to the ventilation tube allows drainage of passively regurgitated gastric secretions away from the airway and serves as a passage for the gastric tube.

Objectives: *Primary Objective:* To compare LMA-Proseal with Endotracheal Tube for ease of insertion. *Secondary Objective:* To compare LMA-Proseal with Endotracheal Tube with regard to haemodynamic changes in patients undergoing laparoscopic surgeries under general anaesthesia.

Methodology: In this Hospital based prospective observational study, sixty ASA PS 1 or 2 patients requiring laparoscopic surgeries were allocated into two groups, 30 each (n=30) based on the technique of ventilation, either using LMA-Proseal or ETT. Prior to induction, patient and airway characteristics were recorded. The primary outcome was the ease of insertion, which was defined in terms of number of attempts and time for insertion.

Results: In this study, the ease of insertion of LMA-Proseal was comparable to ETT. Both were of 100% single insertion and time taken for insertion was 16±2SD for LMA-Proseal and 16±2.5SD for ETT. The hemodynamic changes were found to be more with ETT than LMA-Proseal. Oxygenation and ventilation were maintained in both groups. Success rate of first attempt insertion (group P 86.7% and group E 76.7%) and time taken for insertion of Ryle's tube were less with LMA-Proseal (p value 0.002).

Conclusion: This present study suggests that the use of LMA-Proseal for ventilation in patients undergoing laparoscopic surgeries under general anaesthesia is better compared to ETT. The ease of insertion was comparable and hemodynamic responses were less than with ETT.

Key words: Endotracheal tube, Ease of insertion, Hemodynamic response, Proseal LMA.

Introduction

Laparoscopic surgery is a preferred treatment modality for many gastro-intestinal, urologic and gynaecologic conditions. But it is associated with some peculiar complications related to carbon dioxide insufflation, raised intra-abdominal pressure and a potential risk of pulmonary

aspiration and regurgitation. Till date, the cuffed tracheal tube is considered the gold standard for provision of a safe glottic seal, especially for laparoscopic surgeries under general anaesthesia. The disadvantages of tracheal intubation, which involves rigid laryngoscopy, include concomitant haemodynamic responses and damage to the oropharyngeal structures during insertion. Another serious concern is postoperative sore throat. This precludes the global utility of the tracheal tube and demands a better alternative.

Supraglottic airway devices have emerged as one of the most important developments in airway devices in the past decades. Even though LMA is a highly satisfactory device in securing an airway, its lacunae with positive pressure ventilation (PPV), especially in obese patients and those with decreased pulmonary compliance, led to the designing and development of the LMA Proseal in the late 1990's, with improved ventilatory characteristics.

Proseal laryngeal mask airway (PLMA)¹ has a dorsal cuff, in addition to the peripheral cuff of LMA. It pushes the mask anterior providing a better seal around the glottic aperture and permits high airway pressures without leak². The drain tube parallel to the ventilation tube permits the drainage of passively regurgitated gastric secretions away from the airway and also serves as a passage for the gastric tube³. The LMA-ProSeal is a relatively new airway device in developing nations. This study is therefore undertaken to compare LMA-ProSeal with standard endotracheal tube for the ease of insertion and haemodynamic changes in patients undergoing laparoscopic cholecystectomy surgeries under general anaesthesia.

Methodology

Healthy adult patients of either sex, aged 20-65 years and body weight 40-76 kg who belonged to ASA PS grade I and II, scheduled for elective laparoscopic surgeries under general anaesthesia were included for this study after obtaining written informed consent and approval from the institutional ethics committee. Patients with anticipated difficult airway, obesity (body mass index > 30 kg/m²), oropharyngeal pathology, cardiopulmonary disease, cervical spine fracture or instability, or at increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux disease and pregnant patients) were excluded from the study. 60 consecutive patients eligible for study as per inclusion and exclusion criteria were enrolled. Patients in group P received a PLMA and patients in group E underwent endotracheal intubation.

Study variables included ease of insertion (from number of attempts taken for insertion of LMA-Proseal and Endotracheal Tube and time taken to secure effective airway by LMA-Proseal and Endotracheal Tube), mean heart rate variations at different intervals and mean blood pressure variation at different intervals, ETCO₂ and SPO₂.

Patients were premedicated with oral alprazolam 0.25 mg and oral Pantoprazole 40mg the night before surgery and on the day of surgery. In the operation theatre, intravenous (IV) access was obtained using an 18G canula, standard monitors were attached and baseline parameters were recorded. Injections of midazolam 0.02mg/kg, ondansetron 0.1mg/kg, glycopyrrolate 0.005 mg/kg, and fentanyl 2 µg/kg were administered 1-2 min before induction. After preoxygenation with 100% O₂ for 3 minutes, patients in both groups were given inj. Lignocaine 1.5 mg/kg and then induced with inj. propofol 2 mg/kg I.V. Succinyl choline in the dose of 2 mg/kg was used as a muscle relaxant. After confirming the depth of anaesthesia and muscle relaxation, proper sized LMA-Proseal was inserted in group P patients after deflating cuff and applying lubricant over dorsal surface, with mouth opened

with the help of the left hand and LMA-Proseal held in the right hand. The index finger was placed in the retaining strap and the LMA-Proseal was pressed against the hard palate and advanced into the hypopharynx until resistance was felt. The finger in the retaining strap was pushed towards the occiput, while the other hand exerts counter-pressure to maintain the 'sniffing' position. The Cuff inflated and position was confirmed by auscultation, chest expansion, SPO₂ level and ETCO₂ levels. Similarly, appropriately sized Endotracheal tubes were used for endotracheal intubation in group E patients. After securing airway, patients of both groups were given initial bolus dose of vecuronium 0.1 mg/kg. Patients in both groups were maintained on O₂:N₂O= 50:50, propofol infusion at the rate of 100 mcg/kg/min as anaesthetic agents and vecuronium (0.02 mg/kg) as muscle relaxant with intermittent positive pressure ventilation using circle system. All procedures were done by an expert anaesthesiologist. Pre-induction values of the Heart Rate (HR), Systolic Blood Pressure (SBP), Saturation of O₂ (SPO₂) was noted. At 1st min and 5th min after PLMA insertion or ET intubation these vital parameters were once again noted. All these parameters were observed every 10 min intra operatively along with ETCO₂. The number of attempts required for successful insertion of device was also recorded. Ease of placement of Ryle's tube was noted. Episodes of gastric inflation was noted by asking a surgeon. Oropharyngeal seal pressure was assessed by closing the expiratory valve at a fixed gas flow of 5 l/min and recording the airway pressure at which equilibrium was reached. The airway pressure was not allowed to exceed 40 cm H₂O. After confirming the respiratory attempts on the bag, reversal was done with inj Glycopyrrolate 10 mcg/kg IV and inj. Neostigmine 0.05 mg/kg IV after assessing degree of neuromuscular blockade with a peripheral nerve stimulator. Thorough oropharyngeal suctioning was done, spontaneous eye opening confirmed and tone, power and reflexes noted. Thorough oropharyngeal suctioning was done once again, cuff deflated and patient extubated at deep inspiration. Postoperatively values of HR, SBP and SPO₂ will be noted.

All data were compiled in a specific proforma. The detailed data were entered into the Microsoft excel sheet and subsequently analysed by using appropriate statistical tests.

Results

The demographic profile which included the age, sex, BMI and ASA classification were comparable and no significance differences were observed between the two groups.

Table 1 Comparison of Mallampati class based on group

MPC	Group P		Group E		χ^2	P
	Count	Percent	Count	Percent		
Class 1	2	6.7	2	6.7	0	1.000
Class 2	28	93.3	28	93.3		

The percentage of mallampati class 1 patients is 6.7 % in group P and 6.7% in group E and the percentage of class 2 patients is 93.3% in group A and 93.3% in group E. The statistical analysis was done using the Chi square test and the p value obtained is 1. There is statistically no significant difference in mallampati classes in patients among both groups.

1. Comparison of primary outcome based on group

a. Comparison of number of attempts based on group

The percentage of successful insertion by a single attempt was 100% in group P and group E. It shows LMA- Proseal is as good as ETT in terms of insertion attempts.

b. Comparison of time for insertion based on group

The average time taken for insertion in Group P is 16 ± 2 SD seconds and in Group E is 16 ± 2.5 SD seconds. The statistical analysis was done using independent t test and the p value obtained is 1.000. LMA-ProSeal insertion took only the same time as ETT insertion. (Table 2)

Table 2 Comparison of time for insertion based on group

Group	Mean	SD	N	t	P
Group P	16.0	2.0	30	0	1.000
Group E	16.0	2.5	30		

2. Comparison of secondary outcome between groups**a. Comparison of repositioning based on group**

There was no need of repositioning in both group P and group E.

b. Comparison of number of attempts of Ryle's tube insertion

In 86.7% of group P, Ryle's tube was inserted in the first attempt while in only 76.7% of group E, Ryle's tube was inserted in the first attempt. Statistical analysis was done using independent t test and p value obtained is 0.071. It was statistically insignificant but percentage of first attempt Ryle's tube insertion was higher in group P. (Table 3)

Table 3 Comparison of number of attempts of Ryle's tube insertion

Group	First attempt	Second attempt	t	p
Group P	86.7	13.3	3.268	0.071
Group E	76.7	23.3		

c. Comparison of time for insertion of Ryle's tube

The average time taken for insertion in Group P is 10 ± 2.29 SD seconds and in Group E is 12.07 ± 2.55 SD seconds. The statistical analysis was done using independent t test and the p value obtained is 0.002. It is statistically significant. (Table 4)

Table 4 Comparison of time for insertion of Ryle's tube

Instrument used	Mean	SD	N	t	p
Proseal LMA	10.00	2.29	30	3.307	0.002
ETT	12.07	2.55	30		

d. Comparison of heart rate between groups

The mean heart rate in the pre-induction period in group P is 75/minute and in group E is 75.9/minute. The statistical analysis was done by independent t test and p value 0.452 which means there is no statistical significance between both groups and both are comparable. The mean heart rate in 1 minute, 5 minute and extubation and post operative period 10 mins later are 85.1/minute, 78.4/minute, 89.4/minute and 75.7/minute respectively, and in group E are 90.3/minute, 82.6/minute, 94.1/minute and 78.9/minute respectively and P value are 0.000, 0.002, 0.000 and 0.012 which shows there is statistical difference between the heart rates in both the groups and group P is hemodynamically stable in terms of heart rate. (Table 5)

e. Comparison of systolic BP based on group

The mean systolic BP in the pre-induction period in group P is 120.4mm of Hg and in group E it is 120.8mm of Hg. The statistical analysis was done by independent t test and p value is 0.857 which means there is no statistical significance between both groups and both are comparable. The mean systolic BP in 1 minute,5 minute and extubation and post operative period 10 mins later in group P are 140.6mm of Hg,128.1mm of Hg,145.8mm of Hg and 124.5mm of Hg respectively, and in group E are 146.8 mm of Hg,132.9 mm of Hg,154.7 mm of Hg and 127.4 mm of Hg respectively and P value are 0.003,0.002,0.000 and 0.126 which shows there is statistical difference between the systolic BP in both the groups except during post op 10 minutes later and group P is hemodynamically stable in terms of systolic BP.(Table 5)

Table 5 Comparison of heart rate and systolic BP between groups

Variable	Characteristic	Group P			Group E			t	p
		Mean	SD	N	Mean	SD	N		
Heart rate	Pre-Induction	75.0	4.3	30	75.9	5.2	30	0.76	0.452
	1 Min	85.1	4.7	30	90.6	5.0	30	4.43**	0.000
	5 Min	78.4	4.5	30	82.3	4.7	30	3.22**	0.002
	15 Min	73.5	4.8	30	79.7	4.6	30	5.1**	0.000
	25 Min	71.7	4.1	30	77.9	4.3	30	5.69**	0.000
	35 Min	70.9	3.3	30	77.2	3.9	30	6.77**	0.000
	45 Min	70.7	2.9	30	75.6	4.2	30	5.26**	0.000
	Extubating	89.4	4.6	30	94.1	5.0	30	3.85**	0.000
	Post OP	75.7	4.5	30	78.9	5.2	30	2.58*	0.012
Systolic BP	Pre-Induction	120.4	8.8	30	120.8	8.3	30	0.18	0.857
	1 Min	140.6	7.6	30	146.8	8.1	30	3.06**	0.003
	5 Min	128.1	6.0	30	132.9	5.8	30	3.17**	0.002
	15 Min	119.4	5.1	30	123.6	6.1	30	2.86**	0.006
	25 Min	116.1	5.5	30	118.3	6.2	30	1.46	0.150
	35 Min	114.0	6.1	30	118.5	5.9	30	2.9**	0.005
	45 Min	112.8	5.3	30	118.2	5.1	30	4.02**	0.000
	Extubating	145.8	7.2	30	154.7	8.3	30	4.41**	0.000
	Post OP	124.5	7.1	30	127.4	7.6	30	1.55	0.126

** - Significant at 0.01 level, * - Significant at 0.05 level

f. Comparison of SPO2 based on group

The mean SPO2 at pre-induction, in 1 minute,5 minute ,every 10 minutes , extubation and post-operative period 10 mins later in group P are 99%,100%,100%,100%,100%,100%, 100%,99%,99% respectively and in group E are 99%,100%,100%,100%,100%,100%, 100%,99%,99% respectively and P value are 1.000,1.000,1.000 in pre-induction, extubation and postop 10 minutes later. The statistical analysis was done using independent t test and there is no significant difference between the two groups in SPO2.(Table 6)

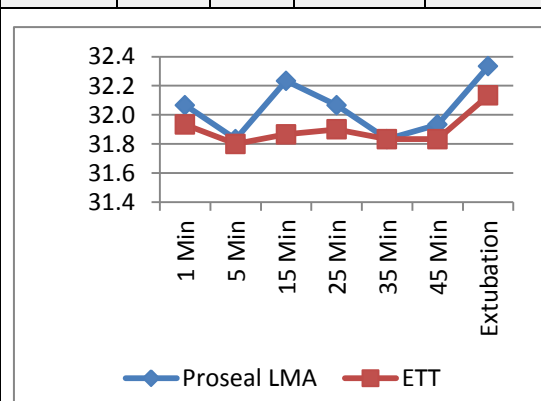
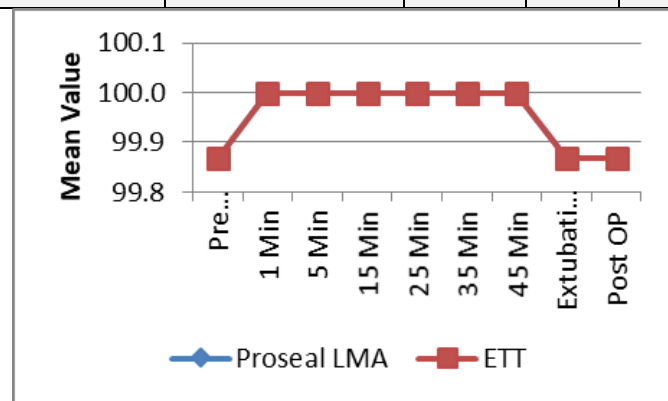
g. Comparison of ETCO2 based on group

The mean ETCO₂ in 1 minute,5 minute ,every 10 minutes in group P are 32.1mm of Hg,31.8 mm of Hg,32.2 mm of Hg,32.1 mm of Hg,31.8 mm of Hg and 31.9 mm of Hg respectively and in group E are 31.9 mm of Hg,31.8 mm of Hg,31.9 mm of Hg,31.9 mm of Hg,31.8 mm of Hg,31.8 mm of Hg respectively and p value are 0.744,0.933,0.417, 0.659,1.000,0.781

respectively. The statistical analysis was done using an independent t test and there is no statistical significance between the two groups in terms of ETCO₂. (Table 6)

Table 6 Comparison of SPO2 ETCO2and based on group

Variables	Characteristics	Group P			Group E			t	P
		Mean	SD	N	Mean	SD	N		
SPO2	Pre-Induction	99.9	0.3	30	99.9	0.3	30	0	1.000
	1 Min	100.0	0.0	30	100.0	0.0	30	-	-
	5 Min	100.0	0.0	30	100.0	0.0	30	-	-
	15 Min	100.0	0.0	30	100.0	0.0	30	-	-
	25 Min	100.0	0.0	30	100.0	0.0	30	-	-
	35 Min	100.0	0.0	30	100.0	0.0	30	-	-
	45 Min	100.0	0.0	30	100.0	0.0	30	-	-
	Extubation	99.9	0.3	30	99.9	0.3	30	0	1.000
	Post OP	99.9	0.3	30	99.9	0.3	30	0	1.000
ETCO2	1 Min	32.1	1.6	30	31.9	1.5	30	0.33	0.744
	5 Min	31.8	1.6	30	31.8	1.5	30	0.08	0.933
	15 Min	32.2	1.8	30	31.9	1.7	30	0.82	0.417
	25 Min	32.1	1.4	30	31.9	1.5	30	0.44	0.659
	35 Min	31.8	1.7	30	31.8	1.6	30	0	1.000
	45 Min	31.9	1.4	30	31.8	1.4	30	0.28	0.781



Discussion

The PLMA is a new entrant to the LMA family with some added features over the classic LMA.^{1,2} This study was conducted with the aim of comparing LMA-ProSeal and ETT as a ventilatory device in 60 patients undergoing laparoscopic surgeries. This study was chosen because increased intra-abdominal pressure from pneumoperitoneum requires higher airway pressures for adequate ventilation, for which the PLMA has proved to be adequate in previous studies³.

The prospective observational study was conducted on patients who presented for laparoscopic cholecystectomy surgery under general anaesthesia. Ethics approval was obtained from our Institution Review Board before the start of the study. A total of 60 patients in ASA grades 1 or 2 and mallampati class 1 and 2 undergoing elective laparoscopic cholecystectomy under general anaesthesia were divided into two groups P and E, 30 each in each group (n=30). In both study groups, female patients are 66.7% and 86.7% respectively and is more as compared to male patients 33.3% and 13.3% respectively since the study was conducted in laparoscopic cholecystectomy surgery. In the patients in Group P, the LMA-Proseal was inserted, and in Group E, the ETT was inserted.

The success of the first insertion or the number of attempts needed for the successful insertion of LMA-Proseal and ETT, time taken for insertion, both together, which define the ease of insertion, need for the airway adjustment during the surgery and ease of insertion of Ryle's tube insertion were analysed. The changes in hemodynamics were analysed in both groups by heart rate and blood pressure changes during pre-induction, 1 minute post insertion, 5 minutes post insertion, every 10 minutes later and during extubation and post operative after 10 minutes for both groups. The adequacy of oxygenation and ventilation was analysed by measuring SPO₂ and ETCO₂ in frequent intervals. The primary outcome was taken as the ease of insertion, which was defined as success on first attempt as evident with the appearance of an adequate end tidal CO₂ trace and no presence of airway obstruction and also by the time taken for insertion. The presence of complete or partial airway obstruction was defined as inability of adequate manual ventilation, loss of capnograph, laryngospasm, obstructed pattern of breathing or desaturation to <95 % for this study. The percentage of successful insertion by a single attempt was 100 % in group P and group E. The time taken for insertion was 16±2 SD in LMA-Proseal and 16±2.5 SD seconds in ETT. The p value was 1.000. Even though it was not statistically significant, it showed that LMA-Proseal didn't take more time than ETT.

Studies by Cook, Shroff and co-workers reported a median effective time of 15 seconds, which was somewhat similar to this study.^{4,5} Sharma and co-workers, in their study of 100 and 1,000 PLMA insertions, reported a mean insertion time of 13.51 seconds and 12 seconds, respectively.^{6,7} The shorter time in this study may be attributed to the qualified anaesthesiologists who performed this study had more experience in working with PLMA.

The most common problem encountered is loss of normal end tidal CO₂ trace and inadequate bilateral equal air entry which is resolved by simple adjustment of the mouth gag or repositioning of the chin. In the present study, none of the patients required repositioning.

A Nasogastric tube was inserted in all patients. The mean insertion time taken to insert the nasogastric tube through PLMA was significantly less (10±2.29SD seconds) than via nose (12.07±2.55SD seconds) in intubated patients. Similarly, the success rate of nasogastric tube in the first attempt was higher via LMA-Proseal than via nasal route in intubated patients (p value 0.002). These factors may be of clinical relevance in patients with hypertension, head injury, and ischaemic heart disease.

There was minimal haemodynamic stress response with LMA-Proseal when compared with endotracheal intubation. These findings are similar to the previous studies^{8,9} All analysis were performed with SPSS version 16.0 statistical software and in all cases a p value of <0.05 was considered statistically significant.

The increase in heart rate and BP during intubation is attributed to the sympathetic stimulation during laryngoscopy and the passage of the ETT through the vocal cords¹⁰. The LMA-Proseal being a supraglottic device, does not require laryngoscopy and does not evoke a significant sympathetic response¹¹. Decrease in this response may be due to diminished catecholamine release. This could be due to the fact that the LMA- ProSeal is simple and atraumatic to insert and does not require laryngoscopy.¹²

Following peritoneal insufflation, CO₂ gets absorbed trans peritoneally, and the rate at which this occurs depends on gas solubility, perfusion of the peritoneal cavity, and duration of the pneumoperitoneum. Both groups maintained adequate oxygenation and ventilation perioperatively and they were comparable.

Maltby *et al.* and Sharma *et al.* found no statistically significant differences in SpO₂ or in ETCO₂ between the two groups before or during peritoneal insufflations^{13,14}

Sharma and colleagues in a later study noted that although all patients had optimal oxygenation, three patients had EtCO₂ in excess of 55 mm Hg after CO₂ insufflation⁷. This was explained by the fact that the airway tube was narrow and the epiglottis got downfolded in some patients. The incidence of epiglottic downfolding reported was as high as 31-66%.

Although endotracheal intubation is considered the gold standard in laparoscopic surgeries done under general anaesthesia, the LMA- Proseal has proved to be an equally effective airway tool in laparoscopic surgery in terms of adequate oxygenation and ventilation with minimal intraoperative and postoperative complications. When compared to endotracheal intubation, the haemodynamic stress response was minimal with LMA-Proseal.

This study has some limitations. Only patients of ASA PS 1 and 2 were involved in this study. So, the results may not be applicable to other patients with significant comorbidities. Similarly, only patients with mallampati class 1 and 2 were involved in this study. So, the results may not be applicable to other patients who are morbidly obese, have potentially difficult airway or any other emergent surgery requiring general anaesthesia.

CONCLUSION

On the basis of our study in adult patients presented for laparoscopic cholecystectomy surgery, the LMA-ProSeal is comparable to ETT in terms of ease of insertion. It also shows to have better ease of insertion of Ryle's tube, with no need for repositioning the airway intraoperatively. The hemodynamic stress response was also found minimal with LMA-Proseal when compared to endotracheal intubation.

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