Section: Anaesthesia

Original Research Article

A COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY AND ENDOTRACHEAL TUBE IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY UNDER GENERAL ANAESTHESIA

Sudhindra P Kanavehalli[1], Ramachandraiah R[2]

[1]Consultant, Intensive Care Unit, Apollo Speciality Hospital, Jayanagar, Bengaluru, Karnataka, India

[2]Professor and Ex HOD, Department of Anaesthesia, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

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Corresponding Author:
Dr. Sudhindra P Kanavehalli,
Email: sudhindra145@gmail.com

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Abstract

Background: The cuffed endotracheal tube (ETT) has for long been considered the gold standard for securing the airway, especially for procedures under general anaesthesia.[1] The disadvantages of laryngoscopy and tracheal intubation are concomitant hemodynamic responses, damage to the oropharyngeal structures and postoperative hoarseness of voice.[2] Supraglottic airway devices like the Laryngeal mask airway (LMA) were used instead to obviate the shortcomings of ETT. However, they will not be able to provide effective airway seals in conditions with raised peak airway pressure, as encountered after the creation of pneumoperitoneum in laparoscopic surgeries. This led to an increased risk of gastric distension, aspiration and inadequate ventilation with LMA until the discovery of ProSeal Laryngeal mask airway (PLMA).[3] The ProSeal LMA (PLMA) is an improvement of the classic LMA with a modified cuff causing better oropharyngeal seal and a drain tube used to provide a channel for regurgitated fluid, prevention of gastric insufflation and insertion of a gastric tube.[4,5] This study is therefore undertaken to compare the efficacy of Proseal laryngeal mask airway (PLMA) and endotracheal tube (ETT) in patients undergoing laparoscopic surgeries under general anaesthesia. **Materials and Methods:** This prospective randomized study was conducted on 60 adult patients, 30 each in two groups, of ASA I-II who were posted for laparoscopic procedures under general anaesthesia. Patients will be randomized for airway management into two groups -Group PLMA (will receive PLMA) and Group ETT (will undergo endotracheal intubation). After premedication and preoxygenation, anaesthesia was induced and PLMA or ETT was inserted and the cuff inflated. A gastric tube (Ryle's tube) was passed in all patients. The position of the airway devices was confirmed by various tests. Anaesthesia was maintained with nitrous oxide, oxygen, sevoflurane and vecuronium. Both devices were compared for their insertion characteristics, haemodynamic changes, oxygenation and ventilatory changes and any intraoperative and postoperative laryngopharyngeal complications (LPM) were noted. **Result:** The two groups consisting of 30 participants each, were comparable in terms of age, sex, BMI, ASA class and baseline haemodynamic parameters. Mean time taken to insert the airway was shorter in Proseal LMA compared to the endotracheal tube (18sec ± 4.2 vs 20sec ±5.3 ; p = 0.11) The first attempt insertion success rate was higher with the endotracheal tube compared to the Proseal LMA, however not significant statistically (83.3% vs 80%; p>0.05).The insertion of gastric tube was easier and significantly faster with Proseal LMA than endotracheal tube(17.3 sec ± 9.2 vs 22.4 sec ± 6.7; p = 0.018) with higher first attempt insertion success rate with Proseal LMA (76.7% vs 70%; p= 0.5593). Most hemodynamic parameters were significantly higher in the group ETT after insertion (p=< 0.05) and also during removal but remained mostly comparable during the period of pneumoperitoneum among both groups. Oxygenation and ventilation (SpO_2, $EtCO_2$ and EtO_2) remained comparable among both groups throughout. The median (range) oropharyngeal seal pressure observed for group PLMA was 35(28-35) cms of H_20. Peak airway pressures and mean airway pressures were significantly higher and dynamic compliance was lower in group ETT (p<0.05) compared to group PLMA. Incidence of sore throat was significantly higher in group ETT, both in the immediate post operative period and up to post operative day 1 (P<0.05). The incidence of gastric distension, cough, trauma to the oropharyngeal structures and blood staining though higher in group ETT, remained comparable statistically. There were no incidences of leak, regurgitation, aspiration, laryngospasm or need for additional airway intervention post operatively in both the groups. **Conclusion:** A properly positioned PLMA proved to be a suitable and safe alternative to ETT for airway management in elective fasted, adult patients undergoing laparoscopic surgeries, providing equally effective ventilation and oxygenation as the ETT with adequate oropharyngeal seal pressure and avoiding significant gastric distension, regurgitation and aspiration. The PLMA also has a significantly lower incidence of sore throat compared to ETT.

INTRODUCTION

Despite tremendous advances in contemporary anaesthetic practice, airway management continues to be of paramount importance to anesthesiologists. To date, the cuffed tracheal tube is considered the gold standard for providing a safe glottic seal, especially for laparoscopic procedures under general anaesthesia.[1] The disadvantages of tracheal intubation, which involves rigid laryngoscopy, are in terms of concomitant haemodynamic responses and damage to the oropharyngeal structures at insertion. Postoperative sore throat is also a serious concern. This precludes the global utility of the tracheal tube and requires a better alternative.[6]

Laparoscopic surgeries are associated with increased intra-abdominal pressure during pneumoperitoneum which in turn may lead to increased risk of pulmonary aspiration. The fear that the supraglottic airway device will not be able to provide an effective seal in conditions with raised peak airway pressure, as encountered after the creation of pneumoperitoneum in laparoscopic surgeries precluded their use. An ideal supraglottic airway device provides a patent airway, adequate ventilation, prevention of aspiration and less damage to the oropharynx and laryngeal structures. Among the various supraglottic airway devices, ProSeal Laryngeal Mask Airway (PLMA) and Laryngeal Mask Airway Supreme (SLMA) are designed to provide effective seals even in conditions of raised airway pressure as encountered in laparoscopic surgeries.

Proseal laryngeal mask airway (PLMA) has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture and permits high airway pressures without leak.[5] The drain tube parallel to the ventilation tube permits drainage of passively regurgitated gastric fluid away from the airway and also serves as a passage for the gastric tube.[6] The PLMA was designed to facilitate positive-pressure ventilation with higher airway pressure than possible with the older LMA (LMA-classic). Other features of the PLMA include a reinforced airway tube that is narrower than that of the LMA-classic (LMAc) and an integrated bite block. The tip of the PLMA lacks the semirigid back plate of the LMAc.[7] The PLMA is a relatively new airway device in developing nations. This study is therefore undertaken to compare PLMA with a standard tracheal tube for the insertion characteristics, hemodynamic changes, respiratory changes and intraoperative and postoperative laryngo pharyngeal morbidity occurring in healthy adult patients undergoing laparoscopic surgeries.

Aim: To compare Proseal LMA with Endotracheal tube in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

Objectives: The comparison would be done with regard to the insertion characteristics, number of attempts for placement of devices, hemodynamic and respiratory parameters and perioperative airway and respiratory complications.

MATERIALS AND METHODS

Source of the Data: The study was conducted in the Department of Anesthesiology and Critical Care, Bangalore Medical College and Research Institute, Bengaluru, in its affiliated hospitals like Victoria Hospital, Pradhan Mantri Swasthya Suraksha Yojana Super Specialty Hospital (PMSSY) and Bowring and Lady Curzon Hospital.

Method of Collection of Data

Study Design: Hospital-based prospective, randomized, controlled clinical study.

Sample Size: Sample size was determined using a two-sided test with $\alpha = 0.05$ and a power of 0.8. for primary variables (O_2 saturation and $EtCO_2$), using the following information from various previous studies: standard deviations of 5% and 5mm Hg for the two variables, respectively, were considered statistically significant. If the statistically significant difference of decrease in oxygen saturation was less than 95% for one of the devices, it was considered to be clinically significant too. The sample size came up to 50 patients with 25 in each group. We included 60 patients with 30 in each group for better results and to compensate for exclusions.

After obtaining informed written consent from patients regarding the procedure, consent for participation and consent from the surgeon, patients were randomized into 2 groups using the chit method

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Group ETT: Endotracheal tube patients (n = 30), **Group PLMA**: Proseal LMA patients (n= 30)

Inclusion criteria

- Patients of ASA physical status-I and II.
- Patients aged between 18–60 years who gave written informed consent.
- Patients undergoing elective laparoscopic cholecystectomy.

EXCLUSION CRITERIA:

- Patient's refusal.
- BMI>30Kg/ m2.
- Presence of respiratory, cardiovascular, neurological, and endocrine disorders.
- Patients on anti-hypertensives, alpha 2 agonists, psychiatric medications.
- Patients with a recent history of upper respiratory infections.
- Patients with hepatic and renal disorders.
- Patients with an anticipated difficult airway.
- Patients at increased risk of aspiration (hiatus hernia, gastroesophageal reflux disease and pregnant patients)

Pre-anaesthetic Examination and Preparation: The study protocol was approved by the Institutional Ethical Committee and clearance was obtained for the same. The pre-anaesthetic examination was done one day before surgery. Relevant investigations were ordered as required. Patients were premedicated with oral alprazolam 0.5 mg the night before surgery. Height and weight were recorded and body mass index was calculated for each patient.

Informed written consent was taken from patients after explaining the anaesthetic protocol briefly. In the operation theatre, after securing intravenous access, non-invasive blood pressure monitor, electrocardiogram, pulse oximetry, Entropy sensor, and neuromuscular transmission probes were connected and baseline parameters were recorded.

Patients were premedicated with Inj. Midazolam 0.02 mg/kg, Inj. Glycopyrrolate 0.005 mg/kg, and Inj. Fentanyl 2 μg/kg, 2 min before induction. After preoxygenation with 100% O2 for 3 minutes, anaesthesia was induced with an injection of Propofol 2.5 mg/kg till the loss of verbal commands. Neuromuscular blockade to facilitate placement of the device was achieved by Vecuronium 0.1 mg/kg. Three minutes later, the corresponding airway was inserted in each group. Proseal LMA was inserted by index finger method, based on patient's body weight - size 3 (30-50 kgs) and size 4 (50-70kgs) and 5 (70-100kgs). Endotracheal tube sizes 7 and 7.5 for females and sizes 8 and 8.5 for males. Water soluble lubricant was applied to both devices before inserting.

The time interval between initiation of insertion to the confirmation of correct placement by bilateral air entry on chest auscultation was noted. A Ryle's tube (gastric tube) was passed in all patients through the gastric drainage tube in case of PLMA and through the nose in case of ETT. The position of airway devices were confirmed by bilateral chest movements, a square waveform on capnography, chest auscultation and an expired tidal volume on the ventilator. Tests specific for Proseal LMA placement were to have no audible leak from the drain tube with peak airway pressure (Ppeak) less than 20 cm H_2O. An audible leak below 20 cm H_2O was taken as significant and suggested a malposition. The second test called the gel displacement test was done by placing a blob of water-soluble gel at the tip of the drain tube (DT) and noting the airway pressure at which it was ejected. If ejected below 20 cms H_2O, it suggested possible malposition. In ETT group, cuff was inflated until there was no audible leak on auscultation over trachea.

Patients were maintained on a mixture of O2:NO2 (40:60) with Sevoflurane as the inhalational agent in the concentration necessary to maintain entropy values between 40-60. Top-up doses of Inj. Vecuronium 0.02mg/kg were given and adequacy of neuromuscular blockade was ensured using the absence of a Train of Four response. All patients were put on Volume Controlled Ventilation(VCV) with Fresh gas flow(FGF) of 5L/min, Tidal volume (Vt) set at 8 ml/kg , rate of 14/min, Inspiratory: Expiratory ratio 1:2 and Positive end-expiratory pressure (PEEP) of 5 cms H_2O. The tidal volume was adjusted subsequently with 1 ml/kg increments or decrements to maintain end-tidal carbon dioxide ($EtCO_2$) between 35 and 45 mm Hg. The aim was to maintain target SpO_2 (>95%) and $EtCO_2$ (<45mm Hg) by adjusting the FiO_2 and tidal volume. When SpO_2 was 94-90% the oxygenation was graded as suboptimal and as failed if it was <90%.For standardization, intra abdominal pressure was maintained at 14 mm Hg after creation of pneumoperitoneum. At the end of surgery, residual neuromuscular blockade was reversed using Inj.Neostigmine 0.05 mg/kg and Inj. Glycopyrrolate 0.01mg/kg and extubated when TOFR (Train of four ratio) was > 0.9. The outcomes measured were as follows:

- Insertion characteristics of the PLMA /ETT and the nasogastric tube (NGT) via the PLMA or via the nose (in ETT) –The number of attempts made and the time taken for insertion were noted.
- Oropharyngeal seal pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 5l/min and recording the airway pressure at which equilibrium was reached. The airway pressure was not allowed to exceed 40 cm H_2O.
- Hemodynamic parameters like Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean Arterial Pressure (MAP), Heart rate (HR), Saturation (SpO_2)were recorded at the following times –Pre-induction (Baseline values), After induction, After airway device insertion- 1st and 3rd minute, After pneumoperitoneum (1st,3rd,5th,10th,15th,20th minute) and After extubation -1 minute.
- Respiratory parameters like Peak airway pressure (Ppeak), Mean airway pressure (Pmean), Plateau

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Pressure (Pplat), Resistance (Raw), Compliance, End-tidal carbon dioxide ($EtCO_2$), End-tidal oxygen (EtO_2), Tidal volume inspired, Tidal volume expired were recorded at the following time intervals -After airway device insertion- 1st and 3rdminute and After pneumoperitoneum (1^{st},3^{rd},5^{th},10^{th},15^{th},20^{th} minute). All parameters were recorded on the spirometry and gas analysis module of S5 Avance Datex Ohmeda™ anesthesia work station.

- Intraoperatively patients were observed for incidence of gastric distension (as told by the operating surgeon) and leak from the airway. During extubation they were observed for signs of regurgitation or aspiration, coughing, blood staining of the device, any trauma to the oropharyngeal structures (lips, tongue, teeth, gums, palate), laryngeal stridor or spasm and need for any airway intervention post operatively.
- Patients were observed for vomiting, sore throat and dysphonia in the immediate post operative period (up to 2hrs) and upto Post operative day 1(from 2hrs-24hrs after surgery).

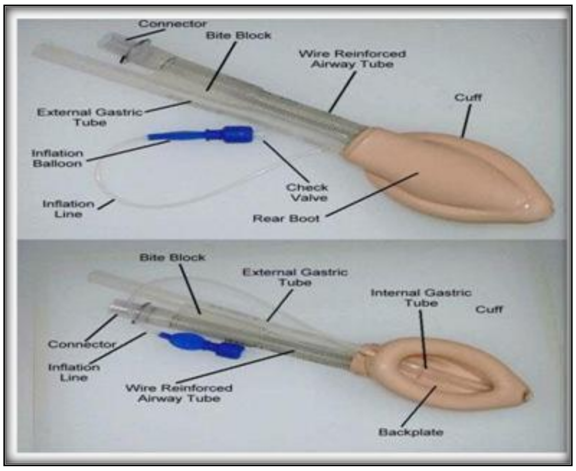

Figure 1: LMA Proseal showing dorsal cuff

Figure 2: Actual Device used during the study

Statistical Methods: All data were compiled in a specific Performa. Descriptive statistics were done for all data and suitable statistical tests of comparison were applied. Parametric data was statistically tested using Student T-test and expressed as mean ± standard deviation (SD). Categorical data was analyzed using the Chi square test and Fischer exact test. A p-value <0.05 was considered statistically significant.

Statistical software: The Statistical softwares namely EpiData analysis version 2.2.2.178 (Odense, Denmark) and IBM SPSS version 22 were used for the analysis of the data.

RESULTS

Our study consisted of 60 patients belonging to ASA grade I and II of either sex aged between 18-60 years, posted for elective Laparoscopic cholecystectomy under general anaesthesia.

Randomization-A simple randomization technique using the chit method was used to randomize these patients into the following two groups:

GROUP ETT, in whom direct laryngoscopy and endotracheal tube was used to secure the air way and GROUP PLMA in whom Proseal LMA of the appropriate size was used.

The results obtained are as follows

The mean age in group ETT was 38.17±9.23 years and group PLMA was 37.47±9.78 with a p-value of 0.77. Hence both groups were comparable with respect to age. The demographic data showed 14 males and 16 females in Group ETT and 13 males and 17 females in Group PLMA. There was no statistically significant difference (p=0.99) between the two groups in terms of gender and hence were comparable.

The mean body mass index in group ETT was 26.28 ± 3.21 and in group PLMA was 24.76 ± 3.65kg/m2. p value was 0.77, thus both groups were comparable with respect to body mass index.

Majority of the patients included in the study belonged to ASA class I in both Group ETT and Group PLMA, however, this was not statistically significant. (p=1.0)

Most of the cases studied belonged to Mallampati’s class II (Group ETT 90 % and Group PLMA 86.7%) However this was not statistically significant (p=0.671). Both groups were identical with respect to Mallampati’s grade. [Table 1]

The first attempt insertion success rate was higher in Group ETT (83.3%) compared to Group PLMA (80%), but it was not statistically significant (p=1).There was a third insertion attempt in group PLMA. [Table 2]

Mean time taken to insert the airway was higher in group ETT (20 seconds) compared to Group PLMA (18 seconds). However it was not statistically significant (p=0.11). [Table 3]

The first attempt insertion success rate of gastric tube was higher in Group PLMA (76.7%) compared to Group ETT (70%). However it was not statistically significant (p= 0.5593). [Table 4]

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The mean time taken to insert gastric tube (Ryle's tube) was much lower in group PLMA (17.3 sec) compared to group ETT (22.4 sec) and the difference was statistically significant. (p= 0.018). [Table 5]

The heart rates of the 2 groups were comparable at induction. The heart rate increased substantially higher in the group ETT at 1 minute and 3 minutes after insertion compared to group PLMA and the difference was statistically significant (p=<0.0001). After pneumoperitoneum, heart rate was on the higher side in group ETT but was statistically significant only at 1 min after pneumoperitoneum (p=<0.0001). After extubation the heart rate increased in both groups, but the increase was more in group ETT and was statistically significant compared to Group PLMA (p=<0.0001). [Table 6]

Systolic BP (SBP) was comparable at pre induction and after induction. After insertion of device, Systolic BP increased in both the groups from baseline values. The increase in group ETT was higher and was statistically significant (p=0.0003). SBP remained comparable among both groups during pneumoperitoneum. After extubation SBP increased in both groups, but increase was more in group ETT and was statistically significant compared to Group PLMA (p=<0.0001). [Table 7]

Diastolic BP (DBP) was comparable at preinduction and after induction. After insertion of device, Diastolic BP increased in both the groups from baseline values. The increase in group ETT was higher and was statistically significant (p = <0.0001). DBP remained comparable among both groups during pneumoperitoneum and after extubation. [Table 8]

Mean BP (MBP) was comparable at preinduction and after induction. After insertion of device, MBP increased in both the groups from baseline values. The increase in group ETT was higher and was statistically significant (p = 0.04). MBP remained comparable among both groups during pneumoperitoneum. After extubation, MBP increased in both groups, but increase was more in group ETT and was statistically significant compared to Group PLMA (p=0.01). [Table 9]

The arterial oxygenation saturation (SpO_2) remained comparable throughout among both groups (p >0.05). The end tidal carbon dioxide ($EtCO_2$) remained comparable throughout among both groups (p>0.05). [Table 10]

Peak airway pressure was higher in group ETT after device insertion compared to group PLMA but was statistically significant (p=0.0001) only at 1 min after insertion. After pneumoperitoneum, peak airway pressures were higher in group ETT at 3rd, 5th, 10th and 15th minute and were significant statistically (p<0.05). [Table 11]

Mean airway pressure (Pmean) was comparable among both groups 1 min after insertion. Mean airway pressure increased 3 mins after intubation in group ETT and was statistically significant (p=0.03). After pneumoperitoneum, mean airway pressures were higher in group ETT at 1st, 3rd minute and were significant statistically (p=<0.05). Mean airway pressure remained comparable between two groups during rest of the surgery. [Table 12]

The dynamic compliance was higher in group PLMA (39.80 ± 9.59)ml/cm H2O after insertion compared to group ETT (29.60 ± 8.05) ml/cm H_2O and was statistically significant (p=<0.0001). After pneumoperitoneum, dynamic compliance remained higher in group PLMA throughout during pneumoperitoneum and the difference was statistically significant throughout (p=<0.05). [Table 13]

The Plateau pressures, airway resistance and End tidal oxygen (EtO_2) remained largely comparable between both the groups.

The average tidal volumes required to maintain adequate ventilation was comparatively lower in group PLMA. However, it was not statistically significant.

The incidence of gastric insufflation was 10% among group PLMA patients. No incidence was seen in group ETT. However this difference was not statistically significant (p=1) [Table 14]. The incidence of blood staining of the device was higher in group ETT (20%) compared to group PLMA (10%). However this difference was not statistically significant (p=0.47).

Table 1: Patient Demographics

Demographics	Group ETT	Group PLMA	p Value
Mean age	38.17±9.23	37.47±9.78	0.77
Gender			
Male	14 (46.66%)	13 (43.3%)	0.99
Female	16 (53.34%)	17 (56.7%)	
Mean Body Mass Index in kg/m2	26.28 ± 3.21	24.76 ± 3.65	0.77
ASA Grade			
ASA1	18 (60%)	18 (60%)	1.0
ASA2	12 (40%)	12 (40%)	
Mallampatti			
MP1	2 (6.7)	4 (13.3)	0.671
MP2	27 (90)	26 (86.7)	
MP3	1 (3.3)	0 (0)	

Table 2: Number of attempts required to insert the airway device

	1 attempt	2 attempts	3 attempts	Total Number
	Number	Number	Number	

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Group ETT	25(83.3%)	5(16.7%)	0(0.0%)	30
Group PLMA	24(80%)	5(16.7%)	1(3.3%)	30
Total	49(81.7%)	10(16.7%)	1(1.7%)	60
Fisher's exact p value=1				

Table 3: Mean time taken to insert airway device among the study subjects

Group	Mean time in seconds time in seconds	Standard deviation	p value
Group ETT	22.4	9.24	0.018
Group PLMA	17.3	6.76	

Table 4: Number of attempts to insert Gastric tube (Ryle's tube)

Group	1 Attempt	2 Attempts	Total
	Number	Number	Number
Group ETT	21(70%)	9(30%)	30
Group PLMA	23(76.7%)	7(23.3%)	30
Total	44(81.7%)	16(16.7%)	60
Chi2= 0.341 df(1) p= 0.5593			

Table 5: Time taken to insert Gastric tube (Ryle's tube) among the study subjects

Group	Mean time in seconds time in seconds	Standard deviation	p value
Group ETT	22.4	9.24	0.018
Group PLMA	17.3	6.76	

Table 6: Comparison of Heart rate between ETT and PLMA group at different time points

Heart Rate	Group ETT (beats/min)	Group PLMA (beats/min)	p value
	Mean(±SD)	Mean(±SD)	
Pre induction	78.86± 7.12	78.80± 7.12	0.97
Post induction	71.06± 5.87	70.57± 5.03	0.72
Post insertion 1min	119.56±8.53	110.03±7.99	<0.0001
Post insertion 3mins	114.17±9.39	103.63±8.03	<0.0001
Pneumoperitoneum			
1 min	109.20±8.49	99.60± 10.32	<0.0001
3 mins	107.20±15.28	99.37± 22.83	0.12
5 mins	91.13± 14.55	90.23± 13.33	0.80
10mins	91.47± 12.32	90.97± 11.87	0.87
15mins	92.67± 10.79	92.67± 10.79	1
20mins	88.57± 8.47	88.57± 8.47	1
Post extubation	115.07±8.29	102.23±8.95	<0.0001

Table 7: Comparison of Systolic Blood Pressure between ETT and PLMA group at different time point

Systolic BP	Group ETT(mmHg)	Group PLMA (mmHg)	p value
	Mean±(SD)	Mean±(SD)	
Pre induction	125.83±10.79	127.67±8.90	0.47
Post induction	114.63±8.29	113.77±6.57	0.65
Post insertion 1min	152.57±8.60	135.83±8.26	<0.0001
Post insertion 3min	147.93±13.88	131.80±7.49	0.0003
Pneumoperitoneum			
1 min	145.50±9.81	142.27±8.72	0.18
3 mins	134.73±14.26	134.57±14.04	0.96
5 mins	132.93±15.10	132.20±13.80	0.84
10mins	128.03±11.25	127.77±11.32	0.92
15mins	130.87±15.72	130.53±15.80	0.93
20mins	126.67±8.16	127.47±6.45	0.67
Post extubation	153.20±9.70	141.10±8.84	<0.0001

Table 8: Comparison of Diastolic Blood Pressure between ETT and PLMA group at different time points

Diastolic BP	Group ETT (mmHg)	Group PLMA (mmHg)	p value
	Mean±(SD)	Mean±(SD)	
Pre induction	82.20± 7.09	82.20± 7.80	1
Post induction	75.00± 7.82	72.43± 5.92	0.15
Post insertion 1min	96.73± 6.78	92.73± 4.88	0.01
Post insertion 3 mins	96.53± 5.54	87.97± 7.63	<0.0001
Pneumoperitoneum			
1 min	85.90± 4.57	85.83± 4.62	0.95
3 mins	80.60± 14.93	79.53± 12.89	0.76
5 mins	78.87± 17.05	77.17± 13.79	0.67
10mins	77.17± 14.06	76.83± 12.79	0.92
15mins	73.60± 12.57	73.80±11.40	0.94
20mins	84.30± 5.84	84.13±5.50	0.91
Post extubation	96.77± 7.04	94.26± 3.87	0.94

Table 9: Comparison of Mean Blood Pressure between ETT and PLMA group at different time points

Mean BP	Group ETT(mmHg) Mean±(SD)	Group PLMA (mmHg) Mean±(SD)	P value
Pre induction	95.27± 6.84	94.50± 6.38	0.66
Post induction	88.47± 5.40	87.37± 4.30	0.38
Post insertion 1min	117.40±6.27	111.30±4.89	0.006
Post insertion 3mins	111.43±6.40	108.27±5.35	0.04
Pneumoperitoneum			
1 min	105.60±6.06	105.10±5.25	0.73
3 mins	97.60± 13.73	96.73± 12.47	0.79
5 mins	96.27± 16.35	94.13± 12.60	0.57
10mins	94.47± 15.31	93.10± 12.39	0.70
15mins	92.97± 13.87	92.60± 13.34	0.91
20mins	100.13±10.23	99.40± 8.29	0.76
Post extubation	117.20±10.09	111.66±5.70	0.01

Table 10: Comparison of arterial oxygen saturation (SpO_2), $EtCO_2$ between ETT and PLMA group at different time points

	Oxygen Saturation(SpO2)			End Tidal CO2 ($EtCO_2$)		
	Group ETT (%) Mean±(SD)	Group PLMA (%) Mean±(SD)	p value	Group ETT (mm hg) Mean±(SD)	Group PLMA (mm hg) Mean±(SD)	p value
Pre induction	99.57± 0.94	99.57± 0.94	1	-	-	-
Post induction	99.93± 0.25	99.93± 0.25	1	-	-	-
Post insertion 1min	99.93± 0.25	99.93± 0.25	1	36.37±1.25	36.37±1.25	1
Post insertion 3 mins	99.93± 0.25	99.93± 0.25	1	36.40±1.90	36.40±1.90	1
Pneumoperitoneum						
1 min	99.70± 0.47	99.70± 0.47	1	33.53±2.84	33.53±2.84	1
3 mins	99.73± 0.45	99.73± 0.45	1	35.23±3.10	35.23±3.10	1
5 mins	99.63± 0.49	99.63± 0.49	1	36.23±1.85	36.23±1.85	1
10mins	99.63± 0.49	99.63± 0.49	1	36.60±1.83	36.60±1.83	1
15mins	99.53± 0.51	99.53± 0.51	1	35.90±2.22	35.90±2.22	1
20mins	99.90± 0.31	99.97± 0.18	0.30	37.13±2.64	37.13±2.64	1
Post extubation	99.70± 0.75	99.77± 0.73	0.72	-	-	-

Table 11: Comparison of Peak Airway Pressure (Ppeak) between ETT and PLMA group at different time points

Peak Airway Pressure (P_{peak})	Group ETT (cm of H_2O) Mean±(SD)	Group PLMA (cm of H_2O Mean±(SD)	p Value
Post insertion 1min	17.10 ± 2.12	15.30 ± 1.49	0.0001
Post insertion 3 mins	17.40 ± 2.39	16.63 ± 3.20	0.29
Pneumoperitoneum			
1 min	20.73 ± 3.86	20.73 ± 4.14	1
3 mins	24.97 ± 3.07	23.10 ± 2.22	0.009
5 mins	25.33 ± 2.01	23.63 ± 2.39	0.004
10mins	25.57 ± 2.79	23.63 ± 2.27	0.004
15mins	25.85 ± 3.82	23.90 ± 2.31	0.02
20mins	23.67 ± 3.07	23.90 ± 2.31	0.74

Table 12: Comparison of Mean Airway Pressure (Pmean) between ETT and PLMA group at different time points

Mean airway pressure (Pmean)	Group ETT (cm of H_2O) Mean±(SD)	Group PLMA (cm of H_2O Mean±(SD)	p Value
Post insertion 1min	7.30 ± 1.37	6.60 ± 1.25	0.07
Post insertion 3 mins	7.87 ± 1.83	7.03 ± 1.13	0.03
Pneumoperitoneum			
1 min	8.57 ± 0.94	7.60 ± 1.28	0.0014
3 mins	9.23 ± 0.94	8.07 ± 1.51	0.0007
5 mins	8.63 ± 1.03	8.47 ± 1.46	0.611
10mins	9.17 ± 0.91	8.77 ± 1.41	0.19
15mins	9.17 ± 0.79	8.93 ± 1.55	0.46
20mins	9.27 ± 1.14	9.00 ± 1.39	0.42

Table 13: Comparison of Compliance between ETT and PLMA group at different time Points

Time	Group ETT (ml/cm H_2O) Mean±(SD)	Group PLMA (ml/cm H_2O) Mean±(SD)	p Value
Post insertion 1min	29.60 ± 8.05	39.80 ± 9.59	<0.0001
Post insertion 3 mins	29.23 ± 8.44	38.03 ± 8.02	0.0001
Pneumoperitoneum			
1 min	17.40 ± 4.32	23.07 ± 6.75	0.0003
3 mins	17.17 ± 4.13	21.23 ± 5.12	0.0013
5 mins	16.80 ± 3.25	20.77 ± 5.18	0.0008

10mins	17.37 ± 4.32	20.60 ± 4.95	0.009
15mins	17.03 ± 3.78	20.60 ± 4.99	0.002
20mins	16.57 ± 3.52	20.67 ± 4.90	0.0004

Table 14: Comparison of incidence of gastric insufflation between ETT and PLMA group

	Present		Absent		Total	
	Number	%	Number	%	Number	%
Group ETT	0	(0.0)	30	(100.0)	30	(100.0)
Group PLMA	3	(10.0)	27	(90.0)	30	(100.0)
Total	3	(5.0)	57	(95.0)	60	
Fisher "exact p value=1						

Table 15: Comparison of incidence of post op cough between ETT and PLMA group

	Present		Absent		Total	
	Number	%	Number	%	Number	%
Group ETT	5	(16.7)	25	(83.3)	30	(100.0)
Group PLMA	2	(6.7)	28	(93.3)	30	(100.0)
Total	7	(11.7)	53	(88.3)	60	
Fisher"s exact p value=0.4238						

The incidence of cough in patients were higher in group ETT (16.7%) compared to group PLMA (6.7%). However this difference was not statistically significant (p=0.42) [Table 15]

The incidence of trauma to oropharyngeal structures were higher in group ETT (16.7%) compared to group PLMA (10%). However this difference was not statistically significant (p=0.70)

The incidence of vomiting was seen only in the immediate post operative period (up to 2 hrs) which was similar and comparable among both groups (p=1). However no incidence of vomiting were reported in both groups after 2 hrs up to post op day 1(ie 2 hrs– 24 hrs)

The incidence of sore throat was higher in group ETT (46.7%) compared to group PLMA (13.3%) in the immediate post operative period. This difference was statistically significant (p=0.004)

The difference between the inspired and expired tidal volumes in both the groups were less than 10% indicating that leak fraction was negligible and adequate seal was maintained during the entire duration of surgery.

The median (range) oropharyngeal seal pressure for PLMA group was 35(28-35) cms of H_20, with no clinically audible leak throughout the surgery. There were no incidences of regurgitation, aspiration, laryngospasm, need for additional airway intervention after extubation or post operative dysphonia reported in both the groups.

DISCUSSION

Although endotracheal intubation has a long history of being the most widely accepted technique in anaesthetic practice,[8] it is not without complications, most of which arise from the need to visualize and penetrate the laryngeal opening,[9] and is associated with multiple disadvantages such as increased sympathetic stimulation resulting in increased blood pressure, increased heart rate and arrhythmias, laryngospasm, bronchospasm etc. However laryngeal mask airways have many advantages over endotracheal tubes such as speed and ease of insertion, improved hemodynamic stability, minimal increase in intraocular pressures, better airway tolerance, and reduced post-operative coughing and sore throat. The laryngeal mask airway (LMA) has been used successfully as both a ventilatory device and a conduit for tracheal intubation.[10] Increasing emphasis on day care anaesthesia has led to a greater use of the laryngeal mask airway, especially the Proseal laryngeal mask airway (PLMA).

Laparoscopic surgeries such as laparoscopic cholecystectomy have gained popularity widely due to better outcomes, reduced hospital stay, better patient compliance and reduced post-operative complications. Most laparoscopic surgeries involve the creation of pneumoperitoneum i.e., insufflations of peritoneal cavity with gases such as carbon dioxide. This creation of pneumoperitoneum results in multiple changes in hemodynamic, respiratory and cardiovascular systems ranging from hypotension, arrhythmias, difficulty in ventilation, raised peak airway pressures, reduction in compliance and functional residual capacity etc.[11] Although general anaesthesia with endotracheal intubation is the gold standard in the management of patients undergoing laparoscopic surgeries, it is associated with multiple disadvantages as mentioned above. Among the other supraglottic airway devices like LMA, I-gel and Proseal LMA which have been used safely in patients undergoing laparoscopic surgeries, Proseal LMA has proved to be more efficacious.[12,13]

In the present study, although PLMA was easier to insert, the first attempt success rate was higher in the ETT group (83.33%) compared to PLMA group (80.3%), but this was not statistically significant. This could mostly be due to the more common and frequent handling and usage of Endotracheal tube than PLMA by most anaesthetists. The mean time taken for successful placement was 18 ± 4 seconds and 20 ± 5 seconds for groups PLMA and ETT, respectively. Shroff P and coworkers compared PLMA with ETT in 121 patients undergoing laparoscopic surgery and found the mean time for

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insertion of PLMA and ETT were 15±10 seconds and 26±11seconds respectively,[14] which corroborated with our study findings. Sharma and coworkers, in their study of 100 and 1,000 PLMA insertions, reported a mean insertion time of 13.51 seconds and 12 seconds, respectively.[3,15] This less time could be attributed to the fact that their study was conducted by anaesthesiologists who had more experience in working with PLMA.

A Gastric tube (Ryle's tube) was inserted in all patients in the present study. The mean insertion time taken to insert through PLMA was significantly less (17.3±6.7 s vs 22.4±9.2 s) with a higher first-attempt success rate compared to ETT. This was possible due to the presence of a special gastric drainage tube in PLMA. When PLMA is properly positioned, the gastric tube can be easily inserted through the PLMA's gastric drainage tube, avoiding the need for additional laryngoscopic manipulation of difficult Nasogastric tube insertions after endotracheal intubations. These factors may be of clinical relevance in patients with hypertension, head injury and ischemic heart disease.

In our study, the heart rate increased substantially higher in the group ETT at 1 minute and 3 minutes after intubation compared to group PLMA and the difference was statistically significant ($p<0.0001$). Even after pneumoperitoneum, heart rate was on the higher side in group ETT but was statistically significant only at 1 min after pneumoperitoneum ($p<0.0001$). After extubation also there was a statistically significant increase in heart rate in group ETT and compared to group PLMA ($p<0.0001$). The increase in heart rate during intubation is attributed to sympathetic stimulation during laryngoscopy and the passage of the ETT through the vocal cords.[16] The PLMA being a supraglottic device does not require laryngoscopy and probably does not evoke a significant sympathetic response. The attenuation of this response may be due to diminished catecholamine release.[17] This could be due to the fact that the PLMA is relatively simple and atraumatic to insert and does not require laryngoscopy.[16]

Systolic BP, Diastolic BP and Mean BP increased in both the groups from baseline values after insertion of the device but the increase in group ETT was higher and was statistically significant. After extubation also SBP and MBP increased significantly in group ETT compared to group PLMA but Diastolic BP remained comparable among both groups. The hypertension and tachycardia seen during extubation in the ETT group may be due to reflex sympathetic discharge caused by pharyngeal and laryngeal simulation. This stimulation is associated with an increase in plasma epinephrine concentration leading to hypertension and tachycardia.[18]

Studies by Lim et al,[19] Piper et al,[20] and Kannan et al,[13] were in concurrence with our hemodynamic findings.

Following peritoneal insufflation, CO_2 is absorbed transperitoneally, and the rate at which this occurs depends on gas solubility, perfusion of the peritoneal cavity, and duration of the pneumoperitoneum.[21] In our present study, both groups remained comparable with respect to adequate oxygenation and ventilation perioperatively.

Maltby et al,[22] Shroff et al,[14] and Sharma et al,[15] found no statistically significant differences in SpO_2 or $EtCO_2$ between the two groups before or during peritoneal insufflations. These findings were similar to the findings in our study.

In our study, the Ppeak was significantly lower in the group PLMA while the airway Resistance (Raw) remained comparable throughout both groups. Though the internal diameter of airway tube of PLMA is narrow compared to that of ETT, the comparatively shorter length of PLMA might be the nullifying factor accounting for similar Raw in both groups. The dynamic compliance was significantly higher in group PLMA after insertion and throughout during pneumoperitoneum compared to group ETT H_2O. Kannan et al,[13] also found similar findings in the first 5 min after insertion of the airway device. Lower compliance noted in group PLMA in their study was attributed to the use of lower tidal volumes during mechanical ventilation.

Achieving adequate ventilation and maintaining a state of normocarbia is of paramount priority in positive pressure ventilation. In our study the average tidal volume needed to achieve adequate ventilation, as evidenced by SpO_2 and $EtCO_2$, was lower in group PLMA throughout compared to group ETT , but the difference was not significant statistically ($p >0.05$). Marcus Schultz et al., in their review, observed that lower tidal volume ventilation strategy had a lesser incidence of developing acute lung injury in patients undergoing major abdominal, thoracic, and cardiovascular surgeries.[23]

The mean airway pressures were significantly higher in group ETT, 3 mins after insertion of ETT and also upto 3 minutes after pneumoperitoneum. The plateau pressures remained comparable between both groups throughout. Our study was one of the first to compare mean airway pressures and plateau pressures between PLMA and ETT, thus making it unique.

Though three patients in group PLMA, had gastric distention compared to no patients in group ETT, this difference was not significant statistically ($p=1$)

The incidence of sore throat, cough, trauma to oropharyngeal structures and blood staining was comparatively higher in the intubation group ETT than in group PLMA, but they were not statistically significant. The virtual absence of sore throat in PLMA group could be explained by the fact that it is a supraglottic device, the cords are not penetrated[24] and mucosal pressures achieved are usually below pharyngeal perfusion pressures.[25]

PLMA may be recommended for patients with cardiac and respiratory comorbidities because of stable haemodynamics seen during insertion and also quicker insertion. We found PLMA to be a safe airway management device for controlled ventilation during the laparoscopic procedures. Saraswat et al,[12] concluded that PLMA is a suitable and safe alternative to ETT for airway management in electively fasted patients undergoing laparoscopic surgeries while Malby JR et al,[22] found that PLMA provided equally effective pulmonary ventilation without clinically significant gastric distension in patients who underwent laparoscopic cholecystectomy.

CONCLUSION

Although endotracheal intubation is the gold standard in laparoscopic surgeries done under general anaesthesia, the PLMA proved to be an equally effective airway tool in laparoscopic surgeries in terms of adequate oxygenation and ventilation with minimal intraoperative and post operative complications. The haemodynamic stress response was also minimal with PLMA when compared to endotracheal intubation. The PLMA maintains adequate ventilation and oxygenation at lower tidal volumes and peak airway pressures without increasing airway resistance and has higher compliance compared to ETT. Lower tidal volumes also ensure lung protective ventilation. It also provides adequate oropharyngeal seal pressure and avoids significant gastric distension, regurgitation and aspiration. The PLMA also has a significantly lower incidence of sore throat compared to ETT. Hence Proseal LMA offers a highly effective alternative to traditional endotracheal tubes for laparoscopic surgeries, providing a refined and efficient approach to airway management.

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