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"A COMPARATIVE EVALUATION OF PROSEAL LMA AND ENDOTRACHEAL TUBE IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERY UNDER GENERAL ANAESTHESIA"

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ABSTRACT

Background and Aim: To compare the efficacy of Proseal laryngeal mask airway (PLMA) and endotracheal tube (ETT) in adult patients undergoing elective laparoscopic surgeries under general anaesthesia. **Material and Methods**: This prospective randomised study was conducted on 60 adult patients, 30 each in two groups, of either sex, ASA I-II and MPG I-II. After preoxygenation, anaesthesia was induced with propofol, fentanyl and succinylcholine. PLMA or ETT was inserted and cuff inflated. Nasogastric tube (NGT) was passed in all patients. Anaesthesia was maintained with O_2, isoflurane and vecuronium. Ventilation was set at 8 ml/kg and respiratory rate of 12/min. **Results**: Demographic and surgery related variables were comparable. The number of attempts and time taken for insertion of airway devices, ease of NGT insertion, haemodynamic changes, oxygenation, ventilation and intra-operative and post-operative laryngopharyngeal morbidity (LPM) were noted. There was no failed insertion of devices. Time taken for successful insertion of device was 20.3 s and 27.5 s for groups P and E, respectively. There were no statistically significant differences in oxygen saturation (SpO_2) or end-tidal carbon dioxide ($EtCO_2$) between the two groups before or during peritoneal insufflation. There was no case of inadequate ventilation, regurgitation, or aspiration recorded. No significant difference in LPM was noted except for post-operative sore throat. **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. It provided equally effective pulmonary ventilation despite high airway pressures without gastric distension, regurgitation, and aspiration.

Key words: Endotracheal tube, Proseal LMA, IPPV, Laparoscopic surgery, Laryngopharyngeal morbidity**.**

I. INTRODUCTION

Traditional open surgeries are progressing to minimally invasive laparoscopic surgeries, which helped to minimize surgical trauma and widened the scope for laparoscopy. Airway management is very crucial for an anaesthesiologist despite significant advances in the anaesthetic practice from time to time. The main anaesthetic concerns during laparoscopic surgeries[1] are achieving adequate ventilation while maintaining normocarbia; avoiding regurgitation and aspiration, which may arise due to

increased intra-abdominal pressure; and attenuating the haemodynamic response associated with pneumoperitoneum.

Endotracheal intubation is considered as the gold standard for providing an adequate and effective glottic seal for positive pressure ventilation and for preventing gastric insufflation and aspiration[2] during laparoscopic procedures under general anaesthesia, where pneumoperitoneum decreases the pulmonary compliance, reduces functional residual capacity and increases airway pressures. However, the use of an endotracheal tube may be associated with various problems. The most important being the deleterious haemodynamic consequences due to reflex sympathoadrenal stimulation caused by tissue irritation of the supraglottic region induced by direct laryngoscopy. Direct laryngoscopy by activating proprioceptors induces arterial hypertension, tachycardia and increased catecholamine concentration proportional to the intensity of stimulus exerted against the base of the tongue[3]. Subsequent tracheal intubation stimulates additional receptors in the larynx and trachea, thus enhancing the haemodynamic responses. Morbidities such as damage to the oropharyngeal structures, dental trauma and vocal cord injury at the time of insertion are worrisome to the anaesthesiologist. Post-operative cough and sore throat is also serious concern. Also, under some conditions, tracheal intubation fails because of a difficult airway, trauma, or an inexpert person. So this warrants searching for a newer alternative device with reduced haemodynamic variations and complications[4].

The introduction of Supraglottic airway devices (SADs) resulted in a paradigm shift in airway management during anaesthesia from a 2-choice (face mask vs ETT) to a 3-choice (face mask vs SAD vs ETT) model[4-6]. The addition of a gastric port improves the safety profile of SADs. Proseal LMA, a second-generation SAD, is a double-lumen, double-cuff LMA. The double-tube design separated the respiratory and the alimentary tracts providing a separate passage for the regurgitated fluids. The double cuff provided a better seal around the glottis, thus providing an option of administering intermittent positive-pressure ventilation[7].

In this study, we hypothesized(null hypothesis) that Proseal LMA can be used as an effective alternative to ETT in laparoscopic surgeries as it provides stable haemodynamics with adequate ventilation and minimal post-operative complications.

The purpose and aim of the present study is to compare the use of the Proseal LMA (PLMA) and Endotracheal tube (ETT) as a ventilatory device in patients undergoing various elective laparoscopic procedures under general anaesthesia with the primary outcome of measuring haemodynamic responses during insertion, intra-operative period and after removal of device; oxygenation and adequacy of ventilation. Secondary variables measured are time to achieve an effective airway, ease of insertion of device and gastric tube, and complications.

II. MATERIAL AND METHODS

This was a prospective, randomized comparative study conducted in sixty adult patients of either sex, between the age group of 18 years and 60 years, belonging to ASA physical status I and II, and MPG I and II, posted for elective laparoscopic surgery under general anaesthesia. Patients with ASA physical status III and IV, Mallampati class III and IV, having anticipated difficult airway, mouth opening <2.5 cm, upper respiratory tract infection or cervical spine disease, undergoing emergency surgeries, or at risk of pulmonary aspiration (Hiatus hernia and Reflux oesophagitis) and those with lack of written informed consent were excluded from the study.

These patients were divided into two equal groups randomly using simple closed envelope method:

- Group-P: Patients received general anaesthesia and airway protection with Proseal LMA (PLMA).
- Group-E: Patients received general anaesthesia and airway protection with Endotracheal tube (ETT).

After intravenous (IV) access was obtained, injection ranitidine 50 mg and injection metoclopramide 10 mg were administered 30 minutes before surgery. In the operation theatre, standard monitors were attached and baseline parameters were recorded. Injections of midazolam 0.02 mg/kg, glycopyrrolate 0.004 mg/kg, and fentanyl 2 µg/kg were administered 1-2 min before induction. After preoxygenation

with 100% O_2 for 3-5 minutes, anaesthesia was induced with injection propofol 1-2.5 mg/kg till the loss of verbal commands. Neuromuscular blockade to facilitate placement of device was achieved with succinylcholine1-2 mg/kg iv after confirmation of successful manual bag-mask ventilation. Following induction and adequate paralysis, the corresponding airway was inserted in each group. In group P, size 3 or 4 PLMA (according to weight) was inserted using index finger technique. In group E, endotracheal intubation (7.5 in females and 8 in males) was performed in standard manner. The time interval between the start of insertion of the airway device until securing the airway and observing a square wave capnograph tracing (first CO_2 trace) was noted.

Correct placement of the devices was confirmed by adequate chest movement on manual ventilation, square wave capnography, the gel displacement test (done by placing a blob of gel at the tip of the drain tube (DT) and noting the airway pressure at which it was ejected) and the suprasternal notch test. The last two tests were specific for group P.

Anaesthesia was maintained with oxygen, isoflurane and injection vecuronium 0.08-0.1 mg/kg iv stat followed by 0.01 mg/kg iv, when required. Positive pressure ventilation with mechanical ventilator was instituted with volume-controlled mode with a set tidal volume of 8ml/kg, FiO_2-0.33%, respiratory rate 12-14/minute and I: E of 1:2 in both the groups.

The outcomes measured were as follows:

- Haemodynamic responses (heart rate, systolic, diastolic blood pressure and mean arterial blood pressure) were recorded before induction; 1, 3 and 5 min after insertion of device; 5, 10, 20 and 30 min after achieving pneumoperitoneum, and 10 min before and 10 min after removal of devices
- Insertion characteristics of the PLMA or ETT and the nasogastric tube (NGT) via the PLMA and the ETT (NGT was introduced in all cases).
- Easy insertion – insertion at first attempt with no resistance; difficult insertion –insertion with resistance or at second attempt; and failed insertion – insertion not possible.
- After 15 minutes of device insertion, inspiratory tidal volume, expiratory tidal volume, minute ventilation, leak volume and leak fraction were recorded.
- Oxygen saturation (SpO_2) and end-tidal carbon dioxide ($EtCO_2$).
- Incidences of gastric distension (by surgeon), regurgitation, aspiration, intra-operative and post-operative laryngopharyngeal morbidity were noted.
- Blood staining of the device on removal.
- Duration of surgery and duration of anaesthesia were noted.

Post-operative sore throat was recorded in the recovery room and graded at 6^{th} and 24^{th} post-operative hours as follows:

- Grade 0- no sore throat.
- Grade 1- mild sore throat (pain on swallowing solids).
- Grade 2- moderate sore throat (pain on swallowing liquids).
- Grade 3- severe sore throat (pain even on swallowing).

Statistical analysis

The sample size was determined by power analysis with $\alpha = 0.05$ and the power of 0.9. Data were collected, tabulated, coded and then analyzed using SPSS® computer software version 6.6. Numerical variables were presented as mean and standard deviation (SD) while categorical variables were presented as percent. As regard to numerical variables, unpaired student-t test was used for inter-group comparison while intra-group analysis was done using the paired Student's t-test. Fisher's exact test was used for categorical data. p-value < 0.05 was considered as significant.

III. RESULT

In this study, no significant difference was found based on the demographic variables, namely age, sex, co-morbidity, MPG and ASA grade between group P and group E (p value > 0.05, non-

significant) (Table 1). The types of surgery, duration of the surgical procedure and duration of anaesthesia were comparable in both the groups (p value > 0.05, non-significant) (Table 2).

Table 1: Demographic and surgery related variables

Variables		Group P	Group E	p-value
Age (Mean±SD) (years)		34.3±13.1	36.63±12.54	0.484
Gender	Male	7	8	0.88
	Female	23	22	0.79
Co-morbidity	Present	5	6	0.9
	Absent	25	24	0.76
MPG	I	17	16	0.84
	II	13	14	0.86
ASA Grade	I	25	24	0.76
	II	5	6	0.89

Table 2: Surgery related variables

	Group P		Group E		p-value
Type of surgery	n	%	n	%	
Diagnostic Hysterolaparoscopy	1	3.33	2	6.66	0.92
Diagnostic Laparoscopy	4	13.33	4	13.33	1
Lap Appendicectomy	7	23.33	7	23.33	1
Lap Cholecystectomy	16	53.33	14	46.66	0.72
Laparoscopic assisted vaginal hysterectomy	2	6.66	3	10	0.9
Duration of Surgery (Mean±SD) (min)	59.73±20.53		53.23±12.33		0.142
Duration of Anaesthesia (Mean±SD) (min)	68.53±20.03		60.46±12.91		0.068

In group PLMA, (Table 3) device insertion success rate was 100% for the first attempt. Insertion was easy in all 30 patients. In group ETT, the device insertion success rate was 93.33% for the first attempt; two attempts were made in 6.66% of patients whereas insertion was easy in 27 patients and difficult in 3 patients. The difference is non-significant as p-value is >0.05. Neither third attempt nor failed insertion reported in either group. Mean time (range) taken for successful device placement was 20.3 s (19.07-21.53 s) and 27.5 s (26.19-28.81 s) for PLMA and ETT, respectively with p-value=0.0051 which is highly significant due to avoidance of direct laryngoscopy in group P (Fig 1).

In group P, (Table 3, Fig. 2) gastric tube was inserted easily through drain port in all 30 patients (100%) due to its preformed structure. In group E, insertion of gastric tube was easy in 23 patients (76.66%) and difficult in 7 patients (23.33%). The difference was statistically significant between the two groups (p-value =0.005).

Table 3: Device insertion characteristics

Characteristics		Group P	Group E	p-value
Attempt of airway device insertion (1/2/3/ failed)		30/0/0/0	28/02/0/0	0.15
Ease of insertion of airway device (%)	Easy	100	90	0.07
	Difficult	0	10	
Time taken for insertion of device, Mean (SD) (s)		20.3 (1.23)	27.5 (1.31)	0.0051
Ease of insertion of gastric tube (%)	Easy	100	76.66	0.005
	Difficult	0	23.33	

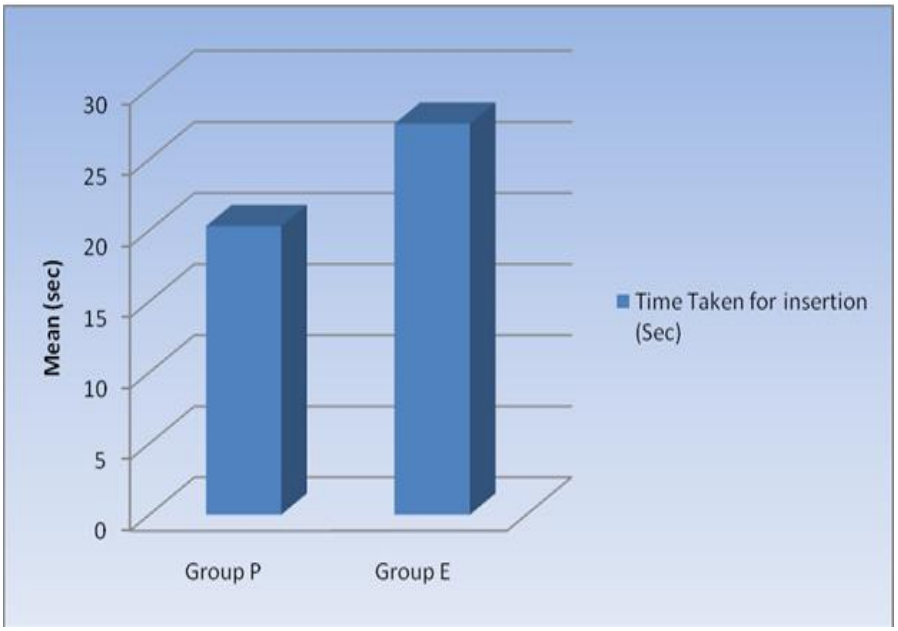

Fig 1: Time taken for airway device insertion

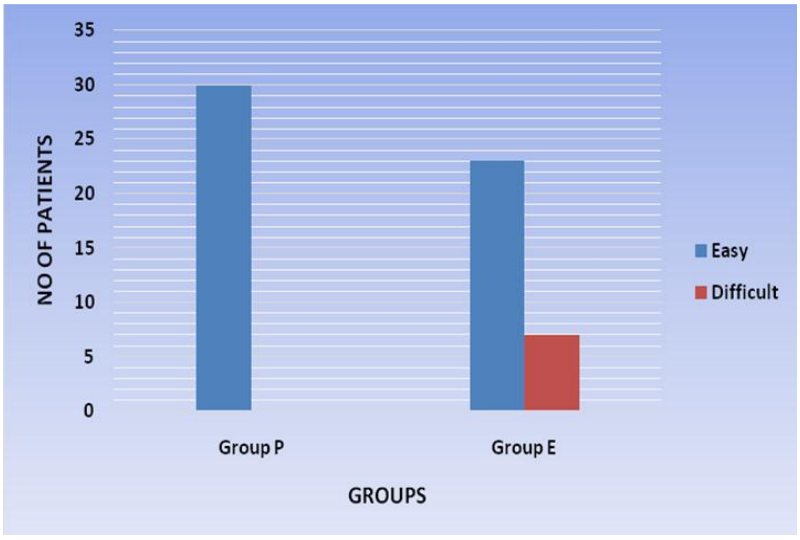

Fig 2: Ease of insertion of gastric tube

On comparing the trends within the groups, after device insertion and during pneumo-peritoneum, haemodynamic parameters (heart rate, SBP, DBP and MAP) were comparable in both groups though the increase in these parameters were more and for longer duration in group E (p-value >0.05) (Fig. 3 and 4). Ten min after extubation, heart rate and blood pressure increased significantly more in group E (p-value <0.05) because unlike ETT, SADs does not cause stimulation of sympathoadrenal axis thus offering less haemodynamic perturbations compared to ETT.

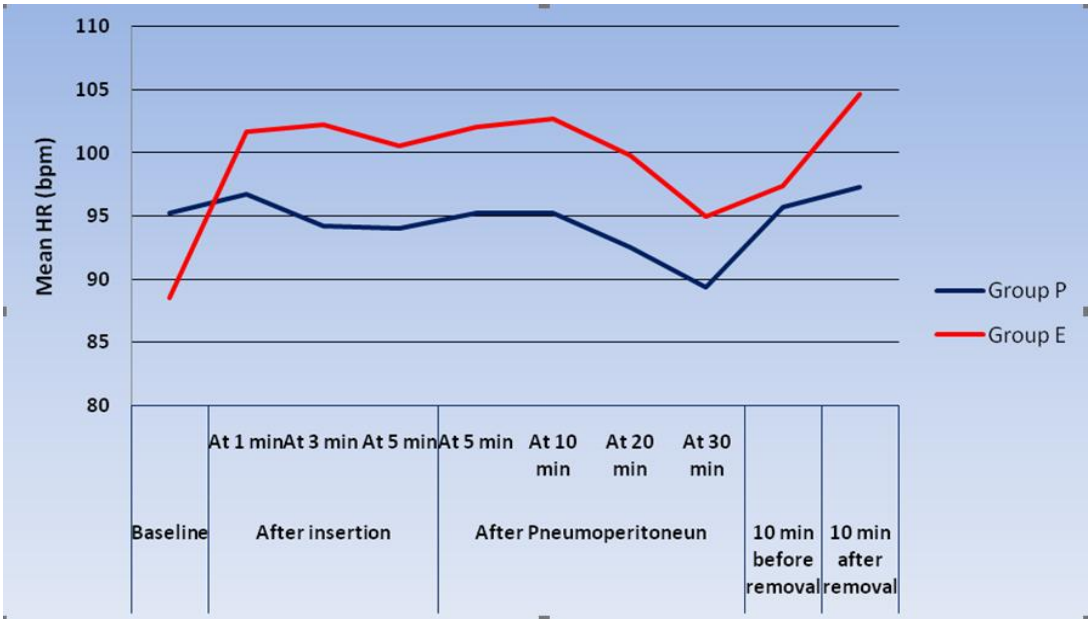

Fig 3: Comparison of heart rate within and between groups

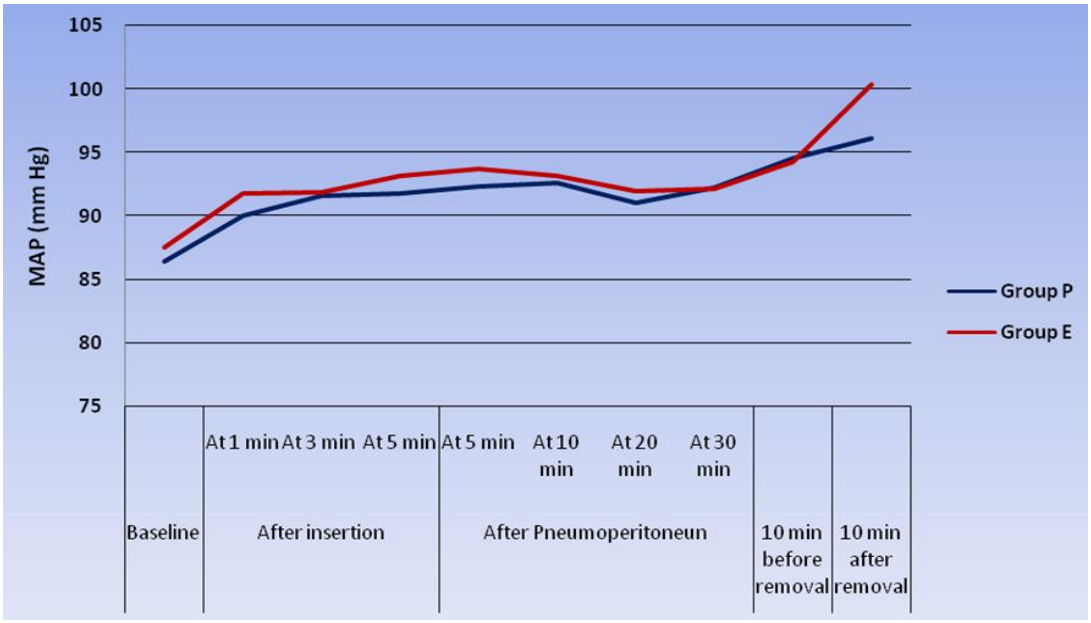

Fig 4: Comparison of Mean blood pressure within and between groups

The SpO_2 and $EtCO_2$ in group P and group E remained stable throughout the procedure when compared to baseline values and the difference between two groups is statistically non-significant (p-value >0.05). The difference in ventilation measurements of minute volume, leak volume and leak fraction between PLMA and ETT groups were not statistically significant (p-value>0.05), either before or during peritoneal insufflation (Table 4).

Table 4: Comparison of Intraoperative Ventilatory Parameters

Intraoperative Ventilatory Parameters	Group P (Mean± SD)	Group E (Mean± SD)	p-value
ITV (ml)	411.83±46.63	401.5±38.35	0.35
ETV (ml)	409.83±46.98	398.03±38.06	0.28
MV (l/min)	5.45±0.55	5.24±0.39	0.09
LV (ml)	2.26±2.04	3.46±2.89	0.06
LF	0.005±0.005	0.0087±0.007	0.06

In the present study, (Table 5) coughing after removal of PLMA was not seen in any patient, while it was seen in 6.67% patients in the ETT group. Blood staining of airway device on removal was seen in 3.33% (1/30) patients in group P and in 10% (3/30) patients in group E (p=0.09, non-significant). Minor trauma to the lip and gums was seen in 2 patients (6.67%) in group E. There was no incidence of intra-operative or post-operative laryngospasm, bronchospasm, in either group. There was no incidence of gastric distension, regurgitation or clinically detectable pulmonary aspiration in either group. Sore throat post-operatively was seen in 3.33% (1/30) patients in group P and in 53.33% (16/30) patients in group E. Post-operatively at 6 hours, no patient in group P but 8 patients (26.67%) in E group complained of sore throat which was restricted to only 1 patient (3.33%) in group E at 24 hours post-operatively (Fig. 5).

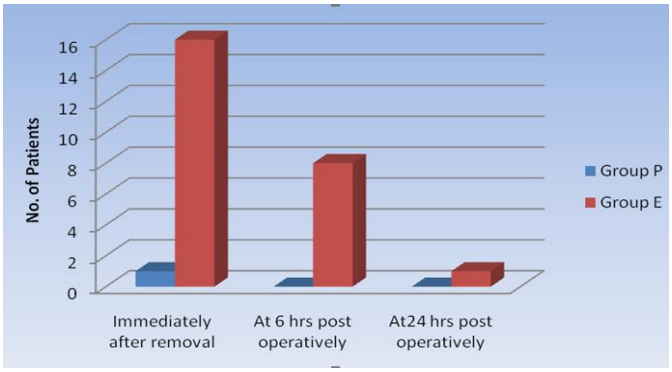

Fig 5: Post-operative Sore throat

Table 5: Laryngopharyngeal morbidity

		Group P (n)	Group E (n)	p-value
Intra-operative	Gastric insufflation	-	-	-
	Regurgitation	-	-	-
	Aspiration	-	-	-
At removal	Coughing	0	2	-
	Blood staining of device	1	3	0.09
	Minor trauma to lip, tongue or teeth	0	2	-
Post-operative sore throat	Immediately	1	16	0.001
	At 6 h	0	8	
	At 24 h	0	8	

IV. DISCUSSION

Supraglottic airway devices (SADs) are gaining popularity as preferred devices for elective and emergency airway management[8]. The PLMA, a second-generation SAD, has a flexible, non-kinkable airway tube with a drain tube (double-tube design) and double-cuff which are added safety features over the classic LMA. The Fourth National Audit Project and the All India Difficult Airway Association (AIDAA) have encouraged the use of second-generation SADs equipped with the passage of a gastric tube in difficult airway scenarios. This study was conducted with the aim of comparing PLMA and ETT as a ventilatory device in 60 patients undergoing elective laparoscopic surgeries under general anaesthesia. We choose this study because increased intra-abdominal pressure from pneumoperitoneum requires higher airway pressures for adequate pulmonary ventilation, for which the PLMA has proved to be adequate in previous[2, 9-10] studies. Although PLMA was easier to insert with higher success rate (100%) in the first attempt than the ETT (93.33%), this was not statistically significant (p-value=0.15). Mean time taken for successful airway device placement was 20.3 s and 27.5 s for groups P and E, respectively (p-value=0.0051). Study by Sharma B et al[11] (mean insertion time 12 s) corroborated with our study findings. In a study conducted by Saraswat N et al[12], mean time (range) taken for successful device placement was 15.77 s (12-21 s) and 16.93 s (11-28 s) for PLMA and ETT, respectively. This significantly lesser time for PLMA insertion could be attributed to avoidance of direct laryngoscopy in group P.

A nasogastric tube (NGT) was inserted in all patients. The success rate of NGT insertion was higher (100%) via Proseal due to its preformed gastric port than via nasal route in intubated patients (76.66%). Our results are consistent with Sharma B et al[11] who successfully placed gastric tube on first attempt in all the 1000 patients. These factors may be of clinical relevance in patients with hypertension, head injury, and ischaemic heart disease.

There was minimum haemodynamic stress response with PLMA when compared with endotracheal intubation. These findings are similar to those of previous studies done by Saraswat et al[12], Borkataki

et al[13], Malviya PS et al[14]. The increase in heart rate and BP during intubation is attributed to sympathoadrenal stimulation during laryngoscopy and the passage of the ETT through the vocal cords. The PLMA being a supraglottic device probably does not evoke a significant sympathetic response due to the fact that the PLMA is relatively simple and atraumatic to insert and does not require laryngoscopy. Similarly, Parikh SS et al[15] and Veena G et al[16] found better haemodynamic stability in group PLMA as compared to group ETT.

Both groups maintained adequate oxygenation and ventilation perioperatively similar to results of study done by Malty JR et al[17], and Malviya PS et al[14]. In a study by Saraswat et al[12], in one patient of PLMA group, oxygen saturation dropped to 94% (suboptimal oxygenation) after placing the patient in reverse Trendelenburg position which returned to normal after repositioning of PLMA. However, Sharma and colleagues[11] in a later study noted that although all patients had optimal oxygenation, three patients had $EtCO_2$ in excess of 55 mm Hg after CO_2 insufflation. This was explained by the fact that the airway tube was narrow and the epiglottis downfolded in some patients. The incidence of epiglottic downfolding has been reported to be as high as 31-66%. The present study found that Proseal LMA provided equally effective minute volume as Endotracheal tube and the difference between these two devices with respect to minute volume, leak fraction and leak volume is found to be statistically non-significant. Our results are in accordance with Malty JR et al[17] who reported that the difference in ventilation measurements of minute volume and airway pressure between PLMA and ETT groups were not statistically significant, either before or during peritoneal insufflation.

There was no incidence of regurgitation or aspiration in either group. Similar results have been reported by others[10, 18]. At device removal, coughing; minor trauma to lips, tongue, and teeth; and blood staining of device were found to be more in ETT group as compared to PLMA though the difference was statistically insignificant. Our results were similar to Malviya PS et al[14] who reported that blood staining of device was not seen in group PLMA and seen in 6/30 (20%) patients in ETT group. In present study, the incidence of sore throat was significantly more in the intubation group E (53.33%) than in group P (3.33%) and results were consistent with Saraswat et al[12], Borkataki et al[13], and Malviya PS et al[14]. All patients were administered gargles and steam inhalation. After 24 hours, none of the patients in the Proseal group had sore throat; however, 1 patient in group E had persistent sore throat till 30 hours. The virtual absence of sore throat in PLMA group could be explained by the fact that it is a supraglottic device and mucosal pressures achieved are usually below pharyngeal perfusion pressures.

Although endotracheal intubation is the gold standard in laparoscopic surgeries done under general anaesthesia, the PLMA proved to be an equally effective airway device in laparoscopic surgeries in terms of adequate oxygenation and ventilation, lesser haemodynamic perturbations and minimum intra-operative and post-operative complications. It provided equally effective pulmonary ventilation despite high airway pressures without significant gastric distension, aspiration, and regurgitation.

The present study was a single-centre study with a relatively small sample size. More studies are required to confirm the overall safety profile of Proseal LMA. The unavailability of microchip sensor limited this study from measuring pharyngeal mucosal pressure directly. Besides this, in patients with difficult airway coming for elective surgery, use of Proseal LMA can avoid unnecessary trauma to the airway while maintaining good oxygenation and adequate ventilation but as this study involved only patients with a normal airway, whether the same outcome can be extrapolated to patients with difficult airway needs further study.

V. CONCLUSION

Hence, we conclude that The Proseal LMA is an excellent and safe alternative airway device to Endotracheal tube for providing adequate positive pressure ventilation in elective laparoscopic surgery with better haemodynamic response, ease of insertion, less time taken for insertion, less number of attempts for successful placement, with the added advantage of easy placement of orogastric tube causing less damage to airway and significantly less post-operative airway morbidity.

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