Comparison of proseal laryngeal mask airway versus endotracheal tube in laparoscopic abdominal surgeries under general anaesthesia- a clinical study.

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Abstract

Background: Traditional open surgeries are progressing to minimally invasive keyhole laparoscopic surgeries. Simultaneously, airway management of patients has also progressed from insufflations to endotracheal intubation (ETT) to lesser invasive devices like Pro Seallary ngeal mask airway (PLMA). Hence, the present study was undertaken to compare the efficacy of PLMA with the standard PVC endotracheal tube in patients posted for elective laparoscopic abdominal surgery under general anaesthesia.**Method:** Total 60 adult patients of ASA grade I or II, age between 18-60 years were enrolled in the study and divided into two equal groups. Group P was proseal laryngeal mask airway group and group E underwent endotracheal intubation. The ease and time for insertion, hemodynamic stress response and postoperative laryngopharyngeal morbidity was notedand compared between two groups. **Results:** The time required to insert the PLMA was less(16.96 seconds) than that of endotracheal tube (22.16 seconds). In group P, insertion was easy (first attempt) in 90% and in group E, 86.6% patients. Hemodynamic response was significantly lower ($p<0.05$) in the PLMA group upto five minutes of insertion of device. Mean time required passing the nasogastric tube in group P was 10.66 seconds and in group E was 20.23 seconds. Postoperative laryngopharyngeal morbidity was less (9.9%) with the PLMA than the endotracheal tube (53.3%). Intraoperative oxygenation and ventilation was adequate in both the groups. **Conclusion:** Thus, the proseal laryngeal mask airway proved to be a suitable and safe alternative to endotracheal tube for airway management in elective, fasted adult patients undergoing laparoscopic surgeries.

Keywords: Endotracheal tube, ProSeal laryngeal mask airway, Laparoscopy, General anaesthesia, Insertion, Laryngo pharyngeal morbidity

Introduction

General anesthesia has undergone many refinements and advances in the last few decades [1]. Respiratory events are the most common anesthetic related injuries, following dental damage. Difficult tracheal intubation accounts for 17% of the respiratory related

injuries and results in significant morbidity and mortality. In fact upto 28% of all anesthesia related deaths are secondary to inability to mask ventilate or intubate [2]. Laryngeal mask airway (LMA) is a suitable alternative to the facemask or tracheal intubation in a wide variety of clinical situations. LMA fills a niche between facemask and endotracheal tube in terms of both anatomical position and degree of invasiveness.However, it was introduced by Dr. Brain in 1980s and caused a revolution in airway management. Today, this device has special position in anesthesiology procedures and among many of anesthesiologists. LMA provides a proper way for ventilating the patient while protecting his or her airway. But usage of LMA is limited by the potential risk of aspiration or low pulmonary compliance [3] and ithas challenged the standard ETT used during general anesthesia.

In 2000, Dr Archie Brain introduced a new design Proseal LMA to provide airway protection in full stomach patients to prevent aspiration. Modification in Proseal LMA provides effective separation of GIT and respiratory tract improves the airway seal and provides good effective controlled ventilation. Proseal laryngeal mask airway 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 pressure without leak. The drain tube parallel to the ventilation tube permits drainage of passively regurgitated gastric fluid away from the airway and serves as a passage for gastric tube [4]. The PLMA is a relatively new airway device in developing countries. Hence the present study was undertaken to compare PLMA with endotracheal tube for the number of attempts and time taken for insertion, oxygenation, ventilation, hemodynamic stress response and postoperative laryngopharyngeal morbidity occurring during general anaesthesia in young healthy adult patients undergoing laproscopic abdominal surgeries.

Materials and methods

After obtaining Institutional Ethical Committee approval and written informed consent from all the patients, this prospective randomized study was conducted in 60 adult patients of ASA grade I or II, age between 18-60 years, posted for laparoscopic abdominal surgeries under general anaesthesia. Patients with increased risk of aspiration (history of gastro-oesophageal reflux disease, hiatus hernia, and pregnant patients), obesity (body mass index > 30 kg/sq. meters), oropharyngeal pathology, cardiopulmonary disease, cervical spines fracture or instability, malampatti grading III, IV and patients not willing to participate were excluded from the study.

Patients were randomized for airway management into two equal groups. Group P was proseal laryngeal mask airway group and group E was to undergo endotracheal intubation with standard PVC cuffed ETT. Patients were pre-medicated with oral Tab. Alprazolam 0.25 mg the night before surgery. After intravenous access was obtained in waiting room, inj. Ranitidine 50 mg IV was administered 30 minutes prior to surgery. Inside the operation theatre, monitors for NIBP, ECG and SpO2 were attached to patients

and baseline parameters were noted. Intravenous injection glycopyrrolate 0.005 mg/kg, midazolam 0.02 mg/kg and fentanyl 1 mcg/kg were administered 2-3 minutes prior to induction in both the groups. After pre-oxygenation with 100% oxygen for 5 minutes, anesthesia was induced with injection propofol 2 mg/kg and suxamethonium 2 mg/kg following induction and complete respiratory paralysis, the corresponding airway devices was inserted in each group. The airway devices were inserted by anesthesiologists with at least 1 year experience with LMA and endotracheal tube. In group P, size 3 or 4 PLMA (according to weight of the patient) was used. In group E, endotracheal intubation was performed with standard Macintosh laryngoscope with blade size 3 or 4 and appropriate size cuffed PVC endotracheal tube was inserted.Time for insertion was recorded from opening of mouth to inflation of cuff after placement of airway device. Correct placement of device was confirmed by adequate chest movement on manual ventilation and square wave capnography. Anesthesia was maintained with oxygen, nitrous oxide 50:50 and sevoflurane on closed circuit with controlled ventilation. Injection vecuronium 0.08 mg/kg was given for muscle paralysis.

Outcomes measured were insertion characteristics of PLMA or cuffed endotracheal tube and nasogastric tube, ease of insertion grades for PLMA and ETT, hemodynamic responses were noted before induction, immediately after insertion, 5, 10 and 15 minutes interval after insertion of airway devices. Rise in heart rate or mean arterial pressure by 10% from pre induction values was considered significant. SpO2 and EtCO2 parameters recorded immediately and at 5, 10 and 15 minutes interval after insertion of airway devices. The aim was to maintain target SpO2 (>95%) and EtCO2 (<45 mm Hg) by appropriate ventilation, respiratory rate and tidal volume. When SpO2 was 94-90% the oxygenation was graded as suboptimal and failed if it was <90%. Postoperative laryngopharyngeal morbidity in the form of sore throat, cough and hoarseness of voice or dysphagia if any was noted up to 48 hours.

Statistical Analysis

Data analysis was done in software STATA, version 10.4, 2009. Categorical variables were summarized in terms of frequencies and percentages. Continuous variables were summarized in terms of mean and standard deviation. Differences in mean of two groups were compared with t-test for two independent samples. Difference in properties of two groups was compared with Chi square test and Fischer's exact test. P value less than 0.05 was considered statistically significant.

Observations and Results

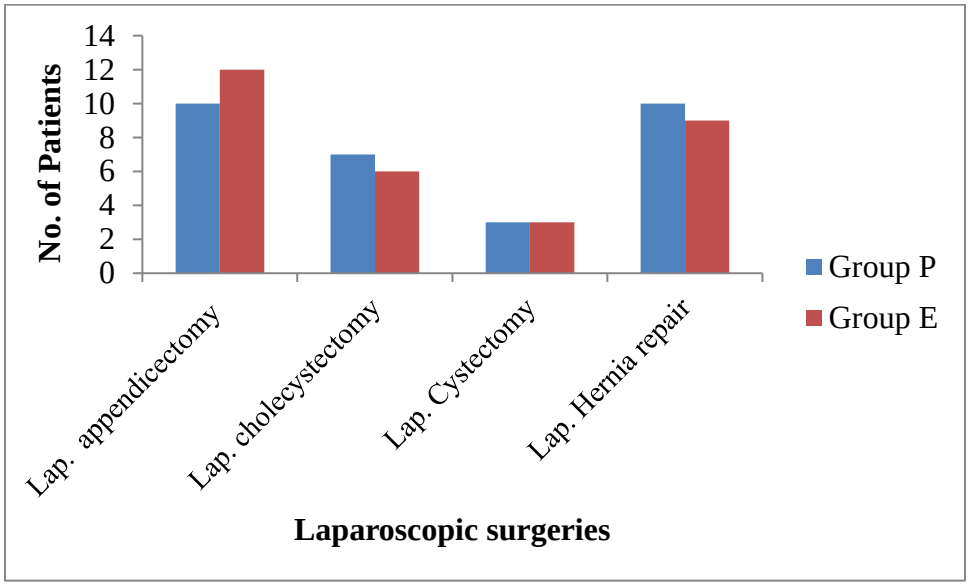
Table 1 shown the demographic data of the patients and which was comparable in both the groups, there was no statistically significant difference between two groups ($p>0.05$).

Table 1: Demographic profile of the patients

Age group (years)		Group P	Group E
20-30		6 (20%)	3 (10%)
30-40		7 (23.3%)	4 (13.3%)
40-50		13 (43.4%)	18 (60%)
50-60		4 (13.3%)	5 (16.7%)
Sex	Male	11 (36.33%)	15 (50%)
	Female	19 (63.67%)	15 (50%)
ASA Grade	I	16 (53.33%)	18 (60%)
	II	14 (46.67%)	12 (40%)

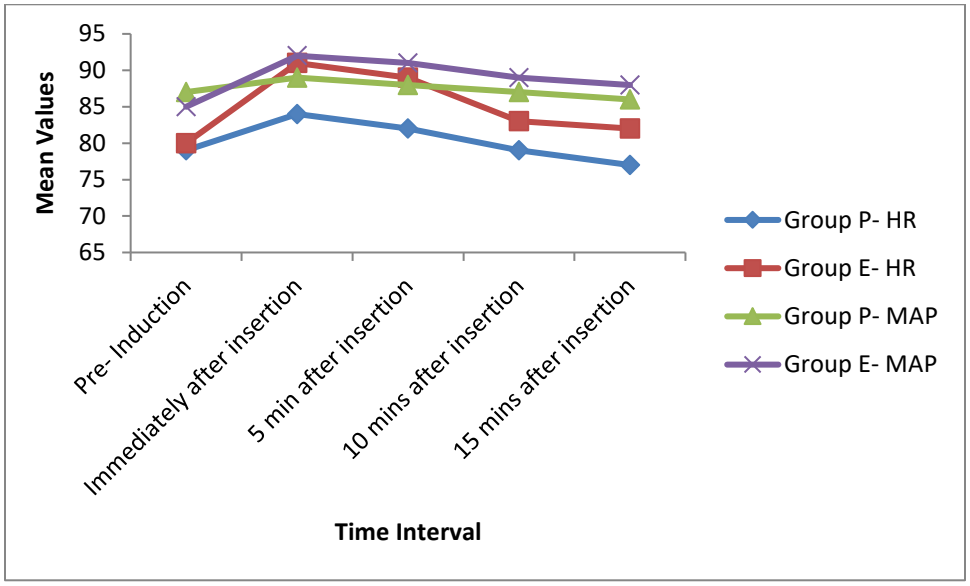
Laparoscopic surgeries were included in the study and distributions of patient according to type of surgeries are depicted in figure 1.

Figure 1: Operative procedures



The mean time for insertion in group P was 16.96±3.96 sec and in group E was 22.16±6.41 sec. There was statistically significant difference was found between groups, (p=0.0004). In group P, insertion was easy (first attempt) in 27 (90%) patients and difficult in 3 (10%) patients while in group E, insertion was easy in 26(86.6%) patients and difficult in 4 (13.33%) patients. There was no statistically significant difference in between two groups, (p=0.68).Hemodynamic response was significantly lower (p<0.05) in the proseal LMA group upto five minutes of insertion of devicethan in group E as shown in figure 2.

Figure 2: Comparison of hemodynamic parameters between two groups



There was statistically significant difference in rise in heart rate and mean arterial pressure from pre induction values was seen up to five minutes after insertion of airway device, (Table 2).

Table 2: No. of patients with more than 10% rise in heart rate and MAP

Time interval	10% rise in HR			10% rise in MAP		
	Group P	Group E	P value	Group P	Group E	P value
Immediately after insertion	5 (16.6%)	22 (73%)	0.001	3 (10%)	15 (50%)	0.001
5 min after insertion	2 (6.67%)	16 (53.3%)	0.001	1 (3.3%)	13 (43%)	0.001
10 min after insertion	0 (0%)	4 (13.3%)	0.056	-	-	-

Mean time required passing the nasogastric tube in group P was 10.66±2.50 seconds and in group E was 20.23±4.18 seconds. There was statistically significant difference was found in the time required to pass the nasogastric tube among groups, (0.0001).Postoperative laryngopharyngeal morbidity was 9.9% in group P and 53.3% in

group E which showed a statistically significant difference (p<0.05), (Table 3). Intraoperative oxygenation and ventilation was adequate in both groups.

Table 3: Postoperative laryngopharyngeal morbidity in two groups

Complications	Group P	Group E	P Value
Sore throat	1 (3.3%)	6 (20%)	<0.05
Cough	2 (6.6%)	9 (30%)	<0.05
Dysphagia	0 (0%)	1(3.3%)	<0.05
Total	3 (9.9%)	16 (53.3%)	0.004

Discussion

Laparoscopic surgeries are day care surgery because it is minimally invasive surgery. So, in present study 60 adult patients belonging to ASA I or II undergoing elective laparoscopic abdominal surgery under general anaesthesia were selected. All patients were given balanced general anaesthesia with controlled ventilation. Anesthetic technique used was standardized.The major responsibility of the anesthesiologist is to provide adequate ventilation to the patient. The PLMA is a new entrant to the family of LMAwith some added features over the classic LMA [6]and PLMA has been proved to be adequate in previous studies [4, 7, 8]. Therefore, current study was conducted with the aim of comparingPLMA and ETT as a ventilatory device.

The demographic data (age and gender) and surgical procedures were comparable between two groups which is similar to the study done by Saraswat et al [3].Time for insertion was measured from opening of mouth to inflation of cuff after placement of airway device. All the devices were inserted by skilledanaesthesiologists along with the investigator. The mean time required to insert the proseal LMA was less (16.96±3.96 sec) than that of endotracheal tube (22.16±6.41 sec) and difference between two groups was statistically significant, this finding is in accordance with the findings of previous studies [3, 8, and 9]. All these studies reported lesser mean time for PLMA insertion and this lesser time could be attributed to the fact that their study was conducted by anaesthesiologists who had more experience in working with PLMA. Although PLMA was easier to insert with higher success rate (90%) in the first attempt than the ETT (86.6%),this was not statistically significant.The finger insertion method was used by Evans et al [14]. There was no incidence of failed insertions of devices in either group, which is comparable with the study done by Saraswat et al [3] and Patel et al [10].

After correct placement, oxygenation and ventilation was adequate in both groups. Intra-operatively, the EtCO2 was comparable in both groups and did not increase beyond 45 mm Hg and also SpO2 did not fall below 98% in either group, this finding is correlated

with the other studies [11-13]. There were no observation of crossovers and no clinically significant difference in SpO2 and EtCO2 or airway pressures before or during peritoneal insufflations in either group as similar to the study by Maltby et al [13]. Thus the proseal LMA and endotracheal tube showed similar efficacy in oxygenation and ventilation in laparoscopic surgeries with controlled ventilation.

There was minimum haemodynamic stress responsewith PLMA when compared with endotracheal intubation; this finding is similar to those of previous studies [7, 12, and 14].The increase in heart rate during intubation is attributedto sympathetic stimulation during laryngoscopyand the passage of the ETT through the vocalcords [7, 15, and 16]. The PLMA being a supraglottic device doesnot require laryngoscopy and probably does not evokea significant sympathetic response. Attenuation of thisresponse may be due to diminished catecholaminerelease [17]. This could be due to the fact that the PLMAis relatively simple and atraumatic to insert and doesnot require laryngoscopy [16]. In current study, there was statistically significant difference in rise in heart rate and mean arterial pressure from pre induction values was seen up to five minutes after insertion of airway device.

Insertion of nasogastric tube was successful in all the cases; there were no cases of failure of insertion in either group.Inproseal LMA, it was inserted via the drain tube and in endotracheal group, it was inserted nasally. Insertion time of nasogastric tube was significantly less in PLMA group. There was statistically significant difference was found in the time required to pass the nasogastric tube in two groups, (0.0001).These results are correlatedwith the earlier studies [6, 8, and 18].Post-operative laryngo-pharyngeal morbidity was noted in both the groups. Incidence of sore throat in group P was 3.3% and in group E was 20%. Incidence of cough in group P was 6.6% and in group E was30%. There was no dysphagia I group P while in group E, 1 patient had dysphagia. In all incidence of post-operative laryngo-pharyngeal morbidity was less i.e. 9.9% in group P and 53.3% in group E which showed a statistically significant difference. Similar results have been reported by other authors [9, 18 and 19]. We have not faced the problem of ventilation and desaturation.

Conclusion

From the results of present study, it can be concluded that the proseal laryngeal mask airway is a suitable and safe alternative to endotracheal tube for airway management in elective, fasted adult patients undergoing laparoscopic surgeries.

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