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A Comparative Evaluation of the Laryngeal Mask Airway Proseal and Tracheal Intubation for Laparoscopic Cholecystectomy

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Abstract

The study evaluated 60 adult patients of either sex belonging to ASA grade I & II, who were randomly allocated into 2 groups of 30 each; Group I-Proseal LMA group and Group II -ETT group. They were premedicated with inj. glycopyrrolate 5-10 mcg/kg and inj.butarphanol 2mg intramuscular 45 minutes prior to surgery. Patients were preoxygenated & anaesthesia was induced using oxygen + inj. propofol (2mg/kg) + isoflurane + inj. vecuronium bromide (0.1 mg/kg). PLMA or ETT was inserted as per group. Insertion characteristics i.e. ease of insertion and insertion time were noted. A 16Fr gastric tube was passed into the stomach in every patient and connected to continuous suction. Anesthesia was maintained with nitrous oxide, oxygen, isoflurane and inj. vecuronium bromide. Ventilation was set at 10 ml/kg and 15 breaths/min. The demographic data of both the groups were comparable. The mean age in this study was 42.2 years (22 females and 8 males) in Group I (PLMA) and 40.8 years (23 females and 7 males) in Group II (ETT). The mean BMI of patients in Group I was 22.7 kg/m² and in Group II was 23.1 kg/m². Insertion of device was graded as easy in 93% of patients in PLMA group and 96% of patients in ETT group. Mean time taken for successful placement of device in PLMA group was 15.83 s and in ETT group was 17.1 s, which was, however, statistically insignificant (p value = 0.095). The insertion of NGT through drain tube of PLMA was easier than via nose in ETT group. The mean insertion time taken to insert NGT through PLMA was significantly less (10.03 s) than via nose (12.7 s) in intubated patients. The anesthetic and peritoneal insufflation times in both groups were comparable. . The ventilation was adequate to maintain SpO₂ of 99% - 100% in both the groups. Based on the study ,it may be said that ,Proseal laryngeal mask airway seemed to be a safe and effective alternative to endotracheal intubation in patients of laparoscopic cholecystectomy.

Key words: laryngeal mask airway, Tracheal Intubation, Laparoscopic Cholecystectomy

Introduction

The laryngeal mask airway (LMA) is a novel supraglottic airway device designed to secure the airway by establishing an end to end circumferential seal around the laryngeal inlet. It is a useful advancement in the airway management, filling a niche between face mask and endotracheal tube. Later improvements were made in construction of prototypes which became available in a range of different sizes. Further studies were conducted & the results have so far confirmed the safety & efficacy of laryngeal mask airway as an alternative to facemask in spontaneously breathing patients.)

On comparison of a facemask & oral airway under anesthesia with LMA, patients with LMA had fewer desaturation episodes, decreased intraoperative airway manipulations and less difficulties in maintaining the airway. LMA when compared with endotracheal tube has a lesser incidence of post operative airway related complications including sore throat, croup and hoarseness, minimal cardiovascular response and better tolerability at lighter planes of anesthesia. Also it can be inserted easily without direct visualization or use of neuromuscular blocking agents and the patients can spontaneously breathe throughout the procedure. 2,3,4 Though the LMA has provided the convenience of "Hands-free" anesthesia, for some anesthesiologists, the combination of LMA and positive pressure ventilation evokes fear of inadequate ventilation, gastric distension and pulmonary aspiration of gastric contents.

LMA presell (PLMA) is a reusable supraglottic airway device offering gastric access PLMA provides better airway protection during regurgitation than LMA. A properly positioned PLMA isolates the airway from fluid within the hypo pharynx.

Materials and Methods

A randomized prospective study was done on 60 patients of ASA physical status I and II of age 18-65 years posted for elective laparoscopic cholecystectomy under general anesthesia at Guru Nanak Dev Hospital attached to Government Medical College, Amritsar.

Exclusion criteria:

- Age less than 18 years and above 65years
- Body mass index > 30 kg/m²
- Mallampatti classification >II
- Symptoms related to laryngopharyngeal abnormality.
- Musculoskeletal abnormalities affecting the cervical vertebrae.

GROUP ALLOCATION

The patients were allocated into 2 groups of 30 each:

1. Group P: PLMA for airway management
2. Group E: ETT for airway management

Observations

The present study was conducted on 60 adult patients, belonging to ASA grade I & II, scheduled for laparoscopic cholecystectomy under general anesthesia. These patients were randomly allocated into 2 groups of 30 each.

Group I (n= 30) - PLMA group; Group II (n=30) - ETT group

All data were collected, tabulated and expressed as Mean: standard deviation. Appropriate statistical analysis was conducted and the data were compared using student's t test. P values were calculated for all tests. A p value < 0.05 was considered as statistically significant, p value <0.001 was considered as highly significant and >0.05 was considered as not significant. The summated results are below.

AGE OF PATIENTS

The mean age was observed to be 42.2 years in Group I and 40.8 years in Group II. The difference in mean age of patients between two groups was statistically insignificant ($p>0.05$).

TABLE I: AGE OF PATIENTS

	Group I (PLMAJ)	Group II (ETT)	Statistical analysis
Mean \pm S.D.	42.2 \pm 11.32 years	40.8 \pm 12.01 years	p value - 0.465 ; NS

Non-significant ($p>0.05$)

SEX DISTRIBUTION OF PATIENTS

In the present study, Group I comprised of 22 females and 8 males and in Group II there were 23 females and 7 males. The difference in sex distribution of patients was statistically insignificant ($p>0.05$).

TABLE 2: SEX DISTRIBUTION OF PATIENT

	Group I (PLMA)	Group II (EIT)	Statistical analysis
Females	22	23	P value = 0.766;NS
Males	8	7	

BODY MASS INDEX OF PATIENTS

The mean BMI of patients in Group I was 22.7:1:2.05 kg/m² and in Group II was 23.1:1:1.81 kg/m². The difference in mean BMI between the two groups was statistically insignificant ($p>0.05$).

TABLE 3: BMI OF PATIENTS

	Group I (PLMA)	Group II (ETT)	Statistical analysis
Mean \pm S.D.	22.7 \pm 2.05 kg/m	23.1 \pm 1.81 kg/m	p value=0.426; NS

NS- Non significant ($p>0.05$)

DEVICE INSERTIONAL CHARACTERISTICS

a) EASE OF INSERTION

The insertion of the device was easy in 28 and moderately difficult in 2 patients of Group I. The insertion of the device was easy in 29 patients and moderately difficult in 1 patient of Group II. This difference was however, statistically insignificant ($p>0.05$).

TABLE 4: EASE OF INSERTION

Ease of insertion	Group I (PLMA)	Group II (EIT)	Statistical analysis
Easy	28 (93%)	29 (96%)	P value = 0.554; NS
Moderately difficult	2	1	
Difficult	-	-	
Impossible	-	-	

NS-Non significant ($P>0.05$)

b) INSERTION TIME

The mean insertion time of the device was 158s(0.26min) ~ 3.1s in group I and 17.18 (0.28min) ~ 2.82s in group II. This difference was statistically insignificant ($p>0.05$).

TABLE 5: INSERTION TIME

	Group I (PLMA)	Group II (EIT)	Statistical analysis
Mean \pm S.D.	15.8 s (0.26min) \pm 3.1 s	17.1s (0.28min) \pm 2.82s	p value=0.095

NS- Non Significant ($p> 0.05$)

NASOGASTRIC TUBE INSERTIONAL CHARACTERISTICS

a) EASE OF INSERTION

The insertion of the nasogastric tube was easy in 27 patients of Group I and 24 patients of Group II. It was moderately difficult in 3 patients of Group I and 6 patients of Group II; which was statistically insignificant ($p>0.05$).

TABLE 6: EASE OF INSERTION

Ease of insertion	Group I (PLMA)	Group II (EIT)	Statistical analysis
Easy	27	24	P value=0.472; NS
Moderately difficult	3	6	
Difficult	-	-	
Impossible	-	-	

b) INSERTION TIME

The time taken for successful passage of NGT was 10.03 s (0.17min) \pm 1.47s 12.7s (0.21min) \pm 1.34s for groups I and II, respectively. The difference in insertion time of nasogastric tube between two groups was statistically significant.

TABLE 7: INSERTION TIME

	Group I (PLMA)	Group II (EIT)	Statistical analysis
Mean \pm S.D.	10.03 s (0.17min): \pm 1.47s	12.78 (0.21min) \pm 1.348	p value=0.000;S

ANAESTHETIC TIME

The mean anesthetic time in Group I was 84 \pm 12.08min and in Group II was 85.6 \pm 13.34min. This difference was statistically (p>0.05).

	Group I (pLMA)	Group II (Err)	Statistical analysis
Mean : \pm : S.D.	84 \pm 12.08 min	85.6 \pm 13.34 min	p value = 0.628; NS

PERITONEAL INSUFFLATION TIME

The mean peritoneal insufflation time in Group I was 75.27:12.20 min and in Group II was 75.87>13.18 min. This difference was statistically insignificant (p>0.05).

TABLE 9: PERITONEAL INSUFFLATION

	Group I (pLMA)	Group II (EIT)	Statistical analysis
Mean \pm : S.D.	75.27 \pm : 12.20min	75.87 \pm : 13.18min	p value =0.855; NS

Discussion

The PLMA is a new entrant to the family of LMA with some added features over the classic LMA. It serves as an acceptable device to maintain a clear airway and provide positive pressure ventilation. There has been

reportedly a reduced risk of gastric insufflation, regurgitation and aspiration of gastric contents associated with PLMA usage.

We conducted a study on 60 adult patients divided into 2 groups of 30 each in PLMA and

ETT group with the aim of comparing PLMA and ETT in laparoscopic cholecystectomy, based on ventilation parameters, ease of insertion of the device and nasogastric tube, gastric distension change, trauma and complications during extubation. The mean age in this study was 42.2 years in Group I (PLMA) and 40.8 years in Group II (ETT). Group I comprised of 22 females and 8 males and in Group II, there were 23 females and 7 males. The mean BMI of patients in Group I was 22.7:1:2.05kg/m² and in Group II was 23.1:i:1.81 kg/m², The demographic data was statistically insignificant.

EASE OF INSERTION OF DEVICE

The ease of insertion of device was graded as easy, moderately difficult, difficult and impossible. In our study, insertion was graded as easy in 93% of patients in PLMA group and 96% of patients in ETT group. The findings of our study are in concurrence with the study done by Miller et al.⁴⁰ Evans et al have also reported easy insertion of PLMA in majority of patients. 11

INSERTION TIME OF DEVICE

PLMA can be inserted using either the introducer, index finger or the thumb. For the purpose of standardization in our study, the index finger technique was used for insertion in all the cases. Mean time taken for successful placement of device in PLMA group was 15.83 s and in ETT group was 17.1 s, which was statistically insignificant (p value = 0.095). These findings are in concordance with the study done by Saraswat et al.⁴⁷ A study done by Cook et al³¹ and Shroff et al³⁹ also corroborated with our findings. Verghese et al⁸ found median insertion time of 15 sec in PLMA. Sharma et al in their study of 100 and 1,000 PLMA insertions, reported a PLMA mean insertion time of 13.51 sand 12 s, respectively. 35,43 This lesser time could be attributed to the fact that their study was conducted by anesthesiologists who had more experience in working with PLMA.

NASOGASTRIC TUBE INSERTIONAL CHARACTERISTICS

Nasogastric tube was inserted along with the device in all patients. The insertion of NGT through drain tube of PLMA was easier than via nose in ETT group. The mean insertion time taken to insert NGT through PLMA was significantly less (10.03 s) than via nose (12.7 s) in intubated patients. This difference in mean insertion time of NGT was statistically significant (p value <0.05). Our findings correlated with that of Saraswat et al wherein the mean insertion time of NGT in PLMA group was found to be 9.77s and in Err group was 11.5s. These factors may be of clinical relevance in patients with hypertension, head injury and ischemic heart disease.

ANAESTHETIC TIME AND PERITONEAL INSUFFLATION TIME

The duration of anesthesia was 84 ± 12.08 min in PLMA group and 85.6 ± 13.34 min in ETT group. The difference in anesthetic times in the two groups was found to be statistically insignificant (p value = 0.628). This is in accordance with study done by Lu et al.

The mean peritoneal insufflation time in Group I was 75.27 ± 12.20 min and in Group II was 75.87 ± 3.18 min. This difference was statistically insignificant ($P > 0.05$).

Conclusion

In this study, the PLMA and the ETT showed similar efficacy during Laparoscopic surgery under general anesthesia with controlled ventilation. PLMA aids easy and rapid insertion of the nasogastric tube. Though there is an increase in airway pressure during laparoscopy, PLMA provides adequate pulmonary ventilation, maintains oxygen saturation and effective elimination of carbon dioxide similar to endotracheal tube. Thus, Proseal laryngeal mask airway is a safe and effective alternative to endotracheal intubation in patients of laparoscopic cholecystectomy, positively influencing the parameters concerning the ease of intubation, time taken for intubation, gastric distension and pulmonary ventilation.

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