

Comparison of Safety and Efficacy of ProSeal Laryngeal Mask Array vs Endotracheal Intubation for Gynecological Diagnostic Laparoscopy

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ABSTRACT

This was a prospective randomized study comparing the safety and efficacy of ProSeal laryngeal mask array (PLMA) vs endotracheal intubation (ETI) in gynecological laparoscopic surgeries undertaken in 80 patients with American Society of Anesthesiologist I and II divided into two groups. The parameters assessed were insertion characteristics, hemodynamic response to insertion, gastric distension, and perioperative complications.

The demographic data were comparable. The first-time success rate was slightly higher for PLMA than for ETI. The time required for achieving effective airway was longer in ETI than in PLMA (25.6 ± 8.1 seconds for ETI vs 18.2 ± 5 seconds for PLMA).

The hemodynamic response to intubation/insertion was more in ETI group than in PLMA group, i.e., there was more rise in pulse rate and mean arterial pressure following ETI than PLMA insertion.

Intraoperatively, no episodes of laryngospasm, bronchospasm, desaturation, and inadequate ventilation were observed in both the groups. Postoperatively, sore throat complaints were observed more with ETI than with PLMA.

Keywords: Endotracheal tube, Hemodynamic parameters, Laparoscopic surgery, ProSeal laryngeal mask array.

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INTRODUCTION

Laparoscopic surgery is an evolving subspecialty with problems of carbon dioxide insufflation, raised abdominal pressure, and danger of regurgitation and pulmonary aspiration. Thus, airway management continues to be of paramount importance to anesthesiologists in order

to maintain adequate ventilation. Till date, the cuffed endotracheal tube (ET) was considered as the gold standard for providing a safe glottis seal, especially for laparoscopic surgeries under general anesthesia.¹ Disadvantages of tracheal intubation include hemodynamic responses to laryngoscopy and damage to the oropharyngeal structures at insertion along with postoperative sore throat. Thus, new airway devices have been added to the anesthesiologist's armamentarium.

"ProSeal laryngeal mask array (PLMA)" modification of Classic LMA is a useful tool in airway management. It differs from standard LMA having a drain tube in addition to a reinforced airway tube, which prevents the epiglottis from occluding the airway. It eliminates the use of aperture bars and prevents inadvertent gastric inflation. The additional dorsal cuff increases the seal, allowing higher seal than the standard LMA, for a given intracuff pressure. The built-in bite-block reduces the chances of damage to device by inadvertent biting by the teeth of the patient and danger of airway obstruction. It can be inserted using an introducer or the finger.²

Our study is to compare PLMA and laryngoscopic tracheal intubation for diagnostic laparoscopy in terms of ease of insertion, time taken for insertion, perioperative hemodynamic changes, oxygenation, ventilation, and perioperative laryngopharyngeal complications.

MATERIALS AND METHODS

This was a randomized prospective study conducted after the approval from the Institutional Ethics Review Board. The study involved comparison between PLMA and the ETI for gynecological laparoscopic surgery with respect to (1) time taken to secure airway; (2) perioperative hemodynamic response; (3) incidence of gastric distension and complications during perioperative period.

The study randomly allocated 80 patients in a tertiary care institute divided into two groups: Aged 18 to 65 years, posted for gynecological laparoscopy, American Society of Anesthesiologists (ASA) I and II, and weight 32 to 75 kg. Patients with inadequate mouth opening (less than 2.5 cm), morbidly obese, having disease with risk of aspiration like gastroesophageal reflux, hiatus hernia,

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oropharyngeal pathology, cervical spine injury were excluded from the study.

Eighty patients were randomly divided into group P (PLMA) and group E (ETI) using computer-generated lists.

After confirming adequate starvation, preoperative workup, and checking, patients who provided informed valid consent were taken inside the operation room. A senior anesthesiologist (minimum 1 year residency in anesthesia) was allowed to insert appropriate size PLMA (3 or 4) with cuff fully deflated and posterior surface lubricated with 2% xylocaine jelly using introducer or ETI size (7 or 7.5) by standard technique.

In both the groups, time taken for device insertion was noted (in seconds or minutes). Oropharyngeal seal pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 4 L/min and recording the airway pressure at which equilibrium was reached. The airway pressure was not allowed to exceed 30 cm H₂O by altering tidal volume and respiratory rate.

The following parameters were recorded perioperatively at regular intervals: Heart rate (HR), mean arterial blood pressure (MAP, mm Hg), end-tidal CO₂ (EtCO₂, mmHg), oxygen saturation (SpO₂). Duration of pneumoperitoneum, duration of anesthesia, and duration of surgery were recorded. For the most gynecological diagnostic laparoscopic procedures, the intraabdominal pressure was kept between 12 and 14 mm Hg. Gastric distension was recorded by laparoscopic camera as distended or not distended by operating surgeons.

The following complications were assessed: Gastric distension/insufflation hypercarbia and bronchospasm, sore throat.

Statistical Analysis

Sample size was calculated considering previous study using EPI calculator at openepi.com.

Results of the study were observed and analyzed statistically. Quantitative data were analyzed using Student’s t-test and qualitative data were analyzed using chi-square test. Statistical difference was considered significant if $p < 0.05$.

OBSERVATIONS AND RESULTS

Groups were comparable with regard to all the demographic data like age, weight, and ASA grades. The mean age in group E was 27.8 ± 3.6 years and in group P was 30.1 ± 6 years and the mean weight in group E was 52 ± 5.5 kg and in group P was 55.1 ± 4.3 kg, and the difference was not statistically significant (Table 1).

Table 1: Time for achieving effective airway (TFEA) (SEC) and number of attempts for securing airway

Parameter	ETI	PLMA	Significance
TFEA (sec)	25.6 (8.1)	18.2 (5)	<0.05 S
Attempts (1:2)	7:1	5:1	>0.05 NS
No. of attempts 1	33	35	
No. of attempts 2	7	5	

S: Significant; NS: Nonsignificant; TFEA: Time for achieving effective airway

The mean time required for achieving effective airway was longer in ETI than PLMA, which was statistically significant (Table 1).

Pulse Rate in ETI and PLMA Groups

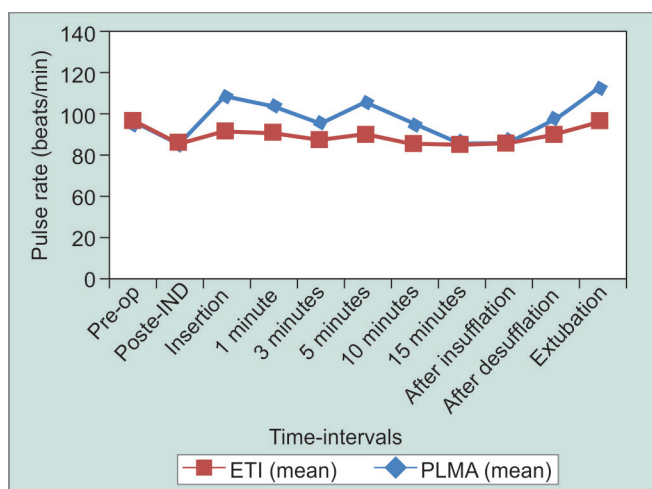
When pulse rate is compared between ETI and PLMA groups at all the time intervals, statistically significant differences were observed at insertion, 1, 3, 5, and 10 minutes, after desufflation and extubation. At all these time intervals, the change in pulse rate was significantly less in PLMA group as compared with ETI group (Graph 1).

Mean Arterial Pressure (mm Hg)

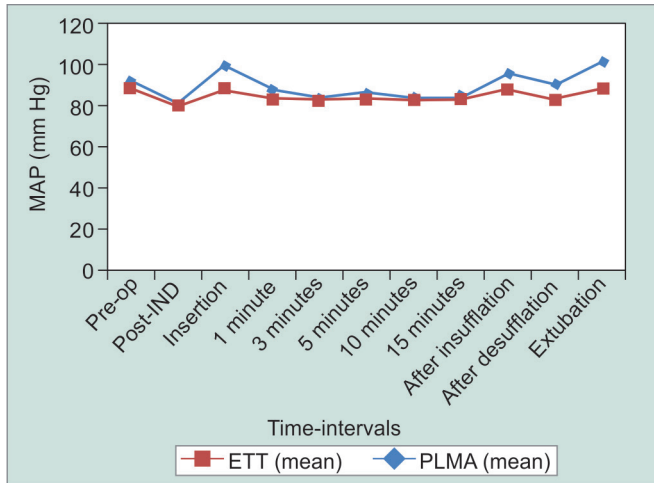
When ETI and PLMA groups were compared, MAP at insertion, 1 minute, after insufflation, after desufflation, and extubation were significantly different ($p < 0.05$). At these time intervals, MAP was significantly lower in PLMA group than in ETI group (Graph 2).

End Tidal Carbon Dioxide

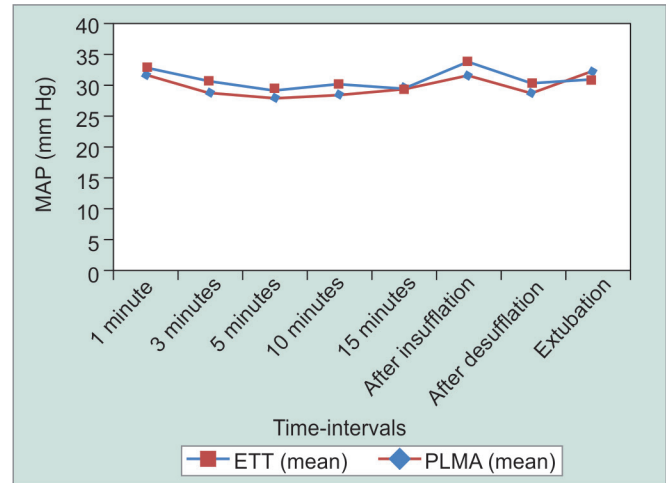
When ETI was compared with PLMA group, EtCO₂ values at 1, 3, 5 minutes, and after insufflations were significantly different between the groups ($p < 0.05$). At all these time intervals, EtCO₂ values were significantly higher in ETI than PLMA, but they are not clinically significant (Graph 3).



Graph 1: Pulse rate (mm Hg) at various time intervals in both ETI and PLMA group



Graph 2: MAP (mm Hg) at various time intervals in both ETI and PLMA group



Graph 3: EtCo2 (mm Hg) at various time intervals in both ETI and PLMA groups .

ADVERSE EFFECTS

Gastric distension was observed intraoperatively after insufflation in six patients in ETI group and five patients in PLMA group (Table 2).

Postoperatively, in ETI group, nine patients had sore throat compared with three patients in PLMA group. This difference was found to be statistically significant. Sore throat complaints were of mild to moderate grade and none of them required active management.

DISCUSSION

Traditional open surgeries are progressing to minimally invasive laparoscopic surgeries, which helped to minimize surgical trauma and widened the scope for laparoscopy.³

The main anesthetic concerns during laparoscopic surgeries are:

- Achieving adequate ventilation and maintaining normocarbia.
- Avoiding regurgitation and aspiration, which may arise due to increased intraabdominal pressure.
- Attenuating the hemodynamic response associated with pneumoperitoneum. There is controversy regarding the optimal anesthetic technique for laparoscopy.⁴

Table 2: Gastric distension

Gastric distension		ETI	PLMA	Total
Present	No.	6	5	11
	%	14.3	12.5	15.9
Absent	No.	34	35	69
	%	85.7	87.5	84.1

Chi-square test	Value	Degrees of freedom (Df)	p-value	Association is
Pearson chi-square	1.7	1	0.6	NS
Not significant				

Endotracheal tube is a rapid, simple, safe, and nonsurgical technique that achieves all goals of airway management, namely airway patency, protecting the lungs from aspiration, and permitting leak-free ventilation during mechanical ventilation, but associated with complications like arrhythmias and hypertension, respiratory complications (laryngospasm, bronchospasm, aspiration with or without regurgitation), and pneumonitis. The mechanical complications include oropharyngeal mucosal injury and laryngopharyngeal complications like sore throat (Table 3).

In our study, for both the groups, the first-time insertion success rates were comparable and statistically insignificant as seven cases in ETI group and five cases in PLMA group, which required two attempts. The time required for achieving effective airway was longer in ETI than PLMA, which was statistically significant.

Similar results were observed by these two studies. Sharma et al¹ conducted a study of 100 consecutive cases of gynecological laparoscopic surgeries. The results showed the PLMA was easier to insert with high success rate on first attempt and required less time. Shroff et al⁵ showed that time required for insertion was shorter for PLMA as compared with ETI.

When pulse rate and MAP were compared between ETI and PLMA groups at all the time intervals, statistically

Table 3: Sore throat (ST) scale

ST scale		ETI	PLMA	Total
Absent	No.	31	37	68
	%	45.6	54.4	85
Present	No.	9	3	12
	%	60	40	15

Chi-square test	Value	Df	p-value	Association
Pearson's chi-square	3.8	1	0.04	S

S: Significant

significant differences were observed at insertion, 1, 3, 5, 10 minutes, after desufflation, and extubation. At all these time intervals, the hemodynamic changes were significantly less in PLMA group as compared with ETI group.

Though there was a statistically significant increase in the pulse rate and blood pressures from the baseline after endotracheal intubation, this difference is not clinically significant (not more than 20% increase from the baseline).

Attenuation of the response to PLMA is due to diminished catecholamine release, as suggested by Lamb et al.⁶ This could in turn be due to the fact that LMA is relatively simple and atraumatic to insert and does not require laryngoscopy before insertion. Wood and Forrest² assessed the hemodynamic response to the insertion of the LMA compared with that of laryngoscopy and tracheal intubation and also showed that the changes in all cardiovascular parameters measured following LMA insertion were significantly less ($p < 0.05$) following laryngoscopy and tracheal intubation. They concluded that airway management with LMA may be used to avoid the hemodynamic response to tracheal intubation where such response is undesirable.⁷

Fujii et al⁸ also evaluated the hemodynamic changes of tracheal extubation or removal of a LMA. Changes in HR, MAP, and rate-pressure product were measured before and 1, 2, 3, 5, and 10 minutes after tracheal extubation or LMA removal. The study thus concluded that removal of LMA is associated with less cardiovascular change than tracheal extubation in both normotensive and hypertensive patients.⁹

COMPARISON OF EtCO₂ and SpO₂

In our study, the changes in EtCO₂ after PLMA or ETI intubation, though statistically significant, had no clinical significance because the EtCO₂ was maintained within normal limits. There was no significant increase in EtCO₂ after CO₂ insufflation. Similar results were quoted by Sharma et al.¹ Shroff et al⁵ also evidenced maintenance of the EtCO₂ within normal limits during the entire duration of the procedure.³

The PLMA formed an effective seal around the glottis as reported by previous workers,^{2,10-12} thus allowing adequate oxygenation before and after CO₂ insufflation in all patients. In our study, no cases of failed ventilation were found in PLMA group. There were no episodes of desaturation noted with either the PLMA or ETI group.

COMPARISON OF GASTRIC DISTENSION

In our study, gastric distension was noted by direct vision with laparoscopic camera. Gastric insufflation was noted in six patients in ETI group and in five patients in PLMA

group, but none of the patients in PLMA group required intubation with a view to avoid further distension.

Similar instances have been found by Maltby et al¹³ using PLMA.^{5,14-17} Chakraborty et al¹² in their study compared gastric distension during laparoscopic cholecystectomy in 60 patients with either PLMA/ETI. They found that the incidence of gastric distension was lower with the PLMA than with the ETI.

COMPARISON OF POSTOPERATIVE SORE THROAT

In ETI group, nine patients had sore throat compared with three patients in PLMA group, which was statistically significant. Sore throat complaints were of mild to moderate grades and none of them required active management. Piper et al¹⁸ compared PLMA and ETI in gynecologic laparoscopies and concluded that PLMA was a safe and effective ventilation device with low stress imposed to patient and low occurrence of pharyngeal and laryngeal complications, especially the incidence of sore throat was less in PLMA than ETI.

Sore throat and dysphonia commonly occur after both endotracheal intubation and LMA insertion. The incidence of sore throat varies in different studies due to variation in size of LMA and ETI used in different studies, design and type of ETI used, lubricating material used. The cuff pressure of LMA and ETI, duration and percent of nitrous oxide also matter in incidence of sore throat.

Perioperatively, no episodes of laryngospasm, bronchospasm, arrhythmias, hypertension, desaturation, and inadequate ventilation were observed in both the groups.

CONCLUSION

The PLMA is an equally effective and safe airway device to conventional tracheal intubation with controlled ventilation for gynecological diagnostic laparoscopy; it is more rapidly inserted and associated with an attenuated hemodynamic response to insertion and removal and has less gastric distension and laryngopharyngeal morbidity.¹⁹⁻³¹

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