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# Prospective Randomized Comparative Study of Proseal™ and Endotracheal Tube for Airway Management in Gynecological Laparoscopic Under General Anesthesia

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**Original Research Article**

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**Abstract:** PLMA is a recent, complex, and ingenious development with some added features of Classic LMA like Modified dual cuff ,Drain tube, positive pressure ventilation at higher peak inspiratory pressure. Study was to evaluate and compare the use of Proseal laryngeal mask airway and endotracheal tube with controlled ventilation in patients undergoing gynecological laparoscopic procedure. 100 patients, ASA risk I & II, posted for elective laparoscopic were recruited in the study. All the patients between 18 to 45 yrs of age were randomly divided in two groups Group PLMA and Group ETT (50 patients each). Attempt of insertion of airway device, Leak pressure, pulmonary ventilation, Hemodynamic; heart & MAP, gastric distention were recorded. All patients were of middle age group, comparable in weight. Mean duration of laparoscopy was comparable in both the groups. **S**ignificant rise in heart rate and mean arterial pressure seen in group ETT after induction of anesthesia .Changes in the end tidal CO2 and peak airway pressure after induction of anesthesia, before & after peumoperitoneum were comparable in two groups. After head low position peak airway pressure is slightly raised in Group PLMA. Gastric distension was noted higher in Group PLMA (8%).Incidence of sore throat (22%), nausea vomiting (14) airway trauma (14%) was higher in group ETT. Hemodynamic stability was better in PLMA group at time of induction and comparable in two groups at time of pneumoperitoneum and trendelenburg position along with pulmonary ventilation. Post operative sore throat, nausea vomiting was higher with endotracheal tube.
**Keywords**: *PLMA* Proseal Laryngeal Mask Airway.

## INTRODUCTION

The airway management of the patients undergoing laparoscopic procedures has progressed from Endotracheal intubation (ETT) to lesser invasive devices, Proseal Laryngeal Mask Airway (PLMA) [1]. The important concern during this procedure is peritoneal insufflations & raised intra abdominal pressure which mandates the requirement of proper glottic seal to prevent pulmonary aspiration & adequate ventilation to eliminate absorbed $CO_2$. The general anesthesia with endotracheal tube has been made the gold standard for this [2]. Although the tracheal tube is considered ideal for laparoscopic procedures, there is consistent inflow of reports highlighting the safety of PLMA in laparoscopic surgery [3]. Over a period of time, new airway devices have been added to the anesthesiologist's armamentarium. The LMA is an innovative device for upper airway management, of which, the PLMA is a recent, complex, and ingenious development with some added feature of Classic LMA like [4]:

- Modified dual cuff to increase the seal.
- Drain tube which provides a channel for regurgitation fluid & Easy Insertion of gastric tube.
- It enables positive pressure ventilation at higher peak inspiratory pressure.

The aim of our study was to evaluate and compare the use of Proseal laryngeal mask airway and endotracheal tube with controlled ventilation in patients undergoing gynecological laparoscopic procedure.

## MATERIALS & METHODS

100 patients, ASA risk I & II, posted for elective gynecological laparoscopy were recruited in the study. All the patients between 18 to 45 yrs of age were randomly divided in two groups, (50 patients each.)
GROUP PLMA: Proseal laryngeal mask airway
GROUP ETT: Endotracheal tube

### Exclusion criteria

- Patients at risk of aspiration
- Reduced pulmonary compliance

- Respiratory tract pathology
- Mouth opening less than 2 fingers
- More than 3 attempts

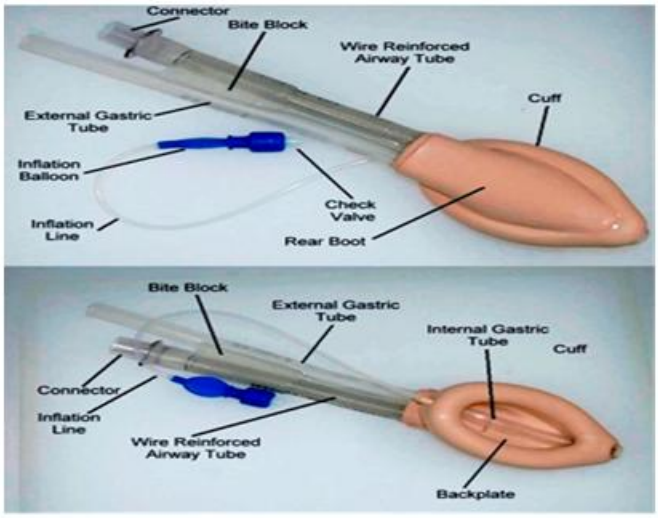


**Fig-1: PLMA Image credit: http://www.sebac.fr/**

Patient's demographic data like age, weight, history & findings of examination of cardiovascular & other systemic examination were recorded. Routine investigations like hemoglobin, renal functional test, urine sugar, albumin, chest X _ray were done in all patients. Specific investigations were also carried out as a when required. All patients kept nil per orally overnight.

On arrival in the operation theatre vital parameter i.e. pulse, blood pressure, ECG, spo2 were recorded. All patients were premedicated with I/V Inj. Ranitidine (50mg), Inj. Metoclopromide (10 mg) Inj. Gylcopyrolate (.004mg/kg), Inj. Fentanyl (2µ/ kg).

Patients were pre oxygenated with 100% oxygen for 3 min. General anesthesia was induced with Inj. Propofol (2-2.5mg/kg) and Inj, succinyl choline. Inj. lignocaine (40-50mg) given to prevent pain on injection with Propofol. IPPV is avoided to prevent gastric inflation.

Correct size of PLMA inserted, position judged by chest inflation, auscultation of breath sounds, capnography .Anesthesia was maintained with inj vecuronium , nitrous oxide, o2 & isoflurane plus intermittent positive pressure ventilation .After that patient put on ventilator on mode; CMV, CMV frequency 12/min, tidal volume 10ml/kg All procedure was also done with endotracheal intubation except conventional laryngoscopy was done with GROUP ETT. Surgeon was blinded for device.

Following observations were done.

1. Attempt of insertion of PLMA whether 1st, 2nd or failed.
2. Position of PLMA
3. Leak pressure was judged
4. Pulmonary ventilation judged
5. Hemodynamic; heart & MAP recorded
6. Gastric distension: by surgeon

- At time of the insertion of laparoscope &
- Upon decompression of pneumoperitoneum,
- Scored stomach size at ordinarily scale (0-10)

0- no distended,
10- Distended

After end of surgery all patients were reversed with Inj. Neostigmine plus inj. Gylcopyrolate & patient is extubated with adequate muscle tone and reflexes.

In case of PLMA air was aspirated from cuff and removed with patient cooperation.

Following observation were done in post operative management

- Blood stain on device( airway trauma )
- Nausea Vomiting
- Sore throat up to 24 hrs
- Dysphagia

**OBSERVATION & RESULTS**

All patients were of middle age group, comparable in weight. Diagnostic laparoscopy constituted the major of surgeries both groups. Other procedures performed were operative laparoscopy, cyst aspiration, myomectomy& laparoscopic assisted vaginal hystrectomy (LAVH). Mean duration of laparoscopy was comparable in both the groups

**Table-1: Demographics**

| FACTOR | PLMA | ETT |
|---|---|---|
| No. of patients | N=50 | N=50 |
| Age in years(Mean±SD) | 32.58 ± 5.69 | 33.28 ± 5.7 |
| Weight in kg | 60.24 ± 6.03 | 59.52±7.77 |
| ASA (I & II) | 46/4 | 45/5 |

**Table-2: No. of Attempts for Securing Airway**

| | PLMA | ETT |
|---|---|---|
| 1[t] attempt | 46 (92 %) | 50 (100%) |
| 2[d] attempt | 4 (8 %) | 0 (0) |

**Table-3: Heart rate: [/min, (Mean ± SD)]**

| Group | Basal parameter | After induction (Placement of device) | Before pneumoperitoneum | After pneumoperitoneum | After head low position | After decompression |
|---|---|---|---|---|---|---|
| PLMA | 81.64 ±7.5 | 85.62± 7.6609 | 81.22 ± 6.105501 | 82.66 ± 12.4 | 91.16 ± 9.5 | 86.4± 7.436 |
| ETT | 79.2 ± 13.70 | 97.22 ± 7.42* | 84.68± 6.145979 | 88.3 ± 7* | 93.3 ± 6.5 | 86.36 ± 8.16 |

Heart rate was comparable in Group PLMA after induction of anesthesia, however significant rise in heart rate seen in group ETT after induction of anesthesia.

**Table-4: Mean arterial pressure [mm of Hg (Mean ± SD)**

| Group | Basal parameter | After induction (Placement of device) | Before pneumoperitoneum | After pneumoperitoneum | After head low position | After desuflation |
|---|---|---|---|---|---|---|
| PLMA | 92.98 ±6.4422 | 95.1± 8.583919 | 100.7867 ±7.004942 | 97.53333 ±5.815376 | 102.75 ±4.65 | 94.30 ±4.49 |
| ETT | 92.94 ±7.9607 | 103.82 ±6.878014* | 91.44 ±7.454606 | 105.16 ±4.375898* | 98.4133333 ±10.3908996 | 97.85333 ±7.853581 |

(*: $p < 0.05$)

Mean arterial pressure is significantly rising after induction of anesthesia in group ETT, comparable in Group PLMA. After pneumoperitoneum MAP were significantly increased in both groups. Then after it remained stable in both groups.

Changes in the end tidal CO2 after induction of anesthesia, before & after pneumoperitoneum & after head low position were comparable in both groups.

**Table-5: ETCO2 [mm of Hg (Mean ± SD)]**

| Group | After induction | Before pneumoperitoneum | After pneumoperitoneum | After head low position | After desuflation |
|---|---|---|---|---|---|
| LMA | 29.26±2.078166 | 29.3±2.07266 | 30.26±2.058432 | 31.36±1.351643 | 29.44± 2.042008 |
| TT | 25.6± 2.498979 | 24.78± 1.329262 | 27.78± 2.10238 | 29.7346939± 1.86 | 24.46± 1.940019 |

**Table-6: Peak airway pressure [cm of H20 (Mean ± SD)]**

| Group | Basal parameter | After induction (Placement of device) | Before pneumoperitoneum | After pneumoperitoneum | After head low position | After desuflation |
|---|---|---|---|---|---|---|
| PLMA | | 19.76± 1.943697 | 19.74± 1.925235 | 19.2± 1.795686 | 24.64± 3.931869 | 22.26± 1.321873 |
| ETT | | 23.4± 1.484615 | 24.14± 1.484752 | 24.3± 1.87627508 | 25.94± 1.93158495 | 24.46± 1.940019 |

Changes in peak airway pressure were comparable in both groups after induction of anesthesia, before and after pneumoperitoneum. Changes in peak airway pressure after head low position is comparable

in group ETT, but slightly increased in Group PLMA. But oxygen saturation on SPO2probe was maintained in both groups.

Gastric distension was noted higher in Group PLMA (8%) as compare to Group ETT (2%) after insertion of laparoscope.

**Table-7: Gastric distension**

| Gastric distension | PLMA | ETT |
|---|---|---|
| After insertion of laparoscope | 4(8%) | 1(2%) |
| After decompression of pneumoperitoneum | 0 | 0 |

**Table-8: Post operative side effects**

| Post operative side effects | PLMA | ETT |
|---|---|---|
| Sore throat | 5 (10%) | 11 (22%) |
| Nausea | 4 (8%) | 7 (14%) |
| Vomiting | 4 (8%) | 7 (14%) |
| Dysphagia | 0 (0%) | 0(0%) |
| Blood stain on device | 5 (10%) | 11 (22%) |

Incidence of sore throat was higher in group ETT (22%) as compared to Group PLMA (10%). Incidence of nausea vomiting was also higher in Group ETT (14) as compared to Group PLMA (8%). Incidence of airway trauma (Blood stain on device were higher in group ETT (14%) as compare to Group PLMA (8%). There was no incidence of dysphagia noted in two groups.

## DISCUSSION

In our study 100 adult female patients belonging to ASA I & II undergoing elective gynecological surgery of short duration around 60-90min were selected. Anesthetic technique was standardized. All patients were given general balanced anaesthesia with controlled ventilation. We have divided patients in two groups into PLMA & ETT. Similar study also noted by Jorge Malt *et al.*, [5] in laparoscopic cholecystectomy, similar study also conducted by same author in 2003 [6] in gynecologic laparoscopy.

Similar comparative study was carried out by Lim Y., Piper SN *et al.*, [7] series of case studies documenting the efficacy of the PLMA in laparoscopy surgeries have been carried out by Evan *et al.*, & Bimla Sharma, Jayshree Sood *et al.*, [8-10].

In our study basal parameter like heart rate & mean arterial blood pressure were noted in both groups & were found to be comparable.

After induction of anaesthesia i.e. placement of device significant rise in heart rate & MAP noted in group ETT in our study compared to other groups. However in PLMA group heart rate & MAP was found to be comparable. These are due to the direct stimulation of trachea by ETT & added stress response to laryngoscopy causes reflex sympathetic stimulation causing tachycardia & hypertension. Proseal $^{TM}$ LMA is supraglottic device so there is no direct stimulation of trachea & less stress response.

Lim Y *et al.*, [5] reported an attenuation of hemodynamic response to PLMA insertion compared with endotracheal tube intubation. Jayshree sood, Prena Shroff *et al.*, [10] carried out similar series of case studies in laparoscopic surgeries using PLMA as airway device observed that there was minimal hemodynamic response to insertion of PLMA thus our observation were in agreements with their studies. After pneumoperitoneum there was rise in heart rate & MAP in ETT group. In PLMA group rise in heart rate was comparable in our study. These changes were due to cardiovascular changes i.e. sympathetic stimulation secondary to hypercarbia (pneumoperitoneum).Finding was similar to previous study done by Prerana Shroff *et al.*, [1].

In our study heart rate & MAP increased after trendelenburg position in both groups, related to the redistribution of body fluids & blood volume with head low position which causes increase in venous return leading to increase in central venous pressure and increase in stroke volume.

In our study changes in End Tidal $CO_2$ ($ETCO_2$) were comparable in both groups throughout the surgery specifically before and after penumoperitoneum and oxygen saturation. $SPO_2$ was also maintained. Both the parameter suggests that Proseal LMA permitted effective ventilation during gynecological laparoscopies as evidenced. This is due to Proseal LMA adapting its shape to various contour of pharynx.

Surekha Kamat *et al.*, [15] in their study observed that changes in $ETCO_2$ were comparable in both PLMA & ETT groups before and after penumoperitoneum. Similar study was showed by Malt JR *et al.*, and Sharma *et al.*, [3, 10]. Our results were comparable with their study.

In our study changes in peak airway pressure was comparable in both the groups before and after

penumoperitoneum. After head low position peak airway pressure was increased in all groups. Slightly increase in PLMA group but lower than ETT group. Its principle could be related to gas flow along with device or within lungs or both. However internal diameter of LMA airway tube was similar to ETT so it likely to be related to reduced pulmonary airway resistance. Berry A, J., Brimacombe *et al*., [11-13] also found lower peak airway pressure in PLMA group as compared to ETT group.

In our study, gastric distension was found 4 cases of PLMA group & 1 case in ETT group after insertion of laparoscope. We have passed Ryle's tube in those cases of PLMA & ETT group. We have avoided bag and mask ventilation during induction to prevent gastric distension as we want to compare gastric distension with each device. The incidence of gastric distension was PLMA in our study, J. Roger concluded that incidence of gastric distension was associated with airway pressure in excess of 20 cm of H2O with clinically unrecognized LMA malposition in the hypo pharynx [14]. In our study, incidences of sore throat & blood stain on device was higher (22%) in ETT group than that of PLMA 10% group. This was explained by the presence of a cuff in the pharynx is much less stimulating than cuff in the trachea & mucosal pressure is lower in PLMA. P. Shroff *et al*., [1] reported incidences of sore throat & blood stain on device in ETT group (10%) & PLMA (5%), Brimacombe *et al.*, ETT (10%) & PLMA (2%). In our study, Incidences of nausea vomiting was 8% in PLMA group and 14% in ETT group. Similar to study by Brimacombe *et al*., PLMA (2%) & ETT 23% [13].

## SUMMARY & CONCLUSION

Ease of insertion of airway device is better in ETT group but hemodynamic stability is better in PLMA as compared to ETT group at time of induction of anesthesia (placement of device), and comparable in both groups at time of pneumoperitoneum and trendelenberg position. PLMA has provided good pulmonary ventilation in gynecological laparoscopy under controlled ventilation. Post operative sorethorat, nausea vomiting was higher with endotracheal tube.

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