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A Comparative Study Of Efficacy Of Proseal Lma And Endotracheal Intubation With Macintosh Laryngoscope In Gynecological Laparoscopic Surgery Under General Anaesthesia

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Abstract
Introduction- *Proseal LMA (laryngeal mask airway) is a useful modulation of the classical LMA, which gives superior hemodynamic stability and protection against perioperative complications when used in laparoscopic procedures.*
Aims and design*-aim of this study to compare the efficacy of Proseal laryngeal mask airway (PLMA) and endotracheal tube (ETT) in elective gynecologic laparoscopic surgeries under general anesthesia and to compare the hemodynamic differences and perioperative complications.*
Methods and Material- *In the prospective randomized controlled study, ASA I-II and 60 patients undergoing gynecologic laparoscopic surgery aged 20-50 were allocated into two groups (n = 30, n = 30). After the induction of anesthesia with inj. Fentanyl, inj propofol & inj. vecuronium, Group E was placed ETT, Group P PLMA. Patients' demographic characteristics, number of attempts for correct insertion, hemodynamic changes, postoperative complications in the form of laryngopharyngeal morbidity were noted. quantitative data were analyzed by using Student't' test. qualitative data were analyzed by using Chi square test.*
Results*- There was no failed insertion of devices. PLMA required 21.9s as compared with ETT which was required 25.4s for insertion of device. Time taken for insertion of NGT was 22.2s in PLMA group and 25.1s in ETT group. No statistically significant difference was found with respect to mean arterial oxygen saturation (SpO_2) & end-tidal carbon dioxide ($EtCO_2$) between the two groups before or during peritoneal insufflation. No episodes of gastric regurgitation or pulmonary aspiration observed in both groups. PLMA provided better protection against postoperative complications like cough (6.7%) and sore throat (6.7%) as compared to ETT with 13.3 and 16.7% incidence respectively.*
Conclusion- *Therefore, we conclude that PLMA provided equally effective lung ventilation in spite of of high airway pressures without visible gastric distension, aspiration and regurgitation. In comparison to PLMA, the haemodynamic parameters after insertion of ETT acknowledges significant increase in stress response. PLMA is comparable with ETT in laparoscopic surgeries in securing a patent airway during controlled ventilation.*
Hence, PLMA is reliable and efficient alternative to endotracheal intubation in patients undergoing laparoscopic surgeries.
Keywords*- Proseal LMA, Pulmonary aspiration, hemodynamic changes*

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I. Introduction

An Anaesthesiologist spend a respectable part of their career in keeping the airway secure and maintaining its patency either by some maneuver or by using artificial airways. In this regard we have spectrum of airway devices starting from facemask to endotracheal tube on either extreme of this spectrum. Over a period of time, new airway equipment has been added to the anesthesiologist's assets.

In recent years several supraglottic devices have been introduced in clinical practice to fill the gap between two extremes. The choice of techniques for airway management depends upon situation and the skills and experience of anesthesiologist.

Tracheal intubation using a laryngoscope has been considered as GOLD STANDARD of airway management under General Anesthesia.[1]

Laryngoscopy and tracheal intubation violate the patient's protective airway responses and can lead to hypertension and tachycardia due to reflex increase in sympathetic and sympathoadrenal activity.[2] Apart from hemodynamic changes other disadvantages are damage to oropharyngeal structures at insertion, post operative sore throat.

Triggering stimuli include passing an endotracheal tube through the larynx or pharyngeal secretions during extubation. It can lead to pulmonary edema due to large negative intrathoracic pressure.

Supraglottic devices are the devices that ventilate patients by delivering oxygen and anesthetic gases above the vocal cords and also overcome certain disadvantages of Endotracheal tubes as: soft tissue, tooth, vocal cords, laryngeal and tracheal damage, exaggerated hemodynamic response, barotrauma, etc.

In addition to the peripheral cuff of LMA, Proseal laryngeal mask airway (PLMA) has a dorsal cuff which pushes the mask anterior to provide a better seal around the glottic aperture and allowing high airway pressures without air leak. The drain tube parallel to the ventilation tube allows drainage of passively regurgitated gastric fluid away from the airway and provides a passage for gastric tube.[3]

For that reason this study was taken on to compare PLMA with standard endotracheal tube for the number of attempts and time taken for insertion, hemodynamic changes, oxygenation, ventilation(end tidal carbon dioxide) and intraoperative and postoperative laryngopharyngeal morbidity occurring during general anesthesia in young healthy adult female patients undergoing gynecological laparoscopic surgeries.

II. Methods

After obtaining the Ethics committee approval and written informed consent, this prospective randomized study was conducted on 60 healthy patients. The patients were of ASA physical status grade I and II, aged 20-50 years female and body weight 30-50 kg, who underwent laparoscopic gynecological procedures under general anesthesia. Patients with anticipated difficult airway, obesity (body mass index > 35 kg/m^2), oropharyngeal pathology, cardiopulmonary disease, cervical spine fracture or instability, or at increased risk of aspiration (gastro-esophageal reflux disease, hiatus hernia, and pregnant patients) were excluded from the study.

Patients were randomized for airway management with the PLMA or endotracheal tube (ETT) by simple chit in box method inside the operation theatre into two groups of 30 each. Patients in group P were to receive a PLMA and patients in group E were to undergo endotracheal intubation.

In the operation theatre, standard monitors were attached and baseline parameters were recorded. After intravenous (IV) access was obtained Injections of midazolam 0.02 mg/kg, glycopyrrolate 0.005 mg/kg, and fentanyl 2 μg/kg were administered 1-2 min before induction. After preoxygenation with 100% O_2 for 3-5 minutes, anesthesia was induced with injection Propofol 2 mg/kg till the loss of verbal commands. Neuromuscular blockade to facilitate placement of airway device was achieved by Vecuronium 0.08 mg/kg. Following induction and adequate paralysis, the corresponding airway was inserted in each patient.

In group P size 3 PLMA (according to weight) used. For the purpose of standardization, we used the introducer for inserting the PLMA for all cases. In group E, size 7 no. endotracheal intubation was performed in standard manner.

We were noted the number of insertions attempts of both devices. Three attempts were allowed for the placement before the device could consider a failure and the device would replace with an ET tube.

The time interval between holding the airway device to confirmation of correct placement by bilateral air entry on chest auscultation was noted.

Correct placement of the devices, was confirmed by:

- Adequate chest rises on manual ventilation
- Square wave on capnography
- Expired tidal volume of more than 8 ml/kg
- No audible air leak from the drain tube with peak airway pressure (PAP) less than 20 cm H_2O. A leak below 20 cm H_2O was taken as significant and suggests a malposition.
- 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 got ejected

The last two tests were specific for group P.

Anesthesia was maintained with oxygen, nitrous oxide, isoflurane.

The outcomes measured were as follows:

- 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.
- Haemodynamic responses (heart rate and mean arterial blood pressure) were recorded before induction; at the time of insertion; 1 and 3, 5, 10 mins after insertion of device; after achieving pneumoperitoneum, and during removal of devices.
- Oxygen saturation (SpO_2) and end-tidal carbon dioxide ($EtCO_2$); at a tidal volume of 10ml/kg, fraction of inspired oxygen (FiO_2) 0.33, respiratory rate of 12/min and I/E of 1:2 were recorded.

- The aim was to maintain target SpO_2(>95%) and $EtCO_2$ (25- 40mm Hg) by adjusting the FiO_2, respiratory rate and tidal volume. When SpO_2 was 94-90% the oxygenation was graded as suboptimal and failed if it was <90%.
- The PAP was recorded when intra-abdominal pressure (IAP) reached 14 mm Hg. For standardisation, IAP was maintained at 12-14 mm Hg.
- Incidences of gastric distension (by surgeon), regurgitation, aspiration, postoperative blood staining of the ET tube and posterior aspect of cuff of PLMA, tongue-lip-dental trauma, laryngospasm and hoarseness were noted.

Statistical analysis

Data were analyzed using Primer software and XL- Stat. P values <0.05 were considered as Significant (S) and P value > 0.05 as statistically Non-Significant (NS). quantitative data were summarized in the form of Mean ± SD, both groups was analyzed using Student's' test. qualitative data were summarized in the form of proportions, were analyzed using Chi square test.

III. Results

Sixty ASA I-II adult female patients, aged 20-50 years scheduled to undergo elective gynecological laparoscopic surgeries were included in present study.

The demographic profile of patients in both groups were comparable with respect to Age (years), weight (Kg), ASA grade, and duration of Anesthesia.

Size 3 PLMA and size 7.0 number cuffed endotracheal tube were inserted in all 30 patients of each group respectively.

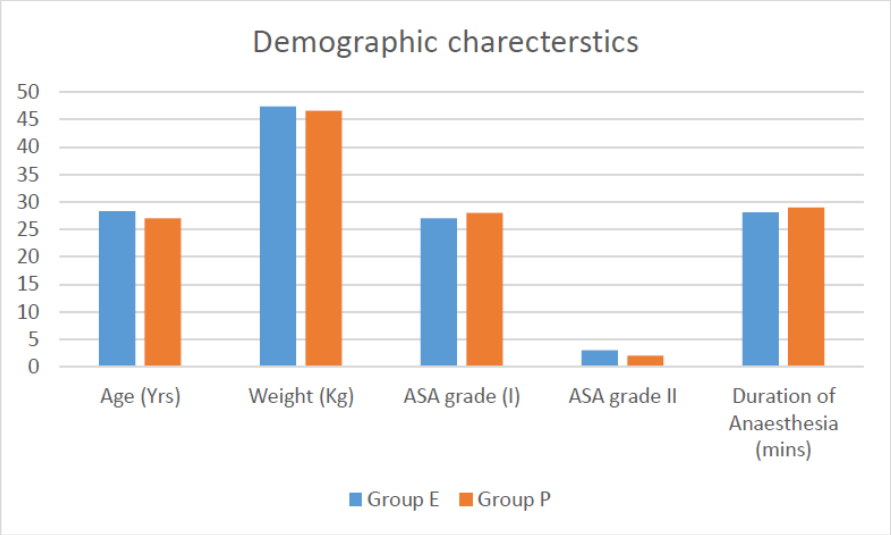

Figure-1

Mean time (range) taken for successful placement was 21.9+-5.4 s and 25.0+-4.6s for PLMA and ETT, respectively. it was statistically significant (p value=0.0181). [Table-1]

In group P Insertion success rate was 93.3% for the first attempt, and two attempts were made in 6.7% patients. in one case in there was leak after device placement for which device was taken out and re positioned. No leak occurred after repositioning. In Group E, the insertion success rate was 83.37% for the first attempt; two attempts were made in 16.7% of patients. There was no failed insertion reported in either group. [Table-1]

Mean Time for NG tube insertion was 22.2 and 25.1 secs in group P and group E respectively. The difference in insertion time was statistically significant (P=0.0398). [Table-1]

NG tube insertion was successful in 96.7% in first attempt whereas 3.3% patient required second attempt in group P. In group E, second attempt required in 20% patients and these differences were also statistically significant (P=0.0117). [Table-1]

Table 1-airway management

Airway device details	**PLMA group**	**ET group**	***P* value**
Attempt of device insertion (1/2/3/ failed)	28/2/0/0	25/5/0/0	-
Time taken for device insertion Mean (SD)	21.9(5.4)	25(4.6)	0.0181
NG tube insertion Attempts (1/2/3/failed)	29/1/0/0	24/6/0/0	0.0117
NG tube insertion time, Mean (SD)	22.2(4.8)	25.1(5.9)	0.0398

The $EtCO_2$ was comparable in both the groups throughout the procedure (P>0.05) and did not increase beyond 40 mm Hg.
No statistically significant difference was found with respect to mean arterial oxygen saturation perioperatively in both the groups. [Figure-2]
Patients in group P required higher mean peak airway pressure as compared to group E patients for adequate ventilation which was statistically highly significant.
No intraoperative complication was observed in any patient of both the group.

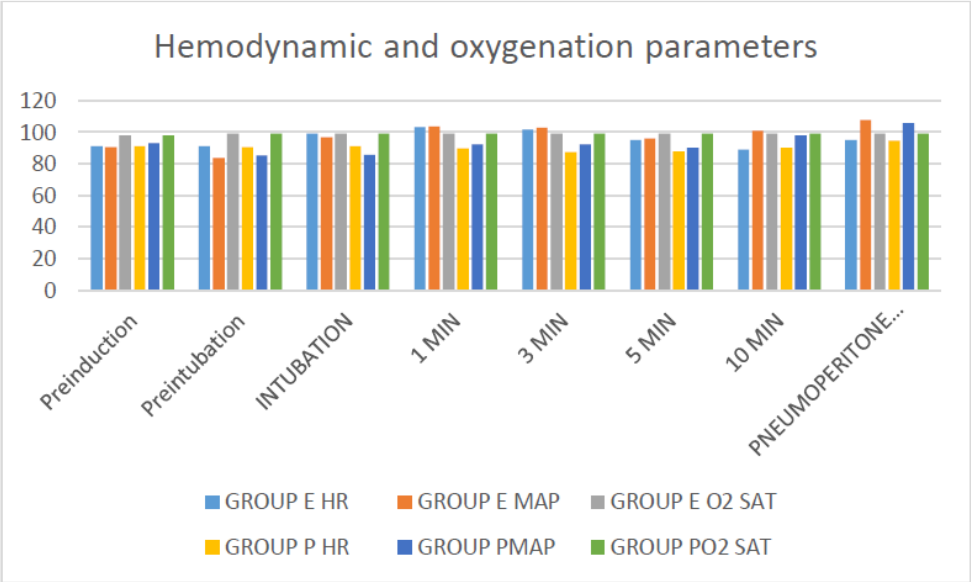

Figure-2

Coughing after removal of PLMA was seen in 6.7% patients, while it was seen in 13.3% patients in the ETT group. [Table-2]
Blood staining of devices on removal was seen in 10% patients in group P and in 20 % patients in group E, were not statistically significant (P=0.1631). [Table-2]
Minor trauma to the lip and gums and other Oral cavity structures was seen in 1 patient (3.33%) in group E but no such events occurred in group P. [Table-2]
Sore throat was seen in 6.7% patients in group P and in 16.7% patients in group E 1st hour postoperatively which was resolved in all patients in next 24 hours. None of the patient in either group complained of dysphagia, dysphonia, or any other complication post operatively. [Table-2]
Within 24 hours, no patient in group P but 2 patients (6.67%) in E group complained of vomiting which resolve on taking medication (4 mg Ondensetron iv). There was no incidence of clinically detectable pulmonary aspiration in either group. [Table-2]

Table 2- Laryngopharyngeal Morbidity

	PLMA group	**ETT** group	***P***
Intraoperative			
1.Air Leak	1	0	
2. Gastric distension	0	0	
3 Regurgitation, Aspiration	0	0	
At removal			
1 cough	2	4	

2 blood stained device 3 oral cavity trauma	3 0	6 1	0.1631
Post operative			
1 vomiting	0	2	
2 Sore throat	2	5	
3 Dysphagia, dysphonia	0	0	

IV. Discussion

The PLMA is relatively new aspirant to the family of LMA with some extended features over the classic LMA.[4]

This study was conducted with the goal of comparing PLMA and ETT as airway device in 60 patients undergoing gynecological laparoscopic surgeries. 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 [1,3 ,5] studies.

All the patients in both the groups weigh between 30–50 Kg (Figure-1). This helped us in alleviating a point of controversy because obesity has significant effect on performance of airway device during positive pressure ventilation. Because all patients in our study were females, hence, in our study, we choose a fixed size 3 PLMA for all cases in Group P.

In our study the first-time success- rates for airway device insertion were higher for PLMA and the time which was required for achieving an effective airway was longer with the ET tube than with the Proseal LMA. This was also in conformity with the study by **Saraswat et al [6]**, **Brain et al [4], Patel et al** [7]and **kihara et al** [8] noted 100 % first attempt success rate of PLMA in their study, while first attempt success rate of PLMA by **Misra et al** [3]and **Saraswat et al** [6] was 88 % and 86.7 % respectively. In present study success rate was 93.3% for the first attempt.

In our study the mean insertion time of group P was 21.9 secs and in Group E it was 25.9 secs, it was statistically significantly lesser in group P (p value=0.0181).

Lim Yet al [9] also noted the shorter effective airway time for the Proseal laryngeal mask airway (20 +/- 2s vs. 37 +/- 3 s, P < 0.001). Similar findings were noted by **Shroff et al [5], Saraswat et al** [6], and **Patel et al** [7] in their studies where time require for securing airway was lesser in Proseal group.

A NGT was inserted in all patients. The mean insertion time taken to insert NGT through PLMA (22.2 secs) was significantly less than via nose (25.1 secs) in intubated patients (P=0.0398). **Shroff et al** [5] (14 secs Vs 27 secs) and **Saraswat at el** [6] (9.77 sec Vs 11.5 secs) also found NG tube quicker to insert through PLMA than Nose (ETT group). **Brain et al** [4] and **Brimacombe et al** [10] noted 100 % first attempt success rate of NG tube with PLMA while first attempt success rate of **Evans et al** [11] and **Natalini et al** [12] was 97 % and 90 % respectively. These factors may be of clinical significance in patients with hypertension, ischemic heart disease.

Following peritoneal insufflation, CO_2 is absorbed transperitoneally, and the rate at which this occurs depends on gas solubility, perfusion of the peritoneal cavity, and duration of the pneumoperitoneum.[11] Both groups maintained adequate oxygenation and ventilation perioperatively. Our study closely proximate with that of **Maltby et al [13]** and **Sharma et al [1]** who found no statistically significant differences in SpO_2 or $EtCO_2$ between the two groups before or during peritoneal insufflations.

Patients in group P required higher mean peak airway pressure as compared to group E patients for adequate ventilation which was statistically significant(P<0.05), but clinically it was not significant. Higher Peak airway pressure in PLMA group was also noted by **Maltby et al [13] & Saraswat et al** [6].

The incidence of **sore throat** was comparatively more in group E (16.7%) than in group P (6.7%) was resolved in all patients in next 24 hours. All patients were administered steam inhalation. **Higgins et al** [14]and **Shroff et al** [5] also found the more incidence of sore throat in patients undergoing intubation than in those in whom a PLMA was used. This could be explained by the study of **Murphy et al** [15], they found that in a supraglottic device and mucosal pressures achieved are usually well below pharyngeal perfusion pressures.

There was no incidence of intraoperative or postoperative laryngospasm, bronchospasm, regurgitation, or aspiration in either group. Similar results have been reported by **Maltby et al [13], Sharma B et al [1] & Higgins et al [14].**

Comparisons between the PLMA and tracheal intubation, PLMA caused less **post-extubation coughing** (TT 50%, 96%, 86% vs. PLMA 0%, 4%, 15% respectively). **Piper et al** [16] found the incidence of coughing was 24% in group E while 0 % in Proseal group. In our study post extubation coughing were also lesser probably because of short duration of procedure and use of relatively small size ET tube in group E.

V. Conclusion

Therefore, we conclude that Proseal LMA provided equally effective lung ventilation in spite of high airway pressures in gynaecological laparoscopic surgery without visible gastric distension, aspiration and regurgitation. In comparison to PLMA, the haemodynamic parameters after insertion of ETT acknowledge significant increase in stress response. PLMA is comparable with ETT in gynaecological laparoscopic surgeries in securing a patent airway during controlled ventilation.

Hence, PLMA is reliable and efficient alternative to endotracheal intubation in patients undergoing gynaecological laparoscopic surgeries.

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