



Original Research Article

Evaluation of the efficacy of proseal LMA versus endotracheal intubation for laparoscopic surgeries

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ABSTRACT

Background: Open surgeries which were done predominantly in previous days are progressing to minimally invasive keyhole laparoscopic surgeries. In same way, airway management has been also progressed from ETT to lesser invasive Laryngeal Mask Airway (LMA).

Materials and Methods: This was a prospective observational study which was conducted in patients who came for lower abdominal laparoscopic surgeries during study period of 3 year. All patients were divided into 2 groups with 30 patients in each group (group A- PLMA, group B - ETT). Age, weight, type of surgery, time required for insertion of device, hemodynamic monitoring, ventilatory parameters, postoperative complications in the form of laryngopharyngeal morbidity were recorded.

Results: In total 60 patients, between the age group of 18-65 year were included which were divided into 2 groups with 30 patients in each group. PLMA required 15.13 seconds as compared to ETT which required 13.33 seconds for insertion of device. The sealing pressure for PLMA was measured by leak test and the average was 32.2 cmH₂O. The mean heart rate, systolic BP, Diastolic BP and MAP at various interval was significantly higher in group B as compared to group A (P-value<0.001 for all). The mean \pm SD of ETCO₂ among the cases studied in Group A and Group B was $36.53 \pm 1.87\%$ and $35.13 \pm 2.51\%$ respectively. Mean of Peak airway pressure (PAP) among the cases studied in PLMA (Group A) and ETT (Group B) was 22.53 mmHg and 18.97 mmHg respectively. No complication or adverse event was noted during post-operative period in PLMA group but in Group ETT, 2 cases were found having blood staining of tube with sore throat in same 2 cases.

Conclusion: PLMA is also proved to be an equally effective airway device in laparoscopic surgeries in the form of adequate oxygenation and ventilation. Also PLMA is associated with minimal intraoperative and postoperative complications. PLMA provided equally effective pulmonary ventilation despite of high airway pressures without significant gastric distension, aspiration and regurgitation.

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1. Introduction

Open surgeries which were done predominantly in previous days are progressing to minimally invasive keyhole laparoscopic surgeries. In same way, airway management has been also progressed from ETT to lesser invasive Laryngeal Mask Airway (LMA).¹ In airway management, the use of supraglottic airway devices have become standard and filling a niche between facemask and tracheal tube in terms of both anatomical position and degree of

invasiveness. These devices provide hands free means to achieve a gas tight airway. The first successful supraglottic airway device, the laryngeal mask airway (LMA) classic became available in 1989, first described by Archie Brain. Second generation supraglottic airway that is Proseal LMA with high seal pressure, has become the benchmark device. Proseal LMA (PLMA) forms a more effective seal than the LMA and has a drainage tube that facilitates passage of gastric tube. LMA once it is correctly placed, it provides the protection against regurgitation as well as prevents gastric insufflation.² This study was undertaken to evaluate the efficacy of Proseal LMA versus endotracheal intubation for

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laparoscopic surgery in selected cases.

2. Materials and Methods

This was a prospective comparative study done in tertiary care center in a teaching institute in Pune after taking approval from ethical committee and included all patients undergoing laparoscopic surgeries, in age group of 18–65 year with ASA I & II grading and BMI less than $<35\text{kg/m}^2$. The written informed consent was taken from all patients. The patients with anticipated difficult airway, those with risk of aspiration and those with oropharyngeal pathology were excluded from study. The preanesthetic checkup was done in detail one day prior to surgery. All the standard monitors were attached. Induction was done with inj. Fentanyl and inj. Propofol. Appropriate size device was inserted in patients undergoing laparoscopic surgeries. The maintenance of anesthesia with O_2 & sevoflurane and muscle relaxant used was inj. rocuronium. The intraoperative parameters like Heart rate, SBP, DBP, MAP, SPO_2 , ETCO_2 , PAW, sealing pressure and postoperative complications like blood staining of device, sore throat and spasm were noted. Correct placement of Proseal LMA was confirmed by- Adequate chest movement on manual ventilation, Square wave capnography, Expired tidal volume of more than 8ml/kg , gas bubble test and Pressure leak test. Any cross over to endotracheal tube during intraoperative events were noted in case of improper placement of PLMA, inadequate seal or unsatisfactory ventilation.

2.1. Statistical data analysis

The data on categorical variables is shown as n (% of cases) and the data on normally distributed continuous variables is presented as mean and standard deviation (SD) across two study groups. The inter-group statistical comparison of distribution of categorical variables is tested using Chi-Square test or Fisher's exact probability test. The inter-group statistical comparison of normally distributed variables is done using independent sample t test. In the entire study, the p-value less than 0.05 are considered to be statistically significant.

3. Results

In total 60 patients were included which were divided into 2 groups as group A and Group B.

The mean age in group A and B were 32.64 year and 37.5 year respectively. Weight of patients in both the groups was (mean) 58 kg and 60.47kg respectively. Maximum and minimum Duration of surgery in both group A and B was 1–3.83 hrs. and 1–3.75hrs.

The minimum – maximum time taken for insertion of device range in Group A and Group B was 10 – 20 Seconds and 10 – 18 Seconds respectively. The mean \pm SD of time taken for insertion of device among the cases studied in

Group A and Group B was 15.13 ± 2.53 Seconds and 13.33 ± 2.66 Seconds respectively.

In our study, sealing pressure for PLMA was measured by leak test and the average was 32.2 cmH₂O.

The mean heart rate at 1-Min, 5-Min, 15-Min, 30-Min, 2-Hr, 3-Hr and after removal of device among the cases is significantly higher in Group B compared to Group A (P-value <0.001 for all). In the same way, mean systolic BP and Diastolic BP at 1-min, 5-min, 30-min, 1-hr, 2-hr, 3-hr and after removal of device among the cases studied is significantly higher in Group B compared to Group A (P-value <0.05 for all). Distribution of mean MAP among the cases studied at 1-min, 5-min 30-min, 1-hr and after removal of device is significantly higher in Group B compared to Group A (P-value <0.05 for all).

The mean \pm SD of ETCO_2 among the cases studied in Group A and Group B was $36.53 \pm 1.87\%$ and $35.13 \pm 2.51\%$ respectively. The minimum – maximum respiratory rate range in Group A and Group B was 12 – 15 per min and 11 – 15 per min respectively.

The minimum – maximum PAP range in Group A and Group B was 17 – 27 mmHg and 13 – 25 mmHg respectively. The mean \pm SD of PAP among the cases studied in Group A and Group B was 22.53 ± 2.69 mmHg and 18.97 ± 2.71 mmHg respectively.

Of 30 cases studied in Group A, none had incidence of blood staining of device and sore throat. Of 30 cases studied in Group B, 2 (6.7%) had incidence of blood staining of device and sore throat.

4. Discussion

There are many developments for minimal invasive surgery which has revolutionized surgical procedures and that has influenced the practice of anesthesiology. Although there are many advantages of Laparoscopic procedures, there are disadvantages as well, like the physiological hemodynamic changes and life-threatening complications such as regurgitation of the gastric contents and potential aspiration due to physiological changes associated with pneumoperitoneum. In view of this, ETT is considered to be gold standard in laparoscopic surgeries to achieve a safe glottic seal. But, for laparoscopic surgeries, anesthetic techniques and airway management have been refined in anticipation of various differences from open surgery.¹

The PLMA is a recent advancement in the family of LMA with some added features over the classic LMA. The design of PLMA with better seal and inclusion of drain tube, makes it a choice of SAD to be used for laparoscopic surgery.²

In our prospective comparative study, 60 patients between age of 18–65 years of ASA I and ASA II category were posted for laparoscopic surgeries under controlled ventilation in various surgeries like appendectomy, umbilical hernia repair, inguinal hernia repair, etc. 60 patients were

Table 1: Inter-group comparison of mean PAP

PAP (mmHg)	Group A (n=30)		Group B (n=30)		P-value
	Mean	SD	Mean	SD	
PAP (mmHg)	22.53	2.69	18.97	2.71	0.001***

Values are mean and SD, P-value by independent sample t test. P-value<0.05 is considered to be statistically significant. ***P-value<0.001.

divided into two groups, PLMA (group A) and ETT (group B), each group included 30 patients. The hemodynamic parameters, ventilatory efficacy as well as adverse effects were monitored in two groups. We chose PLMA as SAD because in previous studies, it has been proved that, for adequate pulmonary ventilation in case of increased intra-abdominal pressure from pneumoperitoneum which require higher airways pressures, there PLMA is proved to be device of choice amongst SADs.

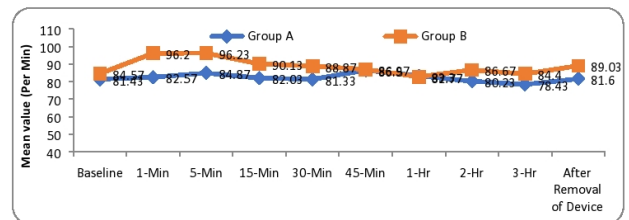
Size of sample, Age, gender, weight and ASA grading when compared in two groups, no statistical difference was seen between two groups. PLMA insertion took 15.13 seconds compared to 13.33 seconds for the traditional ETT insertion. The distribution of mean time taken for insertion of device among the patients studied is statistically higher in group A compared to group B. (p value <0.01). This may be because of larger cuff size of PLMA which may require more time to inflate the cuff.

PLMA cuff pressure measurement done by using cuff pressure manometer and it was maintained within normal range throughout the surgery time. The double cuff arrangement of PLMA prevent the chances of aspiration. Nasogastric tube was inserted in all our cases after confirming that there was no evidence of leak via the drain tube.

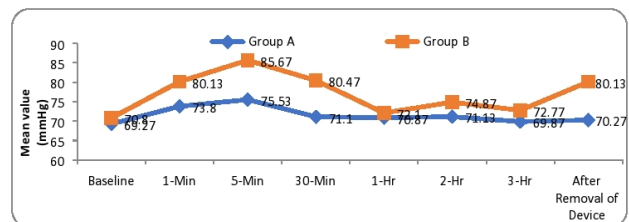
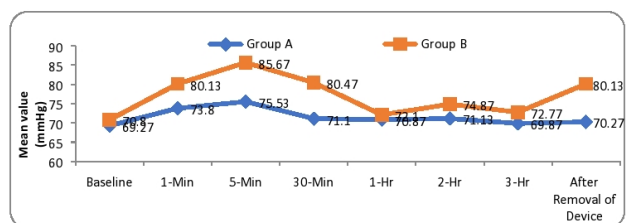
In our study, there was rise in heart rate in both the groups from baseline, during insertion and extubation. The change was statistically highly significant. The magnitude and duration of increase in Heart Rate was more seen in group B than in group A, as shown in Figure 1. Similar results were seen in study done by, Dr S Vinodkumar and Dr. M Vijayasankar, in 2019. They monitored, HR, SBP, DBP, MAP before induction and 1 min, 5 min after intubation, then 5 min after pneumoperitoneum, and every 5min till end of surgery and 5 min after Extubation, and compared between Group I (ETT) and Group II (PLMA). They found that all the parameters are high at the every points mentioned above and concluded that PLMA is hemodynamically more stable than ETT in laparoscopic surgeries. Our observations were comparable with this study.³

Opposed to this findings, Patel et al in 2010 found that there was no change in haemodynamic parameter during insertion and removal of device in the proseal LMA group patients.⁴

In our study, there was rise in SBP, DBP and MAP after 1min, 5min, 30min and after removal of device in both groups but it was significant in ETT group as compared to

**Fig. 1:** Inter-group comparison of mean heart rate

PLMA group, as shown in Figures 2, 3 and 4. The findings in our study were comparable with the study done by Fujii et al., Shahin et al, Garima Agarwal. They found that there was a sustained and significant rise in mean BP in ETT group at 3min post insertion while it came to baseline value at 5min in PLMA group.⁵⁻⁷

**Fig. 2:** Inter-group comparison of mean systolic BP**Fig. 3:** Inter-group comparison of mean diastolic BP

Opposed to these findings, the study done by Lalwani et al (2010) regarding the use of PLMA as an alternative to ETT in paediatric patients. They found that SBP was increased from baseline after insertion of PLMA or ETT and that was statistically insignificant (p>0.05) in both groups.⁸

In our study, the minimum –maximum ETCO₂ range in PLMA and ETT group was 34-40% and 30-39% respectively. The distribution of mean ETCO₂ among

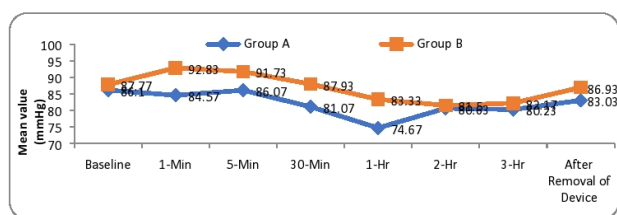


Fig. 4: Inter-group comparison of mean MAP

the cases studied is significantly higher in group PLMA compared to ETT group (p value < 0.05) but it was within acceptable limit. Dave et al evaluated the Proseal LMA as a device for airway management in patients undergoing laparoscopic Surgery and they noted that only two patients PLMA was replaced by ETT in view of increase in ETCO₂.⁹ To achieve the normocapnia, ventilatory parameters designed and the PLMA afford adequate and safe glottic seal. The distribution of RR and FiCO₂ did not differ significantly in our study and RR was adjusted according to the ETCO₂ levels.

In our study, the mean of Peak airway pressure (PAP) among the cases studied in PLMA (Group A) and ETT (Group B) was 22.53 mmHg and 18.97 mmHg respectively. The distribution of mean PAP among the cases studied is significantly higher in Group A compared to Group B (P -value < 0.001) but this was within the acceptable limits as shown in Table 1.

In our study, sealing pressure was measured by leak test and the average was 32.2 cmH₂O. The intraabdominal pressure after pneumoperitoneum was kept in range of 12- 14cmH₂O. The Peak Airway Pressures never crossed the sealing pressure. In the study done by Mishra et al. in 2015, evaluated the effect of pneumoperitoneum and the trendelenburg position on Oropharyngeal Seal pressure in patients undergoing laparoscopic gynecological surgery. He observed that there is a significant increase in Oropharyngeal Seal Pressure after the creation of pneumoperitoneum compared with their baseline values. They concluded that it may be because of the increase in intra-abdominal pressure leading to upward movement of trachea, in an LMA which is already placed and fixed.¹⁰

In our study, of 30 cases in group PLMA, none had incidence of sore throat. Of 30 cases studied in group ETT, two cases (6.7%) had incidence of sore throat and blood staining of device way Pressures never crossed the sealing pressure. Patel MG et al compared the effect of PLMA and ETT in 60 patients of ASA I/II grading undergoing elective lower abdominal surgical procedure, which were divided equally into two groups. Haemodynamic parameters were monitored like heart rate, SBP, DBP, SPO₂ and EtCO₂. In his study, in postoperative period, 40% of patients had coughing and 13.33% had sore throat.⁴

Shroff et al and Higgins et al also found the there was higher incidence of sore throat in patients undergoing

endotracheal intubation than in those in whom PLMA was used.^{11,12} The absence of sore throat in PLMA group can be explained by the fact that it is a supraglottic device and mucosal pressure achieved are usually below pharyngeal perfusion pressure.¹³

Even though the endo-tracheal intubation is the gold standard in laparoscopic surgeries done under GA, the PLMA proved to provide the equally effective oxygenation and ventilation. The haemodynamic stress response was minimal with PLMA as compared to endotracheal intubation. Also the intraoperative and postoperative complications are less with PLMA group. Despite of high airway pressures, PLMA provided equally effective pulmonary ventilation which was not associated with significant gastric distension, aspiration and regurgitation.

5. Conclusion

PLMA provided equally effective pulmonary ventilation despite of high airway pressures without significant gastric distension, aspiration and regurgitation. In comparison to PLMA, the haemodynamic parameters after insertion of ETT reveal significant increase in stress response. PLMA is comparable with ETT in laparoscopic surgeries in securing a patent airway during controlled ventilation.

Thus, PLMA is safe and effective alternative to endotracheal intubation in patients undergoing laparoscopic surgeries.

6. Source of Funding

None.

7. Conflict of Interest

None.

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