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Original research article

An evaluation of proseal laryngeal mask airway as an alternative to endotracheal intubation in patients undergoing laparoscopic surgeries

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Abstract

Introduction: Successful management of airway without adverse events in laparoscopic surgeries is of prime importance which is commonly seen with laryngoscopy and endotracheal intubation. ProSeal LMA having unique features can be used to secure airway without these adverse effects. Our aims in this study primarily are to compare adequacy of ventilation, risk of regurgitation and aspiration of gastric fluid, effect of hemodynamic parameters during and after insertion and throughout the study and ease and time of insertion of device. Secondary parameters are ease of gastric tube insertion and laryngopharyngeal morbidity.

Methods: 60 patients of both sexes between 18 to 60 years of age, ASA physical status 1 & 2, weight between 40 to 65 kg posted for laparoscopic surgeries. After proper consent and premedication. General anaesthesia was administered to the patients who were randomly allotted to groups PLMA and EI. Adequate size device was inserted. Primary and secondary outcomes were recorded.

Result: All statistical tests were "tests of non-inferiority" with type 1 error of 0.05 and a power of 0.8.

Conclusion: ProSeal LMA is an effective alternate to endotracheal intubation in terms of adequacy of ventilation and oxygenation without pulmonary aspiration and gastric regurgitaion. Also provides better hemodynamic stability, less laryngopharyngeal morbidity and less post-operative complication.

Keywords: Laparoscopic surgeries, endotracheal intubation, ProSeal laryngeal mask airway

Introduction

Administering Anesthesia in laparoscopic surgeries demands securing of airway anticipating lot of physiological changes *viz.* respiratory and cardiovascular compliance, inadequate ventilation and risk of regurgitation and aspiration due to peritoneal insufflation. The endotracheal tube is always considered to be the gold standard for laparoscopic surgeries. Conventional laryngoscopy guided endotracheal intubation evokes significant undesirable autonomic and hemodynamic pressure response of hypertension and tachycardia, post-operative complications like sore throat, hoarseness of voice, vocal cord oedema.

Second generation Supraglottic Airway Devices like ProSeal LMA, LMA supreme, Laryngeal Tube Suction, I-gel, Ambu Aura Gain, Ambu Aura Once, Baska Mask etc. have gained popularity. This has advocated the use of second generation Supraglottic Airway Devices (SGDs) for elective and emergency airway management owing to better compliance and safety profile with gastric port. Changes of cardio-respiratory compliance during laparoscopic surgeries do pose a challenge for the efficient use of SGD.

ProSeal LMA, designed in 2000, has an additional posterior cuff which when inflated pushes the mask more anteriorly, providing good airway seal with median seal pressure of 32 cm H_2O and better respiratory compliance during controlled ventilation. It facilitates insertion of nasogastric tube reducing the incidence of aspiration. Considering the above merits and demerits, this study was designed to evaluate the efficient use of ProSeal Laryngeal mask airway primarily for its effectiveness on positive pressure ventilation, effects on hemodynamic parameters, risk of regurgitation/aspiration, ease of insertion and laryngopharyngeal morbidity as compared to endotracheal intubation in patients undergoing laparoscopic surgeries.

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Methods

This prospective, randomized, open labelled study was conducted in a tertiary care hospital between May 2018 to May 2019 on 60 (sample size using test of non-inferiority) consenting patients of ASA I and II status, weighing between 45-60 kg (BMI<30) undergoing laparoscopic surgeries (duration < 4 hours). Patients having anticipated difficult airway or oropharyngeal pathology posing a risk of aspiration were not included in the study. Patients were optimized after a thorough pre-anesthetic evaluation in regards to clinical history and relevant investigations. Proper explanation of procedure, written informed consent, adequate nil per oral hours and proper optimization was ensured on day of surgery. Securing intravenous access with adequate bore cannula, attaching the ASA standard monitors, patients were premedicated with Inj. Glycopyrrolate 0.04 mg/kg, antacid and antiemetic drugs 30 min prior to induction. General Anesthesia with proper preoxygenation, Inj. Propofol 2mg/kg, Inj. Fentanyl 2µg/kg and Inj. Lignocaine 1.5mg/kg were administered. Airway was secured, after adequate bag and mask ventilation, using inj. Atracurium 0.5mg/kg with adequate size of either ProSeal LMA (Group PLMA, n=30) or Endotracheal intubation (Group EI, n=30). The anesthesia was maintained with controlled positive pressure ventilation using same ventilatory parameters in both the groups (aim being to keep SpO2 > 98%, and EtCO2 < 45mm Hg). Proper placement of either of the study device was confirmed with Bilateral equal air sounds on ventilation by stethoscope over chest, Square $EtCO_2$ waveform, expired tidal volume of 7-8 ml/kg, Silent epigastrium by stethoscope auscultation, no audible leak from drain tube, Gel displacement test (In this test drop of gel was placed on drain tube of PLMA and if the drop moved out with ventilation the device position was considered improper). The time between picking up of airway device and establishment of adequate airway was recorded in both the groups.

The number of attempts of insertion and ease of insertion were recorded as below:

- Easy-At first attempt with no resistance.
- Difficult-Insertion with resistance or at second attempt.
- Failed-Insertion not possible or three or more attempts required.

Patients' hemodynamic (Pulse, Systolic Blood pressure, Diastolic blood pressure) and ventilation variables (SpO_2, $EtCO_2$ and Peak Airway pressure) were recorded before induction, 1 minute and 5 minutes after induction, before and after achieving carboperitoneum, after deflation of carboperitoneum and at extubation. Peak airway pressure was recorded before and after achieving carboperitoneum.

A lubricated nasogastric tube was inserted in both the groups. Nasogastric tube size 12 and 14 in PLMA size 3 and 4 respectively while nasogastric tube size 14 or 16 inserted through mouth in ET 7 and 8 respectively. Ease of insertion was noted in both the devices. Complication of aspiration and regurgitation were detected by litmus paper test by detecting pH of secretions. Other complications like hypoxia, hypercarbia, laryngospasm, emphysema etc. were noted. At the end of surgery neuromuscular blockade was reversed with intravenous neostigmine 50 µg/kg and glycopyrrolate 8µg/kg and the patient was shifted to recovery area after extubation.

Results

60 patients were recruited for this study and randomly allocated to either of the group:

Group PMLA, n=30: ProSeal LMA used to secure airway.

Group EI, n=30: Endotracheal tube was used to secure airway.

The demographic parameters were comparable in both the groups.

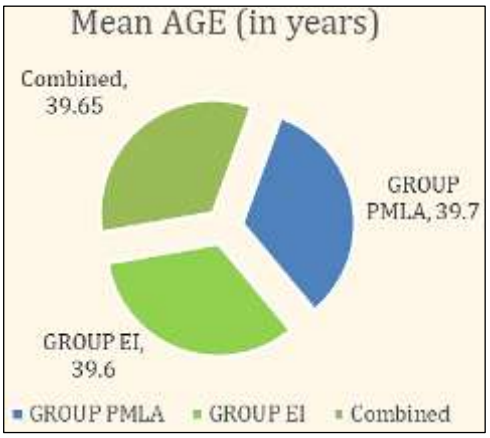

Fig 1: Age Distribution

The mean age of patients in both the groups were around 39.6 in group EI and 39.7 in group PMLA with combined average of 39.65 years.

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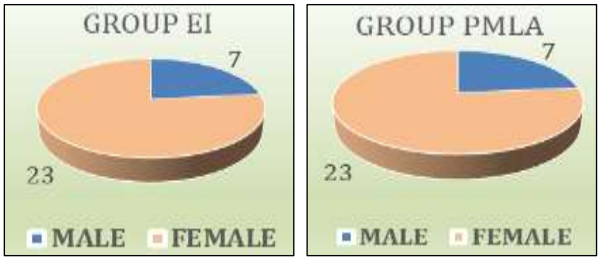

Fig 2: Sex Distribution

The gender distribution was same for both the groups.

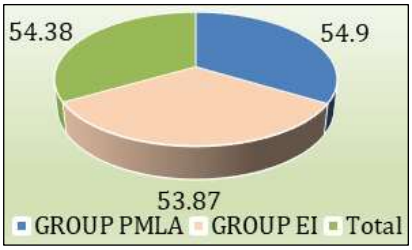

Fig 3: Weight Distribution

The mean weight of patients in both the groups were comparable.

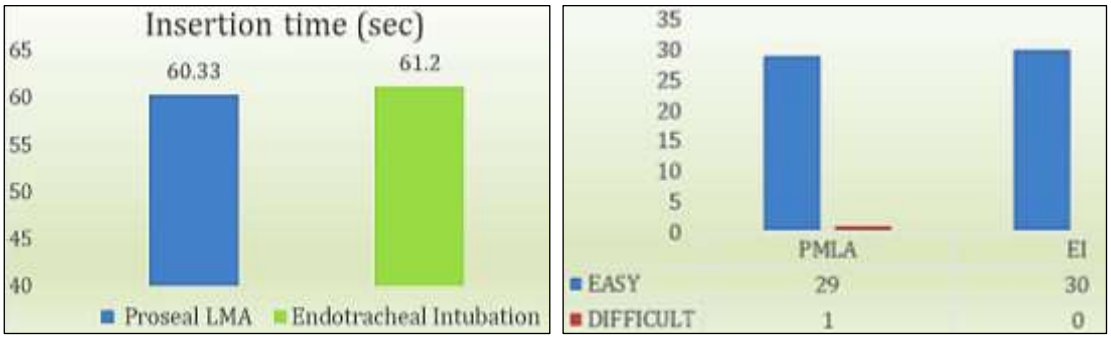

Fig 4: Time of Insertion and Ease of Insertion of Study Airway Device

The mean insertion time for both the devices was comparable and statistically not significant. As far as ease of insertion was concerned, difficulty was faced in one patient in the PMLA group but over all the technicality to insert both the devices was comparable (p>0.05).

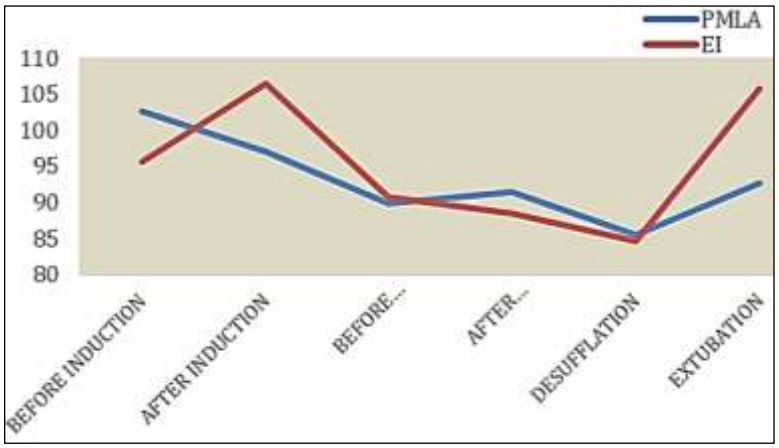

Fig 5: Changes in the pulse rate

Comparing the changes in the hemodynamics with both the devices it was found that pulse was bit high after insertion and at the time of extubation with use of endotracheal tube but at rest all predefined time intervals there was no statistical significance seen in regards to the changes in pulse rate in both the study groups. Pulse in PLMA group after 1 min of induction was 97.13±11.91 and extubation was 92.07±11.55

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as compared to EI group, after 1 min 106.57±12.01 and extubation 105.77±13.53.
There is significant rise in mean blood pressure after 1 min and 5 mins of endotracheal intubation 89.34±8.54 and 82.33±7.72 as compared to PLMA 76.03±5.43 and 74.42±5.85 respectively. At rest all the predefined intervals it was comparable with use of PMLA and EI.

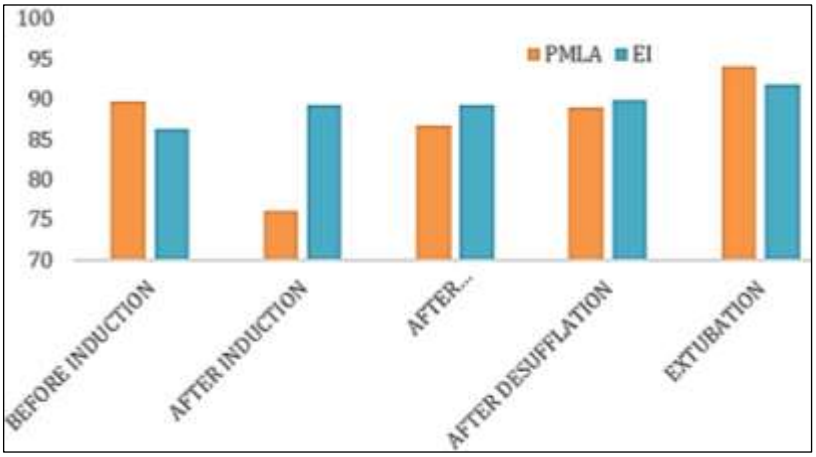

Fig 6: Changes in the Mean Arterial pressure (MAP)

There is significant rise in mean blood pressure after 1 min and 5 mins of endotracheal intubation 89.34±8.54 and 82.33±7.72 as compared to PLMA 76.03±5.43 and 74.42±5.85 respectively. At rest all the predefined intervals it was comparable with use of PMLA and EI.

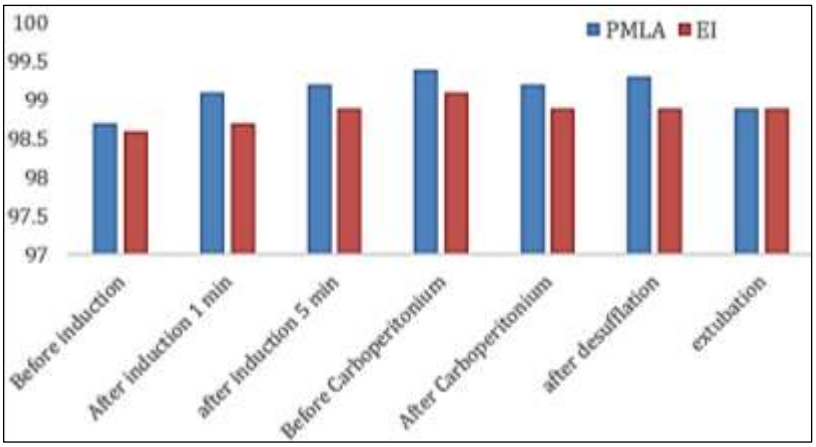

Fig 7: Changes in the Oxygen saturation (SpO_2)

No statistical difference in the values of oxygen saturation was seen in both the groups at all the observed times and no untoward incidence of fall in saturation was noted.

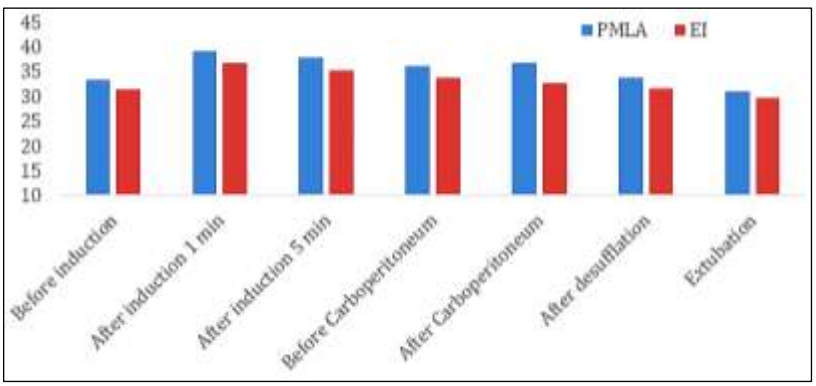

Fig 8: Changes in End tidal Carbon dioxide level ($EtCO_2$)

The end tidal CO_2 values were around 35 in both the groups, respiratory compliance was satisfactorily seen in regards to the mechanical ventilation for laparoscopic surgeries with use of both the study devices.

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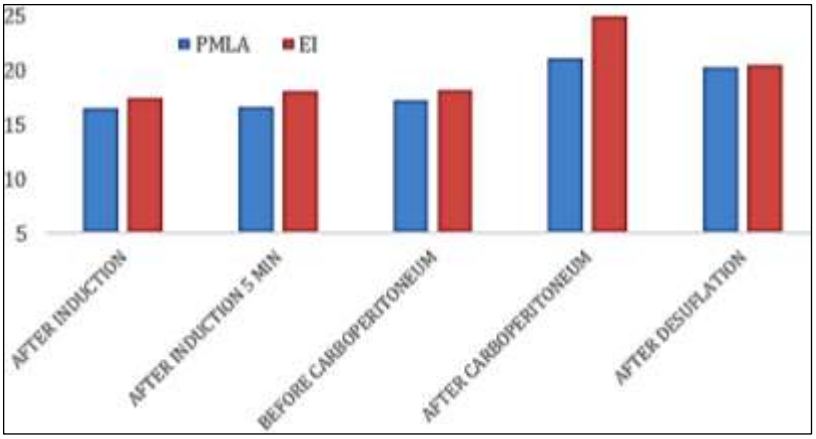

Fig 9: Changes in the mean airway pressure

The mean airway pressure was well within the controlled limits with good respiratory compliance maintained all throughout the surgery in both the study device in concern.
The incidence of complications was noted for both the groups immediately in the recovery room and 24 hours after the surgery. The overall incidence of complications like trauma, aspiration (checked by litmus paper test) were minimum in both the groups.

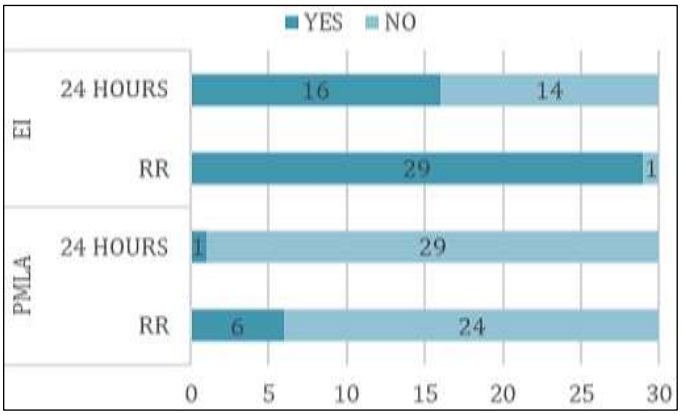

Fig 10: Incidence of Sore Throat in both groups

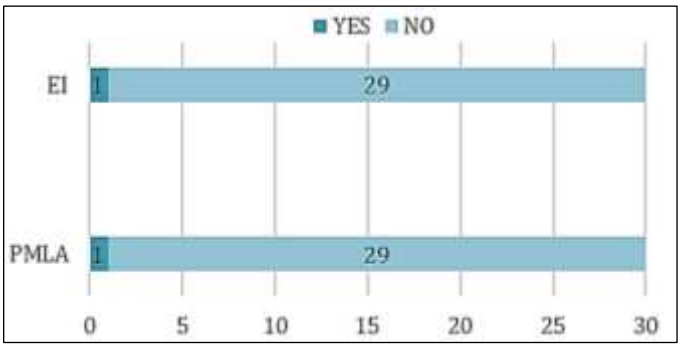

Fig 11: Incidence of Blood present on device

Technical ease of insertion of nasogastric tube for gastric de-sufflation in laparoscopic surgeries was also noted. Some difficulty was observed in 3 patients with use of PMLA.

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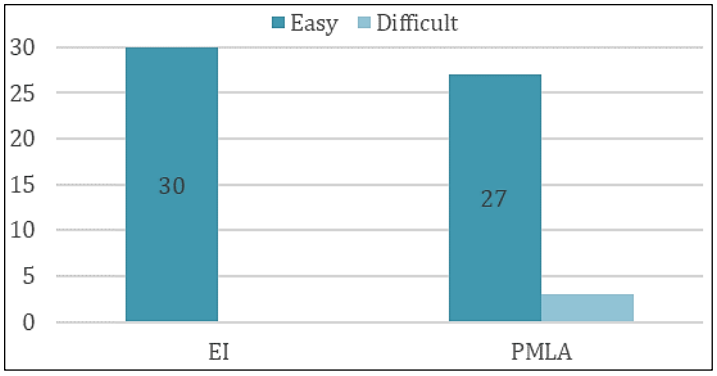

Fig 12: Ease of insertion of Ryle's tube

Discussion

Second generation Supraglottic airway devices have emerged as effective alternative in successful airway management during elective surgical procedures. ProSeal Laryngeal Mask Airway provides more pressure seal as compared to the classic LMA, better respiratory compliance during positive pressure ventilation and less incidence of aspiration owing to the separate drain tube for insertion of nasogastric tube. The markedly attenuated hemodynamic response at insertion of PLMA and its role in difficult airway scenario is a definite advantage over tracheal tube. It also causes less damage to the oropharyngeal structures.

We chose to compare the SGD ProSeal LMA with endotracheal tube during laparoscopic surgeries keeping the above meritorious features. Similar studies by Kapoor *et al*. (2018) comparing PMLA with endotracheal tube, Belena (2015)-use of SGD in laparoscopic surgeries, N Saraswat (2011)-comparison of SGD with EI in laparoscopic cholecystectomies were of the opinion that SGDs can be a suitable alternative for securing airway with comparable respiratory mechanics during General Anesthesia.

The time and ease of insertion of SGDs as compared to the conventional endotracheal intubation was also compared and we found that in 3% of patients there was difficulty felt in insertion of the PMLA. Similar studies by Kapoor D *et al*. [1], Rustagi P *et al*. [2], Parikhs S S *et al*. [4], Patodi V *et al*. [8], Borkataki SS *et al*. [9], Kannan S *et al*. [11], N Sarswat *et al*. [13], Fabregat-López J *et al*. [14], Jain MK *et al*. [17], B Sharma *et al*. [18], M Misra *et al*. [19] compared use of SGD in regards to endotracheal tube taking into consideration the number of attempts for insertion, time taken for securing the airway and correct placement of the device. Our results were comparable as far as the time of insertion and number of attempts were considered to above studies. The reason of difficulty in insertion in 3% of patients in our study would be due to bulky morphology of PLMA and semi rigid structure distal end of drain tubes. In our study, the effective airway achievement time was noted from time of picking up of airway device and establishment of effective airway in seconds. The mean time for PLMA insertion was 60.33 seconds and for Endotracheal intubation was 61.20 seconds which was statistically similar for PLMA and EI (p>0.05).

The adequacy of ventilation and achievement of effective airway were comparable after insertion of device, during and after carboperitoneum and after extubation. The oxygen saturation was never less than 95% in any group throughout the study period. $EtCO_2$ was never above 45 mmHg and there was no need to change the ventilation variables during intraoperative period to maintain adequate ventilation once effective airway was established. Similar results were also observed in other studies like Kapoor D *et al*. [1], Rustagi P *et al*. [2], Parikhs S S *et al*. [4], Patodi V *et al*. [8], Borkataki SS *et al*. [9], Kannan S *et al*. [11], N Sarasvat *et al*. [13], Fabregat-López J *et al*. [14], Jain MK *et al*. [17], B Sharma *et al*. [18], M Misra *et al*. [19] where there was significant difference in the respiratory parameters and the respiratory compliance during the mechanical ventilation. Even after the creation of carboperitoneum major changes in the airway pressures were not observed in our study and few of other studies as reviewed in the literature.

The hemodynamic stability seen all through out the surgery with no significant changes in pulse and mean arterial blood pressures in both the groups. This was also observed in the studies like Kapoor D *et al*. [1], Rustagi P *et al*. [2], Parikhs S S *et al*. [4], Goel L *et al*. [6], Patodi V *et al*. [8], Borkataki SS *et al*. [9], Kannan S *et al*. [11], N Saraswat *et al*. [13], Fabregat-López J *et al*. [14], J Lalwani *et al*. [15], Patel MG *et al*. [16], Jain MK *et al*. [17], B Sharma *et al*. [18], M Misra *et al*. [19].

The incidence of aspiration as confirmed by Litmus test was not observed in any of our patients in both the groups similar to Kapoor D *et al*. [1], Rustagi P *et al*. [2], Parikhs S S *et al*. [4] Saini S *et al*. [5], Goel L *et al*. [6], Patodi V *et al*. [8], Borkataki SS *et al*. [9], Kannan S *et al*. [11], N Saraswat *et al*. [13], Fabregat-López J *et al*. [14], J Lalwani *et al*. [15], Jain MK *et al*. [17], M Misra *et al*. [19]. Slight trauma was observed in two patients while insertion of PMLA due to its bulky structure, but this was also statistically non-significant. Other studies done using various SGDs compared with other SGDs and conventional intubation were also of similar results like Maitra S *et al*. [7], Park SK *et al*. [10], Mishra SK *et al*. [12], B Sharma *et al*. [18].

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Conclusion

Based on the above observations it is concluded that in elective laparoscopic surgeries ProSeal Laryngeal Mask Airway is an effective alternative to Endotracheal intubation as it provides adequate oxygenation and ventilation without pulmonary aspiration and gastric regurgitation. Also, the PLMA provides more hemodynamic stability, causes less laryngopharyngeal morbidity and lesser post-operative complications compared to Endotracheal tube.

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