International Journal of Research in Medical Sciences
Shibin A et al. Int J Res Med Sci. 2023 Jan;11(1):277-283
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20223651

Original Research Article

Comparative study of ProSeal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia

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Received: 21 November 2022
Revised: 13 December 2022
Accepted: 16 December 2022

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ABSTRACT

Background: Supra glottic airway devices (SGAD) is integral to airway management during general anesthesia. PLMA, a second-generation SGAD with a gastric channel and an efficient seal, is an alternative for the COETT, which is the gold standard for securing the airway.

SGAD has the advantage of lesser hemodynamic changes during insertion and removal. This study aimed to compare the hemodynamic and ventilatory changes between PLMA and the endotracheal tube (ETT).

Methods: Prospective randomized study, conducted at Yenepoya medical college hospital on 90 patients undergoing elective laparoscopic surgeries under general Anaesthesia. The patients were divided into groups; group p=45 patients (PMLA) and E=45 patients (COETT). Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), peripheral oxygen saturation (SpO_2) and end-tidal carbon dioxide ($EtCO_2$) were documented at baseline, at 1, 3, 5 and 8 minutes after placement of airway device.

Results: Differences in vital parameters at baseline were statistically insignificant. HR, SBP, DBP and MAP were significantly higher in group E compared to group P at 1st, 3rd, 5th and 8 min after the insertion of the airway device. There was no statistically significant difference in SpO_2 and $EtCO_2$. Post-extubation laryngopharyngeal morbidity was noted in 5 patients with ETT compared to 1 patient with PMLA.

Conclusions: PLMA provides better hemodynamic stability at insertion when compared to ETT. Both PLMA and ETT provide good oxygenation and ventilation during elective laparoscopic surgeries. Insertion at first attempt was more successful with PLMA when compared to ETT.

Keywords: ProSeal laryngeal mask airway, ETT, Supraglottic airway devices, Laparoscopic surgery

INTRODUCTION

Regardless of the various advances in contemporary anaesthetic practices, advances in the field of airway management continue to be most important to anaesthesiologist. Endotracheal intubation and extubation are stressful and are associated with cardiovascular stimulation.[1,2] Other disadvantages of tracheal intubation include hemodynamic reactions to laryngoscopy and damage to oropharyngeal structures during insertion with and postoperative sore throat.

One of the newer advancements in airway management is ProSeal laryngeal mask airway (PLMA), a supra glottic airway device (SAD) which has an additional dorsal cuff as compared to classic laryngeal mask airway (LMA), which helps in pushing the mask anterior to provide a better seal around the glottic aperture and also helps in permitting high airway pressure without leak. PLMA also has a drainage tube which allows the passage of gastric tube for aspiration of stomach contents. Classic LMA is not a very common system for positive pressure ventilation due to fear of gastric distension, gastric aspiration and insufficient ventilation.[4] Positive pressure ventilation may exploit leaks around the LMA cuff, leading to gastric distension and/or inadequate ventilation.

Whereas PLMA offers many advantages over classic LMA. It provides a stronger glottic seal at lower mucosal pressures and isolates the alimentary system from the respiratory tree. PLMA provides a drain tube which is parallel to the ventilation tube, it permits drainage of passively regurgitated gastric fluid away from the airway and it also serves as a passage for gastric tube.

Intubation with PLMA results in a lower stimulation of hemodynamic responses as compared with tracheal intubation via laryngoscopy. LMA provide a more superior emergence from anaesthesia with reduced cardiovascular stimulation and cough reflex. Another use of LMA is, Bailey manoeuvre which involves the replacement of ETT with supraglottic airway device to maintain a patent airway at the end of surgery in difficult airway. If there is a need for reintubation SAD can be used as a tracheal intubation conduit.

The purpose of this prospective study is to compare PLMA with standard tracheal tube for the hemodynamic changes, oxygenation and ventilation.

METHODS

Aim of the study is to compare the hemodynamic and ventilatory changes between PLMA and ETT. Objective of the study is to compare between PLMA and ETT in terms of hemodynamic changes, ventilatory and oxygenation changes during insertion when used for elective laparoscopic surgeries. This prospective randomised single blind clinical study was undertaken to compare ETT and PLMA in terms of hemodynamic, oxygenation and ventilatory changes during insertion when used in elective laparoscopic surgeries. The study was conducted in 90 patients aged between 18-50 years undergoing elective laparoscopic surgeries at Yenepoya medical college hospital, Deralakatte, under general anaesthesia during the period of October 2018 to October 2020. After institutional ethics committee approval study was started. After obtaining written informed consent, 90 ASA PS I and II patients of either sex between 18-50 years of age, undergoing various elective laparoscopic surgeries under general anaesthesia were selected for this study.

Thorough pre-anaesthetic evaluation and relevant investigations were carried out in selected patients after getting written informed consent for the study. The patients were explained regarding both the procedures.

Premedication tab. ranitidine 150 mg at night before surgery and on the morning of the surgery and tab. alprazolam 0.5 mg at night before surgery, was given, on the morning of surgery patients were randomly divided into two groups by closed envelope method.

Group P (PLMA): in this group-45 patients. PLMA to be used to secure the airway. Group E (ETT): in this group - 45 patients. Cuffed ETT to be used to secure the airway.

After shifting to the operating room, monitors were applied for monitoring of the following parameters: HR, non-invasive blood pressure, 3 lead electrocardiogram, peripheral saturation of oxygen.

A peripheral cannula was secured. Intravenous infusion of Ringer lactate was started. Intravenous midazolam 0.02 mg/kg, intravenous glycopyrrolate 5mcg/kg and intravenous fentanyl 2 mcg/kg were given. After preoxygenation with 100% oxygen for 3 minutes, patient was induced with intravenous propofol 2 mg/kg. Neuromuscular blockade to facilitate placement of airway device was achieved by intravenous vecuronium 0.15 mg/kg. Following adequate paralysis, for group P, PLMA of appropriate size was inserted after lubricating the dorsal surface of the device and group E, appropriate size cuffed ETT was placed under direct laryngoscopy. End tidal Carbon dioxide monitoring was connected. The cuffs of both devices were inflated and device was fixed. ETT cuff pressure was maintained at 24 cm of H_2O and PLMA cuff pressure was maintained at 40 cm of H_2O. Patients were ventilated using N_2O: O_2(4:2) and isoflurane 0.6-0.8% in closed circuit with circle absorber and connected to ventilator. Tidal volume 7 ml/kg, frequency 14/minute.

Correct placement of the airway devices was confirmed by: Adequate chest movement on manual ventilation and square wave capnography

In PLMA group, correct device placement was checked by: No audible leak from the drain tube with peak airway pressure less than 20 cm H_2O. The gel displacement test will be done by placing a blob of gel at the tip of the drain tube and the airway pressure at which it was ejected will be noted.

The following parameters was noted: haemodynamic changes: HR, systolic blood pressure, diastolic blood pressure and mean arterial pressure were recorded at baseline, then at 1 min, 3 min, 5 min and 8 min after placement of the airway

Ventilatory changes included peripheral saturation of oxygen were recorded at baseline, then at 1 min, 3 min, 5 min and 8 min after placement of the airway and end tidal carbon dioxide were recorded at 1 min, 3 min, 5 min and 8 min after placement of airway.

After 8 minutes surgeon was allowed to start with pneumoperitoneum. At the end of operation, reversal of neuromuscular blockade was achieved with inj. neostigmine 0.05 mg/kg and inj. glycopyrrolate 0.01

mg/kg. The device was removed after achievement of spontaneous breathing and recovery of consciousness.

Statistical analysis

All data was analysed using statistical package for the social sciences (SPSS) for windows, version 23.0. Continuous variables will be expressed as mean ± SD. Percentages will be used to express categorical variables.

The independent t test was applied to find out the difference between two means. P<0.05 will be considered as the criteria for statistical significance.

Sample size

Sample size was calculated using G power software with level of significance α=5% power 1-β=80%, effect size d=0.6 with 95% confidence interval, the minimum sample size required in each group was 45. Total sample size was 90.

Inclusion criteria

Age between 18-50 years, both male and female genders, ASA physical status 1 and 2, Mallampati class 1 and 2, BMI between 20-25 kg/m^2 were included in the study.

Exclusion criteria

Patients with anticipated difficult airway and patients with GERD or hiatus hernia excluded from the study.

RESULTS

Total of 90 patients fulfilling the inclusion and exclusion criteria were included in present study after obtaining the informed written consent.

Increase in mean heart rate at different intervals found significantly higher in ETT group compared to PLMA.

In the Table 2, increase in SBP at different intervals was found significantly higher in ETT group compared to PLMA.

In both groups there was significant increase in diastolic blood pressure after the insertion of airway in Table 3.

MAP increase at different intervals was found significantly higher in ETT group when compared to PLMA group in Table 4.

The ventilation changes with respect to the SPO_2 and $ETCO_2$, there was no statistical different in both the groups of patients in Table 6.

Table 1: Change in heart rate from baseline at various interval during intubation.

Heart rate during intubation	Baseline (a)	1st min (b)	3rd min (c)	5th min (d)	8th min (e)
PLMA	71.18±7.11	74.98±7.03**	74.13±7.61**	72.04±7.68**	70.71±7.15
ETT	69.53±6.58	97.11±5.5**	97.20±5.47**	90.84±4.56**	82.69±5.34**

*p<0.05 is statistically significant; **p<0.001 is statistically highly significant.

Table 2: Change in systolic blood pressure from baseline at various interval during intubation.

Systolic blood pressure during intubation	Baseline (a)	1st min (b)	3rd min (c)	5th min (d)	8th min (e)
PLMA	123.82±7.09	127.27±7.29**	125.91±7.49**	123.69±7.26	122.62±7.32**
ETT	121.07±7.77	142.71±6.66**	142.40±6.55n**	137.0±5.76**	129.07±5.80**

*p<0.05 is statistically significant; **p<0.001 is statistically highly significant.

Table 3: Change in diastolic blood pressure from baseline at various interval during intubation.

Diastolic blood pressure during intubation	Baseline (a)	1st min (b)	3rd min (c)	5th min (d)	8th min (e)
PLMA	80.58±5.38	83.02±5.28**	82.0±5.29**	80.44±5.23	79.69±5.16*
ETT	78.09±5.35	92.89±5.24**	92.53±4.9**	87±3.9**	81.02±3.4**

*p<0.05 is statistically significant; **p<0.001 is statistically highly significant.

Table 4: Change in MAP from baseline at various interval during intubation.

MAP during intubation	Baseline (a)	1st min (b)	3rd min (c)	5th min (d)	8th min (e)
PLMA	102.13±5.89	105.13±5.94**	103.8±6.19**	102.16±6.22	101.18±6.18**
ETT	99.58±6.26**	117.8±5.66**	117.47±5.5**	112.11±4.42**	104.91±4.05**

*p<0.05 is statistically significant; **p<0.001 is statistically highly significant.

Table 5: Change in SPO2 from baseline at various interval during intubation.

SpO_2 during intubation	Baseline (a)	1st min (b)	3rd min (c)	5th min (d)	8th min (e)
PLMA	99.38±0.8	99.07±0.86**	99.42±0.69	99.76±0.52*	99.84±0.36**
ETT	99.36±0.86	99.0±1.00**	99.33±0.73	99.67±0.56	99.89±0.31*

*p<0.05 is statistically significant; **p<0.001 is statistically highly significant.

Table 6: Change in $ETCO_2$ from baseline at various interval during intubation.

$ETCO_2$ during intubation	Baseline (a)	1st min (b)	3rd min (c)	5th min (d)	8th min (e)
PLMA	31.33±1.52	32.31±1.25**	32.47±0.99**	31.58±1.09	31.29±1.57
ETT	31.27±1.15	32.93±1.00**	32.58±1.17**	31.28±1.23	31.33±1.38

*p<0.05 is statistically significant; **p<0.001 is statistically highly significant.

DISCUSSION

The LMA introduced in 1983 revolutionised the treatment of patients who had previously undergone facial mask anaesthesia, allowing the anaesthetist to have both hands free. Since its commercial launch in 1988, the use of laryngeal masks airway during surgery has grown exponentially. The use of LMA has questioned the belief that tracheal intubation is only appropriate means of ensuring clear airways and positive pressure ventilation.

PLMA is one of the second-generation SADs with a larger, wedge-shaped cuff and incorporates a drain tube to separate the respiratory and gastrointestinal tracts and thus, minimizes the risk of aspiration. Since its introduction in 2000, several studies have demonstrated the feasibility and efficiency of PLMA as an airway device in laparoscopic surgeries. Being non-invasive when compared to endotracheal intubation they have an advantage over ETT intubation as PLMA could be inserted without the aid of a laryngoscope.

In our present study we compared the hemodynamic parameters at various intervals after the insertion of either PLMA or cuffed ETT were used for securing the airway for laparoscopic surgeries. Baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressures and peripheral saturation of oxygen were statistically comparable in both the groups (p>0.05).

Heart rate

HR increased in both groups after the insertion of the airway device. In the PMLA group HR increased by 3.8±1.03 bpm over the baseline at 1st minute, 2.95±1.03 bpm over baseline at 3rd minute, 0.86±1.1 at 5th minute and 0.47±1.24 bpm above base line at 8th minute. In comparison to this ETT group had significantly higher increase in heart rate, 27.58±7.03 bpm over baseline at 1st minute, 27.67±7.61 bpm over baseline at 3rd minute, 21.31±7.68 bpm over baseline at 5th minute and 13.16±7.15 bpm over the baseline at 8th minute from the baseline (69.53±6.58).

In ETT group, the mean increase in heart rate at 1st min was 27.58±7.03 (97.11±5.5) beats per min, at 3rd min was 27.67±7.61 (97.20±5.5) beats per min, at 5th min was 21.31±7.68 (90.84±4.56) and 8th min was 13.16±7.15(82.69±5.34) from the baseline (69.53±6.58). However, similarly, in PLMA group the increase in the heart rate at 1st min was 3.8±0.45 beats per min (74.98±7.03), 3rd min was 2.95±1.03 (74.13±7.61), 5th min was 0.86±1.1 (72.04±7.68) and 8th min was 0.47±1.24 (82.69±5.34) from the baseline (69.53±6.58). The increase in mean heart rate at different intervals was found significantly higher in ETT group compared to PLMA. Similar results were observed by Patodi and colleagues who compared ETT and PLMA in 60 patients who underwent laparoscopic cholecystectomy. In their study in the PLMA group, mean HR increased from 86.20±13.57 bpm to 84.13±15.40 at insertion, 85.13±13.66 bpm at 1 min and 85.67±14.20 bpm at 3 min and 85.47±11.55 bpm at 5 min. In the ETT group HR increase was much higher. The mean HR increased significantly from 86.20±8.14 bpm to 98.40±13.90 at insertion, 103.83±11.70 bpm at 1 min and 101.90±13.77, bpm at 3 min and 94.47±20.00 bpm at 5 min in the ETT group. Similarly, Shah compared PLMA and ETT in 200 patients who underwent beating heart coronary artery bypass graft procedures. She observed in PMLA group mean baseline pulse rate was 83 bpm, which reduced to 77 bpm at 1 minute of insertion, 76 bpm at 3 minutes and 74 bpm 5 minutes after insertion, whereas in ETT group mean baseline pulse rate was 75 bpm, which increased to 82 bpm at 1 minute of intubation, 84 bpm at 3 minutes and 83 bpm 5 minutes after insertion.

Systolic blood pressure

In both the groups there was increase in systolic blood pressure after the insertion of airway. In PLMA group, the mean increase in the SBP at 1st min was 3.45±7.79 mmHg (127.27±7.29), at 3rd min was 2.09±7.49 mmHg (125.91±7.49), at 5th min was 0.13±7.26 mmHg (123.69±7.26) and at 8th min was 1.2±7.32 mmHg (122.62±7.32) from the baseline (123.82±7.09). In ETT group the mean increase in systolic blood pressure at 1st min. was 21.64±6.66 mmHg (142.71±6.66), at 3rd min was 21.33±6.55 mmHg (142.40±6.55), at 5th min was 15.93±5.76 (137.0±5.76) and at 8th min was 8±5.80 (129.07±5.80) from the baseline (121.07±7.77). The increase in SBP at different intervals was found significantly higher in ETT group compared to PLMA. Similar results were observed by Patodi and colleagues, the mean SBP increased from its baseline value, 133.07±10.75 to 148.27±16.47 mm Hg at 1 min,142.80±20.04 mmHg at 3 min and 141.67±9.53 at 5 min, after intubation in ETT group which was statistically significant, ($p<0.05$). Similarly, Shah compared PLMA and ETT in 200 patients who underwent beating heart coronary artery bypass graft procedures. She observed in ETT group mean baseline SBP group was 134.52 mmHg which increased to 148 mmHg at 1 min of intubation, 149 mmHg at 3 min. and reduced to 142 mmHg at 5 min after intubation and then increased to 147 mmHg at 10 min after intubation. In PLMA group the baseline SBP was 135 mmHg which decreased to 134 mmHg at 1st min, 129 mmHg at 3 min of insertion, increased to 134 mmHg at 5 min, and reduced to 118 mmHg at 10 min after insertion.

Diastolic blood pressure

In both the groups there was increase in diastolic blood pressure after the insertion of airway. In PLMA group the mean increase in DBP at 1st min was 2.44±5.28 mmHg (83.02±5.28), at 3rd min was 1.42±5.29 mmHg (82.0±5.29), at 5th min was 0.14±5.23 mmHg (80.44±5.23) and at 8 min was 0.89±5.16 mmHg (79.69±5.16) from baseline (80.58±5.38). In comparison to this ETT group, the mean increase in diastolic blood pressure at 1st min was 14.8±5.24 mmHg (92.89±5.24), at 3rd min was 14.44±4.9 mmHg (92.53±4.9), at 5th was 8.91±3.9 mmHg (87.0±3.9) and at 8 min was 2.93±3.4 mmHg (81.02±3.4) from baseline (78.09±5.35). Mean increase in DBP at different intervals was found significantly higher in ETT group compared to PLMA group. Similar results were observed in study conducted by Veena Patodi and colleagues, in ETT group the baseline DBP was 83.53 mmHg which significantly increased to 94.87 mmHg at 1 min of insertion, 93 mmHg at 3 min, 89 mmHg at 5 min after intubation. In PLMA group, the baseline DBP was 83.53 mmHg which decreased to 77.80 mmHg at 1 min of insertion,78.47 mmHg at 3 min and 81.53 mmHg at 5 min. Similarly in the study by Kalpana Shah, she observed that in ETT group the mean base DBP was 75 mmHg which changed 71 mmHg at 1 min and 3 min of insertion,69 mmHg at 5 min of insertion. In PLMA group, the baseline DBP was 79 mmHg which decreased to 71 mmHg at 1 min, 70 mmHg at 3 min, 67 mmHg at 5 min of insertion.

Mean arterial pressure

MAP increased in both groups after insertion of airway. In PLMA group the mean increase in MAP at 1st min was 3±5.94 mmHg (105.13±5.94), at 3rd min was 1.67±6.19 mmHg (103.8±6.19), at 5th min was 0.03±6.22 mmHg (102.16±6.22), at 8 min was 0.95±6.18 mmHg (101.18±6.18) from baseline (102.13±5.89). In ETT group, the mean increase in MAP at 1st min was 18.22±5.66 mmHg (117.8±5.66), at 3rd min was 17.89±4.42 mmHg (117.47±5.5), at 5th min was 12.53±4.42 mmHg (112.11±4.42), and at 8th min was 5.33±4.05 mmHg (104.91±4.05) from baseline (99.58±6.26). MAP increase at different intervals was found significantly higher in ETT group when compared to PLMA group. Similar results were observed by Patodi and colleagues, in ETT group, the mean arterial pressure increased from baseline 101.64±8.76 mmHg to 112.6±8.89 mmHg at 1 min, 110.18±10.99 mmHg at 3 min and 106.60±12.65 mmHg at 5 min in the ETT group, ($p<0.05$), whereas no statistically significant haemodynamic changes were observed from their baseline values in the PLMA group, ($p>0.05$). Similar results were obtained in study conducted by Shah.[24]

The ventilation changes with respect to the SPO_2 and $ETCO_2$, there was no statistical different in both the groups of patients. Similar results were seen in a study conducted by Saraswat et al., in which the mean change in hemodynamic and respiratory parameters with use of PLMA and ETT in the patients undergoing laparoscopic surgeries under general anaesthesia was evaluated. Results showed that both groups (PLMA group and ETT group) had maintained SpO_2 perioperatively along with the comparable value of $EtCO_2$. Similarly, Shah compared PLMA and ETT in 200 patients who underwent beating heart coronary artery bypass graft procedures. She observed there was no significant difference in the respiratory parameters like SpO_2, pCO_2.[24]

The success rate of insertion at first attempt with PLMA was 97.8% which was higher than the ETT (95.6%). The maximum attempts required for insertion in both the group were 2 attempts. Our findings were in consistent with those noted in most of the studies.[21,33,35] In study by Lim et al the maximum attempts required for insertion were 2 in number and there was no episode of failed ventilation, similar to present study.[36]

In this study, we did not find any regurgitation of gastric content through the drain tube in the case of PLMA, and NGT was inserted through the drain tube of all the patient in PMLA group and under direct laryngoscopy in ETT group in all of our patients and intermittent suction used.

Post operative pharyngolaryngeal morbidity

We found presence of presence of post-extubation cough among the 5 patients (11.1%) in ETT group compared to the 1 patient (2.2%) in PLMA group. These findings were in concordance with various studies.[33,35] Injury to lip, tongue, and teeth was not observed in any of the patients in either group. One patient (2.2%) in ETT group had presence of blood in the tube after extubation. Similar results were observed in other studies.[31,33]

CONCLUSION

The PLMA provides better hemodynamic stability at insertion, good oxygenation and adequate ventilation in comparison to ETT, when used for the airway management in elective laparoscopic surgeries. Successful insertion at first attempt was more with PMLA when compared to ETT. PMLA was associated with reduced postoperative laryngopharyngeal morbidity.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Shibin A, Priyamkari A, Habib RAA. Comparative study of ProSeal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia. Int J Res Med Sci 2023;11:277-83.