Comparing ABG Analysis and Hemodynamics in Patients Undergoing Laparoscopic Cholecystectomy with Either ProSeal Laryngeal Mask Airway or Cuffed Endotracheal Tube as Airway Conduit: A Randomized Trial

Shyamli Jamwal[1], Vatika Bhardwaj[2], Vishwajeet Singh[3], Rajneet Kaur[4]

[1]Assistant Professor, [2]Senior Resident, [3]Assistant Professor, Department of Anaesthesia, Shri Lal Bahadur Shastri Government Medical College, Mandi, Himachal Pradesh 175021, India.[4]Assistant Professor, Department of Physiology, Pandit Jawahar Lal Nehru Government Medical College, Chamba, Himachal Pradesh 176310, India.

Abstract

Background and Aims: ProSeal Laryngeal Mask Airway (PLMA) has been proven to cause minimal hemodynamic fluctuations and postoperative complications when compared to cuffed Endotracheal Tubes (ETT) in laparoscopic surgeries. Hence, present study was done to compare ABG analysis and hemodynamic parameters in patients undergoing laparoscopic cholecystectomy. *Materials and Methods:* Present study included fifty American Society of Anesthesiologist Class I patients weighing 30–70 kg within age group of 20–60 years posted for elective laparoscopy cholecystectomy after the ethical committee clearance and were randomly allocated to either PLMA (Group I) or ETT (Group II) group with 25 in each group. Hemodynamic responses, ABG analysis and postoperative complications were noted and compared. *Results:* There was no demographic difference. When we analyzed heart rate, systolic and diastolic blood pressure, mean arterial pressure values, they were found to be comparable throughout except for those after insertion ($p < 0.05$). The ABG analysis and $EtCO_2$ before pneumoperitoneum and one hour after pneumoperitoneum showed no significant difference ($p > 0.05$) with either of the device. No case of regurgitation or aspiration found in either group. Postoperative complications were mainly seen with ETT Group. *Conclusion:* Metabolic effects of either PLMA and ETT during laparoscopy cholecystectomy were similar but PLMA affects the hemodynamic parameters to a lesser degree making it a better choice.

Keywords: Ventilatory mechanics; ABG analysis; PLMA; Hemodynamics; ETT.

Introduction

The airway management of the patients undergoing laparoscopic procedures has progressed from Endotracheal Intubation (ETT) to lesser invasive devices like ProSeal Laryngeal Mask Airway (PLMA). One of the major advantages of these devices is that they are easily available, can be used even by inexperienced personnel and are almost atraumatic to the airway during insertion. The other advantages of supraglottic devices over ETT include tendency of causing less hemodynamic instability at induction and emergence, minimal

Corresponding Author: **Vatika Bhardwaj,** Senior Resident, Department of Anaesthesia, Shri Lal Bahadur Shastri Government Medical College, Mandi, Himachal Pradesh 175021, India.

E-mail: vatika.b17@gmail.com

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increase in intraocular pressure after insertion, less depth of anesthetic requirements, coughing during emergence is less, improved oxygen saturation at extubation and lower incidence of sore throat.[1]

An understanding of the pathophysiological consequences of increased intraabdominal pressure is important for the anesthesiologist who must ideally prevent or when prevention is not possible, adequately respond to these changes. The raised intraabdominal pressure mandates the requirement of proper glottic seal to prevent pulmonary aspiration and adequate ventilation to eliminate absorbed CO_2. The PLMA provides a significantly higher oropharyngeal leak pressure making it better choice in those patients and situations where a high oropharyngeal leak pressure is required[2], laparoscopic procedure being one of them. This highoropharyngeal leak pressure avoids the leak during positive pressure ventilation and helps maintaining oxygenation well during pneumoperitoneum and hence can be compared with ETT for any changes in $PaCO_2$ in the blood.

One more danger of pneumoperitoneum is tendency to cause regurgitation and gastric distension when combined with positive pressure ventilation. PLMA being a double-lumen, double-cuff LMA provides an additional drain tube permitting access to gastrointestinal tract which further protects against regurgitation.[3]

Combining both adverse effects of ETT insertion and pneumoperitoneum a very well-studied and smooth device like PLMA can be considered, based on this hypothesis and ample of studies with the use of PLMA in laparoscopic surgeries,[4,5] we considered this study.

Materials and Methods

A randomized prospective, double-blind clinical trial was performed. According to a computer-generated plan, patients were then randomly divided into two groups – the ProSeal group as Group I (*n* = 25) and the ETT Group as Group II (*n* = 25).

Institutional ethical Committee approval was taken after which informed written consent was taken from fifty patients who were posted for elective laparoscopic cholecystectomy surgery under general anesthesia over a period of 1 year. Patients included were of either sex, ASA-Grade I weighing 30-70 kg and within age group of 20–60 years.

Exclusion Criteria

- *Problems in airway*: Limited mouth opening, anticipated/known difficult airway, reduced mobility of cervical spine, glottic and supraglottic airway obstruction, pharyngeal abscess/hematoma);

- *Increased risk of aspiration*: Full stomach, gastroesophageal reflux disease, delayed gastric emptying due to opioid or pregnancy.

A detailed history and examination of all patients was done one day prior to surgery. All patients were fasted overnight and were given tablet Alprazolam (0.25 mg) at bedtime and 2 hours preoperatively. Patients were given injection diclofenac sodium 75 mg and glycopyrrolate (0.2 mg) intramuscular 45 minutes prior to induction. An intravenous line was secured followed by injection ranitidine (50 mg) and metoclopramide (10 mg), 40 minutes before surgery.

Patient was then shifted to operating room, ringer lactate was started and all routine monitors were attached (ECG, noninvasive blood pressure and pulse oximetry). It was ensured preoperatively that PLMA or ETT to be used was checked and correct size is available. Preoxygenation for 3 minutes was done which was followed by injection propofol 2 mg/kg and suxamethonium 2 mg/kg for induction of anesthesia. Injection tramadol 0.4–0.5 mg/kg was given as analgesic. Then respective device allocated was inserted.

Group I: PLMA (size 3 in females and size 4 in males) using introducer;

Group II: Cuffed ETT (size 7–7.5 ID for females, size 8–8.5 ID for males).

PLMA cuff was thoroughly deflated with a syringe using cuff-deflating tool & lubrication was applied to the posterior cuff surface. After optimal placement in hypopharynx, mask was inflated with 20–30 ml of air to obtain a required seal. Correct placement of both PMLA and ETT was ensured by chest expansion, auscultation, absence of leak on auscultation of epigastrium and neck, leak test by passage of gastric tube into stomach *via* drain tube and $EtCO_2$. The NGT was inserted 10 minutes after the placement of the device and connected to intermittent suction for the duration of surgical procedure in both the groups. Anesthesia was maintained with isoflurane in oxygen and nitrous oxide (1:2) and intermittent boluses of vecuronium (0.1 mg/kg). Ventilation was controlled mechanically using closed circuit with CO_2 absorber and were ventilated with tidal volume of 8 ml/kg. Respiratory rate adjustments in

ventilator were done for $EtCO_2$ levels above 60 mm Hg or SpO_2 below 92% or any adverse hemodynamic changes. Abdominal cavity was then insufflated with CO_2 and intraabdominal pressure maintained at 10–12 mm of Hg with flow rate between 1.8–2 liters/min. Head up and lateral tilt was provided at the surgeon's request. Hemodynamic parameters - Heart Rate (HR), Systolic, Diastolic & Mean Blood Pressure (SBP, DBP, MAP) and pulse oximetry (SpO_2) were noted at preinduction, after insertion of device, after nasogastric tube (NGT) insertion, before & 10 minutes after pneumoperitoneum and postoperatively.

The presence of any visible secretions or blood on the device was documented, other complications like gastric distension, aspiration etc. were also noted. If secretions present over PLMA their pH was done. Peritoneal insufflation and total anesthetic time were also noted. ABG analysis before pneumoperitoneum and one hour after pneumoperitoneum was also done. Simultaneously, the values of $EtCO_2$ were also noted.

At completion of procedure reversal was given in form of injection neostigmine (0.05 mg/kg)

and glycopyrrolate (0.01 mg/kg). Extubation was done after suctioning and removal of NTG when patient responded on command. Postoperative complications such as cough, vomiting, laryngospasm or any intervention required during emergence was also recorded.

Statistical analysis

The data was analyzed with the help of computer software MS-excel and SPSS12.0 for windows. Outcomes were reported as percentages for qualitative variables and mean and standard deviation for quantitative variables. Unpaired "t" test/Chi-square/Fisher's exact test were employed to evaluate statistical significance between the two groups. A p - value of < 0.05 was considered as statistically significant.

Results

A total of 50 patients were randomized after checking inclusion and exclusion criteria, Fig. 1. Both the groups were comparable in age, sex and
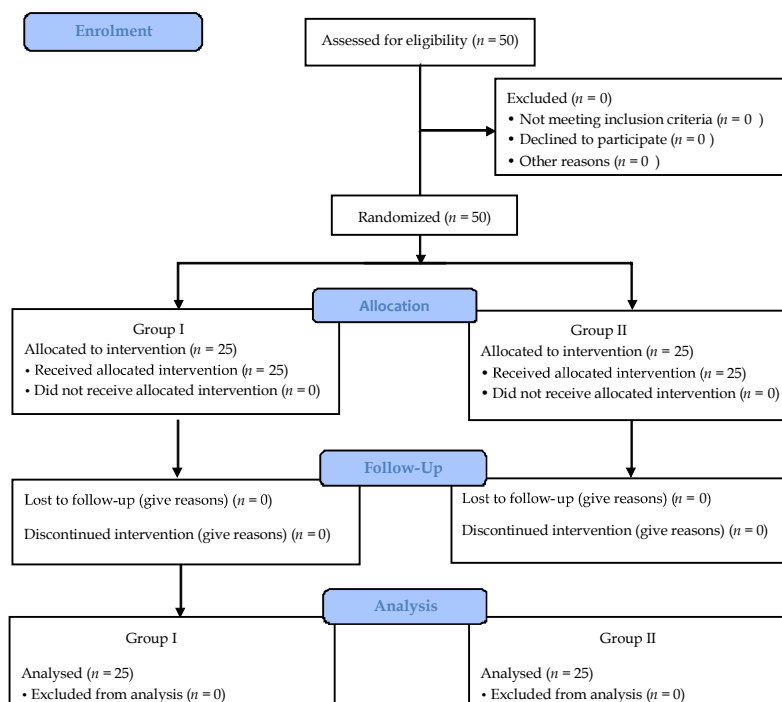

Fig. 1: Consort Flow Diagram.

weight distribution as shown in (Fig. 2).

There was no statistically significant difference in mean values of peritoneal insufflation time being 77.36 ± 16.88 and 80.36 ± 15.6 seconds in Group I and II respectively (p - value = 0.51). The

total anesthetic time was also comparable in both the groups being 93.44 ± 21 min and 98.12 ± 18.86 min with p - value of 0.41, Fig. 2. Insertion success rate for NGT placement in PLMA and ETT Groups was comparable in both the groups i.e. 96% for 1st

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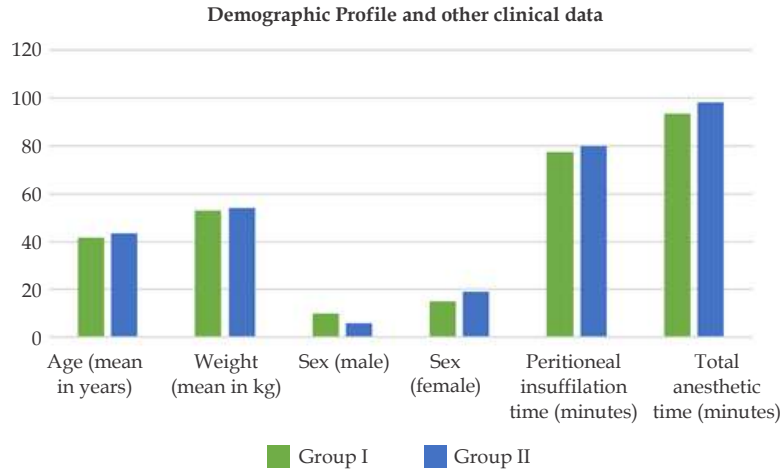**Demographic Profile and other clinical data**

Fig. 2: Showing demographic profile and other clinical data of the two groups.

attempt and 4% for 2nd attempt. No patient required 3rd attempt for any of the devices' placement.

The observations of HR and MAP are shown in Tables 1 and 2, values are in mean ± standard deviation. The SBP and DBP were insignificant between the two groups throughout the surgery except just after insertion of device. The mean SBP was 122.68 ± 12.9 and 138.6 ± 9.98 mm of Hg in Group I and II respectively with a p - value of 0.0001

Table 1: Heart Rate (beats per minute) at various intervals

Time intervals	Group I	Group II	p - value
Preinduction	88.32 ± 13.7	81.4 ± 11.44	0.06
After insertion	87.8 ± 15.08	88.28 ± 9.97	0.89
After NGT	86.6 ± 13.9	82.08 ± 8.27	0.17
Before pneumoperitoneum	84.32 ± 12.7	81.04 ± 7.85	0.27
After pneumoperitoneum	85.84 ± 13.5	82.88 ± 8.08	0.35
Postoperative	84.12 ± 12.7	80.32 ± 8.23	0.21

Table 2: MAP (mm of Hg) at various intervals

Time intervals	Group I	Group II	p - value
Preinduction	92.84 ± 10.18	96.04 ± 8.56	0.23
After insertion	92.92 ± 9.05	104.84 ± 8.13	0.0001
After NGT	92.48 ± 7.62	94.96 ± 4.06	0.15
Before pneumoperitoneum	92.92 ± 8.55	94.04 ± 4.87	0.57
After pneumoperitoneum	95.24 ± 8.29	96.92 ± 5.74	0.40
Postoperative	90.84 ± 7.77	93.72 ± 5.68	0.14

which was significant. The mean DBP was 78.56 ± 9.06 and 88.6 ± 7.82 mm of Hg with p = 0.0001 and was significant.

Arterial Oxygen Saturation (SpO$_2$) was between 94–100% throughout the procedure in both the groups indicating adequate ventilation and any absence of hypoxia. Gastric distension was reported in 1 of our cases in PLMA Group while secretions over PLMA were noticed in 2 of the patients and their pH as determined by litmus paper technique

was > 6. There was no case of regurgitation or aspiration noted in any of the patients in each group. Overall incidence of complications was comparable in both the groups with p = 0.11.

ABG analysis between the two groups was done before creation of pneumoperitoneum and one hour after pneumoperitoneum and the parameters were comparable between the two groups, Fig. 3. The pH values were comparable in both the groups. The mean pH values before pneumoperitoneum

were 7.39 ± 0.01 and 7.39 ± 0.02 in Group I and II respectively with p - value of 1 i.e. not statistically significant. The mean pH values one hour after pneumoperitoneum were 7.41 ± 0.02 and 7.40 ± 0.02 in Group I and II respectively with p - value of 0.38 i.e. not statistically significant. $PaCO_2$ values before and one hour after pneumoperitoneum were also not significant with $PaCO_2$ before pneumoperitoneum being 37.92 ± 0.95 mm Hg

and 37.84 ± 1.14 mm Hg with p - value of 0.78. $PaCO_2$ one hour after pneumoperitoneum being 38.92 ± 1.15 mm Hg and 39 ± 1.55 mm Hg with p - value of 0.83. The values of mean $EtCO_2$ were 37.34 and 41.96 in PMLA Group, 36.88 and 40.15 in ETT Group before pneumoperitoneum and one hour after pneumoperitoneum with p - value of > 0.05 and was insignificant, and was noted at the same time when ABG sample was withdrawn
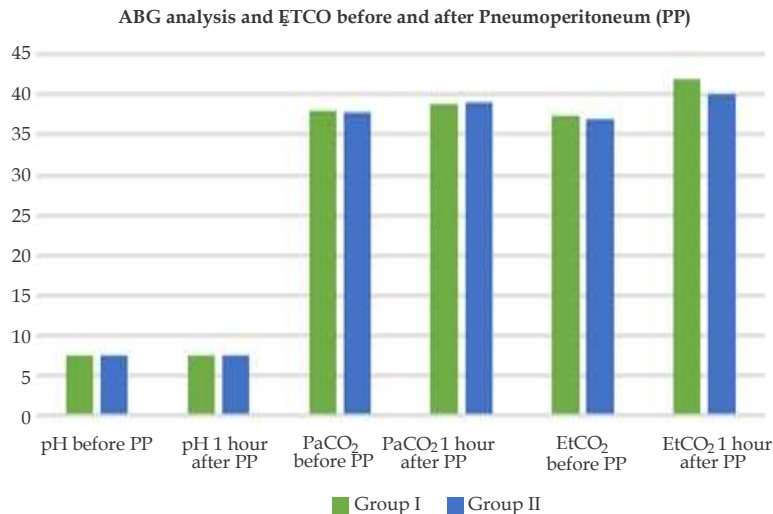

Fig. 3: Showing ABG analysis and $EtCO_2$ before and one hour after pneumoperitoneum.

from the patient. In present study, most of the cholecystectomies were done within 60 minutes and very few extended to 90 minutes hence

duration of exposure to CO_2 was comparable in both the groups and also eliminates the bias caused by duration of pneumoperitoneum.

Table 3: Postoperative complications

Complications	Group I	Group II
1. Cough	2/25 (8%)	8/25 (32%)
2. Laryngospasm	none	1/25 (4%)
3. Bronchospasm	none	none
4. Sore throat	3/25 (12%)	6/25 (24%)
5. Vomiting	1/25 (4%)	none

* Values in number (percentage).

Postoperative complications are shown in Table 3. A total of 6 patients in Group I (24%) and 15 patients in Group II (60%) had the complications. Overall incidence of respiratory events at extubation was comparable with p - value of 0.47.

Discussion

In literature we found ample of studies comparing PLMA and ETT proving it to be an equally

efficacious device as far as insertion characteristics are considered. In present study, we chose laparoscopic procedure because increased intraabdominal pressure from pneumoperitoneum requires the higher airway pressures for which PLMA was originally designed. Moreover, it is proven fact that PLMA can withstand higher oropharyngeal leak pressures,[2] so, we compared it with ETT to see its adequacy in providing good ventilation and oxygenation during laparoscopic surgery.

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When hemodynamic parameters were compared in our study there was not much difference in mean heart rate between both the groups, as was shown by Shroff PP et al.[5] also. However, in PLMA Group they found more heart rate which was statistically significant before and after pneumoperitoneum in contrast to ours. The systolic, diastolic and mean blood pressures in our study were comparable at various intervals but were significant after insertion of both devices. The values were much lower in PLMA Group after insertion as compared to ETT Group proving that it causes less stimulation at intubation and was similar to other studies.[5-7] These studies recommended PLMA for patients with cardiac and respiratory diseases because of stable hemodynamics and quicker insertion and considered it to be a safer airway conduit for ventilation during the laparoscopic surgeries. The mechanism for hemodynamic changes associated with ETT/LMA insertion as quoted by most of the authors is due to altered plasma catecholamine levels. ETT insertion leads to stimulation of afferent pathways both pharyngeal and laryngeal, whereas LMA placement causes partial afferent stimulation that is pharyngeal only. As all sympathetic stimuli are mediated by afferent fibers, their stimulation ultimately leads to the release of catecholamines in the blood which are responsible for the pressor responses in the body. Ultimately from above discussion we can comment that PLMA causes less hemodynamic variability and thus giving it an edge over the ETT for laparoscopic surgery.

Arterial oxygen saturation was between 94–100% throughout the procedure in both groups indicating adequate oxygenation and absence of any hypoxia in our study. This was comparable to other studies.[4,5,8] However, Sharma B et al.[8] also reported transient suboptimal oxygenation (SpO_2 - 94%) in one patient undergoing extraperitoneal inguinal hernia repair which was due to extensive subcutaneous emphysema.

CO_2 is 20 times more soluble than air and oxygen and thus more rapidly absorbed from peritoneal cavity and then excreted from lungs. So, if ventilation is not adequate it can lead to CO_2 accumulation (hypercarbia), respiratory acidosis and hemodynamic alterations. $EtCO_2$ is considered as good noninvasive monitoring modality for determining the minute ventilation required to maintain normocarbia and for estimation of $PaCO_2$ especially during pneumoperitoneum but it takes about 15 minutes for $PaCO_2$ to reach a plateau value after creation of pneumoperitoneum.[9,10] Because of high solubility of CO_2, its vascular systemic absorption is also increased from peritoneum during this period. This, combined with decreased lung compliance during laparoscopic procedure (due to upward shift of diaphragm) leads to increased arterial CO_2 levels and decreased pH. In our study, also the pH and $PaCO_2$ altered after pneumoperitoneum but their values were comparable in both the groups showing that patients were equally well-ventilated with PLMA. Also, $PaCO_2$ analysis helps us to assess ventilation because the normal arterial–to-end-tidal CO_2 gradient increases as the dead space is increased. In our study, we maintained our patients on controled ventilation with nitrous oxide 60% in oxygen, isoflurane and vecuronium intermittent boluses as and when required. We did not adjust any ventilatory parameters in any patient of the two groups during the pneumoperitoneum period as all of them maintained $EtCO_2$ below 60 mm of Hg during that period.

Above findings in our study are also supported by Showket et al.[11] but they studied the pediatric population and concluded that at ventilator parameters designed to maintain normocapnia, the PLMA provided adequate seal. Similar results were seen in other studies.[4,8,12] In a study by Shah et al.[1] who compared PLMA and ETT in the patients undergoing beating-heart coronary artery bypass grafting also found that respiratory parameters such as SpO_2, pCO_2, peak airway pressure and lung compliance were comparable in both groups and occurrence of adverse events was also lower in PLMA Group. ABG monitoring to ascertain $PaCO_2$ levels is not a routine part of laparoscopic procedures due to nonavailability of ABG analyzer machine and the associated costs especially in developing countries. There appears correlation between $EtCO_2$ levels and $PaCO_2$ levels in our study thus $EtCO_2$ may be used as a marker of $PaCO_2$ change in case ABG analyser is not available. In intraoperative complications we found 4% (one patient) incidence of gastric distention with PLMA and no case of gastric distention was found in ETT Group as well. Our findings were supported by Shroff et al.[5] who noted 3% gastric distention in PLMA and none in ETT Group.

In our study, we found no case of regurgitation of gastric contents through the drain tube when PLMA was used because we had ensured previously that all our patients received appropriate premedication to minimize and decrease gastric volume and acidity. Also, NGT was inserted and intermittent suctioning was done in all of our patients. There was no case of regurgitation of gastric contents

into the bowl of PLMA which was consistent with various other studies.[5,6,13]

As found in other studies[8,14,15] we also found no case of pulmonary aspiration in PLMA group, danger of an unprotected airway and any risk of aspiration pneumonitis could not be made as volume was too small to determine that. In both the groups of our study, the peritoneal insufflation time and total anaesthetic time were comparable. There are ample of studies where PLMA was used for as long as 300 minutes without any adverse events supporting findings of our study.[4,15] Shah K et al.[1] used PLMA in beating heart coronary artery bypass grafting surgery showing that it can be used for prolonged surgery as an alternative to ETT.

In our study the group with ETT had more postoperative complications as compared to PLMA as such, thus showing smoother extubation with PLMA. Patients in PLMA Group in our study showed lower incidence of cough and sore throat this can be attributed to the fact that no laryngoscopy was required during its insertion and hence atraumatic to the airway. This also leads to low mucosal pressure causing lesser pharyngeal perfusion pressure. Overall respiratory complications when seen with PLMA Group in our study were less. Laryngospasm was reported in one of the patients in ETT Group as was found in other studies too.[2,5,15] However, in studies by N Saraswat et al.[12] and Patodi V et al.[16] frequency of complications during emergence were significantly more in ETT Group.

We found only one patient with vomiting after PLMA removal in our study. No particular reason for vomiting could be ascertained as no treatment was required and it settled of its own. However, Hohlrider et al.[17] showed that PLMA reduced the absolute risk of postoperative nausea and vomiting by 40% also because of the reason that cuff of PLMA is less stimulating to pharyngeal mucosa as compared to ETT cuff causing lesser airway morbidity in PLMA Group.

Limitations of our study were that we did not analyse the influence of duration of surgery and hence the CO_2 exposure which can be done by including different laparoscopic procedures and analysing their effect. Secondly, we did not measure the oropharyngeal leak pressures. Thirdly, we could have measured the bicarbonate levels, lactate, urea and electrolytes to further support our results but because we took a simple procedure without major intercompartmental fluid shifts we did not do it.

Conclusion

In conclusion ProSeal laryngeal mask airway (PLMA) can be used safely and is equally effective airway conduit to Endotracheal Tube (ETT) for patients of laparoscopic cholecystectomy reason being more stable hemodynamics and its ability to maintain adequate ventilation and oxygenation in such procedures.

So, PLMA can be considered as a better choice in high-risk patients with hypertension, ischemic heart disease and obstructive airway diseases for laparoscopic procedures. We recommend further studies with larger sample size to authenticate the above results.

Conflicts of interest: There are no conflicts of interest declared by the authors.

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