RESEARCH ARTICLE

Comparative Evaluation of ProSeal LMA vs. Cuffed Endotracheal Tube in Patients Undergoing Laparoscopic Cholecystectomy under General Anesthesia

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Background: Proseal LMA (PLMA) has been used for airway maintenance during laparoscopic cholecystectomy. However, there is limited data regarding the effects of pneumoperitoneum, particularly on pulmonary mechanics. Objective of the present study was to evaluate and compare the use of PLMA with a cuffed endotracheal tube (ETT) with regard to changes in pulmonary mechanics, haemodynamic variables, degree of gastric inflation, ease of device insertion and possible adverse events in patients undergoing laparoscopic cholecystectomy.

Methods: After written informed consent and institutional ethics committee approval, we enrolled one hundred patients (ASA physical status1/2), 18-60 years of age who were scheduled to undergo laparoscopic cholecystectomy under general anesthesia (GA). Patients were randomly allocated to one of the two groups of 50 each. Group 1: cuffed endotracheal tube and Group 2: ProSeal LMA. Patients as well as the surgeons were blinded to the airway device used. Insertion parameters, haemodynamic and ventilatory parameters (compliance, resistance and peak/plateau airway pressure) were measured at different time intervals before, during and after pneumoperitoneum.

Results: Statistically significant ($p< 0.05$) but clinically insignificant difference was found in time taken for device insertion in the two groups (21.8 ± 5.9 s group I & 25.4 ± 5.7 s group II). Insertion of orogastric tube was easier and less number of attempts was required with PLMA. Hemodynamic parameters like heart rate, systolic, diastolic and mean blood pressures increased after the ETT insertion while there was a decrease/no change after PLMA insertion. There was a significant decline in the pulmonary compliance in Group 2, which was more pronounced after pneumoperitoneum. During pneumoperitoneum, higher peak and plateau airway pressures were noted in PLMA group than in ETT group. After desufflation these parameters returned to near pre-insufflation levels. There was no episode of arterial desaturation or end tidal carbon dioxide changes in either group.

Conclusion: Our results indicate that in the PLMA group, the degree of changes in pulmonary mechanics caused by the pneumoperitoneum were significant however there was no incidence of arterial desaturation, or gastric regurgitation. Due to better hemodynamic stability with PLMA, it may even be better alternative than ETT in hypertensive/cardiac patients. Hence PLMA is a satisfactory airway device for laparoscopic cholecystectomy under GA, but further studies are required regarding its safety in patients with decreased pulmonary compliance like morbid obesity or obstructive pulmonary disease.

Keywords: Proseal LMA; endotracheal tube; general anesthesia; airway pressures; pneumoperitoneum; orogastric tube; laparoscopy

General anaesthesia (GA) with controlled ventilation using a cuffed endotracheal tube (ETT) remains the gold standard for anaesthetic management during laparoscopic surgeries [1]. This may be owing to elevated intra-abdominal pressure from induced pneumoperitoneum, requiring higher airway pressures to ensure adequate ventilation [2]. However, ETT insertion has intrinsic limitations such as possibility of difficult or failed intubations, exaggerated haemodynamic variations and likelihood of adverse events during intubation [3]. In such situations, ProSeal laryngeal mask airway (PLMA), a second-generation supraglottic device, may provide a suitable alternative for airway management in this subset of patients [1-2]. This device permits peak airway pressure > 30 cm H2O without leak. It has a drain tube, parallel to the ventilation tube, which permits drainage of passively regurgitated gastric fluid away from the airway to prevent aspiration and avoidance of gastric insufflation during positive pressure ventilation [4-5].

There have been a number of reports supporting the use of the PLMA for laparoscopy surgeries [6-13]. However, there

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is limited data regarding the effects of pneumoperitoneum on pulmonary mechanics with PLMA, particularly in laparoscopic cholecystectomy [14-16]. We hypothesized that PLMA maybe a satisfactory and safe alternative to ETT in laparoscopic cholecystectomy surgeries. Hence, the present study was conducted to evaluate and compare the use of PLMA with a cuffed endotracheal tube (ETT) with regard to changes in pulmonary mechanics, haemodynamic variables, degree of gastric inflation, ease of device insertion and possible adverse events by device, in patients undergoing laparoscopic cholecystectomy.

Methods

After approval of protocol by Institutional Ethics Committee (IEC) and written informed consent, 100 patients in the age group of 18 to 60 years, ASA physical status I /II, of either sex scheduled to undergo elective laparoscopic cholecystectomy under GA were included. The patients with known or predicted difficult airway (Modified Mallampati Class 3 or 4), cervical spine disease, body mass index (BMI)≥30 Kg m-2, respiratory tract pathology, limited mouth opening (inter-incisor distance< 2.5 cm), at risk of aspiration like hiatus hernia, gastro esophageal reflux disease, peptic ulcer, full stomach, pregnancy and previous upper gastrointestinal surgery, cardiorespiratory or cerebrovascular disease, laparoscopic cholecystectomy, which got converted to open cholecystectomy, were excluded from the study.

The study design was prospective, randomized and controlled. Using computer generated random number table, patients were randomly allocated to either of the two groups:

Group 1 (n=50) disposable PVC cuffed endotracheal tube and Group 2 (n=50) Proseal LMA

Group allocation was concealed by using opaque sealed envelopes, containing the study group assigned to the patient and decoding was done at the end of study.

After written informed consent, all patients underwent a detailed preoperative evaluation day prior to surgery and relevant preoperative investigations were done. The anaesthetic procedure was explained in detail to those accepted for proposed surgical intervention.

Patients were premedicated with tablet alprazolam 0.25mg at night and morning before surgery and kept fasting overnight. On arrival in the operation room, routine monitors were applied and baseline parameters like heart rate (HR), electrocardiogram (ECG), non-invasive blood pressure (NIBP) and arterial oxygen saturation (SpO2) [S/5 Datex Ohmeda, USA] were recorded. An intravenous line was secured with an 18 G cannula and normal saline infusion started. The head and neck of the patient was kept in sniffing position. Patients were preoxygenated for 3 minutes and general anaesthesia was induced with intravenous (IV) fentanyl 2 µg.kg-1, glycopyrrolate 5 µg.kg-1, lignocaine 1.5 mg.kg-1 and propofol 2-3 mg.kg-1. After checking for ability to achieve adequate mask ventilation, vecuronium 0.1 mg.kg-1 was used to facilitate muscle relaxation. The patient's lungs were manually ventilated by facemask with 1% inspired isoflurane and 50% nitrous oxide in oxygen for three minutes. Once the jaw of the patient was relaxed, the eyelash reflex absent and the patient was apnoeic, airway device was inserted as per group allocation. In Group 1 (n=50), size 7/ 7.5 mm ID (for female) and 8/8.5 mm ID (for male) PVC cuffed endotracheal tube (Portex®, Smiths Medical) was inserted under vision using direct laryngoscopy. Cuff was inflated with appropriate volume of air and tube fixed after checking for bilateral equal air entry and a satisfactory capnogram. Orogastric tube (14 G) was inserted blindly into the oesophagus orally. If unsuccessful, then laryngoscopy was done to facilitate OGT insertion. In Group 2 (n=50), an appropriate sized ProSeal LMA (as per recommendations based on weight) was inserted with cuff deflated using the deflator and water-based jelly applied onto the posterior surface of the cuff. The suction catheter guided insertion technique was used and involved priming the drain tube with lubricated PVC suction catheter so that it protruded 15 cm beyond the tip of the drain tube (DT), which was blindly inserted into the pharynx to a depth of 15 cm followed by digital insertion technique as recommended by the manufacturer [17-18].

The same anaesthesiologist with an experience of more than 20 insertions performed all PLMA placements. After insertion of the PLMA, the cuff was inflated with recommended volume of air and suction catheter was removed. PLMA was attached to the breathing system and successful placement was judged by ability to ventilate without leak and a satisfactory square wave capnograph tracing. After checking for adequate placement, the device was fixed according to manufacturer's guideline. A 14 G orogastric tube was then inserted through the drainage tube to facilitate the decompression of the stomach. Correct placement of gastric tube was confirmed by injection of air and epigastric auscultation.

Once an effective airway was obtained, the oropharyngeal leak pressure (OLP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min, noting the airway plateau pressure (maximum allowed =40 cm H2O) at which there was an audible leak [5,19]. Ease of insertion of PLMA was recorded in terms of number of attempts and time taken for insertion. If the ventilation through the PLMA was satisfactory, specific tests were carried for the adequate placement of the PLMA such as, 'Gel displacement test', 'Suprasternal notch tap test' (Brimacombe bounce) and ease of OGT insertion [17]. Ease of insertion of gastric tube through the DT was judged by the number of insertion attempts and was graded as easy, moderately difficult or difficult.

In the event of partial or complete airway obstruction or a significant leak, the PLMA was removed and reinsertion attempted. Maximum of three attempts to insert the Proseal LMA was allowed. In case of failure to achieve adequate placement after three attempts, alternative method of securing the airway using direct laryngoscopy and endotracheal intubation was employed. Failed insertion was defined by the criteria, which included failed passage into the pharynx, malposition and ineffective ventilation.

After insertion of the airway device; anaesthesia was maintained with isoflurane 0.5 to 1% and 66% N2O in oxygen using closed circuit with controlled ventilation [Aestiva 5 Datex Ohmeda] with a tidal volume 8 ml kg-1, respiratory frequency 12 min-1 and I/E ratio of 1:2 to maintain an end tidal CO2 of 30-35 mm of Hg. Intra operatively FiO2 and respiratory rate was adjusted to maintain SpO2 > 95% and EtCO2 30 – 35mmHg. Intra operative analgesia was maintained with IV fentanyl boluses of 10 – 20 µg and diclofenac sodium 1 mg kg-1.

Intra operatively parameters like HR, NIBP (systolic, diastolic and mean pressure), SpO2, and EtCO2 were

monitored continuously and recorded at T0 (Baseline), T1 (After Induction), T2 (after device Insertion), T3 (just before peritoneal insufflation), T4 (after peritoneal insufflation), T5 (after patient positioning), T6 to T11 (T6, T7, T8, T9, T10, T11 at 5,10, 15, 20, 25 and 30 minutes after peritoneal insufflation respectively), T12 (before peritoneal desufflation), T13 (after peritoneal desufflation) and T14 (after device removal). Ventilatory parameters like pulmonary compliance, airway resistance, peak airway pressure (PAP), plateau pressure (PP), and minute ventilation (MV), were monitored and recorded at the same time intervals until after desufflation. After pneumoperitoneum was created, the intra-abdominal pressures were kept between 12– 14 mmHg. Any episodes of hypoxia (SpO2 < 90%); hypercapnia (EtCO2 >45mmHg) or other adverse events were documented. Patients as well as the surgeon were unaware of the airway device used. For obvious reasons double blinding was not possible.

The surgeon was requested to inspect the stomach through laparoscope and grade the gastric insufflation on a 4 point score: 0= no gastric insufflations; 1= minimal gastric insufflation, not interfering with surgery; 2= interfering with surgery, but not necessitating change of device; 3= interfering with surgery and necessitating change of device [15].

At the end of the surgical procedure IV ondansetron 0.1 mg kg -1 was administered for prophylaxis of postoperative nausea and vomiting (PONV) and the residual neuromuscular blockade was reversed with IV neostigmine 0.5 µg.kg- and glycopyrrolate 10 µg.kg-1. The PLMA/ETT was removed after the patient was awake and able to follow verbal commands. Any adverse events like arterial oxygen desaturation, laryngospasm, coughing etc. were noted. The PLMA/ETT was inspected over both ventral and dorsal aspects for any blood or secretions. Post operatively patients were shifted to post anaesthesia care unit and monitored for HR, NIBP, SpO2, PONV, cough, sore throat and hoarseness of voice. All observations were recorded in a preformed proforma in the perioperative period and analyzed statistically.

Statistical Analysis

Based on the previous studies, a projected difference of 10% between the groups, a type I error of 0.05 and a power of 0.9, a total of 100 patients were studied (50 in each group) [14]. The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation and standard error). Means were compared using Student's t-test for two groups. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using Chi square or Fisher's exact test whichever was applicable. All statistical tests were two-sided and performed at a significance level of α=0.05.

Results

The groups were comparable for age, sex distribution, body mass index, Mallampati grade, duration of anaesthesia, duration of surgery and duration of peritoneal insufflation (Table 1). The Group 1, 50(100%) patients had successful ETT insertion in 1st attempt. In Group 2, 48(96%) patients had successful PLMA placement in 1st attempt and 2(4%) in 2nd attempt (Table 2). In Group 1, the overall time taken for successful placement of ETT was 21.8 ± 5.9 seconds (range 10-23 seconds) while in Group 2, for PLMA placement was 25.4 ± 5.7 seconds (range 15-40 seconds). Difference between the two groups was statistically significant. ($p<0.05$) (Table 2). In Group 1, orogastric tube (OGT) insertion was found to be easy in 30 (60%) patients and moderately difficult in 20 (40%) patients while in Group 2, 45 (90%) patients had easy insertion and 5 (10 %) had moderately difficult insertion.

Stomach was adequately deflated in both the groups. 33(66%) patients in Group 1 and 36(72%) patients in Group 2 had excellent gastric desufflation, while in both the groups' 14 (28%) patients had good gastric desufflation. In Group 1, 3(6%) patients had inadequate gastric desufflation, while none in Group 2. The difference in the 2 groups was statistically insignificant ($p>0.05$). Intra-abdominal pressures in Group 1 and 2 were 12.32 ± 0.51 cms of H2O and 12.34 ± 0.63 cms of H2O respectively and were comparable ($p>0.05$). OLP in Group 2 was 31.88 ± 3.57 cms of H2O. Regurgitation of gastric content was not seen in either of the two groups. Only 2(4%) patients had inadequate placement of PLMA while none of the patients had glottic insertion or tip folding. In both the cases, we could ventilate the patients but the tests detected the malpositioning then the PLMA was removed and reinserted for adequate ventilation.

The difference in the peak airway pressure (PAP) between the 2 groups was statistically significant ($p < 0.05$) at all specified times except at T1 (after induction), T5 (after patient positioning) and T6 (5 minutes post insufflation) where results were found to be comparable ($p > 0.05$) (Figure 1). The difference in the plateau pressure (PP) between the 2 groups was statistically significant ($p < 0.05$) at all specified time points except at T1 (after induction) where results were found to be comparable ($p > 0.05$) (Figure 2). In both groups, there was a statistically significant increase in resistance from baseline after creation of pneumoperitoneum, which decreased to normal after desufflation ($p<0.05$), however the difference between the 2 groups at all specified time points was not significant ($p>0.05$) (Figure 3). The difference in the compliance between the 2 groups at specified times was statistically significant at all times except at T1 (after Induction) and T11 (30 min post insufflation). There was significant fall in compliance in both groups after creating pneumoperitoneum, which came near the baseline after peritoneal desufflation ($p<0.05$) (Figure 4). Data of pumonary mechanics (peak airway pressure, plateau airway pressure, pulmonary compliance and airway resistance) during the period of puemoperitoneum creation (before peritoneal insufflation, during pnuemoperitoneum and after peritoneal desufflation) are tabulated (Table 1). The difference in SpO2, ETCO2 and minute ventilation (MV) between the 2 groups at specified times were comparable ($p>0.05$).

The difference in the HR, SBP, DBP and MAP between the 2 groups at all specified times were comparable ($p>0.05$), except at T2 (after PLMA / ETT Insertion), where the difference was statistically significant. Intraoperative, one patient in both groups had bronchospasm. Five (10%) patients in Group 1, had trauma to the airway as assessed by blood on ETT after extubation while in Group 2, 2(4%) patients had trauma. The difference in the incidence of cough in both the groups was statistically significant

($p<0.05$). Although the incidence and degree of hoarseness was more in Group 1 than in Group 2, it was statistically insignificant ($p>0.05$).

Figure 1- Peak Airway Pressure (PAP) course of Group 1 (ETT) and Group 2 (PLMA). [Black dots showing statistically significant difference between the two groups ($p<0.05$) except T1 (after induction) and T5 (after patient positioning) time points ($p>0.05$].

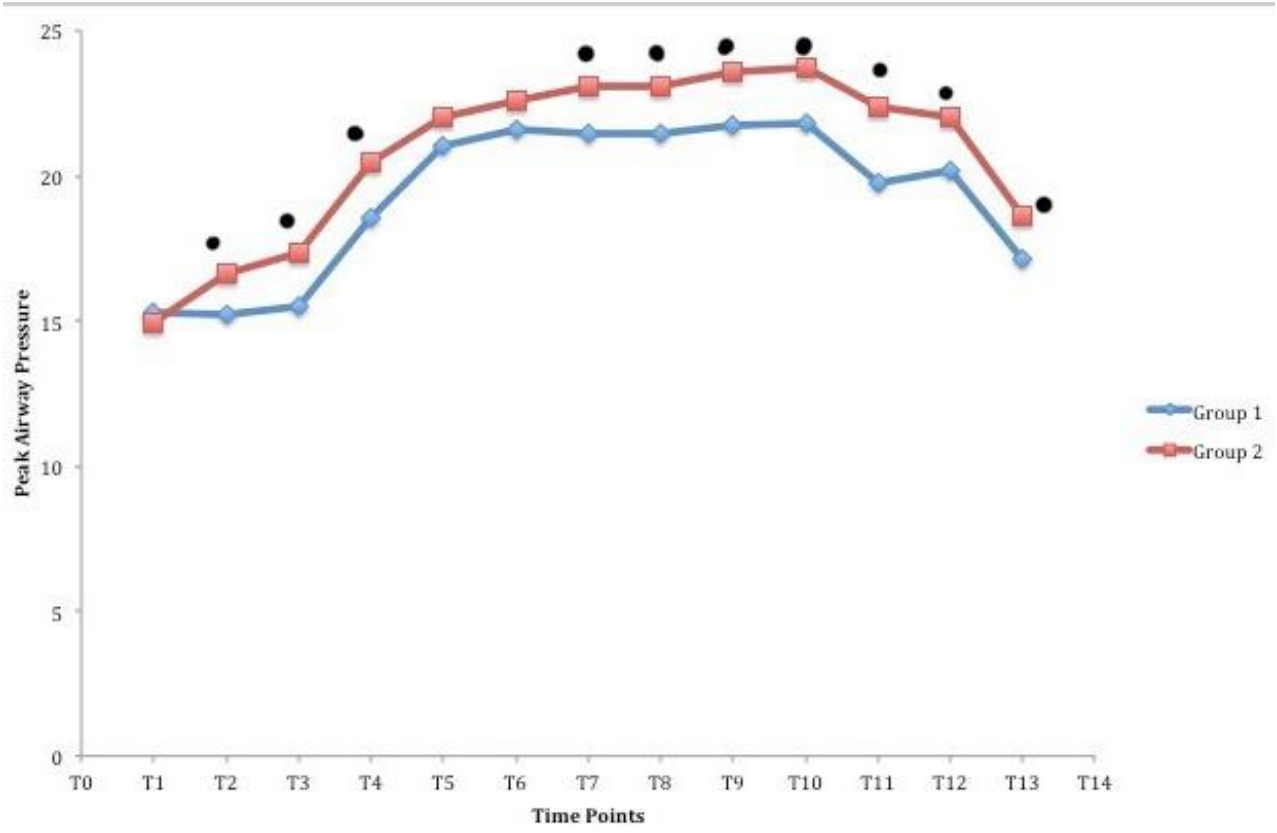

Figure 2- Plateau Pressure (PP) course of Group 1 (ETT) and Group 2 (PLMA). [Black dots showing statistically significant difference between the two groups ($p<0.05$) except T1 (after induction) and T5 (after patient positioning) time points ($p>0.05$].

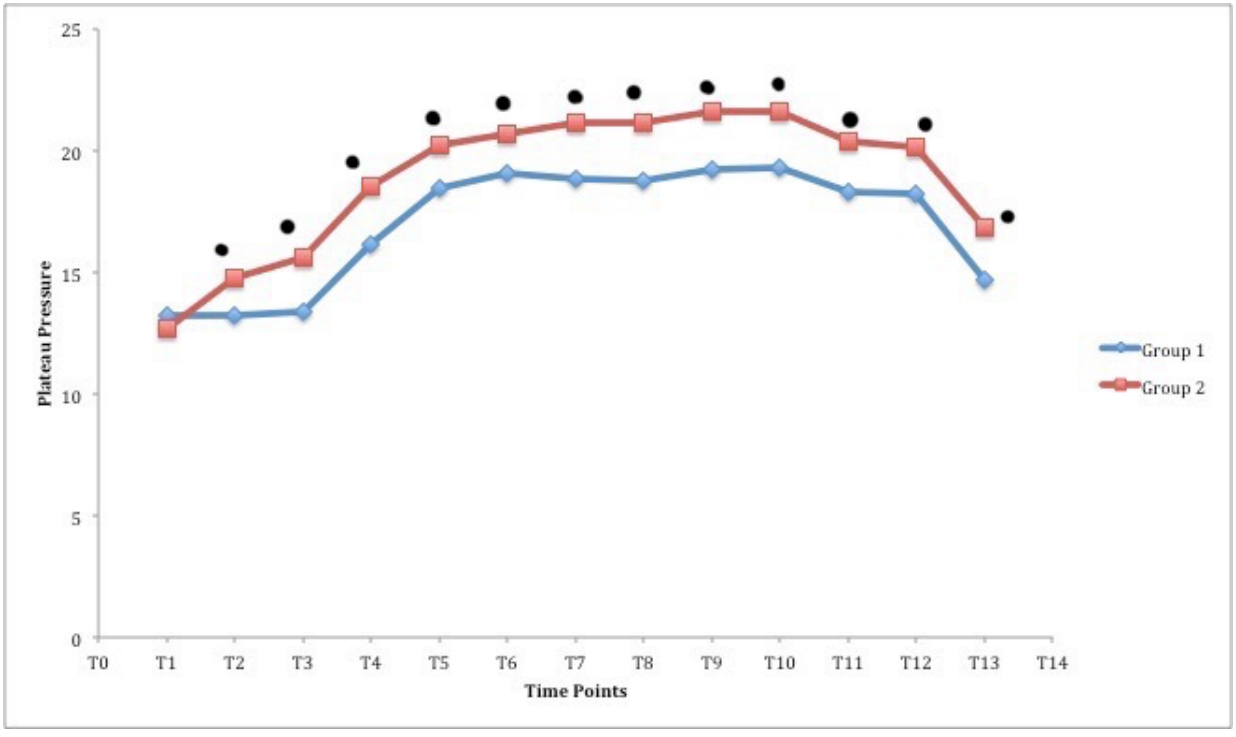

Figure 3- Airway Resistance course of Group 1 (ETT) and Group 2 (PLMA). Difference between two groups is statistically insignificant at all specified time points (p>0.05).

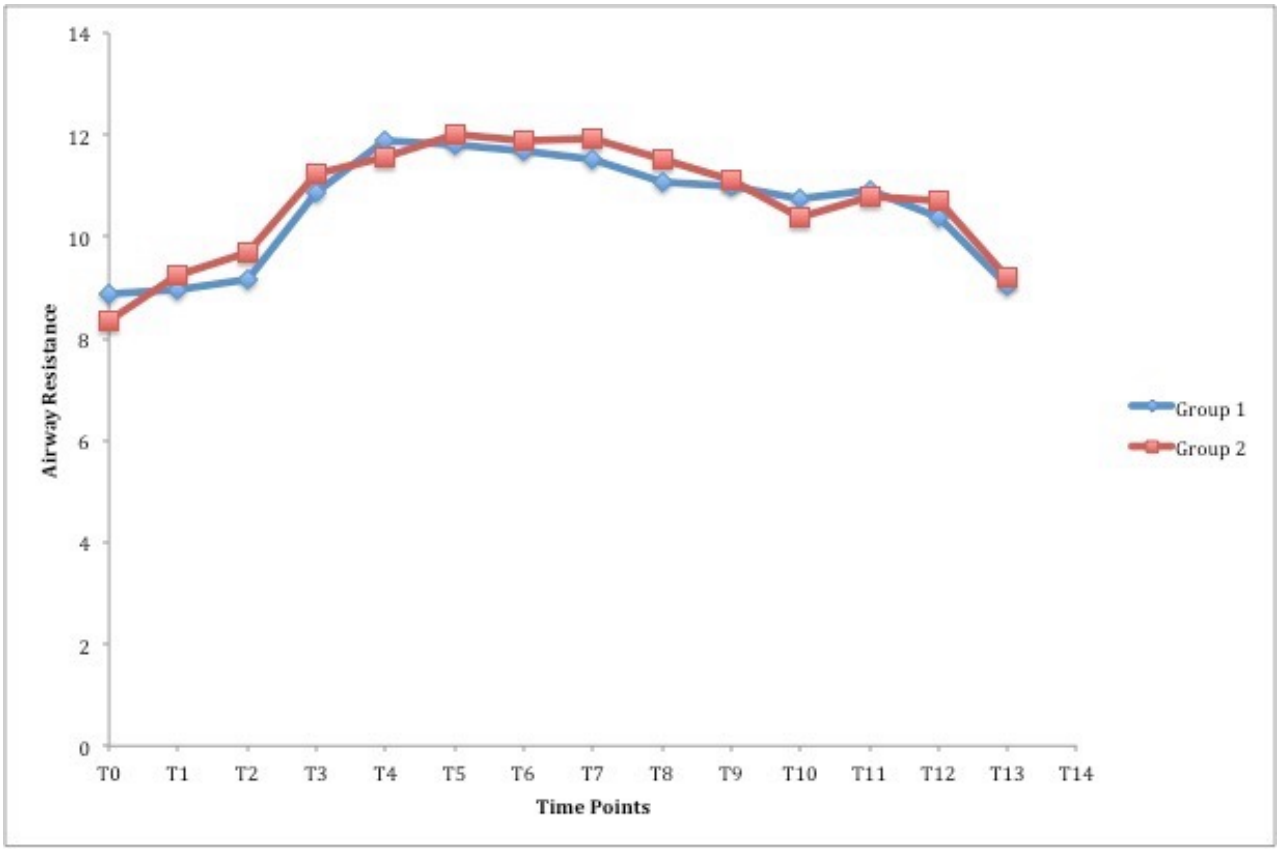

Figure 4- Airway Compliance course of Group 1 (ETT) and Group 2 (PLMA). [Black dots showing statistically significant difference between the two groups (p<0.05) except at T1 (after Induction) and T11 (30 min) time points (p>0.05)].

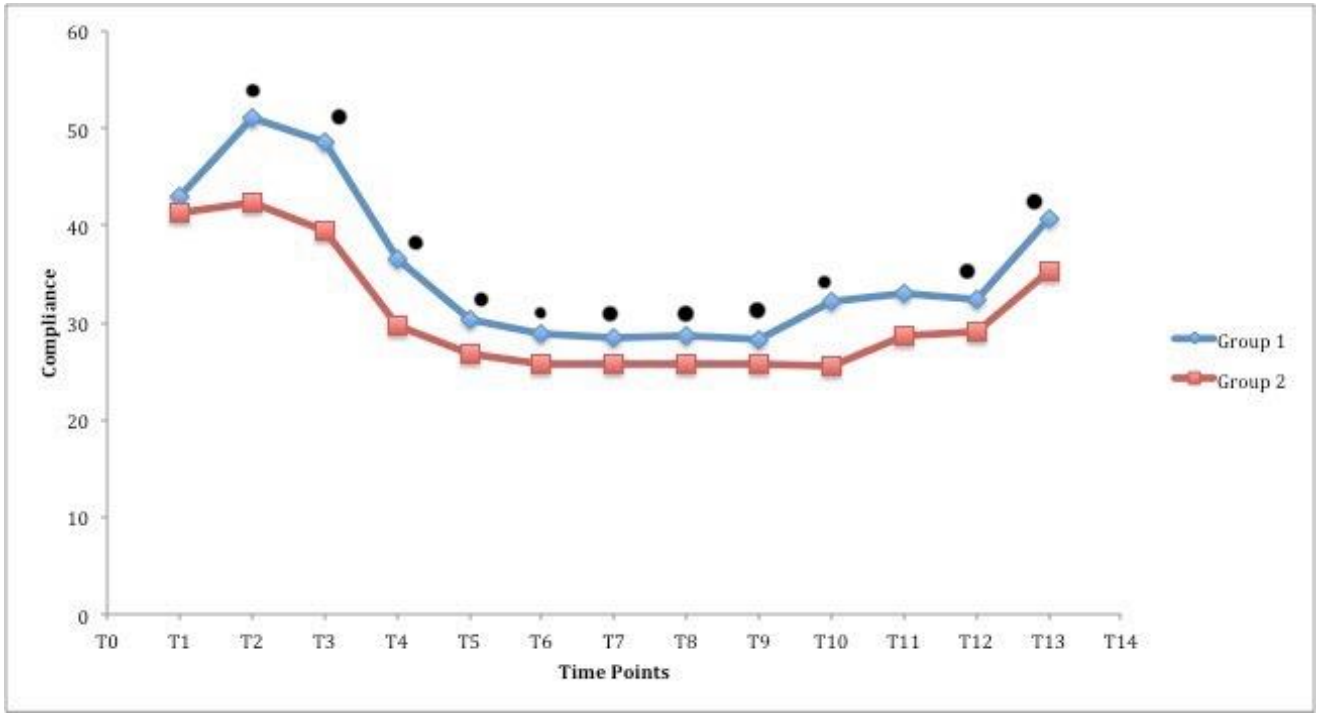

Table 1- Pulmonary mechanics parameters during creation of pneumoperitoneum in Group 1 (ETT) and Group 2 (PLMA).

Parameters	Before Insufflation	Before Insufflation	During Peumoperitoneum	During Peumoperitoneum	After Desufflation	After Desufflation
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Compliance (ml/cmH2O)	48.68±12.40	39.54±8.68	28.36±7.66	25.78±5.94	40.68±9.32	35.20±5.15
Resistance (cmH2O/L/sec)	9.14±1.51	9.7±2.18	11.68±1.59	11.9±2.29	9.02±1.23	9.22±1.83
Peak Pressure (cm H2O)	15.5±2.95	17.36±2.5	21.42±3.32	23.1±2.95	17.12±2.76	18.62±2.20
Plateau Pressure (cm H2O)	13.42±2.87	15.6±2.57	18.84±3.12	21.14±2.63	14.72±2.43	16.82±2.30

Table 2- Device insertion data.

Parameter	Group I	Group II	pValue
Time taken for device insertion (secs)	21.8 ± 5.9	25.4 ± 5.7	0.034
Number of attempts (success rate)			
1st attempt	50	48	
2nd attempt	0	2	

Discussion

In the present study, the two groups were similar with respect to patient demographics such as age, sex distribution, weight, height, BMI, Mallampati score, duration of anaesthesia, surgery and peritoneal insufflation. Both groups show nearly 100% first attempt success rate. Our results are in agreement with similar previous studies that reported that PLMA was equally easy to insert as compared to laryngoscopic guided ETT [6,11,14-16].

In Group 1, the overall time taken for successful placement of ETT was 21.8 ± 5.9 (12-35) seconds while in group 2 (PLMA) it was 25.4 ± 5.7(15-40) seconds. Although statistically significant, the difference between the insertion times between two groups was clinically insignificant. Our results are in agreement with Prerna et al who reported effective insertion time of 26 seconds for ETT insertion [8]. However, they reported insertion time of 15 sec in PLMA group, maybe because they used introducer to facilitate PLMA placement instead of suction catheter guided technique in the present study. The mean PLMA insertion time of mere 12 seconds was observed by Sharma et al in a study of 1000 PLMA insertion [15]. This shorter interval maybe because the anaesthesiologist performing PLMA insertions was more experienced (>50 PLMA insertions) [12,15]. In contrast, Garcia-Aguado et al reported effective ventilation time of 36 ± 24 sec for suction catheter guided PLMA placement [18]. The difference may be attributed to the fact that we have used non-depolarizing muscle relaxant instead of IV target controlled anaesthesia without muscle relaxants [8,18].

The results of present study showed that the difference in the ease and number of attempts required for OGT insertion was statistically significant in two groups. It may be due to the presence of drain tube in PLMA, which aids in the easy placement of OGT. Successful placement of OGT also ruled out posterior folding of the tip of mask as it poses an unrecognized risk of aspiration of gastric contents. Our results are similar to study by Sharma et al who reported 100% success rate of OGT placement in PLMA group [15]. In the present study, we introduced gastric drain tube through oral route in Group 1, after ETT insertion. The overall insertion success rate in both groups was comparable and selecting oral route in Group 1 maybe the contributing factor. Previous studies have shown that nasal route for OGT insertion takes longer time and lower success rate after ETT insertion and may lead to adverse outcomes particularly in patients with hypertension, ischemic heart disease and head injury [8-12].

Gastric insufflation or distension was assessed by the blinded surgeon, on an ordinal scale and it was found that stomach was not distended in either group and did not compromise on the surgeon's ability to perform surgery. We placed a gastric tube in all our patients during pneumoperitoneum. Our results are in agreement with previous studies where no significant gastric distension was observed with PLMA [6, 14, 20]. In contrast, Srivastava et al observed increase of stomach size in 20% of the patients with PLMA insertion and inferred that changes in stomach size represent the changes in visible area rather than actual distension per se [12]. Sharma et al also observed stomach distension in 0.5% of the 1000 patients with PLMA insertion, maybe due to the positive pressure prior to PLMA insertion [15].

The PLMA formed an effective seal around the glottis in our patients (mean OLP: 31.88 ± 3.57 cms of H2O). Our result was in accordance with previous studies [6-15]. Higher OLP of PLMA is due to its intrinsic characteristics such as deep bowl, double cuff having dorsal and ventral components with proximal wedge shape and large surface area. It is desirable that the OLP should be kept less than 40 cm H2O during laparoscopic procedures to minimize the risk of regurgitation and aspiration. In addition, proper and careful selection of PLMA is crucial to achieve an effective

seal around glottis, particularly in the aforesaid procedures [15].

The values for heart rate, SBP, DBP and MAP were comparable in both the groups at all specified times except at the time of device insertion and removal, when there was increase in the heart rate and blood pressure in the ETT group and decrease/no change in the PLMA group. This can be explained by exaggerated sympathetic response and catecholamine release to laryngoscopy and intubation in ETT group, while these responses are attenuated with insertion and removal of the PLMA. Our results are in accordance with previous studies, which also reported lesser haemodynamic stress responses with PLMA, than with laryngoscopic guided ETT, as the response is primarily related to laryngoscopy [7,8,11,12,21-22]. We infer that PLMA maybe a better and safer option for patients with hypertension and or ischemic heart disease, posted for the aforesaid surgical procedure.

Ventilation was equally successful during the period of pneumoperitoneum in both the groups as evidenced by normal values of pulse oximetry, EtCO2, and minute ventilation, in both the groups at all time intervals. Our results are in accordance with previous studies, which observed that ventilation was satisfactory with PLMA in laparoscopic surgeries [6-7,15,18,20]. However, Sharma et al observed significant increase in EtCO2 after pneumoperitoneum in three cases, probably due to narrow tube and down folding of epiglottis [15]. The incidence of down folding is high and is a concern with PLMA device hence requires careful manipulation [23]. In the present study there is a statistically significant though clinically insignificant, fall in the compliance and rise in the airway pressure in PLMA group, which is more pronounced after pneumoperitoneum. This change further supports our suggestion that PLMA should be avoided in patients with pre-operative decreased pulmonary compliance.

There was a statistically significant rise in airway pressures in the PLMA group especially after pneumoperitoneum, however it did not increase beyond the sealing pressure and at no point during surgery, the ventilation/oxygenation was compromised. This marginal increase in airway resistance could be attributed to narrow airway tube of PLMA. Our results are in agreement with that of Sharma et al who reported a significant rise in peak airway pressures after pneumoperitoneum [15]. They concluded that the sealing pressure of nearly twice the PAP before creation of pneumoperitoneum is a reliable predictor of suitable PLMA device chosen [15].

The clinical significance of this observation in healthy individuals with normal BMI may not be significant but may be important in grossly and morbidly obese individuals. Maltby et al studied the use of PLMA in grossly and morbidly obese patients undergoing laparoscopic cholecystectomy and concluded that PLMA may not be an acceptable airway device in this patient population and further studies are required to establish its efficacy [14].

In the present study 1(2%) patient, each in both groups had bronchospasm intraoperatively. The incidence of bronchospasm in both groups is slightly more than that of Sharma et al who reported an incidence of 0.05% with PLMA, probably because of the larger sample size in their study (1000 cases) [15]. In the present study 5 (10 %) patients in Group 1 and 2 (4%) patients in Group 2 had trauma to the airway as evidenced by blood on the device cuff. The difference in the incidence of airway trauma between the two groups was not statistically or clinically significant. These results are similar to the incidence of airway trauma assessed by obvious blood on PLMA as reported by previous studies [11-15].

Only 8% patients in PLMA group had coughing at the time of device removal while 76% of patients in ETT group had coughing at the time of extubation, suggesting that there is smooth emergence of patients at the end of anaesthesia with PLMA. This could have an implication in cardiac patients where smooth emergence is desirable. Incidence and degree of cough, sore throat and hoarseness due to airway trauma was more in Group 1 than Group 2 and were in accordance with the previous studies [6,9,14]. The lower incidence of sore throat and cough in PLMA group maybe owing to the fact that it is a supraglottic device so doesn't pass through the vocal cords and the lateral pressure on the tracheal mucosa is totally avoided.

None of our patients in either group had regurgitation/aspiration during or after surgery because we maintained an intra-abdominal pressure of <15 mmHg during the procedure, which is known to increase the lower oesophageal sphincter tone. This increases the normal barrier pressure of 30 cm H2O and hence provides further protection from passive reflux of gastric contents [14]. We believe that high incidence of regurgitation reported in the earlier studies could have occurred during the learning curve as suggested by Brimacombe [4]. Moreover, the use of muscle relaxants may also have reduced the risk of regurgitation by suppressing the unwanted reflexes (e.g., coughing or retching) and by decreasing the abdominal muscle tone.

Our study has few limitations. First, the intraoperative data was collected un-blinded, a possible source of bias as it was impossible to blind the investigator to the device used. Secondly, we excluded obese patients (BMI> 30) and patients with anticipated difficult airway. Whether the same outcome can be extrapolated to such patients is subject to performance of similar large-scale studies in this patient population. Thirdly, we used detection of audible leakage of gases, as a guide to assess the gastric insufflation, which as a single method, is not a very good indicator of the same and further studies using multiple tests for ascertaining the leak pressure may be required to judge the incidence of gastric insufflation. We did not attempt to limit the cuff pressure in either of the airway device; this may have a bearing on postoperative pharyngolaryngeal morbidity. Lastly, sample size of our study was relatively small. Further studies in a larger patient population would be desirable.

In conclusion, the results of present study showed that PLMA is an effective and safe alternative to ETT for airway management in patients undergoing laparoscopic cholecystectomy under general anaesthesia, as judged by adequate ventilation, good oxygenation, better hemodynamic stability, good perilaryngeal seal and drainage of gastric contents via the drain tube. However, we suggest that an experienced anaesthesiologist should carry out PLMA insertion and correct placement of the device must be ascertained before embarking on the surgical procedure. Further large-scale studies are required to establish the role of PLMA during laparoscopic cholecystectomy in patients with anticipated or unanticipated difficult airway as well as in situations where hemodynamic stability is desirable.

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