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Comparative evaluation of Laryngeal mask airway classic, laryngeal mask airway proseal & endotracheal tube in laparOscopic cholecystectomy

Dr. Vandana Sharma[1], Dr. Surinder Singh[2*]

[1] Assistant Professor, Department of Anesthesiology, Veer Chandra Singh Garhwali Government Medical Sciences & Research Institute, Srinagar, Pauri Garhwal, Uttarakhand, India

[2*] Professor, Department of Anesthesiology, Veer Chandra Singh Garhwali Government Medical Sciences & Research Institute, Srinagar, Pauri Garhwal, Uttarakhand, India

Abstract
Introduction: This prospective, randomized, double –blind study Compare LMA-C, LMA-P & ETT with respect to pulmonary ventilation, hemodynamic & gastric distention during laparoscopic cholecystectomy.
Materials and Methods: We stratified 90 patients aged b/w 18 to 65 years, ASA I & II, BMI </=30, MPS II into three groups C-LMA (n=30), P-LMA (n-30) & ETT (n=30)
Anaesthesia was induced with propofol, fentanyl & vecuroniu. In C- LMA & P-LMA group we used a size 4 for female & size 5 for male. In ETT group 7mm ID for female & 8mm ID for male. Anaesthesia maintained with isisoflurane in N2 O & 30 to 40% oxygen, fentanyl & neuromuscular blocker with mechanical ventilation (tidal volume 8ml/kg)
Results: Difference b/w groups with respect to SP02, ETCO2 a or airway pressure before or during peritoneal insufflations was insignificant ($p \geq 0.05$). No significant difference b/w groups with respect to stomach size ($p \geq 0.05$).
Difference b/w groups with respect to hemodynamic pameters (Blood pressure, pulse rate) was insignificant b/w C-LMA & P-LMA but with respect to ETT group was significant ($p \geq 0.05$).
Conclusion: Correctly placed C-LMA, P-LMA is as effective as ETT for positive pressure ventilation without clinically important gastric distention but for hemodynamic stability C-LMA & P-LMA are superior to ETT.

Keywords: C-LMA, P-LMA & ETT

Introduction
The laryngeal mask airway (LMA) is a novel supraglottic airway device designed to secure the airway by establishing an end to end circumferential seal around the laryngeal inlet. It is a useful advancement in the airway management, filling a niche between face mask and endotracheal tube. Later improvements were made in construction of prototypes which became available in a range of different sizes. Further studies were conducted and the results have so far confirmed the safety and efficacy of laryngeal mask airway as an alternative to facemask in spontaneously breathing patients.1
Though the LMA has provided the convenience of "Hands-free" anaesthesia, for some anaesthesiologists, the combination of LMA and positive pressure ventilation evokes fear of inadequate ventilation, gastric distension and pulmonary aspiration of gastric contents.
LMA proseal (PLMA) is a reusable supraglottic airway device offering gastric access.5 PLMA provides better airway protection during regurgitation than LMA. A properly positioned PLMA isolates the airway from fluid within the hypopharynx.6
Tracheal intubation and controlled ventilation is considered a gold standard for anaesthestic management of a patient undergoing laparoscopic cholecystectomy. The problems common to laparoscopic procedures are due to carbon dioxide insufflation. Pneumoperitoneum leads to increase in intra-abdominal pressure thereby causing elevation of diaphragm, alteration in patient positioning and a potential danger of gastric regurgitation and pulmonary aspiration. All these have an impact upon the ventilatory parameters and haemodynamic parameters.
Hence, a prospective randomized study designed to compare the use of CLMA, PLMA and ETT as a ventilatory device in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with controlled ventilation was conducted in our institute on 90 adult patient.

Material and Methods
After obtaining the Ethical committee approval and written informed consent, this prospective randomised study was conducted on 90 patients of either sex belonging to ASA physical status grade I and II, aged 18-65 years posted for elective laparoscopic cholecystectomy under general anaesthesia.

Exclusion criteria
- Age less than 18 years and above 65 years
- Body mass index > 30 kg/m2
- Mallampatti classification > II
- Symptoms related to laryngopharyngeal abnormality
- Musculoskeletal abnormalities affecting the cervical vertebrae.
- Cardiopulmonary disease, patients with increased risk of aspiration (gastro-esophageal reflux disease, hiatus hernia, and pregnant patients)

Patients were randomized by opening an opaque envelope inside the operation theatre containing the computer generated random assingnment into 3 groups of 30 each:

Group I: C-LMA for airway management
Group II: P-LMA for airway management
Group III: ETT for airway management

All patients included in the study were subjected to a detailed pre-anaesthetic check up and airway assessment one day prior to surgery. These patients were kept nil per orally for 8 hours preoperatively. Patients were given oral alprazolam 0.5 mg, tab ranitidine 150 mg and tab metoclopramide 10 mg the night before the day of surgery and on the day of surgery 30 min before as a prophylaxis against aspiration. Premedication was given with Inj. glycopyrrolate 5-10 mcg/kg and Inj. Fentanyl. 002mg/kg Intramuscular (IV) injection 45 min prior to surgery. After placement of routine monitoring devices viz, pulse oximetry, non-invasive blood pressure monitor and electrocardiogram, base line parameters were recorded. Preoxygenation with an 100% oxygen was done for 3 mins. Anaesthesia was induced with Inj. Propofol 2 mg/kg intravenously (IV) and after confirming bag and mask ventilation, Inj. Vecuronium bromide 0.1 mg/kg intravenously was given and patient was ventilated with O2 and isoflurane (1-2%) for 3 minutes.

In group I CLMA of appropriate size was selected according to body weight. After applying a clear lubricant, CLMA insertion was carried out as recommended by the manufacturer using index finger technique for insertion. The cuff was inflated with 10 to 15 ml of air for pressure up to to 60 cm of water. The correct placement of the CLMA was confirmed by square wave pattern capnograph trace and adequate chest expansion during manual ventilation. Fixation was done by tapping the CLMA over the chin or by using fish mouth taping (maxilla to maxilla). Nasogastric tube insertion was not done in this group.

In group II PLMA of appropriate size was selected according to body weight. After applying a clear lubricant, PLMA insertion was carried out as recommended by the manufacturer using index finger technique for insertion. The cuff was inflated with 10 to 15 ml of air for pressure up to to 60 cm of water. The correct placement of the PLMA was confirmed by square wave pattern capnograph trace and adequate chest expansion during manual ventilation. Fixation was done by tapping the PLMA over the chin or by using fish mouth taping (maxilla to maxilla). A 16 Fr nasogastric tube (NGT) tube was passed through the drain tube and contents were aspirated.

For group III females, size 7.0 mm ID and for males, size 8.0 mm ID ETT were used. Cuff was inflated with 6 to 8 ml of air for pressure up to 25-30 cm of water. Position was confirmed clincially and by capnography. After placement of the endotracheal tube, a 16 Fr. Ryles tube was placed and the gastric contents were aspirated.

For each of the groups anaesthesia was maintained with isoflurane (1-2%) in oxygen and N2O with FiO2 0.5 and administered through circle system with CO2 absorption. Injection vecuronium. 01 mg/kg was given to maintain neuromuscular blockade intermittently the patient's head and neck were covered to conceal the airway device before the surgeon enters the operating room. Any incidence of trauma occurring while insertion of CLMA, PLMA or ETT was recorded.

Ventilation parameters were set at a tidal volume of 8 ml/kg at a rate of 12 breaths/min. Intraoperatively, the minute ventilation was adjusted to maintain an ETCO2 between 35-40 mm of Hg. Abdominal insufflation pressure was limited to 12 -14 mm of Hg. Adequacy of ventilation was assessed by observing the movement of chest wall, minimum air leak in the neck, equally audible breath sounds on manual ventilation, recording of end tidal carbon dioxide (ETCO2).

After the end of pneumoperitoneum, metoclopramide 10 mg and ketorolac tromethamine 30 mg were given intravenously to reduce postoperative nausea and vomiting (PONV). At the end of surgery, isoflurane administration ceased and fresh gas flow was increased to 10 l/min. Mechanical ventilation with ventilator set at a triggering sensitivity of 5 or 6 l/min was maintained until the first spontaneous breath occurred. Muscle relaxation was reversed at the end of surgery with IV atropine 0.01 mg/kg body weight and neostigmine methyl sulfate 0.04 mg/kg. At the end of surgery Just before airway device removal, lung ventilation was manually assisted with continuous positive airway pressure during inspiration maintained at 5 cm H2O by adjusting the adjustable pressure limiting valve. The CLMA, PLMA, ETT, and NGT, were removed when the patient was awake, and able to respond to verbal command.

Insertion time of the device (time from jaw relaxation to connection to an aesthetic circuit and checking of adequate ventilation) was noted. Ease of insertion of the device was assessed and graded as:

- Easy - Insertion in single attempt without resistance
- Moderately difficult - Insertion in single attempt with resistance
- Difficult - Insertion in more than one attempt
- Impossible - Failed insertion

Insertion time of nasogastric tube (after device insertion) was noted for group II and group III

Ease of insertion of nasogastric tube was assessed and graded same as the grading method of the devices.

Measurements of oxygen saturation (SpO2), fraction of inspired oxygen (FiO2), end tidal carbon dioxide (ETCO2), minutes ventilation and peak airway pressure were recorded before peritoneal insufflation and approximately five minutes before peritoneal deflation.

Haemodynamic parameters like mean arterial blood pressure and pulse rate were noted before insertion, at insertion, 5 min after insufflations, at deflation, at removal and 5 min after removal of device.

Assessment of gastric distension was done by the surgeon after inspecting the stomach laparoscopically at: (a) initial entry of the laparoscope and (b) immediately before removal of the laparoscope at the end of the surgical procedure and scored the size of stomach on an ordinal scale 0-10,

0 = empty stomach and
10 = distension that interfere with surgical exposure.

Peritoneal insufflation time and total anesthetic time were recorded.

Intraoperatively, any airway obstruction or inadequate seal with large gas leak was managed by increasing the volume of air in the cuff or manipulation of patient's airway i.e. chin lift, jaw thrust, turning the head, repositioning the airway device.

Any manipulation required was recorded and graded as under:

Excellent - hands free anaesthesiua (if no manipulation was

required).
Good - If manipulations were required only initially.
Fair - If subsequent intraoperative manipulations were needed
Poor - Manipulations required throughout the surgical procedure.
Any incidence of trauma occurring while insertion of CLMA, PLMA or ETT was recorded. The occurrence of cough, vomiting, laryngeal stridor or spasm and the need for airway intervention during emergence from anesthesia were recorded. Any other complication occurring during insertion, maintenance, emergence, or immediate postoperative period were recorded and treated.

Results and Analysis

All data were collected, tabulated and expressed as Mean + Standard Deviation. Appropriate statistical analysis was conducted and the qualitative data were compared using chisquare test, quantitative data are compared using ANOVA. P values were calculated for all tests. A p value < 0.05 was considered as statistically significant, p value < 0.001 was considered as highly significant.

Table 1

	Group I	Group II	Group III	Statistical analysis
AGE (Mean ± SD) in years	42.9±11.13	42.2±11.31	40.80±12,01	P value =0.772
SEX Females: Males	18:12	22:8	23:7	P value = 0.329
BMI (Mean ± SD) in kg/m^2	22.97 ±1.87	22.27 ± 2.05	23.1± 1.80	P value = 0.711
Anaesthesia time (min)	82.57±8.27	84.00±12.00	85.6±13.3	P value =0.592
Peritoneal insufflation time(min)	74.26±11.18	75.27±12.19	73.30±17.96	P value= 0.830

Device Insertional Characteristics

(a) Ease of Insertion

Table 2: Ease of Insertion device

Ease of Insertion	Group I	Group II	Group III	Statistical Analysis
Easy	28 (93%)	28 (93%)	29 (96%)	p value = 0.809; NS
Moderately difficult	2	2	1	
Difficult	-	-	-	
Impossible	-	-	-	

NS - Non significant (p > 0.05)

Insertion Time

Table 3: Insertion Time device

	Group I	Group II	Group IIII	Statistical Analysis
Mean + S.D.	15.8 sec ± 3.1 sec	16.1 sec ± 2.1 sec	17.1 sec ±2.82s	p value = 0.161; NS

Nasogastric Tube (NGT) Insertion Characteristics

(a) Ease of Insertion

Table 4: Ease of Insertion

Ease of Insertion	Group II	Group III	Statistical Analysis
Easy	27	24	p value = 0.554; NS
Moderately difficult (MD)	3	6	
Difficult (D)	-	-	
Impossible (I)	-	-	

(b) Insertion Time

Table 5: Insertion Time

	Group II	Group III	Statistical Analysis
Mean + S.D.	10.03 sec ± 1.47 sec	12.7 sec + 1.34 sec	p value = 0.000 S

Haemodynamic Parameters

Table 6

	GROUP I		GPROUP II		GROUP III		Statistical Analysis	
	PR	MAP	PR	MAP	PR	MAP	PR	MAP
Before Insertion	75.87 ±7.37	78.87±5.24	74.20±7.06	77.07±5.37	77.83±5.54	79.00±5.25	P value =0.116	P value =0.292
At Insertion	81.07±7.41	83.7±4.59	79.73±6.93	82.77±5.01	89.57±5.80	94.00±5.18	P value=0.003	P value=0.002
5 min After Insufflation	84.43±6.98	86.77±3.94	83.87±6.54	86.40±4.98	96.33±5.62	100.27±3.59	P value=0.002	P value=0.000
After Deflation	79.17±7.71	81.93±4.37	77.10±6.53	78.73±6.19	83.13±4.36	88.77±5.32	P value=0.07	P value=0.003
At Removal	83.00±6.86	87.87±4.2	86.03±6.54	88.6±4.58	96.6±3.73	105.57±2.82	P value=0.001	P value=0.001
5 min After Removal	77.10±6.84	78.9±4.67	78.33±7.55	76.47±4.93	83.30±4.03	82.13±5.06	P value=0.007	P value=0.004

Vantilation Parameters

Table 7: Oxygen Saturation (SpO_2)

	Group I				Group II				Group III				Statistical Analysis			
	SPO2	EtCO2	MV	AP	SPO2	EtCO 2	MV	AP	SPO2	EtCO 2	MV	AP	SPO2	EtCO 2	MV	AP
Before peritoneal insufflation (Mean ± S.D.)	99.76 ± 0.42 mmHg	31.97 ±1.99			99.77 ± 0.43 mm Hg				99.73 ± 0.45 mm Hg				p value = 0.942; NS			
5 minutes before peritoneal deflation (Mean ± S.D.)	99.86 ± 0.33 mmHg	34.70±2. 12			99.87 ± 0.34 mm Hg				99.80 ± 0.40 mm Hg				p value = 0.716; NS			
Endtidal carbondioxide																

(b) End Tidal Carbondioxide

Table 8: End Tidal Carbondioxide (ETCO2)

	GROUP I	Group II	Group III	Statistical Analysis
Before peritoneal insufflation (Mean ± S.D.)	31.97± 1.99	30.73 ± 2.02 mm Hg	31.13 ± 2.13 mm Hg	p value = 0.458; NS
5 minutes before peritoneal deflation (Mean ± S.D.)	34.70± 2.12	34.50 ± 2.40 mm Hg	35.00 ± 2.62 mm Hg	p value = 0.445; NS

Minute Ventilation

Table 9: Minute Ventilation (V_{min})

	Group I	Group II	Group III	Statistical Analysis
Before peritoneal insufflation (Mean ± S.D.)	6.83± 0.73L	6.75 ± 0.76 L	6.68 ± 0.83 L	p value = 0.605; NS
5 minutes before peritoneal insufflation (Mean ± S.D.)	6.88± 0.739L	6.9 ± 0.81 L	6.85 ± 0.74 L	p value = 0.977; NS

NS - Non significant ($p > 0.05$)

Airway Pressure

Table 10: Airway Pressure

	Group I	Group II	Group III	Statistical Analysis
Before peritoneal insufflation (Mean ± S.D.)	18.63± 1.90	18.43 ± 2.05 cm H_2O	17.9 ± 2.02 cm H_2O	p value = 0.314; NS
5 minutes before peritoneal insufflation (Mean ± S.D.)	23.73± 1.89	23.03 ± 2.16 cm H_2O	22.3 ± 2.22 cm H_2O	p value = 0.199; NS

NS - Non significant ($p > 0.05$)

Gastric Distension Score

Stomach size at insertion of the laparoscope and change in stomach size during surgery were similar in all the groups.

Table 11(a): Median Entry Score

Gastric Distension Score	Group I	Group I	Group II	Statistical Analysis
Gastric distension score	2	2	3	NS

Table 11(b): Change in Score from Entry Score

Change in Score from entry	Group I	Group II	Group III	Statistical Analysis
↓ 1-2	3	3	1	p value = 0.509; NS
↑ 0-2	26	26	27	
↑ 3-6	1	1	2	

Airway Manipulation Required

Table 12: Airway Manipulation Required

Airway manipulation	Group I (CLMA) (N=30)	Group II (PLMA) (N=30)	Group III (ETT) (N=30)	Statistical Analysis
Cuff Inflation	2	1	0	p value = 0.313; NS
Chin lift/jaw thrust	0	1	1	p value = 1.00; NS
No manipulation required	28	28	29	p value = 0.554; NS

NS - Non significant ($p > 0.05$)

Hands Free Anaesthesia

Table 13: Hands Free Anaesthesia

Hands Free	Group I (CLMA) (N=30)	Group I (PLMA) (N=30)	Group II (ETT) (N=30)	Statistical Analysis
Excellent	28	28	29	p value = 0.351; NS
Good	2	2	1	
Fair	-	-	-	
Poor	-	-	-	

Complications at Extubation

Table 14: Complications at Extubation

	Group I	Group II	Group III	Statistical Analysis
None	28	28	26	p value = 0.173; NS
Cough	1	1	4	p value = 0.161; NS
Nausea/vomiting	-	-	-	NS
Laryngeal stridor/ spasm	-	-	-	NS
PPC	-	-	-	NS
Tracheal Intubation	-	-	-	NS
Any others (Trauma)	1(BS)	1 (BS)	2 (BS)	p value = 0.351; NS

NS - Non significant (p value > 0.05)

We conducted a study, on CLMA, PLMA and the ETT showing similar efficacy during laparoscopic surgery under general anaesthesia with controlled ventilation. PLMA aids easy and rapid insertion of the nasogastric tube. Though there is an increase in airway pressure during laparoscopy, PLMA provides adequate pulmonary ventilation, maintains oxygen saturation and effective elimination of carbon dioxide similar to endotracheal tube. Haemodynamic parameters after insertion of ETT reveal significant increase in stress response in comparison to CLMA and PLMA. Although endotracheal intubation is the gold standard in laparoscopic surgeries done under general anaesthesia, the PLMA proved to be an equally effective airway tool in laparoscopic surgeries in terms of adequate oxygenation and ventilation with minimal intraoperative and postoperative complications. The haemodynamic stress response was also minimal with PLMA when compared to endotracheal intubation. It provided equally effective pulmonary ventilation despite high airway pressures without significant gastric distention, aspiration, and regurgitation.

Thus, Proseal laryngeal mask airway is a safe and effective alternative to endotracheal intubation in patients of laparoscopic cholecystectomy, positively influencing the parameters concerning the ease of intubation, time taken for intubation, gastric distension and pulmonary ventilation and haemodynamic stability with aid of nasogastric tube.

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