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ORIGINAL ARTICLE

Comparative study of LMA Proseal and Tracheal Intubation for patients undergoing Laparoscopic Cholecystectomy in Indian population

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ABSTRACT:
We Compare the use of Proseal LMA and Tracheal Intubation for patients undergoing Laparoscopic Cholecystectomy in this prospective and randomized study. 62 ASA I-II patients, age >18 yrs, scheduled for elective Laparoscopic Cholecystectomy under general anaesthesia were randomly assigned into 2 groups. Group I- LMA PS- placing LMA-PS; Group II- ETT groups:- intubating tracheal tube. Depending upon the group allocation LMA-PS and ETT placed. Before and after placing LMA-PS and intubating tracheal tube patients were measured for SpO_2, H.R, and NIBP. The occurrence of cough, laryngeal stridor and the need for airway intervention during emergence from anaesthesia were also recorded. Surgeon inspected the size of stomach laparoscopically. LMA-PS group provides more haemodynamic stability, less postoperative respiratory events and equally good positive pressure ventilation. Size of stomach was comparable in both groups. The only problem which we found with LMA-PS was some leak around cuff (leak fraction 16.8±6.6 & 8.9±1.6) but acceptable clinically and does not cause ventilatory problem. We therefore conclude that LMA-PS or ETT are equally effective for adequate pulmonary ventilation without gastric distension in non-obese patients in laparoscopic cholecystectomy.
Key Words: Laparoscopic Cholecystectomy, LMA-proseal, Leak fraction, Positive pressure ventilation.

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INTRODUCTION:

Brain designed Laryngeal Mask airway as an alternative to Endotracheal Tube for use with positive pressure ventilation and used successfully in Gynaecologic Laparoscopy in 1983.[1] Laparoscopic upper abdominal surgeries are related to more acute ventilatory complications. Positive pressure ventilation may exploit leaks around the LMA cuff leading to gastric distension and/or inadequate ventilation. During laparoscopic procedures, pneumoperitoneum may cause respiratory embarrassment due to the mechanical effect of the increased intra-abdominal pressure.[2,3] Dynamic lung compliance was reduced by about 40% with increased peak inspiratory and plateau pressures during insufflation. Abdominal distension may impede the movement of diaphragm and restrict lung expansion. The increase in airway pressure in the presence of adequate muscle relaxation reflects the decrease in compliance associated with the elevated intra-abdominal pressure.[4]

LMA proseal (LMA-PS) have its cuff extends over the posterior surface of the mask as well as around its periphery. This pushes the mask anterior to provide a better seal around the glottic apertures and permits peak airway pressure >30 cm water without leak. A drain tube, parallel to the ventilation tube passes through the bowl of the mask and tip of the cuff to lie at the upper Oesophageal sphincter. This permits drainage of passively regurgitated gastric fluid. The LMA-PS may therefore more suitable than LMA classic for Positive Pressure Ventilation.

The purpose of this study is to compare pulmonary ventilation measurements, haemodynamic changes, gastric distension and emergence outcomes between LMA-Proseal and ETT in non obese patients for elective Laparoscopic Cholecystectomy.

METHODS:

After approval from institute's ethical committee and written informed consent from patients, this prospective, randomized and controlled study was conducted. The present study consisted of 62 adults (>18years), ASA physical status I and II, of either sex, undergoing elective Laparoscopic Cholecystectomy under general anaesthesia. The study was conducted over a period of 1st January 2008 to 31st April 2009. Obese (BMI >30 kg/m^2), pregnant and patients with history of gastroesophageal reflex, Hiatus hernia, Diabetes Mellitus, and having risk of pulmonary aspiration were excluded from study.

After exclusion, patients were randomized into two groups of 32 and 30 in LMA PS and ETT group respectively. The LMA Proseal (LMA PS) group placed LMA Proseal and Endotracheal intubation (ETT) group intubated with ETT. Patients that could not be ventilated with LMA PS or in which Ryle's tube insertion failed were considered drop-outs.

Age, sex, weight, height, BMI, and mallampati score were recorded preoperatively. Patients fasted after 10 PM except for clear liquid until two hours before their scheduled time of surgery. Patients were premeditated with oral Alprazolam 0.5 mg 30 min before dinner in night and 2 h before the induction of anesthesia with sips of water. Anesthesia was induced with fentanyl 2.5 µg/kg and propofol 2 mg/kg. Tracheal intubation or LMA-ProSeal was facilitated with vecuronium bromide 0.1 mg/kg. In LMA-PS group appropriate size of LMA-ProSeal was used (generally size 3 for women and size 4 for men). The cuff was inflated till end of audible leak detected by stethoscope. After connecting the LMA PS to anaesthetic circuit we observed chest movement and $EtCO_2$ waveform to confirm correct placement. Apart from this we used 3 additional test to confirm correct placement.

1- Pressure leak test – we set a continuous fresh gas flow (FGF) of 3 l/min, with the circuit connected to the reservoir bag and the adjustable pressure limiting valve closed, we recorded the airway pressure plateau at which an audible leak occurred, we then set tidal volume at 10 ml/kg & frequency 10 /min.

2- Leak fraction[5] – calculated as the fraction of air which was leaked out during positive pressure ventilation.

$$\text{Leak fraction} = \frac{\text{Inspired air}}{\text{Expired air}} \times 100$$

3- Finally we pass appropriate size ryle's tube into the stomach via the drain tube to confirm that the tip of the cuff layed correctly at the upper oesophageal sphincter to assess the ease of passing the gastric tube and to determine whether gastric suction ensured a flat stomach.

In ETT group we used generally 7.5 mm size for women & 8mm for men and inflate the cuff until no leak was audible and passed a ryle's tube through nasopharynx.

The patient's head and neck were covered to conceal the airway device before the surgeon entered the operating room. Anaesthesia was maintained with Isoflurane and Nitrous oxide in 35% Oxygen. Vecuronium was given to maintain the neuromuscular blockade intermittently. After surgery neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrolate 0.01 mg/kg. After gentle suctioning of oral secretions by a 12 F suction catheter, We take out LMA Proseal or ETT accordingly and transfer patient to the postanaesthesia care unit.

SpO_2 H.R, and NIBP were recorded before and after placing LMA-PS and intubating tracheal tube.

High initial FGF (6 L·min–1) was reduced to maintenance flows. The surgeon inserted a trochar into the peritoneal cavity under direct vision. Peritoneal insufflation pressure was preset and maintained at 15 mmHg. Head-up and lateral tilt were provided at the surgeon's request.

Each surgeon inspected the stomach laparoscopically A-initially at entry of the laparoscope and B- immediately before removal of the laparoscope at the end of surgical procedure. They scored the size of stomach on an ordinal scale 0-10. 0=empty stomach & 10-distension that interferes with surgical exposure.

Need of ryle's tube suction to decompress stomach was also noted.

The LMA-PS patients and ETT patients were compared using an independent student t test (for measured variables) and Chi-square Test (for discrete variables). p-value of <0.05 considered significant and <0.001 considered very significant.

RESULTS:

62 patients were included in this study out of which 2 were dropped out because of failure of LMA PS to ventilate in one patient and in another ryle's tube could not be inserted. Therefore 60 patients completed the study (30 in LMA-PS group and 30 in ETT group) .There was no difference between groups regarding to age, sex, weight, BMI, anaesthetic time and peritoneal insufflation time ($P > 0.05$) (Table 1). There was more haemodynamic stability in LMA-PS group. HR and Blood Pressure changes was very significant($P < 0.001$) and significant ($P < 0.05$) in LMA-PS group respectively (Table 2a) where as HR and Blood Pressure changes both was very significant($P < 0.001$) in ETT group (Table 2b). Except Leak fraction there was no difference between groups regarding SpO_2, Et CO_2, FiO_2, minute ventilation(Vmin) and airway pressure before and after peritoneal insufflation (p>0.05) (Table 3a and 3b). Leak fraction was very significant high ($P < 0.001$) after insufflation when compared with before insufflation in both groups. Leak fraction was very significant high ($P < 0.001$) in LMA-PS group as compared with ETT group (Table 4).

There was no significant difference in stomach size. Though exit score was more in LMA PS group but statically not significant ($P > 0.05$) (Table 5). In LMA PS group there

was need of ryle's tube suction to decompress stomach in 6 patient but none in ETT group ($P < 0.05$) (Table 5).
Regarding respiratory events at extubation there was no significant difference between groups except cough which was statistically significant in ETT group ($P < 0.05$) (Table 6).

Table 1: Patient characteristics

	LMA-PS n = 32	ETT n = 30	p value
Sex(F/M)	18/14	16/14	-
Age(yr)	38.56±9.02	40.63±9.88	>0.05
Weight(kg)	53.27±5.50	55.30±5.11	>0.05
BMI(kg/m2)	21.01±1.81	22.03±1.49	>0.05
Anaesthetic time(min)	49.10±7.91	45.37±8.18	>0.05
Peritoneal insuf.Time(min)	40.77±7.48	38.33±8.35	>0.05

Table 2 a: Haemodynamic changes after inserting airway device (LMA-PS)

	Baseline	After inserting airway device	p value
HR	78.77±5.74	88.30±7.94	<0.001
SBP	120.47±6.67	115.67±6.18	<0.05
DBP	76.30±6.91	71.83±5.90	<0.05
SpO2	99.43±.73	100±0	<0.001

Table 2b: Haemodynamic changes after inserting airway device (ETT)

	Baseline	After inserting airway device	p value
HR	79.1±3.87	100.37±5.04	<0.001
SBP	118.63±6.27	128.27±6.78	<0.001
DBP	72.40±6.20	82.63±6.26	<0.001
SpO2	99.47±.62	100±0	<0.001

Table 3a: Ventilation variables before peritoneal insufflation

	LMA-PS n = 30	ETT n = 30	p value
SpO2	100±0	100±0	0
PET CO2	33.23±0.57	33.33±0.55	>0.05
FiO2	33.97±0.49	34.03±0.18	>0.05
Vmin(L)	5.64±0.55	5.81±0.6	>0.05
Airway Press (cm H_2O)	12.33±0.80	12.40±0.56	>0.05
Leak Fraction	0.99±0.41	0.59±0.11	<0.001

Table 3b: Ventilation variables after peritoneal insufflation

	LMA-PS n = 30	ETT n = 30	p value
SpO2	99.06±0.52	99.27±0.52	>0.05
PET CO2	36.17±1.12	35.9±0.93	>0.05
FiO2	34.8±0.61	34.9±0.40	>0.05
Vmin(L)	6.52±0.72	6.68±0.69	>0.05
Airway Press (cmH2O)	14.87±1.14	14.57±0.97	>0.05
Leak Fraction	1.68±0.66	0.89±0.16	<0.001

Table 4: Leak fraction (in percentage)

	LMA-PS	ETT	t value	p value
Before insufflation	9.9±4.1	5.9±1.0	5.22	<0.001
After insufflation	16.8±6.6	8.9±1.6	6.31	<0.001
t value	4.85	8.83	-	-
p value	<0.001	<0.001	-	-

Table 5: Gastric distension change during peritoneal insufflation

	LMA-PS n = 30	ETT n = 30	p value
Entry Score	2.37±0.38	2.40±0.51	>0.05
Exit Score	2.66±0.45	2.44±0.47	>0.05
Need of ryle's tube suction	6	0	<0.05

Table 6: Respiratory events at extubation

Event	LMA-PS n = 30	ETT n = 30	p value
Cough	3	10	<0.05
Laryngeal stridor	1	3	>0.05
PPV	0	0	-
Tracheal reintubation	0	0	-
None	26	17	<0.05

DISCUSSION:

Our results demonstrate that the LMA-PS is as effective as an ETT to maintain pulmonary ventilation within acceptable clinical limits and provides more haemodynamic stability, except in two patients who were dropped out from study because of failure of LMA PS.The results are similar to previous studies of Maltby JR et all [6,7] but the major difference in our study from the previous is difference in Leak Fraction, which was not included in Maltby's study.

Circuit leak of anesthetic gases to the atmosphere during positive pressure ventilation may lead to hypoventilation and theatre pollution. Although Devitt *et al.*[8] and Ho-Tai *et al.,*[9] did not report fresh gas flow, their leak fraction, defined as a fraction of inspired volume, was >20% of tidal volume. This represents a waste of up to 2,000 mL·min–1 (180-200 mL from each of 10 breaths) and would not permit the low fresh gas flow achieved with larger LMAs. In Brimacombe's [10] finding that use of larger size LMAs permit airway pressures >20 cm water with minimal leak with positive pressure ventilation. In my study LMA-PS shows significantly high Leak Fraction before and after peritoneal insufflation but clinically acceptable.

Independent laparoscopic assessment of stomach size was done by surgeon, who were blinded to the airway device being used.[9,11] Increase in stomach size in this study interfered surgical exposure in 6 patient in LMA PS group. This was against the finding in a previous study of the LMA-C and ETT, [6] where none of the 53 patients in the LMA-C group required gastric decompression. However, the observed changes in stomach size may represent changes in visible surface area rather than distension.

None of patient in any group showed regurgitation or aspiration. An increase in intra-abdominal pressure has long been known to cause a reflex increase in the tone of the lower esophageal sphincter (LES).[12] The belief that the increase in intra-abdominal pressure during laparoscopic surgery increases the risk of gastroesophageal reflux was erroneous.[13] Peritoneal insufflation that produces an intra-abdominal pressure of 15 mmHg during the laparoscopy also increases LES tone. This increases the normal barrier pressure of 30 cm water and provides further protection from passive reflux of gastric contents. The reported incidence of clinically significant pulmonary aspiration in healthy patients undergoing elective surgery with the LMA-C is 1 in 5,000 to 1 in 12,000.[14,15] This is a similar order of magnitude to the incidence with ETT or facemask in ASA I or II patients undergoing elective surgery.[16] The drain tube of the LMA-PS may not reduce this incidence, but it does provide easy access for deflation of the stomach and reduction of gastric fluid volume.

CONCLUSION:

We conclude that adequate pulmonary ventilation without gastric distension can be achieved equally well with the LMA-PS or ETT in non-obese patients in laparoscopic cholecystectomy. Separation of alimentary and respiratory tracts represents a significant advance for airway management in selected patients. The only problem with

LMA-PS is some leak, but acceptable clinically and does not cause ventilatory problem. The LMA-PS may prove to be a more acceptable alternative to tracheal intubation for PPV but low flow anaesthesia should be avoided with LMA-PS.

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