Randomized Comparative Study Between The Proseal Laryngeal Mask Airway And The Endotracheal Tube For Laparoscopic Surgery

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Citation

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Abstract

Purpose: Proseal Laryngeal Mask Airway (PLMA) offers a new tool in airway management.

Methods: We decided to evaluate its use during general anaesthesia with positive pressure ventilation in laparoscopic procedures as compared to the Endotracheal tube (ETT) in a prospective randomized study in a teaching hospital. 121 ASA 1 and 2 adult patients of either gender were included after appropriate Ethics committee approval and informed consent from the patient. The main outcome measures were insertion characteristics of the PLMA or ETT and of the nasogastric tube (NGT), incidence of gastric distension, regurgitation, aspiration, trauma and postoperative sore throat were noted. Haemodynamic responses, oxygen saturation and EtCO2 were also recorded at various intervals (minor outcomes). Students't' test was used for statistical analysis.

Results: Time required for insertion was shorter for PLMA as compared to ETT. Nasogastric tube insertion was also faster in the PLMA group. There was statistical significant difference in the pulse rate values before and after pneumoperitoneum was created and in MAP. Oxygen saturation and EtCO2 values were comparable at all the intervals. Rarely sore throat and gastric distension were the complications noticed.

Conclusion: The PLMA and ETT show similar efficacy during laparoscopic surgery under general anaesthesia with controlled ventilation.

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INTRODUCTION

Traditional open surgeries are progressing to minimally invasive keyhole laparoscopic surgeries. Simultaneously, airway management of patients has also progressed from insufflation to endotracheal tube (ETT) to lesser invasive Laryngeal Mask Airway (LMA). LMA has challenged the standard ETT used during general anaesthesia.

The Proseal Laryngeal Mask Airway (PLMA), the latest in the family of LMA, is a useful tool in airway management [1]. It differs from the standard LMA in having a drain tube in addition to a reinforced airway tube. The drain tube traverses the floor of the mask, opens at the tip opposite the upper esophageal sphincter, prevents the epiglottis from occluding the airway, eliminates the need for aperture bars, and prevents inadvertent gastric inflation, permits access to the gastro intestinal tract (GIT) and aids Nasogastric tube insertion. The additional rear cuff increases the seal allowing higher seal than the standard LMA for a given intracuff pressure. The built in bite-block reduces the chances of damage to the device by inadvertent biting by the teeth of the patient and danger of airway obstruction. It can be inserted using an introducer or the finger, which is placed in the location strap. When correctly inserted, the distal tip of the cuff presses against upper esophageal sphincter, the sides face the pyriform fossae and upper border rests against the base of the tongue. As reports and studies of using PLMA for laparoscopic procedure are available, we decided to

compare its use with ETT in our setup over a six-month period [1,2,3,4,5,6,7]. The aim of our study was to evaluate and compare the use of PLMA in patients undergoing laparoscopic procedures under general anaesthesia and controlled ventilation with ETT.

MATERIALS & METHODS

121 ASA 1 and 2 adult patients of either gender scheduled to undergo elective laparoscopic surgery under general anaesthesia were included in the prospective randomized study after acquiring appropriate Ethics committee approval and informed consent from the patient. The patients between 18 – 75 yrs of age and weighing 32 - 82 kg were randomly allotted to either PLMA or ETT group for airway management. Patients with body mass index (BMI) more than 35 kg/m2, inadequate mouth opening (MO), anticipated difficult airway or having disease with risk of aspiration like GE reflux, hiatus hernia etc were excluded from the study. After routine preoperative evaluation laparoscopic procedures were performed under general anaesthesia and controlled ventilation. Cardio scope, pulseoximeter, capnograph, blood pressure monitoring were done through out the procedure. All the patients received midazolam, glycopyrrolate, pentazocine, ranitidine and ondansetron as per the standard recommended dosages. Anaesthesia was induced using thiopentone sodium. Neuromuscular blockade for insertion of the airway device was achieved in both the groups with suxamethonium. Anaesthesia was maintained with oxygen, nitrous oxide, isoflurane and vecuronium. Senior experienced anaesthesiologist throughout the study inserted appropriate size ETT size 7.5 in females and size 9.5 in males) or PLMA (size 3 in females and 4 in males) using introducer. For the purpose of standardization, we used the introducer for inserting the PLMA for all the cases. The main outcome measures were insertion characteristics of the PLMA or ETT and of the nasogastric tube (NGT) via the PLMA and the ETT, incidence of gastric distension, regurgitation, aspiration, trauma and postoperative sore throat were noted. Haemodynamic responses, oxygen saturation and $EtCO_2$ were also recorded at various intervals (minor outcomes). Insertion characteristics of the PLMA or ETT and of the nasogastric tube like ease of insertion, time taken to insert and attempts taken were noted. After insertion of the PLMA the leak test as recommended by placing a blob of gel on the drain tube for evidence of leak was carried out in addition to the checking for audible air leakage. Only if the leak was absent the PLMA insertion was considered as successful. Haemodynamic responses (pulse and MAP), oxygen saturation (SpO_2) and end-tidal carbon dioxide ($EtCO_2$) were recorded at the intervals: Preinduction, after insertion of the PLMA or ETT, after nasogastric tube insertion, before pneumo peritoneum, 10 minutes after pneumo peritoneum and postoperatively. The Nasogastric tube was inserted 10 minutes after the placement of airway device. The same research assistant recorded all the readings. After the laparoscopic procedure, neuromuscular blockade was reversed with glycopyrrolate and neostigmine. Intraoperatively, complications like gastric distension (as seen on the monitor or enquired with the surgeon), regurgitation visible from the nasogastric tube and aspiration were noted. Any evidence of postoperative sore throat was also noted in the recovery room and after 24 hours. Data was analyzed statistically using the unpaired students‘t' test.

RESULTS

Demographic data as seen in table 1 was comparable in both the groups with respect to age, weight, height and BMI. 78% of the patients were females in the PLMA group while 21% were males in the ETT group.

Figure 1

Table 1: Demographic Data

Mean (SD)	PLMA (n=60)	ETT (n=60)	p value (Unpaired)
Age (yrs)	34 (12)	36 (13)	0.3791
Weight (Kg)	54 (10)	53 (13)	0.8411
Height (cm)	155 (6)	156 (7)	0.5005
BMI (Kg/m^2)	22 (4)	21 (4)	0.4802
Gender; Male: Female	13: 47	13: 48	

The mean duration of anaesthesia was 94 (40) (range 40-230) minutes in the PLMA group and 96 (36) (range 55-190) minutes in the ETT group, which was comparable. PLMA was used for a maximum duration for 230 minutes in our study.

Laparoscopic cholecystectomy constituted the majority (81%) of the surgeries in our study. Other procedures performed were diagnostic laparoscopy, laparoscopic appendicectomy, orchidopexy, varicocoele and adhesiolysis as seen in table 2.

Figure 2

Table 2: Type of Surgery

	Number (%)	Number (%)
Surgery	PLMA	ETT
Laparoscopic Cholecystectomy	46 (76)	51 (83)
Laparoscopic Appendicectomy	9 (15)	5 (8)
Diagnostic and Laparoscopic Appendicectomy	0 (0)	3 (5)
Laparoscopic Orchidopexy	2 (3)	0 (0)
Laparoscopic varicocoele	1 (2)	0 (0)
Laparoscopic Adhesiolysis	1 (2)	0 (0)
Laparoscopic Appendicectomy and Varicocoele	1 (2)	0 (0)
Laparoscopic Cholecystectomy and Appendicectomy	0 (0)	1 (2)
Diagnostic Laparoscopy	0 (0)	1 (2)
Total	60	61

The mean time for insertion of PLMA and ETT were 15 (10) and 26 (11) seconds respectively. Nasogastric tube was inserted successfully in all cases with a mean time for insertion of 14 (6) and 27 (13) seconds respectively being quicker via the PLMA. In table 4 it is seen that there was not much difference in the pulse rate at the respective intervals between both the groups. Statistically significant difference was seen only in the values before and after pneumo peritoneum. The MAP was comparable in both the groups except after insertion of the PLMA or ETT the difference in values show statistical difference.

Figure 3

Table 3: Haemodynamics (Pulse: beats per minute, MAP: mm Hg)

Mean (SD)	Pulse			MAP		
	PLMA	p value (Unpaired)	ETT	PLMA	p value (Unpaired)	ETT
Preinduction	98 (22)	0.2343	93 (20)	102 (10)	0.8021	102 (10)
After insertion	104 (16)	0.1659	100 (16)	100 (11)	**0.0038**	108 (16)
Pre nasogastric tube	102 (15)	0.0526	97 (14)	99 (12)	0.4028	101 (14)
After nasogastric tube	100 (16)	0.0761	94 (15)	97 (13)	0.9950	97 (14)
Before pneumo peritoneum	98 (17)	**0.0016**	87 (19)	99 (13)	0.2732	96 (14)
After pneumo peritoneum	98 (17)	**0.0256**	91 (17)	109 (13)	0.8040	109 (14)
Post operative	92 (13)	0.7984	91 (13)	103 (7)	0.6277	103 (8)

Figure 4

Table 4: SpO (%) and EtCO (mm Hg)

Mean (SD)	SpO_2			$EtCO_2$		
	PLMA	p value (Unpaired)	ETT	PLMA	p value (Unpaired)	ETT
Preinduction	98 (0)	0.5768	99 (0)	28 (2)	0.0379	29 (2)
After insertion	99 (0)	0.8541	99 (0)	29 (3)	0.2426	30 (3)
Pre nasogastric tube	99 (0)	0.2840	99 (0)	29 (3)	0.9526	29 (4)
After nasogastric tube	99 (0)	0.7782	99 (0)	29 (3)	0.6338	29 (4)
Before pneumo peritoneum	99 (0)	0.3039	98 (11)	29 (4)	0.6872	29 (4)
After pneumo peritoneum	99 (0)	0.7903	99 (0)	33 (4)	0.0791	31 (5)
Post operative	99 (0)	0.2530	99 (0)	29 (3)	0.1534	30 (3)

Oxygen saturation and end-tidal CO_2 was comparable at all the intervals in both the groups as shown in table 5

Figure 5

Table 5: Complications

Number (%)	PLMA	ETT
Sore throat	3 (5)	6 (10)
Gastric Distension	2 (3)	0 (0)

Sore throat was the commonest complication noted. Three more patients had sore throat after using ETT than when PLMA was used. Other complication noted in our study was minimal gastric distension visible on the laparoscopic television monitor while using PLMA. This however did not disturb the surgeon and was not quantitatively measured.

DISCUSSION

The PLMA is a new entrant to the family of LMA with some added features over the classic LMA [1]. In our study, the PLMA was used in a variety of laparoscopic procedures, 81% of them being laparoscopic cholecystectomy. It was used for a maximum duration for 230 minutes.

PLMA can be inserted using either the introducer, index finger or the thumb. For the purpose of standardization, we used the introducer for all the cases. PLMA insertion took 15 (10) seconds as compared to 26 (11) seconds for the traditional ETT insertion.

We had no difficulty in passing nasogastric tube through the PLMA. Insertion of nasogastric tube through the nose was more time consuming and took 27 (13) seconds in the ETT group as against 14 (6) seconds in the PLMA group. The difference in this data is statistically significant and will be clinically important in patients with hypertension, ischaemic heart disease etc.

The double cuff arrangement of the PLMA prevents the chances of aspiration. Nasogastric tube was inserted in all our cases after confirming that there was no evidence of leak via the drain tube. There was no evidence of regurgitation or aspiration seen as evidenced by the maintenance of saturation and the end-tidal carbon dioxide within normal limits during the entire duration of the laparoscopy. In the study done by Giuseppe etal, the conclusion made was that though the PLMA and the standard LMA showed similar airtight efficiency during laparoscopy, the patency of the PLMA drainage tube should always be confirmed [2]. PLMA cuff pressure measurement would be desirable. However as we did not have the equipment we could not measure it. We also did not have any monitor to measure tidal volume and peak airway pressure which would be desirable.

PLMA may be recommended for patients with cardiac and respiratory problems because of stable haemodynamics and quicker insertion. We found PLMA to be a safe airway management device for controlled ventilation during the laparoscopic procedures. Piper and colleagues found PLMA as a convenient and practicable approach for total intravenous anaesthesia in patients undergoing gynaecologic laparoscopy [3] while Bimla S etal found PLMA as a safe airway device in anaesthetized and paralyzed patients undergoing laparoscopic surgery [4].

We did not include morbidly obese patients in our study. However, JR Maltby etal found a correctly placed LMA-C or PLMA as effective as an ETT for positive pressure ventilation without clinically important gastric distension in non-obese and obese patients but recommended further studies to determine the acceptability of the PLMA for laparoscopic cholecystectomy in obese patients [5,6].

Conclusive results were not seen in the study comparing use of classic LMA for laparoscopic procedures. Lu PP found the PLMA as a more effective ventilatory device for laparoscopic cholecystectomy than the LMA and did not recommend the use of the LMA for laparoscopic cholecystectomy [7].

In our study, 10% of the patients had sore throat in the ETT group as compared to 5% in the PLMA group. The sore throat evaluation performed in recovery room appears as reliable as later evaluations as in the study done by Bimla S et al [4].

CONCLUSION

In our study, the PLMA and the ETT show similar efficacy during laparoscopic surgery under general anaesthesia with controlled ventilation. The PLMA insertion is quicker and it aids easy and rapid insertion of the nasogastric tube under general anaesthesia. Complications are minimal and haemodynamic responses are stable and similar in both the groups. PLMA thus may offer as a reliable and better airway management option for patients undergoing laparoscopic procedures under general anaesthesia with controlled ventilation. A larger and more detailed study involving evaluation of cuff pressure, tidal volume, peak airway pressure and formal evidence of regurgitation and aspiration are recommended for full evaluation.

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