

# **PROSPECTIVE, RANDOMIZED, COMPARATIVE SINGLE BLINDED CASE CONTROL STUDY OF PROSEAL LMA AS AN EFFECTIVE ALTERNATIVE TO ENDOTRACHEAL INTUBATION FOR LAPAROSCOPIC GYNAECOLOGICAL SURGERIES**

**Dr.G.Poonkuzhali MBBS, MD<sup>1</sup>**

*Senior Asst. Professor Department of Anaesthesiology Coimbatore Medical College, Coimbatore, Tamilnadu*

## **I. Introduction**

Dr. Archie Brain developed a new way of linking artificial and anatomical airway, between 1981 and 1987. This new concept called Laryngeal Mask Airway combined the advantages of a non-invasive facemask and the more invasive tracheal tube. Originally LMA was recommended as a better alternative to the face mask. But ever since its development the LMA has challenged the assumption that tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation. Though LMA provided all the above advantages, the risk of gastric distension, pulmonary aspiration of gastric contents and fear of inadequate ventilation acted as a deterrent to the widespread use of LMA.

To overcome the above complications, Dr. Archie Brain designed the Proseal Laryngeal Mask Airway (PLMA) in 2000, with modifications designed to enable separation of gastro-intestinal and respiratory tract, improve airway seal, enable positive pressure ventilation and diagnose mask displacement. A Drain tube (DT) enables diagnosis of mask misplacement, reduces risk of gastric insufflation, regurgitation, and aspiration of gastric contents. Laparoscopic surgery or more appropriately minimal access surgery is well established since last 2 decades. It is the advances in anaesthesia and laparoscopic instrumentation and techniques that have led to remarkable development in the field of gynaecological surgeries. General anaesthesia with controlled ventilation remains the gold standard technique recommended for laparoscopic surgeries. Endotracheal tube was the preferred technique for GA, but few complications do arise with ETT. PLMA is the new airway device that forms a more effective glottic seal and it facilitates passage of a gastric tube. It probably provides protection against regurgitation and prevents gastric insufflation when correctly placed. With this background this study was conceptualized to compare Endotracheal tube and Proseal LMA for elective laparoscopic gynaecological surgery.

## **II. Aim Of The Study**

To compare the advantages and disadvantages of PLMA and Endo Tracheal Tube (ETT) for General Anaesthesia in women coming for elective laparoscopic gynaecological surgery.

## **III. Device Description**

The Proseal MA is made from medical grade silicone and is reusable. It has four main components

1. Mark
2. Inflation line with pilot balloon.
3. Airway tube
4. Drain tube

**Proseal Lma Sizes Available**

Proseal LMA size	Patient selection Guidelines	Proseal LMA airway tube ID(mm)	Maximum cuff inflation Volume (Air)	Gastric Tube	ETT	FOD
1 ½	5-10 kg	6.4	7ml	10 Fr	4.5	3.5
2	10-20 kg	6.4	10ml	10 Fr	4.5	3.5
2 ½	20-30 kg	8.0	14ml	14 Fr	4.5	3.5
3	30-50 kg	9.0	20ml	16 Fr	5.0	4.0
4	50-70 kg	9.0	30ml	16 Fr	5.0	4.0
5	70-100 kg	10.0	40ml	18 Fr	5.0	5.0

It is recommended that the intracuff pressure should not exceed 60cm H<sub>2</sub>O

#### **Device Placement**

PLMA was inserted by using index finger insertion technique. After insertion the tubes should emerge from the mouth directed caudally. Without holding the tubes inflate the cuff with just enough air to obtain an intracuff pressure equivalent to approximately 60cm H<sub>2</sub>O.

#### **The signs of correct placement may include one or more of the following:**

- Slight outward movement of tube upon inflation.
- Presence of smooth oval swelling in the neck around the thyroid and cricoid area. Never over inflate the cuff.

#### **Problems With Plma Placement & Appropriate Corrective Maneuvres**

- An inadequate depth of anaesthesia may result in coughing and breath holding during insertion. Should this occur, anaesthesia should be deepened immediately.
- If the patient's mouth can not be opened sufficiently to insert the mask, first ensure that the patient is adequately anaesthetized. An assistant can be asked to pull the jaw-downward.
- The cuff must press against the palate throughout the insertion manoeuvre; otherwise the tip may fold back on itself or impact on an irregularity or swelling in the posterior pharynx (eq. Hypertrophied tonsil). If the cuff fails to flatten or begins to curl over as it is advanced, it is necessary to withdraw the mask and reinsert it.

#### **Tests for placement:**

##### **1. Depth of insertion:**

It has been observed that when most of the bite block was outside the patient's mouth, PLMA was frequently malpositioned. For women, mean depth of insertion has been found to be 18.6cm and for men 20.9cm.

##### **2. Test for Obstructed Airway:**

Unobstructed placement of PLMA is demonstrated by manual ventilation with rise and fall of the chest and square wave capnograph and normal compliance of reservoir bag.

##### **3. Soap Bubble Test:**

This is done to evaluate the seal with GIT. Non-toxic soap solution is used to create a membrane over DT tip. Any leak during IPPV will dislodge the membrane.

#### **Uses:**

1. Confirms PLMA location behind cricoid cartilage.
2. Confirms zero leak at PLMA - Oesophageal seal
3. Detects negative DT pressure and aerophagia with spontaneous ventilation.
4. Diagnoses oesophageal insufflation during IPPV.

##### **4. Lubricant Jelly Test:**

It evaluates seal with GIT 0.5 to 1ml of lubricant jelly is placed in the proximal end of the DT to seal it. If there is a leak from the DT, the bolus of jelly is blown off.

##### **5. Suprasternal notch tap test:**

This is used to determine whether the leading edge of PLMA lies behind the cricoid cartilage. A non toxic soap solution is placed across the proximal end of DT creating a membrane. The suprasternal notch is the gently tapped. A pulsating soap membrane with tapping confirms the tip location behind cricoid cartilage.

##### **6. Gastric Tube placement test:**

When there is no leak up the DT, then insertion of gastric tube is attempted via DT without using much force. This gives information about the DT patency which is mandatory for safe use of PLMA.

### **Orogastric tube insertion:**

The primary function of the drain tube is to provide a separate conduit from and to be alimentary tract. This is then passed down the DT of PLMA without any haste or force. A slight resistance is normal felt as the tip passes against upper oesophageal sphincter. There is an inherent resistance to gastric tube insertion after 23cm of passage due to angulation of 9<sup>0</sup> in the passage of DT to its tip. There may be difficulty in passing gastric tube due to following reasons.

1. Selection of too large gastric tube
2. Inadequate lubrication
3. Use of cooled gastric tube
4. Cuff over inflation
5. Malposition of PLMA

### **The advantages of inserting gastric tube are**

1. It allows removal of gas or fluid from the stomach
2. Confirm position/ Patency of drainage tube
3. Functions as a guide to PLMA insertion if accidental displacement occurs.

### **The disadvantages of inserting gastric tube are**

1. Risk of tracheal placement
2. Oesophageal perforation rarely
3. The presence of gastric tube may trigger regurgitation by interfering with oesophageal sphincter function.
4. Gastric tube blocks drainage tube so that gas and fluid can not escape from oesophagus.

### **Test For DT Airleak And Patency**

#### **Air leak**

Large volume leaks are detected by listening over drainage tube or feeling the air with hand. Small volume air leaks are detected best by placing water based lubricant or soap bubble over the end of drain tube.

#### **Tests For Patency**

1. Passage of gastric tube
2. Passage of fiberoptic scope
3. Supra sternal notch tap test.

## **IV. Details Of The Study**

Prospective, Randomized, Comparative Single Blinded Case control study of Proseal LMA as an effective alternative to Endotracheal intubation for Laparoscopic Gynaecological Surgery, study was carried out in AOT, Kasthurba Gandhi Hospital, Institute of Social Obstetrics, Chennai from January 2009 to February 2009 after obtaining Institutional Ethical Committee clearance and patients written informed consent.

The study was conducted in 50 female patients in the age group of 18 years and above belonging to ASA I & II, weighing BMI < 30kg /m<sup>2</sup>, posted for elective Laparoscopic Gynaecological Surgeries.

#### **Exclusion Criteria**

- ❖ Severe cardiovascular, Hepatic and Renal disease
- ❖ Patients with difficult airway
- ❖ BMI >30 kg/m<sup>2</sup>
- ❖ History of Gastro Oesophageal Reflux disease
- ❖ History of Hiatus Hernia
- ❖ Nil per oral for 6 hrs

#### **Materials Required**

- ❖ Endotracheal tube 7, 7.5 ID sizes
- ❖ Proseal LMA 3 size
- ❖ Macintosh laryngoscope
- ❖ Stop clock

- ❖ 10ml syringe

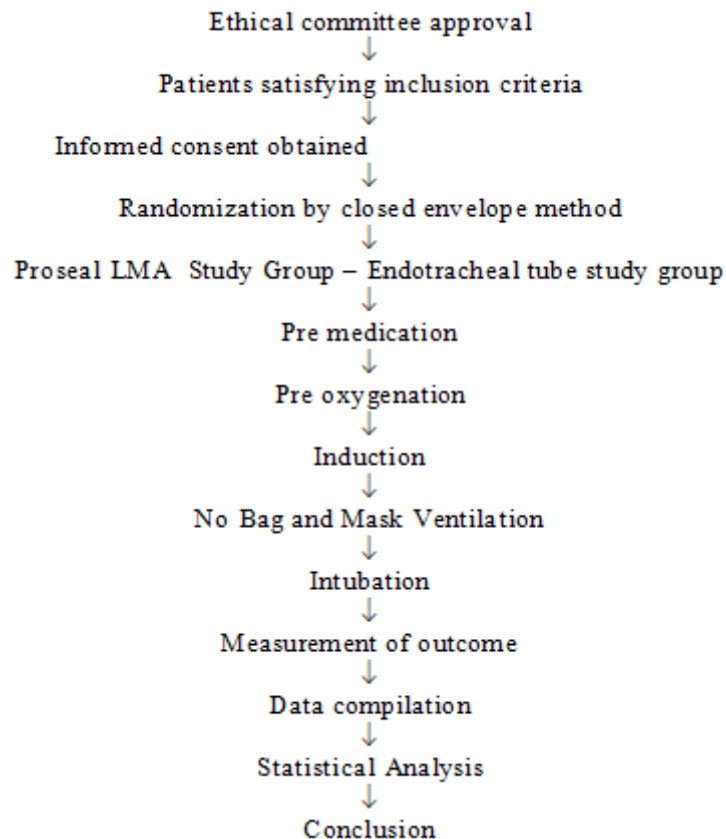
## V. Study Outcome

- ❖ Ease of Intubation
- ❖ Tissue taken for intubation
- ❖ Success rate
- ❖ Number of attempts for successful placement
- ❖ BP, HR, SPO<sub>2</sub> changes to intubation
- ❖ EtCo<sub>2</sub> changes
- ❖ Gastric Distension
- ❖ Airway trauma
- ❖ Post op awareness like sorethroat
- ❖ Post op breathing difficulty like laryngospasm

### Gastric Distension

It was measured by gynaecologist who was operating, gynaecologist was asked about gastric distension just before peritoneal deflation. Gynaecologist's judgement was measured in an ordinal scale from 0 – 10. (0 = empty stomach and 10 = distension of stomach that interfered surgical field.

## VI. Methodology



## VII. Conduction Of The Study

The patients who had come for laparoscopic gynaecological surgery screened for co morbid illness and difficult airway. Age, Height and Weight were assessed. If patients satisfied inclusion criteria, informed consent was obtained and the patients were randomized in to 2 groups using closed envelope technique as proseal LMA group and endotracheal tube group. After the patient was

shifted inside the operating room, intravenous access gained. ECG monitor, Pulse oximeter and non-invasive Blood pressure monitors were connected. Preoperative BP, HR and SpO<sub>2</sub> were recorded.

Patient was premedicated with Inj. Glycopyrrolate 0.2mg and Inj. Fentanyl 2 µg/kg. Pre oxygenated with 100% oxygen at a flow rate of 8L/mt by using tight fitting facemask for 5 mts. Patient was induced with Inj.2% Lignocaine Hydrochloride (Xylocard) 1.5mg/Kg, Inj. Propofol 2mg / Kg & Inj. Suxamethonium 2 µg/Kg. Bag and mask ventilation was avoided between induction and intubation. Pre intubation BP, HR, and SpO<sub>2</sub> were recorded. One minute after giving Inj. Suxamethonium, 3 Size proseal LMA was inserted in sniffing position by using index finger insertion technique. Cuff was inflated with 20ml room air to the manufacturers recommended cuff pressure of 60cm H<sub>2</sub>O before anaesthetic circuit was connected and patient's lung are ventilated. Position of PLMA was confirmed by bilateral chest movement, Square EtCO<sub>2</sub> waveform and silent epigastrium by stethoscope auscultation.

With the PLMA, we filled the proximal 3 cm of the drain tube with the water soluble lubricant jelly, if a gas bubble rose through the jelly during inspiration indicating a gas leak into the oesophagus, we corrected the position of PLMA and repeated the test until no bubble appeared. In the Endotracheal tube group, by using Macintosh laryngoscope, we inserted 7.0/ 7.5mm ID tube in all patients and inflated the cuff until no leak was audible during manual ventilation. A gastric tube was not passed prophylactically in either group. (No gynaecologist requested passage of gastric tube to deflate the stomach in any patients) Post intubation BP, HR, SpO<sub>2</sub> and EtCO<sub>2</sub> were recorded. Time taken for insertion, Ease of intubation and number of attempts were also recorded. Anaesthesia was maintained with 1 MAC sevoflurane/ Halothane and N<sub>2</sub>O: O<sub>2</sub> at 2:1 ratio. Muscle relaxation was maintained with Inj. Atracurium 0.5mg/Kg. Post intubation BP, HR and SpO<sub>2</sub> were recorded at 3 mts and 5 mts interval.

Gynaecologist was requested to initiate the surgical procedure. Trendelenberg tilt # 15\* was provided at the gynaecologist's request. Pneumo peritoneum was created with CO<sub>2</sub> gas and intra abdominal pressure was maintained ≤ 15mmHg. EtCO<sub>2</sub> was recorded after peritoneal inflation. The gynaecologist was requested to look for gastric distension and to grade it in an ordinal scale measuring from 0 – 10. (0 = empty stomach; 10 = distension of stomach that interfered surgery) EtCO<sub>2</sub> was recorded after peritoneal deflation. After completion of surgery and adequate neuromuscular recovery patient was reversed with Inj. Neostigmine 50µg/kg and Inj. Glycopyrrolate 0.4mg. Before extubation a sterile suction catheter was passed through the drainage tube and gastric contents was drained out. After thorough oral suction cuff was deflated and patient was extubated. Blood staining in the airway, cough, laryngospasm / Stridor, sorethroat, and the need for airway intervention during emergence from anaesthesia were recorded. Once the recovery was found adequate, patient was shifted to post operative ward and patients were interviewed for next 24 hours regarding cough, sorethroat and laryngospasm.

### VIII. Observation And Results

This prospective, randomized, comparative, single blinded case control study compares PLMA insertion with endotracheal tube in 50 adult females undergoing elective laparoscopic gynaecological surgery. All data were collected, tabulated and expressed as Mean +/- standard deviation. Appropriate statistical analysis was conducted. All quantitative data were compared using unpaired student's test. All qualitative data were compared using Chi square test. P values were calculated for all tests. A P values 0 to 0.01 was considered as 1% significant, 0.011 to 0.05 was considered as 5% significant, and >0.05 was considered as not significant. The summated results are presented below.

#### Ease Of Intubation

Group	Easy		Difficulty		P = 0.312 Not significant
	No	%	No	%	
PLMA	24	96	1	4	
ETT	25	100	0	0	

The ease by which the patient was intubated judged subjectively.

By using PLMA, 24 cases were intubated easily and one was intubated with difficulty. By using ETT, all 25 cases were intubated easily. Since it is a qualitative data values are compared by using Chi square test. Statistical analysis do not reveal any difference (P = 0.312).

#### Number Of Attempts For Successful Placement

Group	Attempt-I	Attempt -	Mean	Standard
-------	-----------	-----------	------	----------

		II		Deviation	
PLMA	21	4	1.16	0.374	T=2.14 P =0.038 Significance 5%
ETT	25	0	1.0	0.0	

**Successful placement of PLMA is defined by the following criteria**

1. Square wave pattern on capnography
2. No airleak over mouth, stomach, draitube
3. Positive suprasternal notch tap test.
4. Effective ventilation (TV > 8ml/Kg, EtCO<sub>2</sub> <45 mmHg).

PLMA insertion was successful in 21/25 cases in first attempt while 4 patients 4/25 required second attempt. With ETT all 25 patients were intubated in first attempt.

Statistical analysis reveals P value of 0.038 which is significant up to 5% which may be due to small sample size and lack of experience with PLMA.

**Time Taken To Intubate**

Group	Mean	Standard Deviation	
PLMA	37.36	21.07	t=1.13 P =0.265 Not Significant
ETT	32.4	6.212	

The time taken for PLMA/ETT from introduction into oral cavity to the final confirmation of its proper positioning. Time taken for intubation with PLMA is 37.36 and with ETT is 32.4.

Student’s t test reveals P value of 0.265 which is not significant. This indicates there is no difference in intubation time between PLMA and ETT.

**Gastric Distension**

Group	Mean	Standard Deviation	
PLMA	0.56	1.227	t=1.42 P =0.161 Not Significant
ETT	1.08	1.352	

Gastric distension was measured by gynaecologist who was operating. It was measured just before peritoneal deflation in an ordinal scale from 0 – 10. Gastric distension with PLMA is 0.56 and ETT is 1.08. Student’s ‘t’ test reveals P value of 0.161 which is not significant. This indicates that PLMA provides good airway seal and adequate pulmonary ventilation.

**Spo<sub>2</sub> Changes**

	Groups	No	Mean	Standard Deviation	
Pre Op	PLMA	25	99.8	0.50	t=2.25 P =0.804 Not Significant
	ETT	25	99.8	0.62	
Pre intubation	PLMA	25	99.92	0.28	t =0.59 p=0.561 Not significant
	ETT	25	99.96	0.20	
Post Intubation 1 mt	PLMA	25	99.96	0.20	t=0.45 P =0.657 Not Significant
	ETT	25	99.92	0.40	
Post Intubation 3 mt	PLMA	25	99.96	0.20	t=1.17 P =0.248 Not Significant
	ETT	25	99.84	0.47	
Post Intubation 5 mt	PLMA	25	99.92	0.28	t = 0.59 P =0.561 Not Significant
	ETT	25	99.96	0.20	

SPO<sub>2</sub> was measured pre operatively, just before intubation, 1mt, 3mt and 5mt after intubation. The actual values are documented in the tabular column above. Statistical analysis by students t test reveals P value of 0.804, 0.561, 0.657, 0.248 and 0.561 respectively which are not significant. Hence there was no significant oxygenation difference between two techniques.

**Etco<sub>2</sub> Changes**

	Groups	No	Mean	Standard Deviation	
Post intubation	PLMA	25	29.2	2.08	t = 0.18 P =0.861 Not Significant
	ETT	25	29.08	2.71	
After peritoneal inflation	PLMA	25	30.44	2.58	t = 1.16 P =0.251 Not Significant
	ETT	25	29.56	2.77	
After peritoneal deflation	PLMA	25	34.32	3.85	t = 0.78 P =0.441 Not Significant
	ETT	25	33.36	4.83	

EtCO<sub>2</sub> was recorded after intubation, after peritoneal inflation with CO<sub>2</sub> and after peritoneal deflation. The actual values are documented in the tabular column. Student's t test reveals P value of 0.861, 0.251 and 0.441 respectively which are not significant.

This indicates that PLMA provides good pulmonary ventilation.

**Blood Staining In Airway**

Group	Yes	No	Mean	Standard Deviation	
PLMA	1	24	1.96	0.2	t=0.59 P =0.561 Not Significant
ETT	2	23	1.92	0.28	

Blood staining in the airway noted after extubation which indicates airway trauma. It occurred in 1/25 cases with PLMA and 2/25 cases with ETT. Chi square test reveals P value of 0.561 which is not significant. Hence incidence of airway trauma is same in both the groups.

**Post Operative Airway Morbidity**

	Groups	Yes	No	Mean	Standard Deviation	
Sore Throat	PLMA	1	24	1.96	0.200	t=1.41 P =0.161 Not Significant
	ETT	4	21	1.84	0.374	
Laryngo Spasm	PLMA	0	0	2.00	0.0	Not significant
	ETT	0	0	2.00	0.00	

Post operative sorethroat and laryngospasm were assessed for 24 hours post operatively. Sorethroat occurred in 1/25 cases with PLMA and 4/25 cases with ETT. Laryngospasm did not occur in both the groups. Through documented data are clinically relevant statistical analysis reveals P Value of 0.164 which is not significant. Hence incidence of post operative airway morbidity is same in both the groups.

**Haemodynamics Heart Rate**

	Groups	No	Mean	Standard Deviation	
Pre Op	PLMA	25	96.8	20.01	t = 0.92 P =0.363 Not Significant
	ETT	25	92.4	13.13	
Pre Intubation	PLMA	25	98.56	16.98	t = 1.21 P =0.232 Not Significant
	ETT	25	92.96	15.71	
Post Intubation 1 mts	PLMA	25	98.68	17.42	t = 0.65 P =0.518 Not Significant
	ETT	25	101.92	17.74	
Post Intubation 3 mts	PLMA	25	92.6	19.71	t = 1.77 P =0.083 Not Significant
	ETT	25	102.24	18.74	
Post Intubation 5 mts	PLMA	25	87.04	14.85	t = 1.72 P =0.091 Not Significant
	ETT	25	95.00	17.68	

**Systolic Blood Pressure**

	Groups	No	Mean	Standard Deviation	
Pre Op	PLMA	25	127.08	12.36	t = 0.30 P =0.766 Not Significant
	ETT	25	126.08	11.2	
Pre Intubation	PLMA	25	121.04	12.63	t = 0.85 P =0.401 Not Significant
	ETT	25	124.20	13.72	
Post Intubation 1mt	PLMA	25	114.28	18.23	t = 2.30 P =0.026 Significant 5%
	ETT	25	127.60	22.50	
Post Intubation 3 mts	PLMA	25	111.08	18.20	t = 3.20 P =0.002 Significant 1%
	ETT	25	130.52	24.28	
Post Intubation 5 mts	PLMA	25	103.20	14.73	t = 2.93 P =0.005 Significant 5%
	ETT	25	117.68	19.83	

**Diastolic Blood Pressure**

	Groups	No	Mean	Standard Deviation	
Pre Op	PLMA	25	80.04	8.56	t = 1.16 P =0.250 Not Significant
	ETT	25	77.04	9.64	
Pre Intubation	PLMA	25	77.6	9.88	t = 1.20 P =0.236 Not Significant
	ETT	25	74.08	10.84	
Post Intubation 1mt	PLMA	25	71.8	15.97	t = 2.14 P =0.037 Significant 5%
	ETT	25	81.32	15.44	
Post Intubation 3 mts	PLMA	25	72.16	16.53	t = 2.44 P =0.019 Significant 5%
	ETT	25	83.60	16.68	
Post Intubation 5 mts	PLMA	25	64.64	15.11	t = 2.24 P =0.030 Significant 5%
	ETT	25	75.36	18.61	

**Mean Arterial Pressure**

	Groups	No	Mean	Standard Deviation	
Pre Op	PLMA	25	95.7	8.53	t = 0.94 P =0.352 Not Significant
	ETT	25	93.36	9.11	
Pre Intubation	PLMA	25	92.04	9.94	t = 0.43 P =0.668 Not Significant
	ETT	25	90.75	11.26	
Post Intubation 1mt	PLMA	25	85.94	15.38	t = 2.33 P =0.024 Significant 5%
	ETT	25	96.72	17.22	
Post Intubation 3 mts	PLMA	25	85.14	16.45	t = 1.89 P =0.064 Not Significant
	ETT	25	95.62	22.24	
Post Intubation 5 mts	PLMA	25	77.46	14.23	t = 2.56 P =0.014 Significant 5%
	ETT	25	89.42	18.54	

Heart rate, systolic blood pressure Diastolic blood pressure and mean arterial pressure were measured pre operatively, pre intubation, 1mt, 3mt and 5mts after intubation. The actual values are



documented in the tabular column. Statistical analysis by students t test reveals significant blood pressure changes 1mt, 3mt, and 5mts after intubation and no significant difference in heart rate between two techniques. Hence there was a significant haemodynamic response with ETT when compared to PLMA.

### **IX. Discussion**

The Proseal LMA provides an acceptable way to maintain a clear airway and provide positive pressure ventilation. It is also associated with reduced risk of gastric insufflation, regurgitation and aspiration of gastric contents.

This study was designed to evaluate the effectiveness of PLMA when compared to ETT with respect to pulmonary ventilation and gastric distension during gynaecological laparoscopy.

This study was conducted in 50 adult women, ASA I & II, aged 18 years and above undergoing elective laparoscopic gynaecological surgery (both short and long duration procedure).

#### **Ease Of Intubation**

1. Miller DM, Camporota L, et al in 2006 compared PLMA and SLIPA with ETT in 150 patients. Both PLMA and SLIPA were easy to insert (100% success) and ventilate with maximum sealing pressure of 30cm H<sub>2</sub>o (P = 0.4) with no muscle relaxant. The findings of our study are in concurrence with the above data. Both ETT and PLMA were intubated with ease with P value of 0.312.2. N.R. Evans, S.V. Gardner et al in 2002 assessed insertion characteristics of PLMA, airway seal pressure, ease of gastric tube placement in 300 anaesthetised patients. Insertion was successful in 94% of patients and graded as easy in 91 % of patients. Gastric tube placement was successful in 98.6% of patients. In our study 96% of patients (24/25) were graded as PLMA with ease.

#### **Number Of Attempts To Successful Placement**

1. Miller DM, Camporota L, et al in 2006 compared PLMA with ETT in 150 anaesthetised patients. PLMA was easy to insert in all patients with 100% success rate and was easy to ventilate.

In our study, we compared PLMA and ETT in only 50 anaesthetised patients. Sample size is very minimal (33% only). Possible reasons for disparity in numbers of attempts for successful placement may be small sample size and lack of experience.

2. N.R. Evans, S.V. Gardner et al in 2002 assessed insertion characteristics of PLMA in 300 anaesthetised patients. Insertion was successful in 94% of patients.

If we compare the sample size with the above study, sample size in our study is 16.6% only. This again supports the disparity in our results.

#### **Time Taken For Intubation**

1. Miller DM, Camporota L, et al in 2006 compared PLMA, SLIPA with ETT in 150 anaesthetised patients undergoing day care laparoscopic gynaecological surgery. They concluded PLMA and SLIPA were easy to use and less operating room time (P = < 0.001) was required compared to ETT in day care laparoscopies.

In our study no significant difference (P = 0.265) in intubation time between PLMA and ETT. This disparity may be due to small sample size.

#### **Gastric Distension**

1. J. Roger Maltby, Michael T, Beriault et al 2003, compared PLMA with ETT in 209 women undergoing laparoscopic gynaecological surgery in both short and long procedures. They concluded no statistically significant difference between PLMA and ETT with respect to stomach size changes.

This result is comparable with our study (P = 0.161).

2. J. Roger Maltby, Neil C, Watson et al in 2002, Compared PLMA with ETT in 109 patients undergoing laparoscopic cholecystectomy. They concluded that no significant gastric distension in both the groups. This study result is comparable with our study which shows P value of 0.161.

#### **Pulmonary Ventilation**

1. J. Roger Maltby, Michael T. Beriault, compared PLMA and ETT in 209 women undergoing laparoscopic gynaecological surgery, concluded no statistically significant difference between PLMA and ETT groups for SpO<sub>2</sub>, EtCO<sub>2</sub> before or during peritoneal insufflation in short and long period of peritoneal inflation.

This result is comparable with our study result which shows no significant SpO<sub>2</sub> change (P = 0.804, 0.561, 0.657, 0.248, 0.561) measured Pre op, Pre intubation, 1mt, 3mt and 5mts after intubation and there were no significant EtCO<sub>2</sub> changes (P = 0.861, 0.251, 0.44) measured after intubation, after peritoneal inflation and after peritoneal deflation.

2. J.Roger Maltby, Michael Beriaul et al in 2002 compared PLMA and ETT in 109 patients undergoing laparoscopic cholecystectomy concluded no statistically significant difference in SpO<sub>2</sub> / EtCO<sub>2</sub> between two groups.

This result is comparable with our study.

#### **Blood Staining**

1. Brimacombe Joseph, Keller C et al in 2004, In their study on 240 patients, concluded that there was no significant airway morbidity and visible blood staining on PLMA.

This is in concurrence with our study which also shows blood staining in 1/25 cases with PLMA and 2/25 cases with ETT with a P value of 0.561 (not significant)

#### **Post Operative Airway Morbidity**

1. Miller DM, Camporota. L, et al in 2006 in their study on 150 patients, concluded that lower incidence of sorethroat with PLMA than with ETT group (30% Vs 57% and P value < 0.05).

This result in comparable with our study result which shows 1/25 Vs 4/25, P = 0.164.

2. Hohlrieder M, Brimacombe J, et al in 2007 compared PLMA with ET in 200 female patients, concluded that less frequency of sorethroat with PLA (12% Vs 38%, P <0.001). This result is comparable with our study.

#### **Haemodynamics**

1. Miller DM, Camporota L, et al in 2006, compared systolic pressure which was more stable with PLMA in response to insertion than with ETT.

This result is comparable with our study which shows significant systolic blood pressure values (P=0.026,0.002,0.005) 1mt,3mts and 5mts after intubation respectively, diastolic blood pressure values (P 0.037, 0.019, 0.30) 1mt, 3mt and 5mts after intubation and mean arterial pressure changes (P = 0.24, 0.14) 1mt and 5mts after intubation.

2. Piper SN, Triem JG, Rohmkd et al in 2004 compared PLMA and ETT in 104 patients, concluded high MAP with ETT (92 +/- 13 Vs 100 +/- 14mmHg;P < 0.01) and lower HR with PLMA (66+/-13 vs 76 +/- 14 beats/ mt; P < 0.01).

This result is comparable with our study, which shows high MAP 1mt, 3mts, and 5mts after intubation (P = 0.24, 0.14), no significant HR values (P = 0.518, 0.083, 0.091) 1mt, 3mts, and 5mts after intubation.

### **X. Summary**

This Prospective, Randomized, Comparative single blinded case control study evaluate the effectiveness of PLMA over ETT in 50 adult women, ASA I & II, aged 18 years and above undergoing elective laparoscopic gynaecological surgery (Short and long duration) under GA with IPPV.

#### **The conclusions deduced from the study are:**

1. Both PLMA and ETT were intubated with ease (P = 0.312)
2. First attempt success rate with PLMA and ETT was 21/25 and 25/25 patients respectively. Second attempt success rate with PLMA was 4/25 statistical analysis shows 5% significance may be due to small sample size.
3. Both the techniques had comparable and insignificant difference in intubation time (P = 0.265).
4. No significant gastric distension intra operatively with both PLMA and ETT. No gynaecologist requested passage of gastric tube to deflate the stomach intra operatively. So PLMA provides good oropharyngeal seal and pulmonary ventilation.
5. Both the techniques had no significant difference in SpO<sub>2</sub> and EtCO<sub>2</sub> before and during peritoneal insufflation. So PLMA is also a good airway device for laparoscopic surgery.
6. Blood staining on PLMA and ETT was comparable and was not statistically significant.
7. Post operative sorethroat and laryngospasm were not statistically significant in both the groups.
8. Haemodynamically there was significant difference between two groups with regard to systolic blood pressure, diastolic blood pressure and mean arterial pressure and PLMA was found to be a better device than ETT in this aspect.

Hence PLMA is an excellent alternative airway device to endotracheal tube in laparoscopic surgery.

### **XI. Conclusion**

The Proseal LMA is an excellent alternative airway device to ETT in laparoscopic gynaecological surgery with respect to ease of intubation, time taken for intubation, number of attempts for successful placement, gastric distension, pulmonary ventilation, Blood staining of airway and Post operative airway morbidity and a better device with respect to Haemodynamic response.

### **References**

- [1]. Hohlrieder m, brimacombe j, escherizhuber s, ulmer h, keller c et al in 2007
- [2]. Hohlrieder m, brimacombe j, von goedecke a, keller c et al in 2007
- [3]. Miller dm, comporota l, et al in 2006
- [4]. Piper sn, triem jg, rohm kd, maleck wh, schollhorn ta, boldt j, et al in 2004.
- [5]. Giuseppe natalini md, gabriella lanza md, antonio rosano md, et al in 2002
- [6]. N.r.evans, sv. Gardner et al in 2002
- [7]. J.roger maly, michael beriault et al
- [8]. G.natalini, m.e franceschetti et al in 2003