



COMPARISON OF PROSEAL LMA WITH ENDOTRACHEAL INTUBATION IN LAPAROSCOPIC PROCEDURES

KEYWORDS

Dr. DHARA SHAH

Senior Resident, V.S Hospital, Ahmedabad

DR.HIPPAL PATEL

THIRD YEAR RESIDENT IN ANAESTHESIA DEPARTMENT, SMT.N.H.L MUNICIPAL MEDICAL COLLEGE

DR. ANCI SHAH

SECOND YEAR RESIDENT IN ANAESTHESIA DEPARTMENT, SMT.N.H.L MUNICIPAL MEDICAL COLLEGE

DR. ATISHA PATEL

2nd Year RESIDENT IN ANAESTHESIA DEPARTMENT, SMT.N.H.L MUNICIPAL MEDICAL COLLEGE

INTRODUCTION

Traditional open surgeries are progressing to minimally invasive keyhole laparoscopic surgeries. Simultaneously, airway management of patients has also progressed from insertion of endotracheal tube to lesser invasive Laryngeal Mask Airway(LMA).

Laparoscopic procedures have become increasingly popular over last two decades because of small incisions, reduced post operative pain, early ambulation, and shortened hospital stay. They are often being performed on an outpatient basis or require only an overnight admission thus demanding extreme caution in the anaesthetic technique.

General anesthesia with tracheal intubation and controlled ventilation is the gold standard for providing a safe glottic seal, prevent pulmonary aspirate of gastric contents against raised intra abdominal pressure in laparoscopic procedure. The disadvantages of tracheal intubation with rigid laryngoscopy are hemodynamic responses and damage to the oropharyngeal structures during insertion, increased anesthesia and analgesia requirement and endobronchial intubation during pneumoperitoneum. Postoperative sore throat is also a serious concern. Over a period of time, new airway device have been added to anesthesiologist's armamentarium.

The proseal LMA (PLMA) was introduced in 2000 and is one of such new devices. It is a modification of the Classic Laryngeal Mask Airway (CLMA). The PLMA offers several advantages over the CLMA. It provides a better glottic seal at lower mucosal pressures and isolates the alimentary tract from the respiratory tree. It is superior to the CLMA for providing positive pressure ventilation and, at a given intracuff pressure, provides twice the seal pressure of the CLMA.

Proseal LMA produce less hemodynamic effects and also provide " Hands Free ventilation. They are of great value in anaesthetizing professional singers, public speakers etc as they are less traumatic as compared to endotracheal tube. This study is therefore undertaken to compare PLMA with standard tracheal tube for the ease of insertion, hemodynamic changes and complications occurring during general anesthesia in young healthy patients undergoing

laparoscopic surgeries.

Aims of Study

Aims of the study are to compare Proseal LMA with endotracheal Portex cuffed tube intubation in 60 patients undergoing various laparoscopic surgeries under general anesthesia with respect to

- Time taken for insertion.
- Ease of insertion.
- To compare hemodynamic changes during insertion and removal of device.
- Complications

Materials and methods

This prospective, randomized clinical study as carried out after approval from institutional ethical committee. Informed written consent was obtained from each patient and the procedure was explained to the patients. 60 patients of either sex aged 20-50 years and weighing 40-70 kg belonging to ASA grade I-II scheduled for elective laparoscopic surgical procedures like appendectomy, cholecystectomy, hernioplasty, diagnostic laparoscopy, gynecologic laparoscopy were included in this study.

EXCLUSION CRITERIA:

- difficult airway,
- cervical spine disease,
- BMI > 35 kg/m²
- mouth opening < 2.5cm,
- Risk of aspiration (Full stomach hiatus hernia, GERD)
- oral pathology,
- pharyngitis,
- URTI

PRE-OPERATIVE ASSESSMET:

Pre-operative assessment was done one before the planned surgery. Any significant past, family and personal history were taken. General physical examination was done, vitals (heart rate, blood pressure, and respiratory rate) and investigations were noted. airway assessment was done with mallampatti classification.

Technique:

60 patients undergoing elective Laparoscopic procedures were randomized into two groups. Each group included 30

patients.

Group A patients were inserted Proseal LMA device.

Group B patients were inserted Endotracheal cuffed tube.

On the day of surgery, the patients were taken to the operating room, intravenous cannula inserted. ECG monitor, pulse oxymeter and NIBP were attached and data noted.

Premedication:

All patients were Premeditated with: Inj. Ondansetron 4mg I.V

Inj. Glycopyrrolate 0.2mg I.V

Inj. Fentanyl 1ug/kg I.V

Inj. Midazolam 1mg I.V

Induction:

Inj. Sodium Pentothal 6mg/kg (2.5%) I.V

Inj. Lignocaine 1 mg/kg (1%) I.V

Inj. Succinyl Choline 2mg/kg I.V

Device inserted:

Group A:

Proseal LMA size was selected according to the weight of patients. Before induction cuffed was fully deflated and posterior surface was lubricated with 2% xylocaine jelly inserted through the oral cavity using the digital technique.

Group B:

Patients were intubated with Endotracheal cuffed tube of appropriate size by standard technique.

After insertion of PLMA, Cuff was inflated with air as per manufactures instructions and EtCO₂ was attached and correct placement of device (effective airway) was confirmed by bilateral chest movement and square wave capnography during manual ventilation.

Time taken for insertion were noted. It is the time between the picking up the airway device and obtaining effective airway.

Numbers of attempts were recorded, 3rd attempt considered as a failure of insertion of device.

EASE OF INSERTION:

GROUP A: Proseal LMA, Size: 3/4

Easy insertion = Insertion at first attempt with no resistance.

Difficult insertion = Insertion with resistance or at second attempts.

Failed insertion = Insertion not possible.

GROUP B: Endotracheal Intubation, Size: 7/7.5/8/8.5/9

Grade I : No extrinsic manipulation of larynx required.

Grade II : External manipulation of larynx required.

Grade III : Intubation possible with stylet.

Grade IV : Failed intubation.

(Grade I & II consider- Easy, Grade III- Difficult, Grade IV- Failure)

Monitoring:

Pulse/min

Blood pressure in mmHg

EtCO₂

ECG monitoring

SPo₂

Heart rate, Blood Pressure, oxygen saturation were recorded at various interval i.e.

Pre-operative

Before insertion

After insertion

5 Min and 10 Min after insertion

5 Min and 10 Min after creating pneumoperitoneum

5 Min and 10 Min after release of pneumoperitoneum

After removal

5 Min after removal.

Gastric Tube: gastric tube no 14 inserted in each patients.

Maintenance: By Assisted/Controlled ventilation with Oxygen (50%) + Nitrous oxide (50%) + isoflurane + Inj. vecuronium (Loading dose 0.1 mg/kg and maintenance dose 50 mcg/kg)intermittently I.V sos

Position:

After giving proper position bilateral air entry and vitals were checked and then surgery was allowed.

Reversal:

After return of spontaneous ventilation

Inj. glycopyrrolate 0.008 mg/kg +

inj. Neostigmine 0.05 mg/kg i.v. given.

Extubation:

At the end of surgery anaesthetic agent discontinued. When the patients awoken (met with adequate power & tone and to generate adequate tidal volume) Proseal LMA/ Tracheal tube were removed after full deflation of cuff and thorough oral suction. After removal of Proseal LMA or tracheal extubation, 100% O₂ was administered through a face mask.

After removing the airway devices, they were closely inspected for traces of gastric fluid or blood. Duration of anaesthesia and surgical procedure were recorded. Any adverse events (regurgitation, aspiration, bronchospasm, laryngospasm, desaturation < 95% SPO₂) were documented. Incidence of nausea and vomiting were noted. All patients were questioned after 6hr for sore throat or hoarseness of voice.

In our study , we enrolled surgeries lasting from 15 min to 110 mins in both the groups.

All the quantitative data were analyzed using unpaired t-

test. The results were expressed as Mean + SD 'P' value < 0.05 was taken as statistically significant and 'P' values < 0.001 were taken as highly significant.

Observations & Results

The data was collected, compiled and analyzed statistically. All continuous variables are reported as Mean±Standard deviation. Group comparisons of normally distributed variable were tested by two sample independent't' test. Test of proportions has been applied for comparisons of qualitative variables and categorical data.

A 'P' value of 0.05 or less was considered to indicate a statistically significant difference for all statistical tests.

TABLE- I DEMOGRAPHIC DATA

Variable	Group A (M ± SD)	Group B (M ± SD)
Age (Yrs)	31.4 ± 4.18	30.5 ± 4.02
Height (cms)	155.46 ± 6.63	152.3± 8.25
Weight (kg)	55.93 ± 4.40	56 ± 3.99
BMI	23.27± 2.19	24.3± 2.57
ASA Grade (I.II)	24:6	23:07

TABLE – I shows the demographic data of both group. There were no significant difference between groups regarding to Age, BMI and ASA grade.

TABLE- II SURGICAL PROCEDURE

Surgical Procedure	Group A	Group B
Lap TL	13	14
Lap cholecystectomy	2	3
Lap appendicectomy	3	3
Lap hernioplasty	4	2
Gynecological Laproscopy	8	8
Total	30	30

Table- II shows surgical procedures carried out in both groups.

TABLE- III TIME FOR INSERTION

	Group A (PLMA)	Group B (ETT)	P value
Effective airway insertion time (sec)	18.47± 3.19	18.8 ± 4.58	0.747

TABLE- III shows effective insertion time for both groups. There were no statistically significant differences between both groups.

TABLE- IV EASE OF INSERTION

Ease of insertion	Group A (PLMA)		Group B (ETT)	
	No	%	No	%
Easy	27	90	24	80
Difficulty	03	10	06	20
Failed	00	00	00	00
Total	30	100	30	100

Table- IV shows Ease of insertion is more with Group A (90%) than Group B (80%).

TABLE- V PULSE RATE

TIME	GROUP A	GROUP B	P value	Significance
PRE-OP	80.8± 5.05	80.86 ± 6.62	0.969	NS
BEFORE INSERTION	81.4 ± 4.46	82.33 ± 4.61	0.4304	NS
AFTER INSERTION	84.67± 5.36	98.87 ± 7.99	0.0001	S
5 MIN	82.26 ± 5.21	91.33 ± 5.66	0.0001	S
10 MIN	81.86± 5.63	90.6 ± 7.94	0.0001	S
AFTER PNEUMOPERITONEUM 5 MIN	87.6 ± 5.62	98.67 ± 8.87	0.0001	S
10 MIN	84.13± 4.16	98.6 ± 6.43	0.0001	S
RELEASE OF PNEUMOPERITONEUM 5 MIN	82.13 ± 6.62	91.13 ± 7.67	0.0001	S
10 MIN	79.13± 5.70	87.26 ± 5.71	0.0001	S
AT TIME OF REMOVAL	86.26 ± 4.44	96.86± 6.53	0.0001	S
AFTER 5 MIN	81.13± 5.02	86.93 ± 8.52	0.0021	S

TABLE- V shows mean pulse rate at various interval in both groups.

Preoperative and Baseline reading were comparable in both groups. No significant rise in pulse rate is noted in Group A during surgery and at removal, while significant rise noted in Group B , not returning to baseline value after 5 mins after extubation.

TABLE- VI SYSTOLIC BLOOD PRESSURE

TIME	GROUP A	GROUP B	P VALUE	Significance
PRE-OP	124.6 ± 10.32	124.26± 9.29	0.8938	NS
BEFORE INSERTION	126.4 ± 8.84	126.26± 8.72	0.9510	NS
AFTER INSERTION	128.67 ± 7.28	142.47± 9.70	0.0001	S
5 MIN	125.47± 6.76	139.67± 8.48	0.0001	S
10 MIN	122.87± 7.91	137.8 ± 6.87	0.0001	S
AFTER PNEUMOPERITONEUM 5 MIN	137.87± 6.25	149.87 ± 7.29	0.0001	S
10 MIN	134.93 ± 5.45	139.93 ± 5.18	0.0006	S
RELEASE OF PNEUMOPERITONEUM 5 MIN	128.53± 7.79	136.06± 5.79	0.0001	S

TIME	GROUP A	GROUP B	P VALUE	Significance
10 MIN	125.53 ± 6.12	132.07± 7.05	0.0003	S
AT TIME OF REMOVAL	126.4 ± 6.59	142.47± 6.42	0.0001	S
AFTER 5 MIN	121.33 ± 4.52	134.4± 5.37	0.0001	S

TABLE- VI shows changes in mean SBP at various periods in both groups. After insertion SBP was increased in both groups, but more increased in group B (142.47 + 9.07) as compared to group A (128.67 + 7.28). SBP remained elevated throughout surgery in group B. SBP reached to baseline after removal in group A, while it remained higher in group B.

TABLE- VII DIASTOLIC BLOOD PRESSURE

TIME	GROUP A	GROUP B	P VALUE	Significance
PRE-OP	77.8 ± 4.52	77 ± 4.78	0.508	NS
BEFORE INSERTION	76.6 ± 4.67	77.13 ± 4.29	0.6488	NS
AFTER INSERTION	78 ± 4.42	89.13 ± 6.03	0.0001	S
5 MIN	80 ± 5.38	87.87 ± 4.81	0.0001	S
10 MIN	78.93 ± 5.35	87.33 ± 4.17	0.0001	S
AFTER PNEUMOP-ERITONEUM 5 MIN	86.8 ± 3.88	93.73 ± 5.11	0.0001	S
10 MIN	85 ± 4.09	89.93 ± 4.62	0.0299	S
RELEASE OF PNEUMOP-ERITONEUM 5 MIN	81.13 ± 6.42	86.6 ± 4.11	0.0002	S
10 MIN	80 ± 5.01	82.4 ± 4.68	0.0601	S
AT TIME OF REMOVAL	79.73 ± 6.42	88.8 ± 3.39	0.0001	S
AFTER 5 MIN	75.33± 4.28	82.87 ± 4.26	0.0001	S

TABLE- VII shows mean DBP at various periods in both groups. After insertion DBP was increased in both groups, but more increase in group B (90.6+9.27) as compared to group A (80.53+8.77). DBP remained significantly elevated in group B throughout surgery. The DBP reached to baseline level after removal in group A (PLMA) while it remains higher in group B (ETT).

TABLE- VIII MEAN ARTERIAL BLOOD PRESSURE

TIME	GROUP A	GROUP B	P VALUE	Significance
PRE-OP	93.07 +5.01	92.14 + 5.12	0.4799	NS

BEFORE INSERTION	93.24+ 4.98	93.33 + 4.91	0.9440	NS
AFTER INSERTION	94.23 + 4.36	104.23 +7.52	0.0001	S
5 MIN	94.93 + 4.52	105.09 + 5.21	0.0001	S
10 MIN	93.57 + 5.13	104.15 + 4.11	0.0001	S
AFTER PNEUMOP-ERITONEUM 5 MIN	103.82 + 3.32	112.11+ 4.96	0.0001	S
10 MIN	101.95 + 3.08	106.64+ 4.23	0.0021	S
RELEASE OF PNEUMOP-ERITONEUM 5 MIN	96.93 + 6.03	103.09 + 3.32	0.0001	S
10 MIN	95.13+ 4.64	98.96+ 4.55	0.0021	S
AT TIME OF REMOVAL	95.51+ 6.14	106.73+ 3.21	0.0001	S
AFTER 5 MIN	90.89 + 3.86	100.04 + 3.99	0.0001	S

TABLE- VIII shows mean arterial blood pressure at various periods in both groups. After insertion MAP was more increased in group B (105.72±10.19) as compared to group A (94.77±8.49). MAP remained elevated throughout surgery in Group B.

TABLE-IX EtCO2

	GROUP A	GROUP B	P VALUE	Significance
PRE-OP	NIL	NIL	NIL	
BEFORE INSERTION	NIL	NIL	NIL	
AFTER INSERTION	34.6± 3.09	34.5± 2.84	0.8966	NS
5 MIN	34.53± 3.09	34.63± 2.42	0.8895	NS
10 MIN	34± 2.66	34.6± 2.11	0.3371	NS
AFTER PNEUMOP-ERITONEUM 5 MIN	38.2± 2.10	38.03± 1.97	0.7476	NS
10 MIN	36.9 ± 2.04	36.76± 2.14	0.7963	NS
RELEASE OF PNEUMOP-ERITONEUM 5 MIN	33.86± 2.14	34.56± 2.01	0.1966	NS
10 MIN	33.53± 2.02	33.3 ± 1.68	0.3663	NS

	GROUP A	GROUP B	P VALUE	Significance
AT TIME OF REMOVAL	NIL	NIL	NIL	
AFTER 5 MIN	NIL	NIL	NIL	

Table-IX shows EtCO₂ at various time in both the groups. There was no significant change noted in both the groups at all measured interval during surgery.

TABLE- X COMPLICATIONS

Complications	Group A		Group B	
	No	%	No	%
Airway Trauma (blood stain on device)	03	10	06	20
Cough	02	6.67	06	20
Sore throat	02	6.67	07	23.33
Vomiting	00	00	02	6.67
Hoarseness of voice	00	00	02	6.6

TABLE-X shows the complications in both groups. Airway trauma was noticed in 10% of patients in PLMA group and 20% of patients in ETT group. Cough and sore throat were more with group B (ETT) as compared to group A (PLMA) and Vomiting and Hoarseness were noted with group B (ETT).

Discussion

Proseal LMA is a new entrant to the family of LMA with some added features over the classic LMA such as low mucosal pressures and drain tube to vent out air and regurgitate material from the stomach. They produce lower hemodynamic instability during placement as they avoid stimulating the infraglottic structures. There is ease of insertion and smooth awakening.

Demographic data: There was no significant difference in demographic data between the two groups regarding age ,BMI ,ASA grade.

Surgical Procedure: Patients undergoing elective laparoscopic surgery i.e. Tubal ligation ,Cholecystectomy ,Appendicectomy ,Hernioplasty and Gynecological procedures were selected. Duration of surgery was ranging from 15 mins to 110 mins in both the groups.

Time of Insertion: The mean time taken for successful placement was 18.4 s and 18.8 s for group A and Group B respectively, Which was not statistically significant.

Ease of Insertion: Ease of insertion was more with PLMA (90 %) than ETT (80 %). There was difficult insertion in 20% of patients in group B. There were no failed insertions in any patients of both the groups.

Hemodynamic responses: (Pulse Rate ,SBP,DBP,MBP):

The increase in pulse rate and blood pressure during intubation is attributed to sympathetic stimulation during la-

ryngoscopy and the passage of the ETT through the vocal cords. The PLMA does not require laryngoscopy and probably does not evoke a significant sympathetic response. Attenuation of this response may be due to diminished catecholamine release which can be attributed to the fact that PLMA is relatively simple and atraumatic to insert.

During induction , With PLMA insertion , no change in pulse rate or BP was noted. While with ETT insertion, significant rise is seen in both attributed to laryngoscopy.

Following peritoneal insufflations, CO₂ is absorbed transperitoneally, and the rate which this occurs depends on gas solubility, perfusion of peritoneal cavity and duration of pneumoperitoneum.

In PLMA group, mild rise in hemodynamics were noticed in response to CO₂ returned to normal values after 10 mins.

In ETT group, Pulse and BP increased significantly after creation of pneumoperitoneum which is controlled by hyperventilation and use of volatile anesthetic agents.

During extubation, No significant change is seen in PLMA group suggesting smooth emergence from anesthesia. While again significant rise in both were noticed , not returning to baseline value after 5 mins of extubation .

EtCO₂ and Spo₂:Both groups maintained adequate Oxygenation and ventilation perioperatively. There is no significant difference in EtCO₂ and Spo₂ level recorded at different time interval in both groups.

Complications: Being a supraglottic device and mucosal pressure achieved by PLMA are below pharyngeal perfusion pressure, chances of sore throat and airway trauma are much less than ETT. The incidence of airway trauma was more noticed in ETT group (20%) than in PLMA group (10%) .Cough and sore throat are more with group B (ETT) as compared to group A (PLMA). Vomiting and Hoarseness were noted with group B (ETT) only. There was no case of regurgitation, desaturation and laryngospasm in our study.

Conclusion

- Proseal LMA is safe and useful alternative to endotracheal intubation in elective fasted adult patients undergoing various laparoscopic surgeries under general anaesthesia.
- It is judged by stable haemodynamics , adequate oxygenation & ventilation and less complication.