A Dissertation on

COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY VS. ENDOTRACHEAL TUBE FOR LAPAROSCOPIC SURGERY

MD BRANCH X
(ANAESTHESIOLOGY)

MADRAS MEDICAL COLLEGE
THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY
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DECLARATION

I hereby declare that this dissertation entitled **"COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY VS. ENDOTRACHEAL TUBE FOR LAPAROSCOPIC SURGERY"** has been prepared by me under the guidance of **Prof.Dr.G.SIVARAJAN, M.D., D.A.,** Professor and Head of Department of Anaesthesiology, Madras Medical College, Chennai in partial fulfillment of the regulations for the award of the degree of M.D. (Anaesthesiology), examination to be held in March 2007.

This study was conducted at Madras Medical College and Government General Hospital, Chennai.

I have not submitted this dissertation previously to any university for the award of any degree or diploma,

Date: Signature of the Candidate

Place: Chennai Name: Dr.R. KANNAN

CERTIFICATE

This is to certify that the dissertation **"COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY VS. ENDOTRACHEAL TUBE FOR LAPAROSCOPIC SURGERY"** presented herein by **Dr.R.Kannan**, is an original work done in the Department of Anaesthesiology, Madras Medical College and Government General Hospital, Chennai for the award of Degree of M.D. (Branch X) Anaesthesiology under my guidance and supervision during the academic period of 2004-2007.

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Date:
Place: Chennai

Prof.Dr.G.SIVARAJAN, M.D., D.A.
Professor & HOD,
Department of Anaesthesiology
Madras Medical College & Hospital,
Chennai .

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Date:
Place: Chennai

Prof.Dr.KALAVATHI PONNIRAIVAN, M.D.
Dean,
Madras Medical College & Hospital,
Chennai.

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CONTENTS

INTRODUCTION

Dr. Archie Brain, between 1981 and 1987, developed a new way of linking artificial and anatomical airways. This new concept known as laryngeal mask airway was different from other forms of airway management.[1]

Combining the advantages of a non-invasive facemask and the more invasive tracheal tube, the laryngeal mask airway was created to fill an important functional gap that existed between standard methods of airway control that were in use then.

Originally the device 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 the LMA has provided the convenience of “Hands-free” anesthesia, for some anaesthesiologists, the combination of LMA and positive pressure ventilation evokes fear of inadequate ventilation, gastric distension and pulmonary aspiration of gastric content.

To overcome the above complications Dr.Archie Brain, designed the proseal LMA (PLMA) and it was introduced in 2000. Modifications were designed to enable separation of

gastrointestinal and respiratory tracts, improve airway seal, enable positive pressure ventilation and diagnose mask displacement.[2] A drain tube (DT) enables diagnosis of mask misplacement and also aims to reduce risks of gastric inflation, regurgitation and aspiration of gastric contents.

There are 59 randomized control trials and 79 case reports about PLMA. There are 27 Proseal LMA Randomized control trial studies and summed data to compare insertion time, insertion success and airway seal pressure with the LMA.

There are four reports comparing Proseal LMA and tracheal intubation, one during laparoscopic cholecystectomy,[3] two during gynecological laparoscopy[4,5] and one comparing haemodynamic changes during airway insertion / removal[6].

The Proseal LMA has been more thoroughly evaluated by peer reviewed publications than other new supraglottic airway devices introduced in the last 5 years. These include the laryngeal tube[7] laryngeal tube sonda, airway management devices, pharyngeal airway express, Cobra perilaryngeal airway. Unlike these devices, many of which have been modified on several occasions since introduction, the Proseal LMA has not. Comparative evaluations are only available with the laryngeal tube[7] and laryngeal tube sonda.

Hence a prospective randomized study was designed to compare the Proseal LMA and Endotracheal tube regarding haemodynamic changes, positive pressure ventilation and gastric distension during laparoscopic procedures.

AIM OF THE STUDY

The aim of the study was to evaluate the effectiveness of Proseal LMA compared to endotracheal tube during laparoscopic procedures based on the Haemodynamic Changes, Ventilatory Parameters and Gastric Distension.

PROSEAL LMA

The proseal laryngeal mask airway (PLMA) was designed and developed by Archie Brain in 2000, with a primary goal to construct a laryngeal mask with improved ventilatory characteristics and that also offered protection against regurgitation and gastric insufflation.

DEVICE DESCRIPTION[8,2]

The proseal LMA is made from medical grade silicone and is reusable. It has four main components[1]

1) Mask
2) Inflation line with pilot balloon
3) Airway tube
4) Drain tube

The cuff of the mask has identical proportions but different dimensions amongst sizes. All the components are latex free. It is recommended that proseal LMA be used a maximum of 40 times before being discarded.

MODIFIED FEATURE	INTENDED PURPOSE
A second cuff attached to the dorsal surface.	• To improve seal by pushing the ventral cuff more firmly into the periglottic tissue.
A ventral cuff that is larger proximally	• To form a better seal by plugging gaps in the proximal pharynx.
A large conical – shaped distal cuff to deeper bowl.	• To form a better seal with the hypopharynx. To form a better fit in laryngopharynx.
A parallel, narrow bore, double – tube configuration	• To increase the stability and to improve seal by allowing the tongue to form a more effective plug.
A flexible, wire-reinforced airway tube	• To prevent the double-tube configuration from being too stiff.
A drainage tube	• To facilitate gastric tube insertion • To divert regurgitated fluid away from the respiratory tract • To prevent gastric insufflations • To provide information about device position.
A drainage tube distal aperture that is sloped anteriorly.	• To allow the deflated tip to form a fine leading edge for insertion.
A plastic supporting ring around the distal drainage tube.	• To prevent the drainage tube collapsing when the cuff is inflated

A drainage tube that passes within the bowl	• To avoid altering the external shape of the cuff. • To function as a mask aperture bar for the accessory vent
A rectangular depression in the proximal bowl tube	• To function as an accessory ventilation channel • To prevent pooling of secretions at the distal aperture of the airway
A built in bite block	• To prevent airway obstruction • To prevent damage to the device during biting. • To provide information about depth of insertion.
Locating strap	• To help fuse the airway and drainage tube together. • To prevent finger slipping of the tube
No back plate	• To keep the proximal cuff in midline • To reduce rigidity and allow room for the dorsal cuff

No Mask aperture bars.

- To reduce resistance to gas flow

ACCESSORIES

Introducer Tool

The introducer tool is a reusable clip-on / clip – off device that comprise a thin, curved, malleable, metal blade with a guiding handle similar to the intubating LMA. The inner surface and curved tip are coated with a thin layer of transparent silicone to reduce the risk of trauma. The distal end fits into the locating strap and the proximal end clips into the airway tube above the bite block with the proximal drainage tube resting to one side.

Cuff Deflator

This is a dedicated deflation device to aid complete deflation for successful sterilization, optimum insertion and positioning in the patient.

SIZES AVAILABLE

Proseal LMA Mask Size	Patient Selection Guidelines	Proseal LMA Airway Tube ID (mm)	Maximum Cuff Inflation Volume (Air)	Maximum Size		
				Gastric Tube	ETT (mm)	FOB (mm)
1 ½	5-10 kg	6.4	7 ml	10 French	4.5	3.5
2	10-20 kg	6.4	10 ml	10 French	4.5	3.5
2 ½	20-30 kg	8.0	14 ml	14 French	4.5	3.5
3	30-50 kg	8.0	20 ml	16 French	5.0	4.0
4	50-70 kg	8.0	30 ml	16 French	5.0	4.0
5	70-100 kg	10.0	40 ml	18 French	6.0	5.0

These are maximum volumes that should never be exceeded. It is recommended that the cuff be insufflated to 60cm H_2O intracuff pressure.[9]

USE

PREPARATION FOR USE

CLEANING

Thoroughly wash the cuff and airway tube, drain in warm water using dilute (8-10% w/ w) Sodium bicarbonate solution until all visible foreign matters are removed. Ensure the areas behind the proseal LMA introducer strap and under the internal drain tube are clean. Clean the tubes using a small soft bristle brush (approximately ¼ inch (or) 6mm in diameter for adult size devices). Gently insert the brush through proximal end of the drain tube. Thoroughly rinse the

cuff, airway tube and drain tube, with warm flowing tap water to remove residues. Carefully inspect the proseal LMA to ensure that all visible foreign matters have been removed. Care should be taken to ensure that water does not enter the device through the valve.

STERILISATION

Steam autoclaving is the only recommended method for sterilisation of the proseal LMA. Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backwards to obtain a high vacuum. For complete deflation it is recommended that proseal LMA cuff deflator is used. Ensure that both the syringe used to deflate the cuff and the valve is dry. The maximum temperature should not exceed 135^0C or 275^0F. The proseal LMA introducer and cuff deflator should be cleared and sterilised in the same manner as proseal LMA. The same cautions apply.

PERFORMANCE TESTS

Non – Clinical tests that must be conducted before each use of the device.

1) VISUAL INSPECTION

Ensure that the thin walled section of the drain tube lying within the mask bowl is not torn or perforated, and that there is no contamination between the tube and the mask.

Examine the transparency of the tubes. Do not use the proseal LMA if the tubes are discolored as this impairs the ability to see and effectively remove foreign particles during cleaning, or to see regurgitated fluids during use.

Examine the surface of the device for damage including cuts, tears or scratches.

Examine the 15mm connector. It should fit tightly into the outer end of the airway tube.

2) INFLATION AND DEFLATION

Using a syringe, fully deflate the device, so that the cuff walls are tightly flattened against each other. Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other. Do not use if the cuff walls reinflate immediately and spontaneously, even if only slightly.

Inflate the cuff from complete vacuum with 50% more air than the recommended maximum inflation volume. Any tendency of the cuff to deflate indicates a presence of a leak and should be evident within 2 minutes. Examine the symmetry of the inflated cuff. There should be no asymmetrical bulging at either end or sites. Inspect the interior of the drain tube from both ends of the mask. Ensure that the thin walled section of the tube is not collapsed, where it passes through the distal end of the mask.

While the device remains 50% over inflated, examine the inflation pilot balloon. The balloon shape should be a thin slightly flattened elliptical shape not spherical.

PRE-INSERTION PREPARTION

Prior to insertion and sterilisation of the device, the cuff should be fully deflated to a flattened wedge shape. The cuff walls should not have any wrinkles and the cuff should be straight at the distal end.

This shape facilitates atraumatic insertion and correct position in the patient. It reduces the risk of entry of the distal end into the valleculae or glottis and avoids it becoming caught against epiglottis or arytenoids. The correct cuff shape can be accomplished through use of proseal LMA cuff deflator as follows:

Insert the proseal LMA, partially inflated, with its distal end exactly level with the tip of the indicating arrow as shown. The mask bowl should face curved surface of cuff deflator.

Release the hands to compress the mask

Use a syringe to deflate the cuff

Whilst deflating, pull back gently on the inflation line to ensure all air is removed from the mask.

Deflate to a vacuum, disconnect the syringe and release the proseal LMA.

Ensure that the back of the mask is straight, without any curvature of the distal end; the distal end should be maximally flattened.

ALTERNATIVE METHODS OF CUFF DEFLATION

- Using original silicone LMA proseal cuff deflator
- Manually by compressing the distal end between finger and thumb
- Lubrication of the posterior surface of the cuff should be performed just before insertion

to prevent drying of the lubricant. Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant. It is recommended that a bolus of lubricant can be applied to the posterior tip of the deflated cuff. It is not necessary to spread of the lubricant over the mask surface. A water soluble lubricant such as K-Y jelly, should be used.

INSERTION[8]

Insertion Success Rates

Fisher's method shows that the first time success rate for the LMA is higher than the PLMA, but overall success is similar. One study reported a higher first-time success rate with the introducer tool, but this finding awaits confirmation. The introducer tool makes insertion easier because it occupies less space than finger, and facilitates full depth of insertion. Overall insertion success is higher for the PLMA than the Laryngeal tube airway (100% versus 92%). The highest insertion success rates are with the gum-elastic bougie – guided technique; both Brimacombe et al and Howath et al reported 100% success at the first attempt.

PROCEDURE

Check the size of PLMA, shape of the cuff and its lubrication

POSITIONING

Ideal recommended position is extension of the head with flexion of neck (the sniffing

position)

INSERTION METHODS

Having acquired an adequate anaesthetic depth, the device may be inserted using one of the following methods:-

- using PLMA introducer
- Using index finger or the thumb
- Using gum elastic bougie

1) PLMA introducer Insertion Technique:-[16]

- Place the tip of the proseal LMA introducer into the retaining strap at the rest of the cuff.
- Fold the tubes around the convex surface of the blade
- Fix the proximal end of the airway tube into the matching slot in the tool
- Press the tip of the cuff upward against the hard palate and flatten the cuff against it. Slide the cuff further inwards against the palate.
- Jaw may be pushed downwards[22] momentarily to assist entry between the teeth.
- Keeping the PLMA introducer blade close to the chin, rotate the device inwards, in one smooth circular movement. During insertion follow the curve of the rigid insertion tool. The jaws should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downwards, blocking further passage of the mask. Advance into the hypopharynx until a definite resistance is felt.

- Before removing the introducer, a non-dominant hand is brought from behind the patient's head to stabilize tubes. This prevents the device from being pulled out of place, when introducer is removed. . It also permits the device to be pushed further inwards in the event that full insertion has not been achieved by the Introducer alone. At this point, the PLMA should be correctly located with its tip firmly pressed up against the upper esophageal sphincter
- Remove the introducer in same circular motion.

2) Index Finger Insertion Technique:-

- Finger insertion technique is not recommended for PLMA sizes 1 ½ - 2 1/2 . These sizes have dedicated introducer.
- Hold the PLMA like a pen, with the index finger pushed into the introducer strap.
- Under direct vision, press the tip of the cuff upward against hard palate and flatten the cuff against it.
- As the index finger passes further into the mouth, the finger joint begins to extend. The jaws should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downwards, blocking passage of the mask.
- Push the jaw downwards,[22]with middle finger or instruct an assistant to pull the lower jaw downwards momentarily.
- Using the index finger to guide the device, press backwards toward the other hand, extending counter pressure. Do not use excessive force.
- Advance the device into the hypopharynx until a definite resistance is felt. Full insertion

is not possible unless the index finger is fully extended and the wrist is fully flexed.

- Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube. This prevents the device from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point, the PLMA should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.
- Remove the finger

3) Thumb Insertion Technique:-

Thumb insertion technique is not recommended for PLMA sizes 1 ½ - 2 1/2 . These sizes have a dedicated introducer.

This is useful if it is impossible to get access to the patient from behind, or to rapidly gain an airway while initiating CPR

- Operator stands facing the patient
- The thumb is inserted into strap
- Insertion is similar to that using index finger
- The thumb should be used to extend the head just prior to completing insertion. This prevents the unopposed backward movement of the thumb causing undesired head flexion.

4) Gum Elastic Bougie Guided Insertion[12,13]

The PLMA drainage tube is primed with a lubricated, gum elastic bougie with its straight end first and with sufficient length protruding from the proximal drainage tube to grab it.

- the gum elastic bougie is placed in the esophagus with its straight end first under gentle laryngoscope guidance.
- The scope is removed
- The PLMA is railroaded along the bougie, following the palatopharyngeal curve, and using the digital – insertion technique.
- The cuff then is inflated, and ventilation is commenced.
- The PLMA should be held to prevent dislodgement during removal of gum elastic bougie.
- Alternatively, the gum-elastic bougie can be placed in the esophagus first and the PLMA attached second.
- Alternatively, the laryngoscope can be used in situ and PLMA inserted under direct vision.

DEVICE INFLATION

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 intra cuff pressure equivalent to approximately 60cm H_2O.[9]

During cuff inflation do not hold the tube as this prevents the mask from settling into its correct location. A small outward movement of the tube is often noted as the device seats itself in the hypopharynx.

Never over inflate the cuff after insertion. Cuff should be inflated with at least 25% of the maximum recommended volume to ensure effective seal with gastrointestinal tract. Signs of correct placement may be one of the following:-

- slight outward movement of the tube upon inflation.
- The presence of smooth oval swelling in the neck around the thyroid and cricoid area.

DEVICE FIXATION[13]

Once inflated the device should be fixed in place using fish mouth taping (Maxilla to Maxilla). Gentle pressure is applied to outer end of the airway tube as it is fixed. This ensures that the tip of the mask is pressed securely against the upper oesophageal sphincter. Correct fixation is more critical for PLMA because any migration proximally of tip from hypopharynx will result in air leakage up the DT during positive pressure ventilation(PPV).

INSERTION PROBLEMS

- 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 cannot be opened sufficiently to insert the mask, first ensure that

the patient is adequately anaesthetized. An assistant can be asked to pull the jaw downwards.

- The cuff must press against the palate throughout the maneuver, otherwise the tip may fold back on itself or impact on an irregularity or swelling in the posterior pharynx. If the cuff fails to flatten or begins to curve over as it is advanced, it is necessary to withdraw the mask and reinsert it . If difficulty persists with the chosen technique, one of other techniques described should be used.

Diagnosis of correct and incorrect mask position and maneuvers to correct them:

Malposition occurs in approximately 5% to 15% of patients at the first attempt, but most occurrences are recognized easily and corrected.

Fine malpositions have been described, including the following:-[16,17,20]

1) Distal cuff in laryngopharynx (7%)
2) Distal cuff in glottic inlet (3%)
3) Distal cuff folded over (3.4%)
4) Severe epiglottic downfolding (0.5%)
5) Glottic compression (0.4%)

Maneuvers to correct, incorrect mask position[2]

a) Cuff in laryngopharynx or glottis:-

When the proseal is not inserted deeply enough, the distal cuff will sit in the

laryngopharynx. When it takes an anterior path during insertion, the distal cuff will sit in the glottic inlet. Pushing the PLMA further usually corrects the laryngopharyngeal malposition, but glottic malposition requires reinsertion.

b) Cuff folded over:-

Folding over occurs when the distal cuff impacts against the posterior oropharyngeal wall. Several techniques have been used to correct this malposition, including the following:-

1) Reinsertion using a lateral approach with the cuff entering the oropharynx from the side of the hard palate.
2) Reinsertion with the drainage tube stiffened by priming it to the distal end with a gum elastic bougie or stylet.
3) Gum-elastic bougie guided re-insertion
4) Digital correction by sweeping a finger behind the cuff.

c) Severe epiglottic downfolding:-

This occurs when the epiglottis is dragged inferiorly by the cuff and completely covers the glottic inlet. To correct this occurrence, the proseal should be reinserted with the head and neck in a more extreme sniffing position, or with jaw thrust applied, or with he epiglottis elevated through the use of a laryngoscope.

TESTS FOR PLACEMENT

1) Depth of Insertion[10]

It has been observed that when most of the bite block was outside the patient's mouth, PLMA was frequently malpositioned. The total length of a bite block is 5-6cm in both size 4 & 5 and the middle of the bite block is located 18.0 and 19.0cm from the beveled tip of the DT in size 4 & 5 respectively. For women, mean depth of insertion has been found to be 18.6cm[2] and for men 20.9cm. Usually most of the bite block is inside patient's mouth and anaesthetists must suspect malposition in < ½ of the bite block is within the mouth. When this happens, other tests should be done to confirm positioning.

2) Test for obstructed airway

Manually ventilate the patient and observe rise and fall of the chest wall, the capnograph for a square wave tracing and the feel and filling of an anaesthesia bag.

3) ***Soap bubble Test***[18,19]

This is done to evaluate the seal with GIT. A small amount of non-toxic bubble solution is dispensed in a bottle cap. New examining gloves are put on, fingertip made wet with the solution and the DT touched to create a membrane. Any leak during PPV will cause the bubble solution to bulge. This is a useful aid when learning to use the PLMA. This is also a valuable technique to routinely monitor safe PLMA usage.

USES

1) Confirms PLMA location behind the cricoid cartilage.

2)Detects negative DT pressure and aerophagia with spontaneous ventilations

3)Diagnose dangerous oseophageal insufflation during PPV.

4) Lubricant Jelly Test

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

5) Suprasternal Notch Test[15,21]

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

Mechanism Tapping the suprasternal notch leads to compression of distal tip of PLMA causing distortion of DT. This makes the extremely sensitive soap membrane to bulge with tapping and if this happens, Suprasternal notch test is positive.

6) Gastric Tube Placement Test

When there is no leak up the drain tube, then insertion of a 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 the alimentary tract. Ensure the tube is at or above room temperature and well lubricated with a water based jelly before insertion. This is then passed down DT of proseal LMA without any haste or force. A slight resistance is encountered as the tip of catheter passes gently against upper oesophageal sphincter. There is an inherent resistance to gastric tube insertion after 23cm of passage, due to an angulation of degrees in the passage of DT to its tip. There may be a difficulty in passing a 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[16]

The advantages of inserting a gastric tube are that:-

- It allows removal of gas or fluid from the stomach
- The process of insertion provided information about the position or patency of drainage tube
- It can function as a guide to PLMA re-insertion if accidental displacement occurs.[14]

The disadvantages are that

- There is a risk of tracheal placement
- There is a risk of trauma, the worst – case scenario being oesophageal perforation
- The presence of gastric tube may trigger regurgitation by intervening with oesophageal sphincter function and gastric tube blocks the drainage tube so that gas and fluid cannot escape from esophagus.

Tests for drainage tube air leak and patency:-

Air Leak

Air leak up the drainage tube during PPV demonstrates that gastro-intestinal and respiratory tracts are not isolated from one another. Large volume air leaks can be detected readily by listening over the drainage tube or feeling the air with a hand. But small-volume is detected best by placing water – based lubricant or a soap bubble over the end of the draining tube.

Drains tube patency and testing:-

If the drainage tube is not patent it cannot fulfill of its functions. Testing of drain tube patency is mandatory for safe use of PLMA. There are 3 tests of drainage tube patency.

- Passage of gastric tube
- Passage of FOB
- The suprasternal notch test[15,21]

Other potential indications of PLMA:-

1) Emergency medicine
2) Difficult airway
3) Paediatric use[23,24]

LAPAROSCOPIC SURGERY – ANAESTHETIC IMPLICATIONS

Physiological changes during laparoscopy[25]

Three major forces that uniquely alter the patient's physiology during laparoscopy

- Increase in intra-abdominal pressure
- Effects of patient positioning
- Carbon dioxide

EFFECTS OF PNEUMOPERITONEUM[26]

Cardiovascular Changes

- Increase in heart rate
- Increase in mean arterial pressure
- Increase in systemic vascular resistance
- Increase in myocardial filling pressure
- Increase in Central Venous Pressure
- Increase in Pulmonary Capillary Wedge Pressure

- Decrease in Cardiac Output

Regional Circulatory Changes

Cerebral: Increased intra cranial pressure ‘

(Due to decreased venous drainage of lumbar plexus due to inferior vena cava compression)

Hepatoportal : Decreased portal & hepatic blood flow

Gastrointestinal Tract: Intramural Acidosis

Splanchnic Ischemia

Renal: Decreased renal blood flow

Decreased Glomerular filtration rate

Lower Limb: Decreased femoral vein blood flow

Respiratory Changes

- Decreased functional residual capacity
- Decreased vital capacity
- Restricted diaphragmatic excursion
- Decreased compliance
- Ventilation perfusion abnormality
- Raised airway pressure
- Endobronchial intubation

- Cephalad displacement of mediastinum

EFFECTS OF HYPERCARBIA [27]

Cardiovascular system

Local Effects

- Direct depression of myocardial contractility and rate of contraction.
- Direct stimulation of myocardial irritability and arrythmogenicity

Systemic Effects

- Stimulation of CNS and sympatho adrenal system
- Increase in cardiac output
- Increase in heart rate
- Increase in blood pressure
- Increase in Central Venous Pressure

Respiratory System

- Increase in minute ventilation
- Bronchodilatation
- Pulmonary Vasoconstriction

Central Nervous System

- ↑ PCO_2 – Direct cortical depression
- ↑↑ PCO_2 – Stimulates sub-cortical hypothalamic areas

  Increase in cortical excitability & Seizures
- ↑↑↑ PCO_2 – Cortical and sub cortical suppression
- Increase in cerebral blood flow
- Increase in intracranial pressure

Neuro- Endocrine System

- Increased epinephrine and nor-epinephrine
- Increased cortisol
- Increased renin / aldosterone
- Increased anti-diuretic hormone
- Increased atrial natriuretic peptide

Renal System

Sympathetic Stimulation

↓

Catecholamine release

↓

Decrease renal cortical blood flow

Afferent arterial constriction Increase abdominal pressure > 15mm Hg

↓

Decreased GFR

↓

Decreased Urine Output

Gastro Intestinal System

Diffusion of Co_2 into bowel

↓

Post Operative Nausea and Vomiting

EFFECTS OF POSITIONING[26]

Reverse Trendelenberg

- Decreased right atrial pressure
- Decreased venous return
- Decreased pulmonary capillary wedge pressure
- Decreased mean arterial pressure
- Decreased cardiac output

Trendelenberg position

- Decreased Vital capacity
- Decreased functional residual capacity
- Decreased lung compliance
- Increase in cerebral blood flow
- Increase in cardiac output

COMPLICATIONS[26]

Injuries from instruments

- Bleeding
- Organ perforation
- Injury to blood vessels
- Subcutaneous emphysema
- Peritonitis
- Wound infection

Due to pneumo peritoneum

- Bowel ischemia
- Gastric Regurgitation
- Compression of inferior venacava
- Decreased venous return
- Decreased cardiac output
- Increase in intra-thoracic pressure

- Pneumothorax
- Barotrauma
- Atelectasis
- Nausea and Vomiting

Due to Hypercarbia

- Acidosis
- Arrythmias
- Hypertension
- Increase in heart rate
- Increase in intracranial pressure
- Co_2 Embolism

Trendelenberg Position

- Venous congestion of head and neck
- Increase in venous pressure
- Increase in intracranial pressure
- Retinal haemorrhages & Detachment
- Increased intraocular pressure
- Endobronchial Intubation
- Ventilation perfusion mismatch
- Hypoxia

- Neuropathy & Nerve injuries
- Corneal & Conjunctival edema

Advantages of Laparoscopy[26]

- Minimally invasive
- Decreased blood loss
- Decreased postop pain
- Decreased postop ileus
- Early ambulation
- Decreased wound related complications
- Decreased hospital stay
- Cost effective
- Quick return of respiratory functions.

REVIEW OF LITERATURE

The proseal laryngeal mask Airway designed by Dr. Archie Brain, is based on the classic Laryngeal Mask Airway and it was introduced in 2000.

Modifications were designed to enable separation of gastrointestinal and respiratory tracts, improve the airway seal, enable controlled ventilation and diagnose mask misplacement. A drain tube enables diagnosis of mask misplacement and also aims to reduce risks of gastric inflation, regurgitation and aspiration of gastric contents.

So, PLMA gained widespread popularity for Laparoscopic surgeries. Over the years, case reports, surveys, and small series have described the uses, comparison with other SADS, and its rare complications.

1)Lu pp,Bricombe J,Yang C,Shym;Br JA;2002[41]

They did study to test the hypothesis that PLMA is a more effective ventilatory device than LMA for Laparoscopic cholecystectomy. They concluded that PLMA is more effective ventilatory device for Laparoscopic cholecystectomy than LMA. Further they recommended against the use of the LMA for Laparoscopic Cholecystectomy.

2) Maltby JR, Beriault MT, Watson NC, Liepert DJ, Can J. Anaesth 2002[3]

The study was done to compare PLMA with endotracheal tube with respect to pulmonary

ventilation and gastric distension during laparoscopic cholecystectomy. They concluded that a correctly seated PLMA or endotracheal tube equally effective pulmonary ventilation without clinically significant gastric distension in all non-obese patients.

3) Natalini G, Canza G, Rosano A, Dell Agnolo P, J Clin, Anaesthesia ; 2003[42]

They compared the airway seal and frequency of sorethroat with the LMA-Proseal and LMA during Laparoscopic surgery. They concluded that the LMA – proseal and LMA show similar airtight efficiency during Laparoscopy .

4) Malt by JR, Beriault MT, Watson NC, Fick GH 2003 [4]

They conducted a study to compare the laryngeal mask airways, LMA and PLMA with the endotracheal tube with respect to pulmonary ventilation and gastric distension during gynaecologic laparoscopy. They came to a conclusion that correctly placed LMA and PLMA is as effective as an endotracheal tube for positive pressure ventilation without clinically important gastric distension in non-obese and obese patients.

5) Piper SN, Triem JG, Rohm KD, Maleck WH; Schollhorn TA; 2004[5]

The aim of study was to assess the practicality of PLMA during laparoscopic surgery with pneumoperitoneum compared to Endotracheal intubation. They concluded that PLMA is a convenient and practicable approach for anaesthesia in patients undergoing laparoscopic surgery.

6) ***Joseph Brimacombe MB, Christian Keller MD, Lawrence Brimecombe MG; Anas. Analg 2002;***[43]

The aim of study was to compare PLMA & LT Airway in paralyzed Anaesthetised adult patients undergoing pressure controlled ventilation, with respect to insertion success rates and time, efficacy of seal, ventilatory parameters, airway interventional requirements. They concluded that PLMA offers advantages over the laryngeal tube airway in most technical aspects of airway management in paralyzed patients.

7) ***Cornelivs J. O' Connor Jr, Carl J. Borromeo; Michael S. Stin; Anaesth Analg 2002***[15]

They evaluated the Suprasternal Notch Test in 50 consecutive patients. In all 50 patients the SSN Test has been positive. They believed that positive SSN Test reliably indicates the presence of the PLMA tip behind cricoid cartilage.

8) ***M.S. Stin and C.J. O'Connor Jr; BJ Anaes. 2003***[10]

They measured depth of insertion in satisfactorily positioned PLMAS.

They concluded most of the integral bite block lies within the oropharynx. It was never normal for the entire bite block to stick out of mouth. The position of the integral bite block relative to the upper incisors gives valuable information during assessment of PLMA position.

9) ***Christian Kellar , MD; Joseph Brimacombe, MB; Axel Kleinsasser MD; Alen Loeckinser, MD; Anaes Analg 2000***[44]

In this randomized, cross – over cadaver study, they determined whether PLMA

prevents aspiration of regurgitated fluid.

They concluded that correctly placed PLMA allows fluid in esophagus to bypass the oropharynx in the cadaver model.

10) Brimecombe J; Keller C. European J Anasth 2003[45]

They evaluated the stability of the LMA – Proseal and LMA in different head and neck positions.

They concluded that the anatomical positions of the PLMA and LMA is stable in different head and neck positions, but head-neck-flexion and rotations are associated with an increase, and head-neck-extension with a decrease in oropharyngeal leak pressure and intra-cuff pressure.

11) Michael S. Stin, MD, Cornelins J.O' Conner Jr; Anaes Analg [46] 2002:95:1782-87

They used a hyperventilation Tests, maximum minute ventilation Test (MMV Test) to aid in diagnosis of upper airway obstruction alters PLMA insertion.

The patients in this study was briefly hyperventilated for 15S yielding a MMV value equal to 4x(breaths/15s) x (exhaled tidal volume).

12) N.R. Evans, S.V. Gardner and M.f.M. James,[47] Br J Anaesth; 2002; 88; 4584-587

They did a study in 103 patients, by filling the hypopharynx with methylene – blue dyed

saline introduced down the drainage tube once the mask was in place. At the beginning and end of the procedure, a FOB was passed down the airway tube to observe any dyed saline in the bowl of mask.

They concluded a correctly positioned PLMA can isolate the airway from the fluid in hypopharynx.

13) Shinichi Kihara, MD; Joseph Brimacombe; Anasth analg; 2005;97;280-284 [39]

They did a study based on PLMA size selection in Anaesthetised male and female adult patients.

They concluded, when sex is used to select the appropriate size of proseal LMA, Size 4 preferable for women ; Size 5 for men.

14) Christian Keller MD; Joseph Brimacombe MB; Anal Kleingasser MD; and Lawrence Brimacombe; Anasth Analg 2002; 94; 737-740 [44]

They evaluated PLMA as a temporary ventilatory device in grossly and morbidly obese patients before laryngoscope – guided Tracheal intubation

15) Rachael M. Craren, Stephen R. Larer ; Tim M.Cook, Jerry P.Nolan CJ Anasth: 2003; 50;718-20

They evaluate the use of PLMA to facilitate percutaneous dilatational tracheostomy (PDT)

They concluded that PLMA provides a reliable airway and allows effective ventilation during PDT. The passage of FOB through the PLMA and glottis is easy and provides a clear view of upper trachea.

16) Nyarwaya JB, Mazoit JX, Samiik; anaesthesia; 1994 [33]

Cardio-respiratory changes Induced by pneumo-peritoneum and head-up tilt may generate alveolar ventilation to perfusion ratio changes and increased systemic vascular resistances. The reliability of end-tidal carbon dioxide tension and pulse oximetry in predicting arterial carbon dioxide partial pressure and arterial oxygen saturation may therefore be affected. So a study was designed to find if pulse oximetry and end-tidal carbon dioxide tension monitoring were reliable during laparoscopic surgery. They concluded that end-tidal carbon-dioxide partial pressure and pulse ox metric saturation allow reliable monitoring of arterial carbon dioxide partial pressure and arterial oxygen saturation in the absence of pre-existing cardio-pulmonary disease and / or acute perioperative disturbance.

17) Wurst H. Schurte – Steinberg H, Finsterer U; Anaesthetist; 1995 [48]

Two groups of 22 patients each were studied in a prospective randomized fashion during laparoscopic cholecystectomy and carbon dioxide pneumoperitonium with regard to end-tidal and arterial PCO_2 and pulmonary elimination of carbon dioxide. They found that it during laparoscopic cholecystectomy with carbon dioxide pneumoperitonium patients were ventilated with constant minute ventilation, a moderate increase in $PaCo_2$ of about 10mm Hg occurred. They concluded that it $PaCO_2$ is to be held constant during

pneumoperitonium, minute ventilation has to be increased by about 40%

18) Bures E, Fusciardi J, Languetot H; Alta Anaesthesiol Scand [49]; 1996

During laparoscopic cholecystectomy the arterial – end-tidal Co_2 gradient (Pa-$ETCO_2$) has been variously shown to be unchanged, increased, decreased or even negative. The goal of this study was to evaluate Pa-$ETCO_2$, and to determine the proper contribution of ventilatory adequacy in regard to the increase of $PETCO_2$. They concluded that only erroneous Co_2 loading, and not ventilatory adequacy, could explain such increase in $PETCo_2$ and $PACo_2$ in cases of limited Co_2 insufflating pressure in ASA l-ll patients.

19) Hirvonen EA, Poikolainen EO, Paakkonen ME; [56] Surg Endosc; 2000

The increased intra-abdominal pressure during pneumo-peritoneum, together with the head-up tilt used in upper abdominal laparoscopies would be expected to decrease venous return to the heart. The goal of this study was to determine whether laparoscopy impairs cardiac performance when preventive measures to improve venous return are taken, and to analyze the effects of positioning, anaesthesia, and increased intra-abdominal pressure. With the passive head-up tilt in awake and Anaesthetised patients, the cardiac index, central venous pressure, and pulmonary capillary wedge pressure decreased, and systemic vascular resistance increased. They concluded that the head-up positioning accounts for many of the adverse effects in haemodynamics during laparoscopic cholecystectomy.

20) EC – Ganzovria, Avramor MN, Budacs, Moric M Tuman KJ Anaesth ; 2003 [6]

They evaluated haemodynamic changes, between PLMA versus ETT. They concluded that PLMA had more haemodynamic stability than ETT in response to insertion / intubation, intra-OP and after removal / Ex-tubation

MATERIALS AND METHODS

STUDY DESIGN

This study was a randomized prospective comparative study.

STUDY SETTING AND POPULATION

After obtaining patients written informed consent and institutional ethical committee clearance, the study was carried out in the General Surgery Operation Theatre, Government General Hospital, Chennai from July 2006 to August 2006.

The study was conducted in 40 adult patients of either sex between the age group of 18 – 60 years belonging to ASA – I & II posted for elective laparoscopic surgeries (Cholecystectomy & Appendicectomy) at the Government General Hospital, Chennai.

Inclusion Criteria

- Adults of either sex
- 18 – 60 years
- ASA physical status I & II
- Mallampati Class I – II

Exclusion Criteria [36]

- Known difficult airway
- Cervical spine disease
- Mouth opening < 2.5cm
- Patients with risk of aspiration like
    i) H/o hiatus hernia
    ii) Reflux oesophagitis

Study Method

Patients were randomized into 2 groups

1) Group I (Group E) – ETT for airway management
2) Group II (Group P) – PLMA for airway management

All Patients were fasted overnight. They were given aspiration prophylaxis with Inj-Ranitidine 50mg I.V. and Inj-Metaclopramide 10mg I.V. 1 hr before surgery [37, 38]. Patients premedicated with Inj-Glycopyrrolate 0.2mg 1hr before surgery. After the placement of monitoring devices and preoxygenation, all the patients were induced with Inj-Propofol 2.5mg/kg I.V., Inj.-Fentanyl 2µg/kg I.V., and Inj-Vecuronium 0.1mg/kg I.V. Patients were intubated with cuffed ETT of appropriate sizes in the group ETT and appropriate sizes of the PLMA in the PLMA Group.

Group ETT

For women ETT size 7.0/7.5mm and for males size 8.0/8.5mm was used. Cuff inflated

to maximum Of 25-30cm H_2O. Position was confirmed clinically and with capnography. After placement of ETT, Ryle's tube was introduced for continuous drainage.

Group PLMA

In the PLMA Group PLMA was introduced as per the body weight chart. The mask was inserted using the index finger as recommended by the anufacturer [40].

The cuff was inflated to a pressure of 60cm H_2O, which was maintained at this pressure throughout the procedure with cuff pressure monitor. Closed circle breathing system with sodalime was used. Correct placement of the device was confirmed clinically and by capnography. In addition the following tests were carried out to check whether the PLMA was correctly placed:-

- Square wave capnography
- The gel displacement Test [18]
- The Suprasternal Notch Test [15]

No. of attempts was noted . An easy of insertion was defined as the one in which there was no resistance to insertion in the pharynx in a single maneuver. In a difficult insertion there was resistance to insertion or more than one maneuver was required for the correct placement of the device.

A maximum of three insertion attempts were allowed before placement of the device was considered failure.

PLMA was fixed in a manner fish mouth tapping (maxilla to maxilla) A gastric tube (Size 14-16) was then passed through drain tube. Ease of placement of the gastric tube was recorded and its correct placement confirmed by injection of air and epigastric auscultation.

Anaesthesia was maintained with N_2O: O_2 (2:1), isoflurane 1% and Neuromuscular blockade maintained with inj. Vecuronium 0.02mg/kg

Positive pressure ventilation with mechanical ventilator was instituted with a set tidal volume of 8ml/kg FiO_2 0.33%, respiratory rate 12 b/p/m I/E of 1:2 in both the groups. The following parameters were noted intra-operatively

I. Heart rate, systolic, diastolic and mean blood pressure before induction, and 1min, 5min after insertion of PLMA / intubation with ETT and 5 min after achieving pneumoperitoneum and then at every 5min intervals.

II. Saturation (SPO_2) and end tidal Co_2($ETCo_2$), was observed in same manner

III. SPO_2 was maintained > 95% and $ETCo_2$ < 45, by adjusting the FiO_2, respiratory rate, and tidal volume. If the SPO_2 decreased the FiO2 was increased and if the SPO_2 did not improve, the tidal volume was increased to 10ml / kg. If $ETCo_2$ increased above 45, respiratory rate was increased to 14 b.p.m, then 16 b.p.m. followed by tidal volume increase up to 12ml/kg.

A period of three minutes was allowed between adjustments of FiO_2, tidal volume, and respiratory rate. When SPO_2 was 90-94% the oxygenation was graded as suboptimal and failed if it was <90% with $ETCo_2$ readings, sub-optimal ventilation was between 45-50 or failed if the reading was > 50.

A peak airway pressure was recorded in the same time points and the intra-abdominal pressure were kept between 12 to 14mm Hg.

* Episodes of gastric distension during the procedure was noted by the surgeon and they were recorded.

* All the patients in the PLMA group were tested for any occurrence of regurgitation using litmus paper postoperatively.

Residual blockade was reversed with 1.2mg atropine and 2.5mg neostigmine.

Post operatively the following problems were noted

Cough

- Sore throat
- Nausea
- Vomiting

OBSERVATION AND RESULTS

The proseal LMA (PLMA) and Endotracheal Tube (ETT) were compared based on the following parameters:-

* Haemodynamic Changes : Heart rate
  Systolic blood pressure
  Diastolic blood pressure
  Mean arterial pressure

before induction, 1min, 5min after Intubation/insertion, 5min after pneumoperitoneum and then every 5min till extubation. Then 5min after extubation.

* Ventilatory Parameters:

  End tidal Co_2 ($ETCo_2$)

  Oxygen saturation (SPO_2)

  Tidal volume and respiratory rate

  FiO_2

  Airway Pressure

  Noted as the same manner as above.

- Gastric distension
- No. of attempts of insertion / intubation
- No of attempts to pass a Ryle's tube

Study material

A total of 20 cases each was randomly allocated to one of the following two groups of study viz. Group I – Endo tracheal Tube (ETT); Group II – proseal LMA.

Statistical method

The descriptive statistics of the variables studied are represented as two-way tables. The categorical factors are represented by the number and frequency (%) of cases. The continuous variables are represented by measures of central frequency (like mean, median & mode) and deviation (say, standard deviation and range). The differences in the proportions are tested for statistical significance using non-parametric Chi-square test for variables measured on nominal scale. When testing for two factors, the Mann-Whitney "U" test or Wilcoxon two sample test (by Kruskal-Wallis "H" test which is equivalent to chi-square) is used. For variables measured on a continuous scale, when testing for two groups, Student "t" test is used to test for statistical significance in the differences of the two means.

Table 1: Distribution of age of cases by groups[$]

Age	Gr. I	Gr. II	p-value
No. of cases	20	20	
Mean	29.0	28.7	
S.D.	12.97	13.10	0.94
Median	25	24	
Mode	20	20	
Range	17-62	17-62	

[$] *Not statistically significant*

The mean age was observed to be almost the same in Group I than Group II and not statistically significant.

Table 2: Distribution of cases by groups and sex[$]

Sex	Gr. I (n=20)		Gr. II (n=20)		p-value
	No.	%	No.	%	
Male	10	50.0	12	60.0	0.53
Female	10	50.0	8	40.0	

[$] *Not statistically significant*

A male preponderance is forthcoming in Group II but the difference in the distribution between the two groups is not statistically significant.

Table 3: Distribution of weight of cases by groups[$]

Weight	Gr. I	Gr. II	p-value
No. of cases	20	20	
Mean	54.9	53.9	
S.D.	5.80	5.41	0.60
Median	52.5	50.5	
Mode	50	50	
Range	50-66	50-66	

[$] *Not statistically significant*

The distribution of cases by weight and the difference in the mean values are observed to be not statistically significant between Group I and Group II.

Table 4: Mean Distribution of cases by groups and HR

HR	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	93.1 13.5	85.0 19.7	0.14
1 min after intubation /insertion Mean SD	94.6 18.27	87.0 27.4	0.31
5 min after intubation /insertion Mean SD	92.5 8.41	82.2 14.38	0.008*
5 min after pneumoperitoneum Mean SD	99.1 9.83	86.8 14.71	0.003*
5- min Mean SD	96.8 9.99	84.1 13.37	0.002*
10-min Mean SD	94.8 9.25	82.2 12.58	<0.001*
15-min Mean SD	93.4 8.36	79.6 12.57	<0.001*
20-min Mean SD	91.0 8.3	77.5 11.82	<0.001*
25-min Mean SD	89.1 7.87	77.4 11.00	<0.001*
30-min (n=30) Mean SD	n=16 86.5 8.86	n=14 79.2 11.28	0.06
35-min (n=24) Mean SD	**N=13** 86.6 10.63	**N=11** 78.0 12.11	0.08
40-min (n=16) Mean SD	**N=7** 82.4 10.75	**N=9** 72.8 7.31	0.05*
45-min (n=11) Mean SD	**N=6** 79.8 14.1	**N=5** 73.6 5.03	0.38
5 min after extubation Mean SD	97.1 12.17	78.6 10.2	<0.001*

** statistically significant*

The distribution of cases by grade of Heart Rate (HR) and the mean values were observed to be generally

statistically significant between Group I and Group II at the majority of different time points viz. between 5 minute after intubation and 25 min, at 40 min and 5 min after extubation.

Table 5: Distribution of cases by groups and systolic blood pressure

Systolic blood pressure	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	122.7 9.10	124.7 9.26	0.51
1 min after intubation /insertion Mean SD	130.4 16.42	110.1 14.31	<0.001*
5 min after intubation /insertion Mean SD	119.4 14.21	112.4 10.24	0.08
5 min after pneumoperitoneum Mean SD	137.4 16.72	120.8 13.48	0.001*
5-min Mean SD	130.1 10.78	117.6 14.58	0.004*
10-min Mean SD	129.0 9.93	117.8 12.26	0.003*
15-min Mean SD	125.0 7.65	116.7 9.21	0.004*
20-min Mean SD	124.9 7.97	115.2 9.80	0.001*
25-min Mean SD	124.4 6.63	115.1 9.08	<0.001*
30-min (n=30) Mean SD	N=16 123.9 6.99	N=14 116.7 13.01	0.07
35-min (n=24) Mean SD	N=13 121.8 7.72	N=11 115.8 13.31	0.19
40-min (n=16) Mean SD	N=7 122.4 10.64	N=9 119.8 12.71	0.66
45-min (n=11) Mean SD	N=6 121.7 13.46	N=5 122.4 14.57	0.93

5 min after extubation Mean SD	134.1 5.9	117.1 7.6	<0.001*

** statistically significant*

The distribution of cases and the mean values of systolic blood pressure were observed to be generally statistically significant between Group I and Group II at the majority of different time points viz. at 1 minute after intubation, between 5 minutes after pneumoperitoneum and 25 min and at 5 minutes after extubation.

Table 6: Distribution of cases by groups and diastolic blood pressure

Diastolic blood pressure	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	82.7 8.24	84.3 6.94	0.51
1 min after intubation /insertion Mean SD	87.2 13.35	73.0 15.55	0.004*
5 min after intubation /insertion Mean SD	77.7 21.52	74.9 11.05	0.61
5 min after pneumoperitoneum Mean SD	96.2 14.24	84.2 12.51	0.008*
5-min Mean SD	88.6 11.74	80.2 13.39	0.04*
10-min Mean SD	87.3 11.43	83.0 11.05	0.23
15-min Mean SD	84.4 8.64	79.8 10.73	0.15
20-min Mean SD	83.6 8.99	78.3 12.46	0.13
25-min Mean SD	83.7 8.85	80.0 11.21	0.26
30-min (n=30) Mean SD	N=16 83.8 9.67	N=14 80.9 13.45	0.49
35-min (n=24) Mean SD	N=13 83.2 8.41	N=11 79.5 12.75	0.40

40-min (n=16) Mean SD	N=7 81.3 10.56	N=9 82.8 13.02	0.81
45-min (n=11) Mean SD	N=6 78.0 9.06	N=5 85.2 10.47	0.25
5 min after extubation Mean SD	87.3 9.86	80.9 9.08	0.04*

** statistically significant*

The distribution of cases and the mean values of diastolic blood pressure were observed to be statistically significant between Group I and Group II at the following different time points viz. 1 minute after intubation, 5 minutes after pneumoperitonium, and 5 minute after estuation.

Table 7: Distribution of cases by groups and MAP

MAP	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	95.9 7.95	97.7 7.03	0.44
1 min after intubation /insertion Mean SD	101.3 13.88	84.5 12.34	<0.001*
5 min after intubation /insertion Mean SD	95.2 14.63	88.6 10.1	0.10
5 min after pneumoperitoneum Mean SD	110.1 11.22	95.6 11.95	0.001*
5-min Mean SD	101.6 11.22	92.2 14.11	0.03*
10-min Mean SD	101.4 10.46	93.7 11.21	0.03*
15-min Mean SD	97.5 7.30	92.0 9.57	0.05*
20-min Mean SD	97.1 7.62	90.0 11.39	0.03*
25-min Mean SD	97.4 7.86	92.1 10.08	0.07
30-min (n=30) Mean SD	N=16 96.7 8.15	N=14 93.6 14.17	0.48

35-min (n=24) Mean SD	N=13 95.5 7.16	N=11 91.9 12.83	0.40
40-min (n=16) Mean SD	N=7 95.0 9.92	N=9 94.8 12.49	0.97
45-min (n=11) Mean SD	N=6 93.3 9.54	N=5 93.4 7.64	0.99
5 min after extubation Mean SD	101.6 7.4	92.6 8.07	<0.001*

** statistically significant*

The distribution of cases and the mean values of MAP were observed to be statistically significant between Group I and Group II at the following different time points viz. 1 minute after intubation, between 5 minutes after pneumoperitonium and 20th hour and 5 minute after estuation.

Table 8: Distribution of cases by groups and ET CO2$^{\$}$

ETCO2	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	31.3 2.5	31.5 2.97	0.82
1 min after intubation /insertion Mean SD	33.2 2.88	33.1 2.88	0.91
5 min after intubation /insertion Mean SD	33.3 3.15	33.5 3.3	0.88
5 min after pneumoperitoneum Mean SD	37.9 4.61	37.8 4.59	0.92
5-min Mean SD	37.2 2.43	37.2 2.43	-
10-min Mean SD	38.1 3.49	38.2 3.51	0.96
15-min Mean SD	36.5 1.79	36.4 1.76	0.86
20-min Mean SD	36.1 1.83	36.0 1.79	0.79

25-min Mean SD	35.3 2.83	35.2 2.80	0.91
30-min (n=30) Mean SD	N=15 35.5 3.6	N=15 35.4 3.58	0.96
40-min (n=20) Mean SD	N=10 35.8 1.81	N=10 36.0 1.70	0.80
45-min (n=14) Mean SD	N=7 35.9 1.86	N=7 35.9 1.86	-

[$] *Not statistically significant*

The distribution of cases and the mean values of ETCO2 were observed to be generally not statistically significant between Group I and Group II at all the different time points.

Table 9: Distribution of cases by groups and TV[$]

TV	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	518.5 59.41	511.0 50.7	0.67
1 min after intubation /insertion Mean SD	434.5 42.86	433.5 40.95	0.94
5 min after intubation /insertion Mean SD	436.5 44.28	430.5 40.32	0.66
5 min after pneumoperitoneum Mean SD	443.5 44.75	437.5 41.91	0.66
5-min Mean SD	454.0 39.79	434.5 41.1	0.14
10-min Mean SD	440.5 44.42	434.5 41.1	0.66
15-min Mean SD	435.5 42.98	434.5 41.1	0.94
20-min Mean SD	440.5 44.42	439.5 42.73	0.94
25-min Mean SD	490.5 149.82	489.5 149.68	0.98
30-min (n=30) Mean SD	N=14 451.4 47.05	N=14 450.0 45.06	0.94
40-min (n=20) Mean SD	N=10 448.0 52.66	N=10 446.0 49.93	0.93
45-min (n=14) Mean SD	N=7 428.6 50.14	N=7 428.6 50.14	-

[$] *Not statistically significant*

The distribution of cases and the mean values of TV were observed to be generally not statistically significant between Group I and Group II at all the different time points.

Table 10: Distribution of cases by groups and RR[$]

RR	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	14.9 1.31	14.9 1.33	0.91
1 min after intubation /insertion Mean SD	12.1 0.45	12.1 0.45	1.00
5 min after intubation /insertion Mean SD	12.0 0.0	12.0 0.0	-
5 min after pneumoperitoneum Mean SD	12.3 0.98	12.3 0.98	1.00
5-min Mean SD	13.8 0.89	13.7 0.98	0.74
10-min Mean SD	13.7 0.98	0.37 0.98	1.00
15-min Mean SD	13.7 0.98	0.37 0.98	1.00
20-min Mean SD	13.8 1.1	13.8 1.1	1.00
25-min Mean SD	13.8 1.12	13.8 1.12	1.00
30-min (n=30) Mean SD	N=15 13.8 1.19	N=15 13.0 3.53	0.37
40-min (n=20) Mean SD	N=10 13.8 1.14	N=10 13.8 1.14	1.00
45-min (n=14) Mean SD	N=7 13.7 1.38	N=7 13.7 1.38	1.00

[$] *Not statistically significant*

The distribution of cases and the mean values of RR were observed to be almost similar in Group I and Group II at all the different time points and hence not statistically significant.

Table 11: Distribution of cases by groups and FI O2[$]

FIO2	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	49.2 3.8	49.2 3.8	1.00
1 min after intubation /insertion Mean SD	33.0 0.0	33.0 0.0	-
5 min after intubation /insertion Mean SD	33.9 3.8	33.9 3.8	1.00
5 min after pneumoperitoneum Mean SD	33.0 0.0	33.0 0.0	-
5-min Mean SD	33.0 0.0	33.0 0.0	-
10-min Mean SD	33.0 0.0	33.0 0.0	-
15-min Mean SD	33.0 0.0	33.0 0.0	-
20-min Mean SD	33.0 0.0	33.0 0.0	-
25-min Mean SD	33.0 0.0	33.0 0.0	-
30-min (n=30) Mean SD	N=15 33.0 0.0	N=15 33.0 0.0	-
40-min (n=20) Mean SD	N=10 33.0 0.0	N=10 33.0 0.0	-
45-min (n=14) Mean SD	N=7 33.0 0.0	N=7 33.0 0.0	-

[$] *Not statistically significant*

The distribution of cases and the mean values of FIO2 were observed to be almost similar in Group I and Group II at all the different time points and hence not statistically significant.

Table 12: Distribution of cases by groups and AWP[$]

AWP	Gr. I *(n=20)*	Gr. II *(n=20)*	p-value
Before induction Mean SD	17.5 3.09	17.4 3.63	0.92
1 min after intubation /insertion Mean SD	18.7 2.70	18.6 2.60	0.91
5 min after intubation /insertion Mean SD	19.7 3.25	19.6 3.20	0.92
5 min after pneumoperitoneum Mean SD	22.2 2.62	21.8 2.45	0.62
5-min Mean SD	23.2 2.78	22.9 2.41	0.72
10-min Mean SD	23.1 2.78	22.9 2.57	0.86
15-min Mean SD	23.1 3.01	23.2 3.1	0.96
20-min Mean SD	22.9 3.18	23.0 3.34	0.92
25-min Mean SD	22.2 3.12	22.3 3.31	0.92
30-min (n=30) Mean SD	N=15 22.1 3.93	N=15 22.2 4.00	0.96
40-min (n=20) Mean SD	N=10 22.2 2.35	N=10 21.9 2.28	0.78
45-min (n=14) Mean SD	N=7 21.7 2.45	N=7 21.7 3.45	1.00

[$] *Not statistically significant*

The distribution of cases and the mean values of AWP were observed to be generally not statistically significant between Group I and Group II at all the different time points.

Table 13: Distribution of cases by groups and attempt Proseal[$]

(n=20)

Attempt	Gr. I		Gr. II		p-value
	No.	%	No.	%	
1 Yes	18	90.0	18	90.0	1.00
2 No	2	10.0	2	10.0	

[$] *Not statistically significant*

Table 14: Distribution of cases by groups and attempt Ryle's tube[$]

(n=20)

Attempt	Gr. I		Gr. II		p-value
	No.	%	No.	%	
1 Yes	18	90.0	18	90.0	1.00
2 No	2	10.0	2	10.0	

[$] *Not statistically significant*

Table 15: Distribution of cases by groups and GD score[$]

(n=20)

GD score	Gr. I		Gr. II		p-value
	No.	%	No.	%	
1	18	90.0	18	90.0	1.00
2	2	10.0	2	10.0	

[$] *Not statistically significant*

All of the above factors are equally distributed among the two groups in various categories and hence are not statistically significant.

DISCUSSION

The proseal LMA designed by Dr. Archie Brain is based on the LMA and was introduced in 2000.

The inventor's aims of the modifications are (i) avoidance of gastric inflation during controlled ventilation. (ii) Less need for tight occlusion of the upper oesophageal sphincter (UES) by the mask tip in the event of regurgitation, because of the presence of DT; (iii) Opportunity to pass an orogastric tube (OGT) (iv) Channeling of regurgitated stomach contents. Changes were also designed to improve airway seal. An important design function of the DT was to allow rapid diagnosis of mask misplacement.

When PLMA is correctly positioned, the airway orifice lies over the glottis and the DT tip lies behind the cricoid cartilage at the origin of esophagus. Airway and DT each form uninterrupted routes from these sites to outside of the mouth. This functional separation of the respiratory and gastrointestinal tracts is important in understanding potential advantages of the PLMA over the LMA and other supraglottic airway devices. In this regard one might consider the PLMA to act as an "artificial Larynx", rather than simply an airway tube.

Previous laryngeal mask studies indicate only minor haemodynamic responses to LMA insertion with a 0-20% increase in heart rate and mean arterial pressure [51]. ***Brawn et al*** [52] stated that haemodynamic responses to PLMA insertion were similar to those of a LMA, in their

randomized comparative trial of 280 patients anaesthetized with a standard technique. Two randomized studies of 335 patients with varying anaesthetic techniques reported haemodynamic variables change less than 10% in PLMA [53, 54].

In this study, the heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure were monitored before induction, 1 min,5 min after insertion / intubation, then 5 min after pneumoperitonium, and every 5min till end of surgery and 5 min after Extubation / Removal, and compared between Group I (ETT) and Group II (PLMA).

The distribution of cases by grade of HR, SBP, DBP and MAP, the mean values were observed to be statistically significant ($P<0.05$) between Group I (ETT) and Group II (PLMA) at every time points mentioned above.

The Group II PLMA is more haemodynamically stable than Group I ETT which was in concordance with the study done by ***EC-Ganzavria et al*** [6].

Regarding ventilatory parameters the SPO_2, $ETCo_2$, TV & RR, Fio_2, and Airway Pressure were monitored before induction, 1 min & 5min after intubation / Insertion, 5min after pneumoperitoneum then every 5 min till end of surgery, and compared between Group I (ETT) & Group II (PLMA).

The distribution of cases by grade of SPO2, $ETCO_2$, TV & RR, FIO_2 , and Airway Pressure, the mean values were not statistically significant ($P>0.05$) between Group I (ETT) &

Group II (PLMA) at every time point mentioned above. This was in concordance with studies done by ***maltby et al*** 3,4 and ***piper SN et al*** [5].

The overall proseal LMA insertion success reported in 33 studies, and 2,581 PLMA Insertions ranged from 90-100% [2, 39, 9, 47, 13].

First time proseal LMA insertion success reported in 28 studies, and 2,388 PLMA insertions ranges from 76% to 100% .[37.3, 2, 39, 9,47,3].

In this study the PLMA was correctly placed in first attempt in 18 cases (90%). In 1st patient PLMA could not be placed correctly even after 3 attempts. And in the 2nd patient the PLMA was inserted in the second attempts. This goes with accordance with the above mentioned studies.

Endotracheal intubation was successful in first attempt in all 20 cases.

Regarding orogastric Tube (OGT) insertion, seventeen studies with 1,384 attempts via PLMA drain tube reported 95% first time OGT passage [2, 4 & 12, 55, 52, 3].

Higher success rates for OGT passage (up to 100%) are reported when efforts are made to eliminate folding of mask tip [12, 14].

In this study OGT insertion was a success in first attempt in 18 (90%) cases and in

second attempt in 2 cases via PLMA drains tube.

OGT insertion after intubating with ETT, was successful in the first attempt in all cases (20).

Design and performance features of the PLMA are expected to reduce gastric distension, regurgitation and pulmonary aspiration compared to the LMA.

Miller et al [56] stated that PLMA provided better airway protection during regurgitation than LMA. Keller C. et al [57] concluded that a properly positioned PLMA isolates the airway from fluid within the hypopharynx.

In this study, the occurrence of regurgitation if any, was tested using litmus paper on the posterior surface of the PLMA, immediately after its removal. None of the patients showed any signs of regurgitation.

In this study gastric distension score was not statistically significant between Group I (ETT) and Group II (PLMA). The highest gastric distension score -2 was seen in two patients in both groups.

SUMMARY

The comparative evaluation of the proseal LMA with tracheal intubation for laparoscopic surgeries showed no significant difference between the two groups based on the demographic variables. The PLMA group maintained better haemodynamic stability than ETT group throughout the procedure. The ventilatory parameters (SPO_2, $ETCo_2$, TV&RR, FIO_2, Airway Pressure) showed no significant difference between 2 groups. The first time insertion success rate was 90% in PLMA group & 100% in ETT group. The first time passage of an OGT was 90% in PLMA group & 100% in ETT Group. There was no significant difference between the two groups based on gastric distension score noted by surgeon.

CONCLUSION

0n comparing Proseal LMA and endotracheal tube for laparoscopic surgeries, it was found that the haemodynamics were more stable when Proseal LMA was used. Proseal LMA was as effective as endotracheal tube during positive pressure ventilation in preventing gastric distension and aspiration when correctly placed. So Proseal LMA is an effective alternative to endotracheal tube in patients where the haemodynamic stability is much desirable during laparoscopic surgeries.

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COMPARISON OF LMA-PROSEAL AND ET FOR LAPRASCOPIC INTRAABDOMINAL SURGERY

NAME : AGE / SEX:

I.P.NO.:

WEIGHT : HEIGHT:

PHYSICAL STATUS: ASA

MPC: ETT/LMA-PROSEAL:

VITAL SIGNS: PRE OP:

PULSE: BP:

RESP RATE:

BLOOD INV:

CXR:

ECG:

PRE MEDICATION :

Inj. Glycopyrrolate		0.2mg	I.V.	just before procedure
Inj. Midazolam		1mg	I.V.	
Inj. Metaclopramide	10mg		I.V.	
Inj. Ranitidine		50mg	I.V	

INDUCTION

Inj. Propofol	2.5mg/kg	I.V.	
Inj. Fentanyl	2µg/kg		I.V.
Inj. Vecuronium	0.1mg/kg	I.V.	

MAINTENANCE: $N_2O : O_2$ 66.33% + Isoflurane

PARAMETERS:

1. HEMODYNAMIC STABILITY :

	HR	**SOSTOLIC BP**	**DIASTOLIC BP**	**MAP**
Before induction				
One minute after insertion / intubation				
5 minute after insertion / intubation				
5 minute after pneumoperitoneum				
After estuation / removal				

2. ADEQUACY OF VENTILATION

	SPO2	PET CO2	V	RR	Fio2	PAP
Before induction						
One minute after insertion / intubation						
5 minute after insertion / intubation						
5 minute after pneumoperitoneum						
After estuation / removal						

Oxygenation :- Optimal / suboptimal/failed
Ventilation: Optimal / suboptimal/failed

- INTRA ABDOMINAL PRESSURE ARE KEPT BETWEEN 12-14 mm Hg
- EASE OF PLACEMENT OF PROSEAL: 1 / 2 / 3 FAILED
- EASE OF PLACEMENT OF RYLE'S TUBE: 1 / 2 / 3 FAILED
- EPISODES OF GASTRIC DISTENSION :

(Noted by surgeons)

INTRA OP PROBLEMS

- ASPIRATION – REGURGITATION
- LITMUS PAPER TEST: POSITIVE / NEGATIVE
- HYPOXIA
- HYPERCARBIA
- BRONCHOSPASM
- TONGUE – LIP- DENTAL TRAUMA

POST-OP PROBLEMS

- COUGH
- SORE THROAT
- NAUSEA
- VOMITING