Original Research Paper

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Anesthesiology

COMPARISON OF CLASSIC AND PROSEAL LMA IN ANAESTHETISED AND PARALSYSED PATIENTS COMING FOR GYNAECOLOGICAL SURGERIES

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ABSTRACT This study was conduted to compare Classic LMA and Pro-seal LMA in term of FOB, Ease of Insertion, Time taken for insertion, no. of attempts and complications. This study was conducted over a period of one year in Institute of Obsterics and Gynaecology in Madras Medical College after Ethical Committee clearance.

KEYWORDS : LMA- Laryngeal Mask Airway FOB- Fibre optic Bronchoscope CPM- Cuff Pressure Monitor

INTRODUCTION

Adversity makes man look for better options!

It all started with invent of Anaesthesia ! Induction of general anaesthesia resulted in loss of upper airway reflexes and reduction in tone of pharyngeal structures which resulted in potential life threatening complications like obstruction of upper airway and accidental aspiration of gastric contents! Anaesthesilogists started felling the need for devices to secure the airway. This lead to the Introduction of tracheal intubation for giving general anaesthesia which was first done by William MacEven in the year of 1880. But this invention though gold standard is not devoid of certain limitations even today viz. It often requires neuromuscular blockade, stimulates unwanted reflex sympathetic activity and may damage the vocal cords and the tracheal mucosa. An alternative method of using the traditional facemask with or without Guedel's airway was used for anaesthesia in patients who were staryed and breathing spontaneously. But even these two devices (facemask, Guedel's airway) had their own limitations. The facial characteristics of individual patients, particularly those with beards or without teeth, do not always conform to the relatively uncompromising shape of traditional facemasks. Whereas the Guedel's airway can prevent the airway obstruction due to tongue fall after induction of anaesthesia but not due to the loss of tone of pharyngeal muscles. It is more difficult to maintain a good seal with the mask for prolonged periods than an endotracheal tube. It not tires the Anaesthesiologist but also keeps his hands unavailable to manage any other emergency during the conduct of anaesthesia.

Astonishingly, more than a century after the introduction of the endotracheal tube anaesthesia, a new invention developed in Great Bristain by a determined, single minded anaesthesiologist revolutionised the airway management! The Laryngeal Mask Airway was born!

The LMA was conceived and designed by Dr. Archie Brain in UK in 1981 and following prolonged research was released in 1988. Dr. Archie Brain worked on the idea of decreasing the size of the anaesthetic mask so that instead of applying it over the face it could be applied over the laryngeal opening. Seventy prototypes and several thousand patients later the Dunlop Rubber company made some latex and silicone masks to the inventor's specifications. The first independent clinical trial of LMA was carried out at Northwick Park Hospital in 1987 and within one year the design was finalised and four sized were available. By September 1990 all british hospitals performing operations had LMA on their anaesthesiamachines! But this device was also not full proof against complications like aspiration. Hence Dr. Brain's penchant for improvisation lead him to the invention of Pro-seal LMA the LMA (PLMA) with a drainage tube and an extra cuff dorsally! The PLMA was introduced by Dr. Archie Brain in 2000. It is the most complex and most specialized device and is widely believed to replace all other models of LMA.

But although newer versions are increasingly seen in the anaesthesiologist's armoury the classic LMA has its own place! Hence we decided to compare these two LMAs to find our which LMA sits properly into the laryngopharynx and gives a better seal around the glottis. We also have endeavoured to find out which LMA amongst the two is better in terms of ease of insetion, time take for insertion. Number of attempts for insertion and the complications.

AIM OF THE STUDY:

To compare Classic LMA and Pro-seal LMA in anaesthetised patients coming for Gynaecological surgery in terms of :

1) Fibreoptic view (FOB)
2) Oropharyngeal sealing pressure (OSP)
3) Ease of insertion
4) Time taken for insertion

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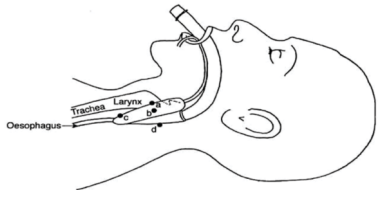
6) Complications.

LARYNGOSCOPIC ANATOMY:

The laryngoscopic anatomy or the structures visualised during a laryngoscopy determine the success in the airway. But before doing the laryngoscopy it is of utmost importance to bring the oral pharyngeal and the laryngeal axis in a single line by giving head extension and neck flexion like in sniffing the morning air position. At laryngoscopy, the structure visible first is the base of the tongue and as the scope progresses the valleculae and the anterior surface of the epiglottis become visible. The laryngeal aditus then comes into the view. The inlet of the larynx looks backward and upward into the laryngeal part of the pharynx. The laryngeal aditus is wider in front that behind and is bounded in front by the posterior aspect of the epiglottis, with its prominent epiglottis tubercle. The aryepiglottic folds are seen on either side running posteromedially from the lateral asoects if the epiglottis. The aryepiglottic folds are thin in front but become thicker as they pass backwards where they cntain the cuneiform and comciculate cartilages. Within the cavity of larynx, there are two folds of mucous membrane on each side. The upper fold is the vestibular fold and is also called as the false vocal cords whereas the lower fold is the vocal fold is the vocal fold also known as the true vocal cords. The vestibular fold is formed by mucous membrane

Covering the vestibular ligament and is vascular and pink in colour. The vocalcords appear as pale, glistening ribbons that extend from the angle of the Thyroid cartilage backwards tothe vocal processes of the arytenoids. Between the cords is the triangular opening of the rima glottis, through which can be seen the upper two or three rings of the trachea.

When a Laryngeal Mask Airway sits properly in the larynx, its tip should lie at the upper sphincter of the oesophagus, the margins should lie against the pyriform fossa and the upper end of the LMA should lie behind the base of the tongue. The tip of the epiglottis may rest either within the bowl of the mask or under the proximal cuff.



CLASSIC LMA:

The Classic LMA was invented by Dr. Archie Brain in the year 1981 and introduced in the year 1988.

The Classic LMA is made from medical grade silicone. It consists of a curved tube connected to an elliptical spoon shaped mask at a 30

degree angle. There are two flexible vertical bars at the entry of the tube into the mask to prevent obstruction of the tube by the epiglottis. The mask is surrounded by an inflatable cuff. An inflation tube and self-sealing pilot balloon are attached to the proximal wider end of the mask. A black line running longitudinally along the posterior aspect of the tube helps to orient it after placement. At the machine end of the tube it has a standard 15 mm connector.

The Classic LMA is available in 7 sizes and the choice of the correct size is according to the patient's weight. When there is doubt, a larger rather than a smaller size should be chosen for the first attempt.

INSERTION:

The Classic LMA can be inserted by the following techniques:

1.Standard technique:

This technique involves using a midline or slightly diagonal approach with the cuff fully deflated. The patient should be placed in head extension and neck flexion position. The mouth is opened and holding the LMA like a pen, with the index finger pressing on the point where the tube joins the mask, the tip of the cuff is placed against the inner surface of the upper incisors or gums with the aperture facing anteriorly. The mask is pressed back against the herd palate to keep it flattened as it is advanced into the oral cavity, using the index finger to push upward against the palate. A change of direction can be sensed as the mask tip encounters the posterior pharyngeal wall and follows it downward. By withdrawing the other fingers as the index finger is advanced and slight pronation of the forearm it is often possible to insert the mask fully into position with a single movement. The longitudinal black line on the shaft should lie in the midline facing the upper lip.

2.180 Degree Technique:

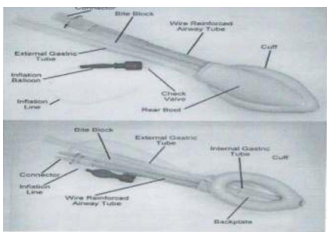
In this technique the LMA is inserted with the laryngeal aperture pointing cephalad and then rotated it 180 degree as it enters the pharynx.

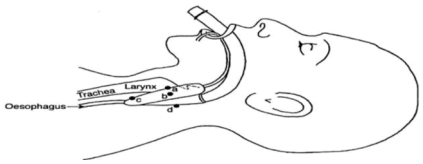
3.Partial Inflation:

In this technique the LMA cuff is partially inflated before insertion. This has found to increase the success rate of insertion.

The Pro-seal LMA was designed by Archie Brain in the late 1990s with the primary goal of constructing a laryngeal mask with improved ventilatory characteristics and protection against regurgitation and gastric insufflation. It has a modified cuff and a drain tube.

The Pro-seal LMA is a reusable MA made from medical-grade silicone. It has two cuffs one ventral and another dorsal cuff. The ventral cuff is larger and is attached to the dorsal cuff. The bowl of the mask is deeper and has nor aperture bars. The inflatable portion extends around the back. The design is such that when inflated, the mask is pushed anteriorlyand the glottis becomes enveloped in the bowl. It has a flexible wire reinforced airway tube along with an integral gastric access/venting port and a tube which traverses through the PLMA bowl. This design is unique and was made specially keeping in mind the risk of gastric insufflation during positive pressure ventilation. When properly positioned, the distal orifice of this drain tube should lie in the upper esophagus. An orogastric tube can be passed through this drain tube and the stomach and oesophagus contents can be evacuated. To prevent the drain tube from collapsing on the inflation of the cuff there is a plastic supporting ring around the distal drain tube. It has an aperture at the distal end which slopes anteriorly and allows the deflated tip to form a fine leading edge for insertion. A rectangular depression present in the proximal bowl functions as an accessory ventilation channel tube. The Pro-seal LMA also has a built-in bite block which fuses the airway and drain tubes together and prevents airway obstruction and damage to the device during biting. The bite block also provides information about depth of insertion.





Sizes

It is currently available in sizes: 1 , 1.5 , 2 , 2.5 , 3 , 4 , and 5. Size selection is similar to the Classic LMA and can be either weight based (size 3 for adults and children, 30-50 kg; size 4 for normal adults, 50-70 kg; and size 5 for large adults, 70-100 kg) or gender based (size 4 for female patients; size 5 for male patients).

INDICATIONS

Indications are similar to the Classic LMA, but the Pro-seal is preferable whenever a better seal, better airway protection, and access to the gastrointestinal tract are required like laproscopic surgeries. It may be a better alternative for any elective surgery where Classic LMA is used with controlled ventilation and also for cardiopulmonary resuscitation.

Contraindications

Patients at risk of aspiration befor induction of anaesthesia.

Insertion techniques

There are three primary insertion techniques for the Pro-seal LMA:

1) **Digital insertion:** The LMA is completely deflated and held like a pen with the index finger of the operator at the junction of the tube and the bowl. The patient's head is extended and the neck is flexed. The LMA is inserted into the oral cavity withthe operator standing at the head of the patient and the LMA aperture facing caudally. While going over the posterior surface of the tongue the tip of the cuff is pressed upwards against the hard palate. The LMA is advanced into the hypopharynx till a resistance is felt. The cuff is then inflated with just enough air to seal to a intra cuff pressure around 60 cms H2O.

2) **Introducer-guided insertion:** The introducer tool is a reusable clip-on/clip-off device that compreses a thin, curved, malleable, metal blade with a guiding handle. Its 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 drain tube resting to one side. The locating strap (insertion strap) keeps the proximal cuff in the midline, provides an insertion slot for the introducer tool and also prevents the finger slipping off the tube during insertion.

3) **Gum clastic bougle or duodenal tube guided insertion:** Which guides the Pro-seal around the oropharyngeal inlet and into the hypopharynx. The guided insertion technique includes neck flexion, head extension, full deflation of the LMA Pro-seal cuff and the following steps: (1) under gentle laryngoscope-guidance, the distal portion of a cooled well-lubricated 125cm long duodenal tube is placed 10-15cm intothe oesophagus whilst the assistant holds the airway device and proximal portion of the duodenal tube; (2) the laryngoscope is removed; (3) the airway device is inserted using the digital insertion technique whilst the assistant stabilises the proximal end of the duodenal tube so that it does not penetrate further into the oesophagus; and (4) the duodenal tube is then advanced in the stomach while the airway device is held in position. Correct placement of the duodenal tube in the stomach was assessed by suction of gastric fluid or detection of injected air by epigastric stethoscopy.

CUFF INFLATION AND FIXATION

The cuff volume required to form an effective seal with the respiratory tract is lower for the pro-seal than the Classic LMA. The cuff should be inflated with at least 50%of the maximum recommended volume to ensure an effective seal with gastrointestinal tract for prevention of aspiration and gastric insufflation. A properly placed PLMA can withstand peak inflation pressure of approximately 35cms H2O without leak as compared to 25 cmsH2O offered by the LMA Classic.

Signs of correct ProSeal placement.

a. Correct position of bite block
b. Chest expansion and capnography
c. Seal pressure >20 cms H2O
d. Gel displacement test a blob (1ml) of water soluble lubricant jelly is placed over the proximal opening of the pro-seal drain tube. Ejection of the gel from the drain tube on gentle inflation of the bag indicates presence of leak.
e. Gastric tube placement
f. Fibre-optic examination

Sterilization of the LMAs:

The LMA should be first be washed in warm water with a dilute (8-10%) sodium bicarbonate solution or a mild detergent. The inside of the airway tube should then be steam autoclaved according to manufacturer's instructions. Generally a temperature of 135 degrees Celsius is used. The LMA is then allowed to cool to room temperature before use.

FLEXIBLE FIBREOPTIC BRONCHOSCOPE

It contains a fibreoptic system that transmits an image from the tip of the instrument to an eyepiece or video camera at the opposite end. The main component of the fiberscope is the insertion cord which contains a collection of approximately 10,000 glass fibers, 25ueach in diameter. Each fiber is coated with a 1 ulayer of glass having a different optical density to keep the light the light from being lost during transmission. This helps in total internal refelxtion of the light entering the fiber. Individual fibers cannot prove a good resolution and hence the need for a collection of approximately 10,000 fibers in a bundle. The fiberscope contains another set of fiberoptic bundle to set as a cable for transmitting light from a light source to the end of the insertion cord. Using Bowden cables connected to a lever at the hand piece, the tip of the instrument can be oriented, allowing the practitioner to navigate theinstrument into the glottis and further. It also includes a channel for suctioning or instrumentation.

The components of the flexible fiberscope system are:

1) Eyepiece
2) Control section
3) Insertion cord
4) Universal cord for light transmission
5) Light source

The eyepiece contains the lenses. The operator's visual acuity can be focused with the help of an adjustment ring.

The control section of the fiberscope contains the angulation control lever for flexing and de-flexing the distal tip of thefiberscope. Nearly 360* visualization can be achieved along with theses movements and rotation of the fiberscope. In the adult and larger paediatric fiberscopes, this section also contains the suction or biopsy channel, the connectors and their ports. This channel can also be used for oxygen insufflation, instillation of saline or local anaesthetics, placement of biopsy wire or for suction.

The insertion cord is the most fragile part of the fiberoptic bronchoscope. It encases the fiberoptic and optical bundles, the angulation wires and the channel for suction. The fiberoptic bundles can break on acute or forcible bending and can appear as black dots in the image and may lower illumination intensity.

The universal cord transmits the light from the light source. It is attached to the fibescope at the level of the control sedation.

USES OF THE FLEXIBLE FIBREOPTIC BRONCHOSCOPE:

Diagnostic:

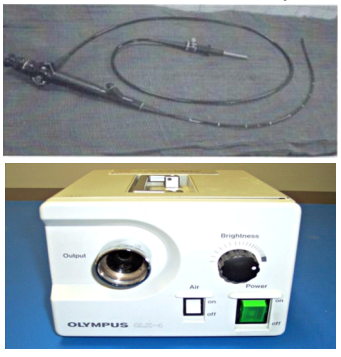
1) To view abnormalities of the airway.
2) To confirm the position of Endotracheal tube, Laryngeal Mask Airway etc.,
3) To obtain tissue specimens of the lung in a variety of disorders by biopsy, bronchoalveolar lavage, or endobronchial brushing
4) To evaluate a person who has bleeding in the lungs, possible lung cancer, a chronic cough, sarcoidosis.

THERAPEUTIC:

1) To remove secretions, blood, or foreign objects lodged in the airway.
2) Laser resection of tumors or benign tracheal and bronchial strictures.
3) Stent insertion to palliate extrinsic compression of the tracheobronchial lumen from either malignant or benign disease processes.
4) Bronchoscopy is also employed in percutaneous tracheostomy.
5) Tracheal intubation of patients with difficult airways is often performed using a flexible bronchoscope.

COMPLICATIONS AND RISKS

Though the complications from flexible bronchoscopy are extremely low, care needs to be taken to avoid trauma to the mucous membrane of the airways, laryngospasm and excessive bleeding while doing biopsy. Fiberoptic intubation should be avoided in presence of pharyngeal abscess and blood and secretions in the oral cavity.



REVIEW OF LITERATURE

1) Pravesh Kanthed et al conducted a study in anaesthetised paralysed children to compare LMA Classic with LMA Proseal. A prospective randomised study was carried out in which 100 children of either sex, aged 1 - 8 years, weighing 10 – 30 kg of ASA physical status I – II who were scheduled for elective lower abdominal or inguinal surgical procedures were enrolled. Children were randomly allocated to either PLMA or CLMA group. After induction of anaesthesia with 50% nitrous oxide in oxygen and sevoflurane (6 – 8%) and neuromuscular blocade with atracurium besylate 0.5 mg/kg the device was inserted. The ease of insertion, no.of attempts were noted. The PLMA or CLMA was connected to a circle breathing system and the cuff was inflated to a pressure of 60 cm H2O using a cuff pressure monitor. After ensuring effective ventilation of the deice by bilateral chest movements and square wave capnograph trace on manual ventilation, the oropharyngeal seal pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 5 litres/min and recording the airway pressure at which equilibrium was reached. The fibreoptic grading of the airway tube was carried out. The fibreoptic position was graded as 1:vocal cords not seen;2:vocal cords and anterior epiglottis visible; 3:vocal cords and posterior epiglottis visible ; 4:vocal cords and posterior epiglottis visible; 4:only vocal cords visible. The complications like nausea, vomiting, laryngospasm, bronchospasm, regurgitation, aspiration, blood on mask and hoarseness were noted. They also noted the ease of insertion of the orogastric tube. They found that the ease of insertion was similar for both devices. The mean time taken to obtain an effective

airway were comparable in the two groups. First attempt success rate was similar between PLMA and CLMA. (94% and 98% respectively). There was statistically significant difference (P<0.001) between the two groups with respect to OSP, with PLMA group exhibiting higher OSP (18.72 cm of H2O) than CLMA group (15.43 cm of H2O). There was no statistically significant difference in the fibreoptic grading between the two groups. In 2 patients in PLMA group, the fibreoptic grade was 1 due to medial in folding of cuff of PLMA in these cases. The complications were comparable and no statistical significance was found. They concluded that PLMA is easy to insert in paediatric population and though the fibreoptic grading was similar for PLMA and CLMA, the greater OSP, adequateventilation and oxygenation without any gastric distension with the PLMA would give it an upper hand over CLMA.

2) H.Shimbori et al did a similar study in 60 ASA physical status I-II patients aged 1 – 6 years weighing 10 – 20 kg undergoing herniorrhaphy, myringotomy and orchiopexy. They found that the ease of insertion and airway sealing pressure were similar between the two LMAs. They tested only size 2 LMA which lacks a rear cuff. They attributed the similarity between the two LMAs to lack of this rear cuff in the size 2 LMA which is instrumental in forming a better seal than classic LMA. They also found no difference in the fibreoptically determined anatomical positions of the two LMAs.
3) Duncan Johnson and David Lardner et al also compared LMA Classic and LMA Proseal during positive pressure ventilation in children. They randomly allocated 49 children, ASA I and II, 10 – 20 kg to receive either a size 2 CLMA or PLMA. Oropharyngeal leak was defined as airway plateau pressure during inspiratory hold with a closed APL valve and FGF of 200ml/ kg/ min. A blinded observer assessed gastric insufflations by epigastric auscultation. They also did not find any significant difference between the 2 groups for OPL. They graded the laryngeal view through a 5.3 mm fibreoptic bronchoscope as: 1) Trachea in line with distal lumen of LMA and clear view of glottis.
2. Glottis and posterior epiglottis visible.
3. Glottis and anterior epiglottis < 50% glottis obscured.
4. Glottis and anterior epiglottis >50% glottis obscured.
5. Glottis not seen.

Grades 1 – 3 were taken as satisfactory.

Laryngeal view was rated as satisfactory more often with the PLMA. Thus they concluded that size 2 CLMA and PLMA have similar functional characteristics during IPPVwith a manageable airway leak in most patients at Pinsp < 20 cm H2O but for fibreoptic laryngoscopy , the PLMA is a significantly better conduit.

4) Brimacombe J and Keller C compared PLMA with the standard LMA in 60 paralyzed, anesthetized adult patients. Both the devices were inserted in each patient. They noted the airway sealing pressure and fibreoptic position during cuff inflation from 0 to 40 ml in 10 ml increments. Gastric tube insertion was attempted with the PLMA if there was no gas leak from the drainage tube. They found that it was more difficult to insert the PLMA unless an introducer tool was used. Airway seal pressure was found to be 8 – 11 cm H2O higher for the PLMA at all cuff volumes (P<0.00001) and was higher in female patients for both devices. Fibreoptic position was found to be better with the LMA at all cuff volumes (P<0.00001) but vocal cord visibility was similar. For PLMA, gastric tube placement was successful in all the patients.
5) A.I.J. Brain et al introduced the LMA Proseal via a preliminary crossover comparison with the standard mask in 30 adult female patients undergoing procedures under general anaesthesia. They paralysed all the patients before inserting the devices. They defined effective ventilation as ability to achieve expired tidal volume of more than 8 ml/kg. They found that ease of insertion was equal for both the devices. The insertion tool did not affect the ease of insertion. At an intracuff pressure of 60 cm of H2O, they found the mean seal pressure were twice as high with the Proseal LMA as with the standard LMA. They graded the fibreoptic view as 1=full view of cords, 2= view of cords partially blocked by epiglottis, 3= only arytenoids visible, 4= no laryngeal structures visible. A score of 1 was found in 15 Proseal LMAs and 13 Classic LMAs, whereas scores of 2 and 3 were found in 5 Proseal and 7 Classic LMAs. But statistically the difference was not significant. They found that the nasogastric tube insertion was easy in 28 patients and difficult in 2 patients in the Proseal LMA. The complications were comparable between the two LMAs in their study.
6) Brimacombe J et al also did a multicenter syudy in 2002 in which three hundred eighty four nonparalyzed anesthetised patients of ASA I – II status were subjectedrandomly to PLMA or CLMA for airway management. They also subjected 50% of thepatients randomly for orogastric tube placement. Unblinded postoperative data. They had a higher first attempt success rate for the CLMA (91 vs 82%, P = 0.015). The time taken to achieve an effective airway with the CLMA was less than that for PLMA (P=0.02). But the PLMA was found to provide a more effective seal (P< 0.0001). They found a better view fibreoptically with the CLMA (P< 0.0001). Orogastric tube insertion was found to be more successful after two attempts (P< 0.0001) and quicker with the PLMA. They also had failure of PLMA twice in the form of leak and stridor and of the CLMA once due to laryngospasm. Total intraoperative complications and incidence of sore throat were similar for both the groups. Their conclusion was that in anesthetized, nonparalyzed patients, it was easier and quicker to insert the CLMA but the oropharyngeal seal was better and the placement of orogastric tube placement was faster in patients with PLMA. There was no statistically significant difference between the two groups in terms of intraoperative and postoperative complications.
7) Lardner DR et al had done a study comparing the two LMAs in ventilated children receiving neuromuscular blockade. They conducted a randomized, controlled, single – blinded study in 51 ASA I or II children weighing 10 – 20 kg. They found that the oropharyngeal leak pressure measured by neck auscultation was higher for the PLMA compared to the CLMA (P=0.009). But when they measured the oropharyngeal leak pressure by inspiratory hold maneuver they did not find any significant difference. The fibreoptic view of larynx was found to be satisfactory more often with the PLMA rather than the CLMA group (P= 0.003). Gastric insufflations during leak determination was more common with the CLMA (P = 0.006). They concluded that the size 2 PLMA gave a higher leak pressure by auscultation and lesser gastric insufflations compared to CLMA in children undergoing IPPV with neuromuscular blockade and that the fibreoptic view was marked better with the PLMA.
8) Bimla Sharma et el did a comparative evaluation of respiratory mechanics of PLMA vrs I – gel in patients undergoing laparoscopic cholecystectomy. They evaluated boththe LMAs in terms of dynamic compliance, the oropharyngeal sealing pressure and the fibreoptic view. They studied the respiratory mechanical parameters (dynamic compliance, resistance, work of breathing, measured minute ventilation and peak airway pressures) of the two LMAs using the respiratory mechanics module (RESP MECH MODULES M F 4RM0777G, GE Medical Systems by Novametrix Medical Systems, Wallingford, USA) and found that the respiratory mechanics parameters using the two devices were comparable apart from the dynamic compliance, which was significantly higher with i – gel (P< 0.05). The oropharyngeal leak pressure as measured by closing the expiratory valve of the circle at a fixed gas flow of 5 litres/min and recording the pressure at which an audible sound was heard from the mouth, was higher for PLMA (P= 0.007). The fibreoptic grading was comparable in the two groups but malrotation was found more commonly with the i–gel. They concluded that both the LMAs provided optimal ventilation and oxygenation but the PLMA formed a better seal while the i-gel provided a higher dynamic compliance.
9) Woo Y C et al did a study in which they compared PLMA with Streamlined Liner of the Pharynx Airway (SLIPA) in mechanically ventilated paralyzed patients undergoing laparoscopic gynaecologic surgery. One hundred and one patients were subjected to SLIPA or PLMA group. They found the two devices to be comparable in terms of insertion success rate, gastric insufflations, perilaryngeal leakage, fibreoptic score, respiratory mechanics and severity of sore throat, and incidence of blood and regurgitated fluid on the device. However they found that SLIPA caused less perilaryngeal gas leakage than the PLMA with change in head position and during insufflations of teh peritoneal cavity.
10) Janakiraman, C, Chethan DB et al, Anaesthesia 2009 june; 64(6): 674-8 In a randomised cross-over study, they compared the performance of a single use i-gel supraglottic airway and reusable classic laryngeal mask airway (CLMA) in 50 healthy anesthetised

patients who were breathing spontaneously. Primary outcome was successful insertion at first attempt. Secondary outcomes included overall insertion success rate ease of insertion, leak pressure and fibreoptic position. Success rate for insertion at the first attempt was significantly different (54% with i=gel vs 86% withCLMA : P=0.001). Overall success after two attempts (when the anaesthetist was allowed to change the size of the device) improved to 84% with i-gel vs 92% with CLMA; P=0.22. Leak pressure was higher for the i-gel (median 20 cm H2O) than the CLMA (median 17 cm H2O); P=0.023. The fibreoptic view through the device was significantly (p=0.03). They conclude that with the current sizing recommendations, the i-gel is not an acceptable alternative to CLMA. However because of the significantly improved success rate after a larger sized i-gel was used, they recommended the manufacturer to review the sizing guidelines to improve the success rate.

11) Natalini G, franceschetti 34 Br J anaesth, 2003 mar;90(3):323-6 They compared the standatd laryngeal mask airway and the proseal laryngeal mask airway in obese patients. Sixty obese patients (BMI>30) were randomized to receive mechanical ventilation (tidal volume 7 ml/ kg, PEEP 10 cm H(2)O, through either the PLMA or the LMA. A gastric tube was used in all patients. Cuff pressure was set at 60 cm H(2)O and increased progressively until excessive leak occurred. The incidence of sore throat was assessed at recovery and after i week. They observed that the mean leak fraction was 6.1 (SD2.9)% with the LMA and 6.4 (3.5)% with the PLMA (p=0.721). with no sign of ventilation problems, the drainage tube was not patent in three patients. The cuff pressure was >100 cm H(2)O in 38% of the LMA group and 7% of the PLMA group (p=0.05). the incidence of sore throat was similar in both groups and it was similarly scored in the recovery room and i week after surgery. Their conclusion was that both the PLMA and the LMA can be used for mechanical ventilation of obese patients. The patency of the PLMA drainage tube needs to be checked constantly even when an optimal airtight seal is present. In obese patients the LMA requires a greater cuff pressure than the PLMA , but sore throat is not related to the cuff pressure. Sore throat assessment in the recovery room appears as reliable as assessment later.
12) T.M.COOK,C.VERGHESE et al (Br.journal of anaesthesia 2002) did a randomised study comparing PLMA and cLMA in anesthetised , unparalysed patients. They found that the proseal took more time and more attempts to insert successfully thanthe classic laryngeal mask airway. Insertion was successful on the first attempt in 81% of cases with the proseal and 90% with the classic laryngeal mask airway. The proseal required more air ti achieve an intracuff pressure of 60 cm H2O (6ml more for size 4 and 12 ,l more for size5). Laryngeal seal pressure was better with the proseal than the classic laryngeal mask airway. Median seal pressure was 29 cm H2O with the proseal and 18 cm H2O with the classic laryngeal mask airway. Laryngeal seal pressure was greater than 40 cm H2O in 87% of patients with the proseal and 41% with the classic laryngeal airway. Laryngeal seal pressure was greater than 40 cm H2O in 21% of patients with the proseal and in none of the patients with the classic laryngeal masl. Once placed, the proseal remained a stable and effective airway. Gastric tube insertion through the drain tube was attempted in 147 cases and was successful in 135 (92%). They concluded that the proseal was more difficult to insert than the cLMA but allowed positive pressure ventilation more reliably than the CLMA.
13) Suman sarkar et al did a study on use of the proseal laryngeal mask airway in facilitating percutaneous dilatational tracheostomy in 60 patients in intensive care unit. They found that pro-seal LMA provides a reliable airway and allows effective during percutaneous tracheostomy . They inserted a fiberopitc bronchoscope through the proseal LMA to aid the correct placement of the guidewire and found that the passage of the fiberscope through the poseal LMA was easy and provided a good and clear view of the glottis as well as trachea.
14) Uday Ambi et al compared classic and proseal LMA in 50 paralyzed and anaesthetize adult patients. They concluded that the proseal LMA caused minimum change in the haemodynamics on insertion and formed a reliable airway securing device as it formed an effective glottis seal and ensured better ventilation than classic LMA.
15) Soad A. Mansour et al compared the safety and efficacy of proseal LMA with classic LMA and endotracheal tube during elective surgery in paralysed adult patients. They found that there was significant haemodynamic response in all 3 groups on insertionas well as removal of device. The fiberoptic score was comparable in both the LMAs. The rate of insertion was also comparable. Oxygenation and ventilation after carboperitoneum was optimum in proseal LMA and endotracheal tube but was suboptimal in the classic LMA. They found that the complications like sore throat, bronchospasm and postoperative vomiting were more common with endotracheal tube and less in both the LMAs.
16) Birmacombe et al assessed the stability of classic LMA and proseal LMA in various head and neck positions in thirty anaesthetised and paralysed adult male patients. They found that both the LMAs had a stable anatomical position despite changes in head and neck positions as judged with fiberopitc bronchoscope. The head and neck flexion and rotation were associated with an increase and head and neck extension a decrease in oropharyngeal sealing pressure and intracuff pressure.
17) Bikramjit Das et al compared classic and proseal LMAs were comparable in terms of hemodynamic response and oropharyngeal sealing pressure. The time taken for insertion and the airway trauma was found to be more with proseal than classic LMA in their study.
18) Tulay Hosten et al compared supreme LMA and proseal LMA in anaesthetrised patients posted for laparoscopic cholecystectomy and found the oropharyngeal sealing pressure to be comparable in both the groups. The attempt success rate was equal in both the groups. The first attempt success rate was equal in both the LMAs. The mean airway device insertion time was significantly shorter with supreme LMA. The pharyngolaryngeal morbidity was also similar in both the groups.
19) Joo Hyun jun et al in their study compared the ease of proseal LMA insertion and the foberoptic scoring in the presence of a difficult airway and with different head position. They concluded that a difficult airway and a change in head position did not alter the ease of PLMA insertion and the fiberoptic score. They recommended that the head position can be selected according to the individual patient's condition.
20) Keller C et al (2000) did a study on interobserver variability of a fibreoptic scoring system for assessing the position of LMA, the flexible LMA(FLMA) and the intubating laryngeal mask airway (ILMA) and a comparison between the standard, flexible and intubating laryngeal mask airways. Thirty anaesthetised adult patients were studied in random order in a triple crossover manner. Two observe blinded to each others findings scored the fibreoptic positon as follows: 4, only vocal cords visible; 3, vocal plus posterior epiglottis visible;2, vocal cords plus anterior epiglottis visible; 1, vocal cords not seen. Interobserver variability was graded as excellent for the LMA (ICC=0.89), FLMA (ICC=0.87)and ILM(ICC=0.79). They found the fibreoptic scores to be higher for the LMA and FLMA compared with the ILM group (both p<0.001). They suggested that fibreoptice scoring has potential utility for research and clinical practice with laryngeal mask airways.

MATERIALS AND METHODS:

STUDY DESIGN:

This study was conducted in institute of obstetrics and gynaecology, Chennai from January 2012 to march 2012. The study was a single blinded, randomised, prospective comparative evaluation of the two supraglottic devices.

Study setting and population:

After obtaining institutional ethical committee clearance, sixty ASA I-II female patients undergoing short duration gynaecological surgeries under general anaesthesia were enrolled for the study. The insertion of the devices and collection of the data was done by the author.

Patient selection: Inclusion criteria:

1. 18-60 years
2. BMI<30kg/m2
3. ASA I-II
4. MPC I-II airway
5. Sugery:elective
6. Who have given valid informed consent

Exclusion criteria:

1. Not satisfying inclusion criteria
2. Patients with difficult airway
3. Pregnant female

4. History of gastro oesophageal reflux disease
5. Patients with acute or chronic respiratory disease.
6. Patients with museloskeletal abnormality affecting cervical vertebra.
7. Patients with history of allergic reactions to the drugs used in they study.

The current study was designed to find out whether a functional difference exists between LMA proseal and LMA classic in terms of ease of insertion , airway leak, fibreoptic laryngeal view and the complications.

The sample size was calculated using power analysis to get an expected 30% difference between the two groups in ease of insertion, oropharyngeal leak pressure, fibreptic view and the complications with alpha =0.05 and power of beta =0.8.

The patients were randomly assigned to one of the two groups viz group P (proseal) and Group c (classic) using a closed envelope with predetermined numbers and then single blinded.

The patients were evaluated the day before surgery with complete medical history, physical examination and investigations. They were kept fasting overnight and tab.ranitidine 150 mg and tab.meto clopramide 10mg were given as acid aspiration prophylaxis the night before surgery.

In the operation theatre, ECG, pulse oximeter and non invasive blood pressure monitors were connected. The patients were premedicated with inj. Glycopyrrolate 0.2 mg I.M., inj. Ranitidine 50 mg and inj. Metoclopramide 10 mg I.V half an hour before inductionof general anaesthesia. Inj. Fentany 12 mg/kg was given to all patients 5 mins prior to induction. The patients were preoxygenated with 100% oxygen for 3minutes. Preinduction baseline cardio-respiratory parameters like H.R.,B.P and oxygen saturation were recorded. Anaesthesia was induced by inj. Propofol 2mg/kg followed by neuromuscular blockade with inj. Atracurium 0.5 mg/kg. Patient was entilated with bag and mask with sevoflurane and oxygen for 3 minutes and an appropriate sized LMA , based on body weight was inserted. The patient was given a morning sniffing the air position by giving head extension and neck flexion. In patients weighing between 30 – 50 kg size 3 LMA was used and in patients weighing between 50 – 70 kg size 4 LMA was used in both the groups as per the manufacturer's instructions. Both the devices were inserted by the standard technique as per the manufaturer's instructions. Proseal LMA was inserted without the introducer to maintain parity between the insertion techniques of both the LMAs. After insertion the cuff was inflated with the recommended volume of air for that particular size. The proper insertion of LMA was confirmed by ability to achieve effective ventilation that is adequate chest movement bilaterally and the ability to achieve an expiratory tidal volume of 7 ml/kg. The LMA was fixed and the cuff pressure was checked with the help of Portex cuff pressure monitor and ensured to be 60 cm of H2O. Anaesthesia was maintained with oxygen in nitrous oxide (1:3) with sevoflurane 1–2% and additional doses of Inj atracurium if the patient came out of neuromuscular blockade before the end of surgery. The ease of insertion, the number of attempts for insertion and the time taken for insertion were recorded. Then the H.R.B.P. and the oxygen saturation at 1 and 5 minutes post insertion of LMA were also noted down.

Ease of insertion was graded as:

1. Easy, without any resistance
2. Difficult, with some resistance
3. Impossible

In case of failure to insert the LMA properly as judged by an audible leak or inability to achieve adequate chest expansion, the device was removed and reinserted. Maximum three attempts were allowed and if effective ventilation could not be achieved endotracheal intubation was planned.Time taken for insertion was defined as time elapsed between picking up of an airway device in hand and achieving effective ventilation.

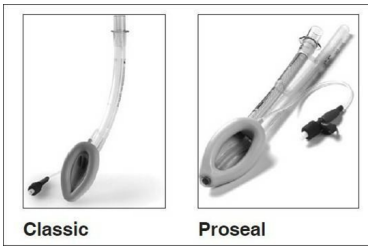
The oropharyngeal leak was determined by closing the adjustable pressure limiting (APL) valve of the circle system at a fixed gas flow of 3 litres/min and recording the airway pressure at which equilibrium was reached (maximum allowed was 40 cm H2O). Equilibrium was taken as the point at which an audible leak could be heard from the mouth. The Dragger machine with the provision of recording airway pressures was used.

After recording the above observations, at 4.9 mm fibreoptic bronchoscope was passed through the LMA till its tip lies 1 cm proximal to the end and the view was assessed by a standard score devised by Brimacombe and Keller.

Grade 1 : vocal cords not seen
Grade 2 : vocal cords and anterior epiglottis seen Grade 3 : vocal cords and posterior epiglottis seen Grade 4 : only vocal cords seen.
Grade 3: and 4 were taken as desired views, grade 2 as satisfactory while grade 1 as non satisfactory view.

The surgery was then allowed to commence and intraoperative and postoperative complications like bronchospan, aspiration, nausea, vomiting, sore throat and blood staining of the device after removal were noted and treated.

At the end of surgery, the neuromuscular blockade was reversed with Inj. glycopyrrolate and inj. neostigmine and the LMA was removed when patient was conscious and obeying commands. Patient was shifted to recovery room and observed for 6 hours and the sore throat was assessed immediately and 6 hours after surgery.



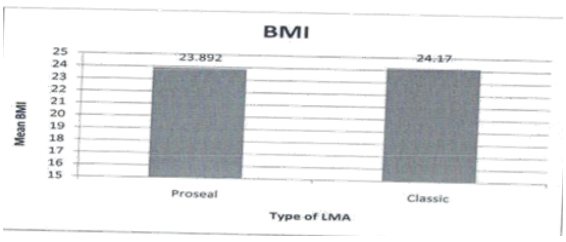
OBSERVATIONS AND RESULTS:

This study was conducted in sixty ASA I – II adult female patients who underwent elective short duration gynaecological surgical procedures. It was ensured that they had fulfilled the inclusion and exclusion criteria as mentioned in the chapter materials and methods. The data was analysed using G-Power statistical tool. The qualitative parameters such as ease of insertion, number of attempts, fibre-optic score and the complications were analysed using the Pearson Chi – square test. The quantitative parameters such as demographic data, the time taken for insertion, the oropharyngeal sealing pressure (OSP) and the hemodynamics were analysed using the unpaired T test.

Demographic Characteristics

The two groups PLMA and CLMA were comparable with respect to the demographic characteristics. There was no significant difference between the two groups in terms of age in years of the BMI.

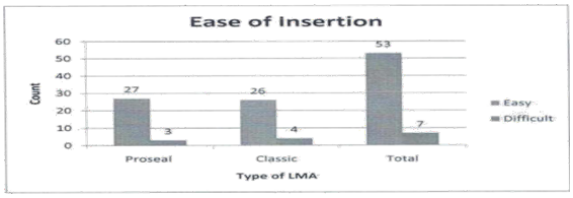
	Group PLMA	Group CLMA	P value	Statistic Significance
Age	38.63	42.17	0.138	NS
BMI	23.89	24.17	0.649	NS



EASE OF INSERTION

	Proseal	Classic	Total
Easy	27	26	53
Difficult	3	4	7
Total	30	30	60

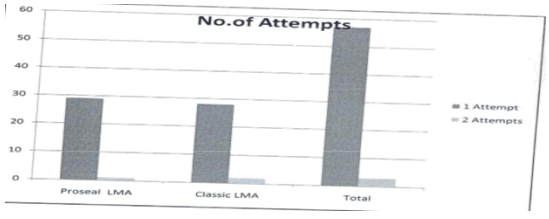
The ease of insertion of both the device was comparable and the p value was nor significant . Out of the total number of 60 patients, the insertion was easy in 53 cases and was difficult in only 7 cases. It was noticed that, within the cases easy for insertion, 50.9% were those of Proseal LMA and 49.1% were those of Classic LMA. 90% of the cases of Proseal LMA had easy insertion whereas 86.7% cases of Classic LMA had easy insertion. This is evident from the table and charts.



Number of Attempts Required for Insertion

No of attempts	Proseal	Classic	Total
First	29	28	57
Second	1	2	3
Total	30	30	60

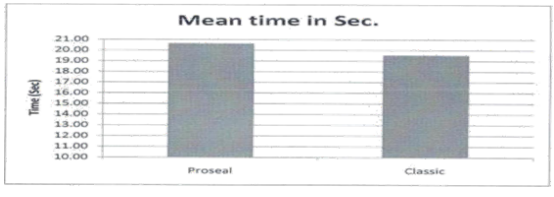
The number of attempts required for insertion was also comparable and the p value was not significant. Out of the total number of 60 patients, the insertion was achieved in first attempt in 57 patients and second attempt was required only in 3 cases out of which 2 were for Classic LMA and one was for Proseal LMA.



Time taken for Insertion

	Group PLMA	Group CLMA	P value	Statistic Significance
Mean Time (Sec)	20.63 = 3.908	19.53 = 6.067	0.407	NS

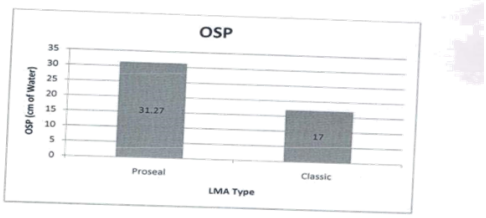
Time taken for insertion was also comparable and the p value was not significant. The mean time required for insertion of Proseal LMA was 20.63 seconds as against the mean time of 19.53 seconds required in case of Classic LMA.

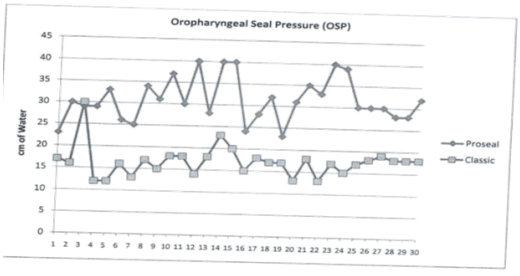


Oropharyngeal Sealing Pressure (OSP)

	Group PLMA	Group CLMA	P value	Statistic Significance
OSP (cm of water)	31.27 = 5.065	17.00 = 3.464	< 0.001	S

The oropharyngeal sealing pressure was found to be significantly higher with the proseal LMA. The mean OSP achieved with PLMA was 31.27 compared to 17 cm of H2O with the Classic LMA. The P value was <0.001 and was statistically significant. The maximum OSP with PLMA was 40 cm of H2O and it was achieved thrice. The maximum OSP with CLMA was 30 cm of H2O but it was attained only once.

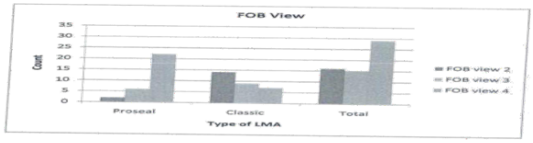


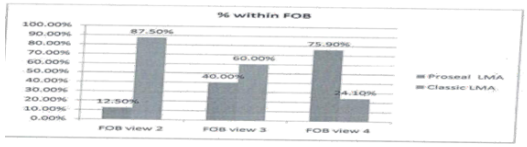


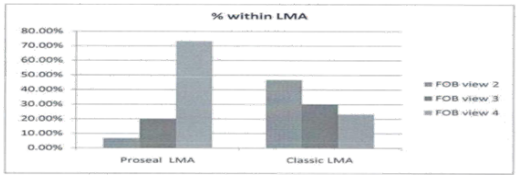
Fibre – optic Score

	Proseal	Classic	Total	P – value	Statistical Significance
FOB view 2	2	14	16	<0.001	S
FOB view 3	6	9	15		
FOB view 4	22	7	29		

The fibreoptic view was found to be significantly better with the Proseal LMA than the Classical LMA. Grade 3 and Grade 4 were taken as the desired views whereas Grade 2 was taken as satisfactory. It was seen that, out of 30 patients with Proseal LMA, the view was Grade 4 in 22, Grade 3 in 6 and Grade 2 in 2. Whereas, Classic LMA gave Grade 4 view in 7 patients, Grade 3 view in 9 patients and Grade 2 view in 14 patients out of the total number of 30.None of the patients in both the groups had Grade 1 view. This difference is highly significant statistically with the P-value being less than 0.001. Out of the total number of 44 cases which gave the desirable view i.e., Grade 3 and Grade 4 FOB views, 63.6% cases were those of Proseal LMA and only 36.7% cases were those of Classic LMA. Within the total number of 30 cases each of Proseal LMA and Classic LMA, the desirable view was achieved in 93.3% cases of Proseal LMA and only 53.3% cases in case of Classic LMA.





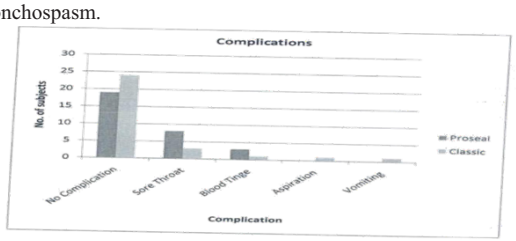


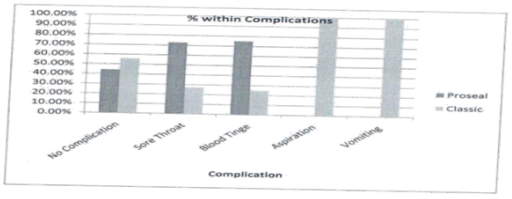
COMPLICATIONS

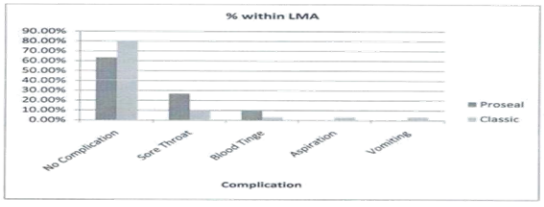
	Proseal	Classic	Total
No Complication	19	24	43
Sore Throat	8	3	11
Blood Tinge	3	1	4
Aspiration	0	1	1
Vomiting	0	1	1
Total	30	30	60

In terms of development of either intraop ot postop complications, the difference between the two groups was not found to be significant. Out of total number of 60 cases, 43 did not have any complications at all. 17

cases in which complications were observed, the majority of 11 developed sore throat, 4 had blood tinge and 1 each aspiration and vomiting. None of the cases had severe complications such as bronchospasm.



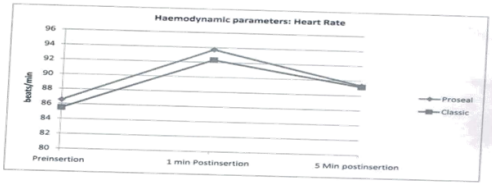




Haemodynamic parameters: Heart Rate

Heart Rate	Proseal	Classic	P – value	Statistic Significance
Preinsertion	86.53 = 9.822	85.47 = 10.624	0.688	NS
1 min Postinsertion	93.73 = 7.524	92.33 = 12.047	0.591	NS
5 min Postinsertion	89.33 = 6.682	89.17 = 9.660	0.938	NS

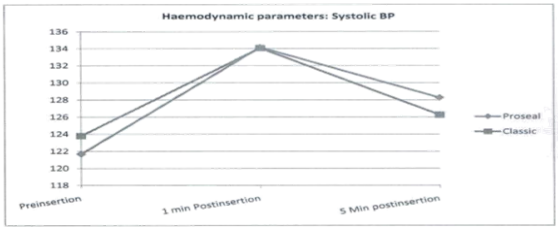
Comparison of preinsertion, 1 min postinsertion and 5 min postinsertion Heart Rate in proseal and Classic LMA cases did not show any statistically significant difference as evidence from the above table.



Haemodynamic parameters: Systolic BP

Systolic BP	Proseal	Classic	P – value	Statistic Significance
Preinsertion	121.67 = 11.050	123.8 = 13.522	0.506	NS
1min Postinsertion	134.17 = 11.920	134.07 = 19.142	0.981	NS
5min Postinsertion	128.27 = 11.471	126.27 = 18.103	0.611	NS

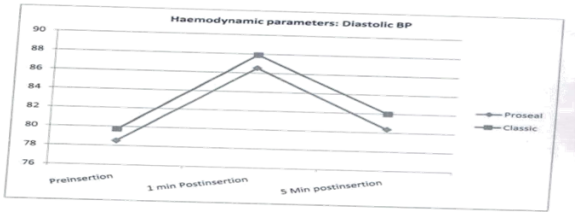
Comparison of preinsertion, 1 min postinsertion and 5 min postinsertion Systolic Blood Pressure in Proseal and Classic LMA cases did not show any statistically significant difference either.



Haemodynamic parameters: Diastolic BP

Diastolic BP	Proseal	Classic	P – value	Statistic Significant
Preinsertion	78.50 = 7.758	79.73 = 8.497	0.559	NS
1 min Postinsertion	86.53 = 8.939	87.9 = 19.951	0.733	NS
5 min Postinsertion	80.37 = 8.904	82.00 = 9.176	0.487	NS

Comparison of preinsertion, 1 min postinsertion and 5 min postinsertion Diastolic Blood Pressure in Proseal and Classic LMA cases too did not show any statistically significant difference.



DISCUSSION:

This study was conducted in Institute of Obstetrics and Gynaecology (MMC, Chennai) between January 2012 to March 2012 and involved 60 patients in ASA I – II physical status. They were randomized into 2 groups PLMA and CLMA and the following parameters were analysed:

1. Ease of insertion
2. Number of attempts for insertion
3. Time taken for insertion
4. Fibreoptic score
5. Orophatyngeal sealing pressure
6. Complications

We have demonstrated in our study that the Proseal LMA forms a more effective seal around the larynx than Classic LMA functionally as well as anatomically.

The demographic data was comparable between the two groups hence the bias against age and weight distribution was ruled out.

In our study, we found that the ease of insertion was comparable in both the groups. The LMAs could be inserted in all the patients and there was no failure or the need to insert an alternative device or intubate the patient. The Proseal LMA being bulkier than the classic LMA, an introducer is recommended. But we inserted it without the introducer and found no difficulty in ease of insertion. The time taken for insertion of the two devices and the number of attempts for insertion were similar for both the devices with the p value being not so significant. This was in accordance with the findings of Pravesh Kanthed et al and H.Shimbori et al who did a similar study in children. The pilot study done by A.I.J. Brain et al in adult female patients during the introduction of the Proseal LMA also had similar findings. But the studies done by Brimacombe et al in adult patients concludes that the Proseal was more difficult to insert and took longer time for insertion than the Classic LMA. This discrepancy could be because of the insertiontechnique. They also compared the time for insertion with and without the introducer and found that the use of introducer made the insertion of Proseal easy. However A.I.J.Brain et al found that the introducer made no difference with regards to the ease of insertion.The primary variables studied in our study were the Fibreoptic scoring and the oropharyngeal sealing pressure. The fibreoptic score was better with Proseal LMA more often than with Classic LMA. The fibreoptic scores were (1,2,3,4): Classic LMA (0,14,9,7) and Proseal LMA (0,2,6,22). The p value was placed at <0.001 and was highly significant. This finding correlated with the study of Lardner et al who also found that the Proseal gave a better view of the cords. A.I.J.Brain et al also found that the proseal LMA gives full view of the cords more number of times than the Classic (15 for proseal vrs 13 for classic) but statistically the difference was not significant in their study. The fibreoptic scoring of the LMA has many implications. It is very difficult to predict the placement of LMA clinically and fibreoptic assessment is the gold standard for assessing the placement of LMA. A properly placed LMA not only provides good seal around the larynx

and improve ventilation but also decreases the risk of aspiration. Also a separate study done by T.M.Cook et al with the use of a Proseal LMA and a Ravussini cricothyroid needle in the management of laryngeal and subglottic stenosis causing airway obstruction has shown that a good fibreoptic view can help in procedures like vocal cord biopsy in patients with growth over the vocal cord. A study done by Rosilu Ferreira Barbosa with Proseal LMA for surfactant administration in the treatment of Respiratory Distress Syndrome in a premature infant has demonstrated that surfactant can be delivered effectively through the LMA. Here also the proper placement of the LMA is the key for the proper dispersion of the drug. The reasons for Proseal LMA giving a better view of the larynx could be that its dorsal cuff pushes the ventral cuff more firmly into the periglottic tissues and thus not only forms a better seal around the larynx but also prevents rotation of the LMA and thus provides stability to the device.

The orophayngeal pressure was the other primary variable tested. We found significant difference between the 2 LMAs in terms of the leak pressure with the p value being <0.001. This was in accordance with most of the studies in adult patients though the studies done by Duncan Johnson et al and H.Shimbori et al in paediatric patients found no difference between the 2 groups with regard to the leak pressure. They used size 2 Proseal LMA which lacks the dorsal cuff and have sighted that as a reason for finding no difference between the 2 groups. While similar studies by Pravesh Kanthed et al in paediatric patients with size 2 Proseal LMA have found a significantly higher leak pressure with the Proseal LMA.

The complications were comparable between the 2 groups and the p value was not significant.

SUMMARY:

Laryngeal Mask Airway has come a long way since its introduction in the year 1988 with multiple modifications coming up. The Proseal LMA is one such modification of the Classic LMA which incorporates additional features like a dorsal cuff and a drain tube by virtue of which it forms a better seal around the larynx. But, as mentioned earlier, although newer versions are increasingly seen in the Anaesthesiologist's armoury, the Classic LMA has its own place.

Hence we have compared these two LMAs in terms of ease of insertion, the time taken for insertion, the number of attempts required for insertion, the fibreoptic view after the insertion, the oropharyngeal sealing pressure and complications.

This study was performed on 60 ASA I – II physical status female patients who were undergoing elective short duration gynaecological surgeries under general Anaesthesia. The ethical committee approval and the patient's consent were obtained before starting the study. The study was a single blinded randomised study and the observations were done by the author after inducing general anaesthesia with a standard protocol.

We observed no significant difference between the two LMAs in terms of ease of insertion, number of attempts and time taken for insertion. The fibreoptic view was significantly better with the Proseal LMA. The Oropharyngeal sealing pressure also was significantly higher than that of Classic LMA. There was no difference in the two LMAs in terms of complication both intra and postop. The haemodynamic response on insertion was also found to be comparable between the 2 LMAs.

CONCLUSION:

We hereby conclude that, Proseal LMA not only gives a better anatomical fit int the laryngopharynx as compared to the Classic LMA but also allows significantly better ventilator conditions as assessed by the fiberoptic view and the oropharyngeal sealing pressure, respectively. There is no difference between the two LMAs in terms of ease of insertion, intra and postop complication and haemodynamic parameters.