COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VS ENDOTRACHEAL TUBE AS A VENTILATORY DEVICE IN ANAESTHETISED PARALYSED PATIENTS FOR VARIOUS ELECTIVE LAPAROSCOPIC PROCEDURES.

A STUDY OF 100 CASES

Dissertation submitted for the Degree of

Doctor of Medicine

(Branch-X Anaesthesiology)

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THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY
CHENNAI.

CERTIFICATE

This is to certify that the dissertation entitled **"A COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VS ENDOTRACHEAL TUBE AS A VENTILATORY DEVICE IN ANAESTHETISED PARALYSED PATIENTS FOR VARIOUS ELECTIVE LAPAROSCOPIC PROCEDURES"** is a bonafide record work done by DR. R.GANESAPANDIAN, in the Depar.ent of Anaesthesiology, Government Rajaji Hospital, Madurai Medical College, Madurai.

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DECLARATION

I**, DR. R.GANESAPANDIAN** solemnly declare that the dissertation titled **"A COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VS ENDOTRACHEAL TUBE AS A VENTILATORY DEVICE IN ANAESTHETISED PARALYSED PATIENTS FOR VARIOUS ELECTIVE LAPAROSCOPIC PROCEDURES''** solemnly declare that the dissertation titled **"** has been prepared by me.

This is submitted to The Tamilnadu Dr.M.G.R.Medical University, Chennai, in partial fulfillment of the regulations for the award of MD degree Branch X [Anaesthesiology].

Madurai. **DR. R.GANESAPANDIAN**

Date:

ACKNOWLEDGEMENT

I am deeply indebted to all the patients for submitting themselves for this study and I express my heartfelt gratitude to all of them.

It was with great trepidation and with a sense of unknown that I ventured into one of the novel and most advancing branches of Medicine, Anaesthesiology. It is to the credit of my teachers that I managed to stay and began working on my dissertation.

If not for my Professor **DR.S.SUBBIAH,** MNAMS, DA., M.D., DCH., Chief and Head of Depar.ent of Anaesthesiology, Madurai Medical College, Madurai who gave invaluable guidance and inspiration, this study would not have consummated to its logical conclusions. I sincerely thank him for his encouragement and support at every stage of this study.

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TABLE OF CONTENTS

INTRODUCTION

Laparoscopic surgery is an evolving subspeciality and is not only limited to minor gynaecologic surgery or cholecystectomy but has extended to procedures such as appendecectomy, hernia repairs (inguinal, epigastric and incisional), advanced gastrointestinal, urologic and gynaecologic procedures.

The problems common to all such procedures are a) carbon dioxide insufflation in the body-intraperitoneal or extraperitoneal b) raised intra abdominal pressure and c) potential danger of regurgitation and pulmonary aspiration. The anaesthesiologist must ensure a patent airway and adequate ventilation. Till date the cuffed endotracheal tube is considered as ideal for providing a safe glottic seal especially for laparoscopic procedures under general anaesthesia. But over a period of time new airway devices have been added to the anaesthesiologist's armamentarium.

The ProSeal laryngeal mask airway (PLMA) is one such new device. It is a modification of the Classic Laryngeal Mask Airway (LMA). The cuff of the PLMA is specially designed with an aim to provide a more effective seal around the glottis than the Classic

LMA and the drain tube provides a bypass channel for regurgitated gastric contents.

The Classic LMA is not a very popular device for positive pressure ventilation for fear of gastric distension, aspiration of gastric contents and inadequate ventilation. The PLMA offers several advantages over the Classic LMA. It provides a better glottic seal at lower mucosal pressures and isolates the alimentary tract from the respiratory tree. It is superior to the Classic LMA for providing positive pressure ventilation and, at a given intracuff pressure, provides twice the seal pressure of the Classic LMA.

The purpose of this prospective study was to compare the use of the PLMA & Endotracheal tube as a ventilatory device in anaesthetised, paralysed patients for various elective laparoscopic procedures in terms of (a) haemodynamic response to insertion of the PLMA and endotracheal tube intubation, (b) Ventilatory parameters, (c) Postoperative complications.

The study is undertaken with utmost care and the results of the study are discussed.

AIM OF THE STUDY

To compare the use of the PLMA & Endotracheal tube as a ventilatory device in anaesthetised, paralysed patients for various elective laparoscopic procedures in terms of

(a) Haemodynamic response to insertion of the PLMA and endotracheal tube intubation.

(b) Ventilatory parameters.

(c) Postoperative complications.

(d) Ease of gastric tube Placement

(e) Episodes of gastric insufflations

HISTORY

The laryngeal mask airway, a new device in the concept of airway management during anaethesia was invented by Dr. Archie brain at the London hospital, Whitechapel in 1983. Initially laryngeal mask airway was recommended as a better alternative to the facemask for airway management in anaesthetised patients. Clinical testing of several hundred handmade prototypes by the inventor between 1981 and 1988 led to the development of at least 27 varieties with potential clinical applications, five of which are used in anaesthetic practice. Soon after its introduction into the clinical practice in 1988, the laryngeal mask airway has found to be a more effective ventilating device than the facemask and to cause less stimulation of protective airway reflexes and of the cardiovascular system than endroacheal tube. With more than 15 years in clinical use, the laryngeal mask airway has been used safely and effectively in more than 150 million patients world wide, and its clinical applications have greatly expanded to benefit virtually every subspeciality of anaesthesia.

Over a period of time new airway devices have been added to the anaesthesiologist's armamentarium. The ProSeal laryngeal mask airway (PLMA) is one of such new devices.

REVIEW OF LITERATURE

A new type of device to maintain the airway during anaesthesia, the laryngeal mask airway was invented by Dr. A.I.J. Brain in 1981. He published his first report in the year 1983. This device offered some of the advantages of endotracheal intubation and also was useful in patients with difficult intubations. The laryngeal mask was made available to clinical practice in the year 1988. Since then its use has spread rapidly and it is gaining a firm place in anaesthetic practice. The LMA allowed spontaneous breathing as was as intermittent positive pressure ventilation.

The **LMA ProSeal** is the next generation of airway management for the Operating Room. Introduced in October 2000, the **LMA ProSeal** is designed to:

- Improve the laryngeal seal without increasing mucosal pressures
- Separate the respiratory and alimentary tracts
- Provide higher airway seal

1,The ProSeal Laryngeal Mask Airway: A Randomized,Crossover Study with the Standard Laryngeal Mask Airway in Paralysed, Anesthetised Patients.

*Brimacombe, Joseph M.B., Ch.B., F.R.C.A., M.D. *; Keller, Christian M.D.*

The authors tested the hypothesis that ease of insertion, airway sealing pressure, and fiber optic position differ between the PLMA and the standard laryngeal mask airway (LMA). For the PLMA, they also assess ease of gastric tube placement and the efficacy of an introducer tool. They concluded that, PLMA is capable of achieving a more effective seal than the LMA and facilitates gastric tube placement, but it is more difficult to insert unless an introducer tool is used. When correctly positioned, the PLMA isolates the glottis from the upper esophagus with possible implications for airway protection.

2, LMA-Classic and LMA-ProSeal· are effective alternatives to endotracheal intubation for gynecologic laparoscopy

J. Roger Maltby, MB FRCA FRCPC*, Michael T. Beriault, MD FRCPC*, Neil C. Watson, MB FRCPC*, David J. Liepert, MD FRCPC* and Gordon H. Fick, BSc MSc PhD†

They compared the laryngeal mask airways (LMA), LMA-Classic (LMA-C) and LMA-ProSeal· (PLMA) with the endotracheal tube (ETT) with respect to pulmonary ventilation and gastric distension during gynecologic laparoscopy. They concluded that correctly placed LMA-C or PLMA is as effective as an ETT for positive pressure ventilation without clinically important gastric distension in non-obese and obese patients.

3, ProSeal *versus* the Classic laryngeal mask airway for positive pressure ventilation during laparoscopic cholecystectomy†

Authors: P.P. Lu; J. Brimacombe; C. Yang; M. Shyr

They tested the hypothesis that the ProSeal laryngeal mask airway (PLMA) is a more effective ventilatory device than the Classic laryngeal mask airway (LMA‡) for laparoscopic cholecystectomy. They concluded that PLMA is a more effective ventilatory device for laparoscopic cholecystectomy than the LMA.

4, ProSeal laryngeal mask airway in 120 pediatric surgical patients: a prospective evaluation of characteristics and performance.

Wheeler.M

They studied the use of PLMA in 120 children aged 4 months to 13

years (5-50 kg). The following data were collected prospectively: induction agent, number of placement attempts (limited to three), placement success or failure, PLMA size, leak pressure, ventilatory pattern [spontaneous (SV) or controlled positive pressure ventilation (PPV)], success or failure of gastric suction tube placement, hypoxemia, dislodgement, laryngospasm, bronchospasm, aspiration, and traumatic placement.They concluded that, although the PLMA can be used with SV or PPV, the higher leak pressure achieved with the PLMA, and the ability to evacuate fluid and air from the stomach suggest that it may be a useful alternative to tracheal intubation for procedures in which PPV is desired in children aged 4 months to 13 years.

5, Advantages of ProSeal and SLIPA airways over tracheal tubes for gynecological laparoscopies. Miller.DM, ,Camporota L. They compared the efficacy of the ProSeal LMA and SLIPA supralaryngeal airways (SLA) with the standard tracheal tube (TT) in 150 consecutive day-case laparoscopic gynecological surgery procedures requiring general anesthesia. They concluded that the ProSeal LMA (reusable) and SLIPA (single-use) SLAs were easy to

use without requiring muscle relaxants, and reduce operating room time compared to the ETT technique in day case laparoscopies.

6, The ProSeal laryngeal mask airway: a review of the literature.

Cook..,**Lee.G**,**Nolan.JP**.

They analysed the published literature relating to the ProSeal LMA (PLMA): a modification of the "classic LMA" (cLMA) with an esophageal drain tube (DT), designed to improve controlled ventilation, airway protection and diagnosis of misplacement. They concluded that PLMA has similar insertion characteristics and complications to other laryngeal masks. The DT enables rapid diagnosis of misplacement. The PLMA offers significant benefits over both the cLMA and TT in some clinical circumstances.

7, The Proseal LMA is a useful rescue device during failed rapid sequence intubation: two additional cases.

Cook ., **Brooks TS**, **Van der Westhuizen J**, **Clarke M**.

They report two cases where the ProSeal laryngeal mask airway (PLMA) was successfully used as a rescue device, after failed tracheal intubation, during rapid sequence induction. They concluded that the correctly placed PLMA has potential advantages over the CLMA for airway rescue in the circumstance of failed emergency intubation in a patient with a potentially full stomach. In the two cases reported, the PLMA provided effective rescue of the

airway.

THE PROSEAL LARYNGEAL MASK AIRWAY

DESIGN AND DESCRIPTION

The laryngeal mask airway is designed to secure the airway by establishing circumferential seal around the laryngeal inlet with an inflatable cuff. It is an useful advancement in airway management filling a niche between the face mask and tracheal tube in terms of both anatomical position and the degree of invasiveness.

DESCRIPTION

THE PROSEAL LARYNGEAL MASK AIRWAY

The *LMA* airway is an innovative supraglottic airway management device. Since its commercial introduction in 1988, the *LMA* airway has been used in over 100 million patients for routine and emergency procedures.

The *LMA-ProSeal is* an advanced form of *LMA airway* that may be used for the same indications as the original *LMA* airway now known as the *LMA-Classic*. The features of the *LMA-ProSeal* provide

more patient management options. They may expand the procedures where the device can be used. While the *LMA-Classic* may be used with low-pressure positive pressure ventilation (PPV), the *LMA-ProSeal* has been specifically designed for use with PPV with and without muscle relaxants at higher airway pressures.

The *LMA-ProSeal* does not protect the airway from the effects of regurgitation and aspiration.

The *LMA-ProSeal* has four main components: cuff, inflation line with pilot balloon, airway tube and drain tube. All components of the *LMA-ProSeal* are latex-free.

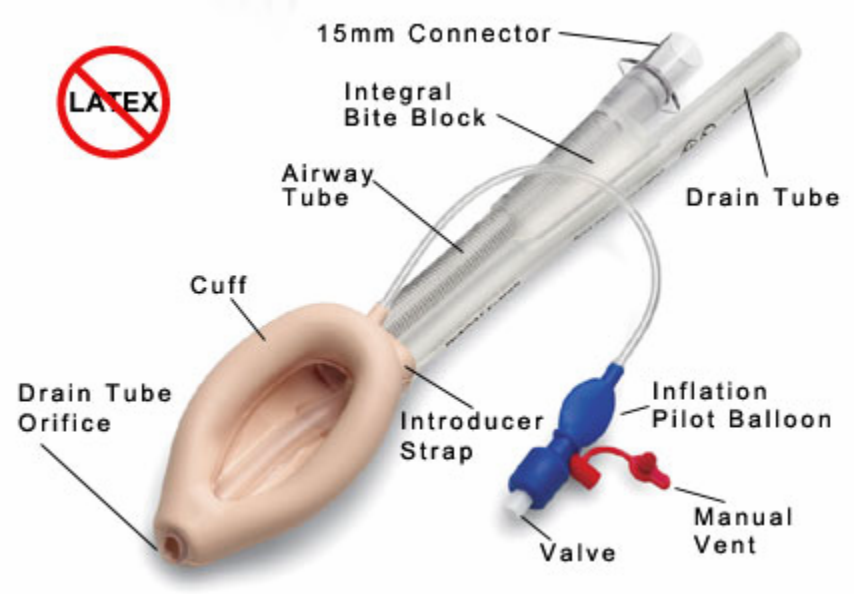


Figure 1: The components of the LMA – Proseal

The cuff is made of a softer material than the *LMA-Classic* and is designed to conform to the contours of the hypopharynx, with its lumen facing the laryngeal opening. The mask has a main cuff that seals around the laryngeal opening and a rear cuff which acts to increase the seal. Attached to the mask is an inflation line terminating in a pilot balloon which inflates and deflates the mask via a valve. Within the mask, a drain tube provides a conduit that communicates with the upper esophageal sphincter. The airway tube is wire reinforced which resists kinking and terminates with a standard 15 mm airway connector.

The removable *LMA-ProSeal Introducer* is provided to aid insertion of the *LMA-ProSeal* without the need to place fingers in the mouth. The Laryngeal Mask Company recommends that the

LMA-ProSeal be used a maximum of 40 times before being discarded. A dedicated deflation device (*LMA-ProSeal Cuff-Deflator*) is available to help obtain complete deflation of the *LMA-ProSeal* for successful sterilization, optimum insertion and positioning within the patient.

In addition to the well-known characteristics of the *LMA-Classic,* the new design provides the following features:

• A revised cuff arrangement allows a higher seal than the *LMA-*

Classic for a given intra-cuff pressure.

• A drain tube communicates with the upper esophageal sphincter and permits venting of the stomach and blind insertion of standard gastric tubes, in any patient position, without the need to use Magill's forceps.

• A double tube arrangement reduces the likelihood of device rotation; the revised cuff profile, together with the two tubes, results in the device being more securely anchored in place.

• A built-in bite-block reduces the danger of airway obstruction or tube damage.

• A strap for the *LMA-ProSeal Introducer* also accommodates the index finger or thumb for manual insertion.

• The position of the drain tube inside the cuff is designed to prevent the epiglottis from occluding the airway tube. This eliminates the need for aperture bars.

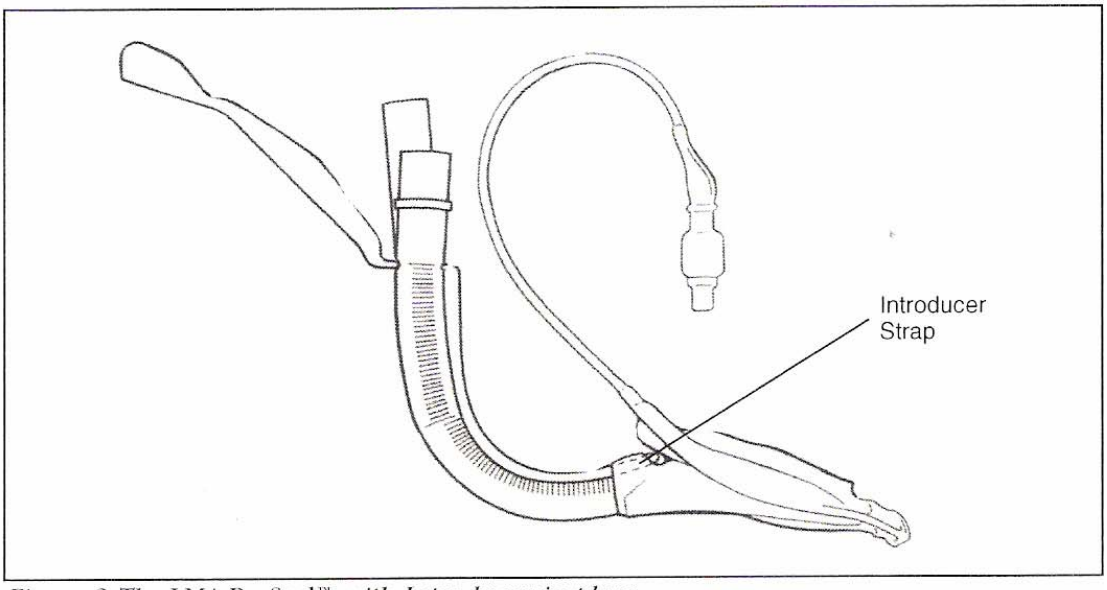


Figure 2: The LMA-ProSeal™ *with Introducer in place.*

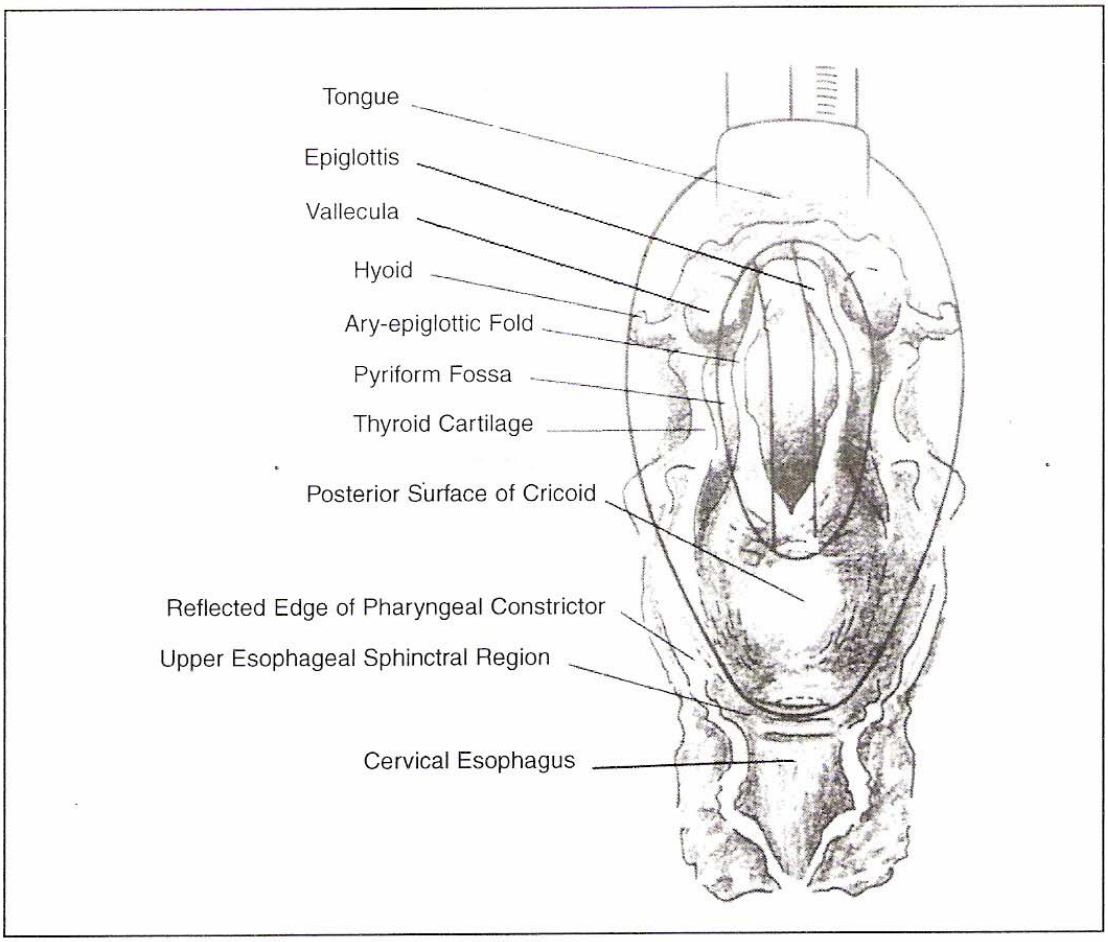
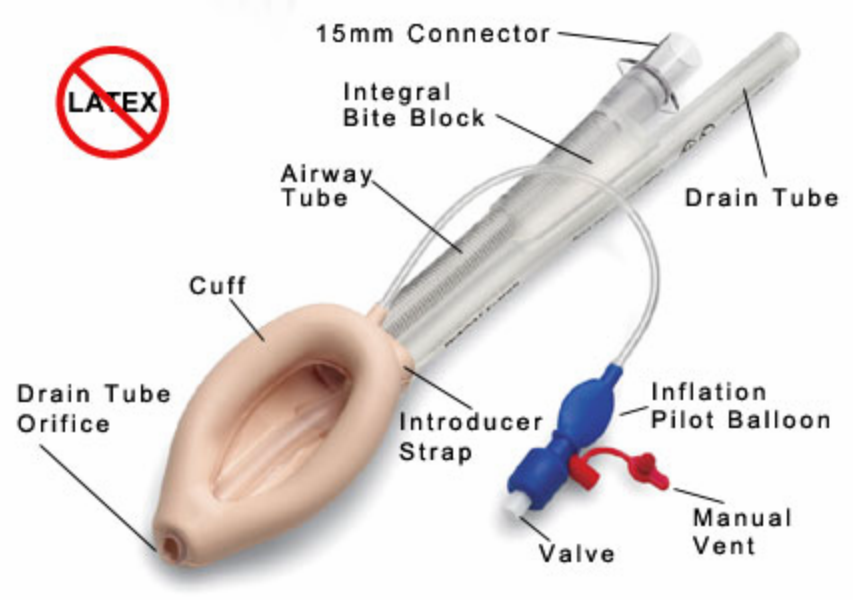


Figure 3: Dorsal view of the LMA-ProSeal™ *showing position in relation to pharyngeal anatomy.*

The *LMA-ProSeal* is designed to be a minimally stimulating airway device. When fully inserted using the recommended insertion technique, the distal tip of the *LMA-ProSeal* cuff presses against the upper esophageal sphincter. Its sides face into the pyriform fossae and the upper border rests against the base of the tongue.

DEVICE ACCESSORIES

- Includes a built-in bite block that protects against occlusion.
- A removable **Introducer** that allows insertion without the need to place fingers in the mouth
- A specially designed **Cuff-Deflator** to remove all air and produce optimal cuff shape for insertion.



Introducer

Cuff-Deflator

LMA ProSeal Cuff-Deflator

- The *LMA-ProSeal Cuff-Deflator* is a dedicated deflation device.

- The *Cuff-Deflator* is recommended to help obtain complete deflation of the *LMA-ProSeal*.

- A completely deflated, smooth leading edge facilitates insertion and avoids deflection of the epiglottis or entry of the tip into the glottis.

- The *Cuff-Deflator* also is an important tool to assure all air is removed from the *LMA-ProSeal* prior to autoclaving to prevent rupture or herniation.

- Reusable and autoclavable.

INDICATIONS AND CONTRAINDICATIONS

Indications

The *LMA-ProSeal* is indicated for use as an alternative to the face mask for achieving and maintaining control of the airway during routine and emergency anaesthetic procedures.

The *LMA-ProSeal* is not indicated for use as a replacement for the endotracheal tube, and is best suited for use in elective surgical procedures where tracheal intubation is not necessary.

The *LMA-ProSeal* is also indicated in a known or unexpected difficult airway situation.

The *LMA-ProSeal* is also indicated as a method of establishing a clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation. The *LMA-ProSeal* should be used only when tracheal intubation is not possible.

Contraindications

Due to the potential risk of regurgitation and aspiration, we should not use the *LMA-ProSeal* as a substitute for an endotracheal tube in the following elective or difficult airway patients on a non-emergency pathway:

• Patients who have not fasted, including patients whose fasting cannot be confirmed.

• Patients who are grossly or morbidly obese, more than 14 weeks pregnant or those with multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.

The *LMA-ProSeal* is also contraindicated in:

• Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the *LMA- ProSeal* forms a low-pressure seal around the larynx.

• Patients where the peak airway inspiratory pressures are anticipated to exceed 30 cm H2O.

• Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for *LMA-*

ProSeal use.

When used in the profoundly unresponsive patient in need of resuscitation or in a difficult airway patient on an emergency pathway (i.e.," cannot intubate, cannot ventilate"), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway. The *LMA-ProSeal* should not be used in the resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist *LMA-ProSeal* insertion.

ADVERSE EFFECTS

Both minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration) following use of the *LMA-Classic* have been reported in the published literature.5 Review of published literature suggests that the incidence of aspiration with the *LMAClassic* is low (~2:10,000)5,6 and is comparable to the incidence of aspiration associated with outpatient general anesthesia with the face mask or endotracheal tube.6 There have been no published reports of long-term morbidity or mortality associated with the *LMA*. airway secondary to aspiration.5

The incidence of sore throat following *LMA-Classic* use is

approximately 10% (range 0-70%), and is usually mild and shortlived; 5 however, severe or prolonged sore throat, sometimes accompanied by dysphagia, has been reported in patients in whom an improperly cleaned or sterilized mask has been used.Unusual neurovascular events reported with *LMA-Classic* use include rare cases of hypoglossal nerve injury, transient tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, and vocal cord paralysis.These complications may be the result of poor insertion technique or excessive cuff pressure. Adverse events reported with *LMA-Classic* use include aspiration, regurgitation, vomiting, bronchospasm, gagging, hiccup, transient glottic closure, coughing, retching, laryngeal spasm, breath holding, arytenoid dislocation, trauma to the epiglottis, larynx, posterior pharyngeal wall, uvula, tonsils and minor abrasions, tongue cyanosis, lingual nerve paralysis, vocal cord paralysis, tongue macroglossia, hypoglossal nerve paralysis, parotid gland swelling, dry mouth, dysphagia, feeling of fullness, sore throat, mouth ulcer, dysarthria, dysphonia, hoarseness, stridor, pharyngeal ulcer, pulmonary edema, stridor, laryngeal hematoma, head and neck edema,myocardial ischemia, and dysrhythmia.

Pre-insertion preparation

Prior to insertion, the cuff should be tightly deflated so that it forms a smooth wedge shape without any wrinkles. This can be accomplished through use of the *LMA-ProSeal Cuff-Deflator*; alternatively, we have to compress the mask tip between finger and thumb to achieve the correct wedge shape. While deflating, we have to pull back gently on the inflation line to obtain the correct shape for insertion.

A completely deflated, smooth leading edge facilitates insertion, avoids deflection of the epiglottis, or entry of the tip into the glottis.

Optimal deflation facilitates complete insertion of the *LMA-ProSeal*, with the distal end in contact with the upper esophageal sphincter.

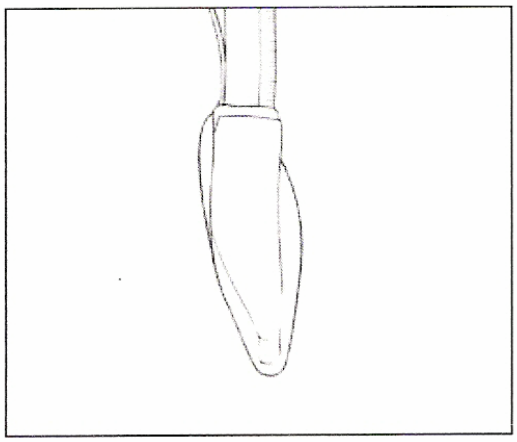
Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant. Apply a bolus of lubricant to the posterior tip of the deflated cuff. It is not necessary to spread the lubricant over the mask surface.

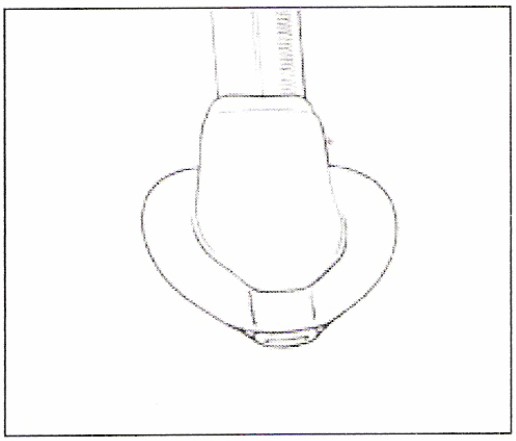
We should lubricate only the posterior surface of the cuff to

avoid blockage of the airway aperture or aspiration of the lubricant.

A water-soluble lubricant, such as K-Y Jelly, should be used. We should not use silicone-based lubricants as they degrade the components.

Lubricants containing lidocaine are not recommended for use as it may delay the return of protective reflexes and may provoke an allergic reaction.





Figures 4a and 4b: LMA-ProSeal™ *cuff properly deflated for insertion.*

INSERTION

Introduction

Before using the *LMA-ProSeal*, we should be familiar with the instructions contained in the product manual. If the device is inserted incorrectly, an unreliable or obstructed airway may be obtained.

Before insertion it is important to note the following points:

We have to check that the size of the device is appropriate for the patient .The ranges are approximate and clinical judgment should be used in selecting an appropriate size.

Table 3: *LMA-ProSeal* . Selection Guidelines

***LMA*. Size**	**Patient Size**	**Max. Cuff Inflation Volume (Air)***	**Largest Size**	
			OG Tube	**Salem Sump®**
Size 3	Children 30-50 kg	Up to 20 mL	16 Fr	14 Fr
Size 4	Adults 50-70 kg	Up to 30 mL	16 Fr	14 Fr
Size 5	Adults 70-100 kg	Up to 40 mL	18 Fr	16 Fr

* These are maximum volumes that should never be exceeded. It is recommended the cuff be inflated to
60 cm H_2O pressure.

Table 4: Airway Tube Internal Diameters (mm)

***LMA* Size**	***LMA-ProSeal***	***LMA-Classic***	***LMA-Flexible***
Size 3	9.0	10.0	7.6
Size 4	9.0	10.0	7.6
Size 5	10.0	11.5	8.7

Table 5: Maximum FOB and ETT Sizes (mm)

LMA-ProSeal	**Maximum FOB**	**Maximum ETT**
Size 3	4.0 mm	5.0 mm uncuffed

Size 4	4.0 mm	5.0 mm uncuffed
Size 5	5.0 mm	6.0 mm cuffed

FOB = Fiberoptic Scope ETT = Endotracheal Tube

• The cuff must always be fully deflated by firmly pulling back on the deflating syringe and gently pulling on the inflation line.

• We have to check the shape of the cuff and its lubrication, as described previously.

• We should have a spare sterile *LMA-ProSeal* ready and prepared for immediate use. Where possible, an alternative size of *LMA-ProSeal* should also be available.

• We should Pre-oxygenate and implement standard monitoring procedures.

• We have to achieve an adequate level of anesthesia before attempting insertion. Resistance or swallowing indicates inadequate anesthesia. Retching indicates inadequate anesthesia and/or inappropriate technique. Inexperienced users should choose a deeper level of anesthesia.

• The ideal head position is extension of the head with flexion of the neck in the position normally used for tracheal intubation ("the sniffing position"). This can be achieved by pushing the head from

behind with the non-dominant hand during the movement of insertion. A pillow can also be used to keep the neck flexed.

• When using the *Introducer*, it may be possible to reduce or eliminate head and neck manipulation.

• Excessive force must be avoided at all times.

Induction methods

The following induction methods are compatible with the insertion of the *LMA-ProSeal*:

• **Propofol.** This is the agent of choice for insertion as it optimally obtunds upper airway reflexes and produces appropriate relaxation. Between 2.5 and 3 mg/kg may be necessary in unpremedicated ASA I patients. Insertion can often be achieved within 30 seconds after induction.

• **Gas induction or gas with a vapor.** This provides excellent conditions for insertion in children. The depth required is slightly more than that required for insertion of a Guedel-type airway. However, the inexperienced user should insert the *LMA-ProSeal at* an anesthesia level closer to that required for surgical procedures.

• **Thiopental or other barbiturate induction.** Barbiturates on their own are not ideal induction agents for *LMA-ProSeal* insertion.

If used on their own, it is recommended that anaesthesia be deepened using an inhalational agent for several minutes before attempting insertion. Co-induction, using midazolam 2-5 mg intravenously three minutes before induction with thiopental, may simulate conditions using propofol.

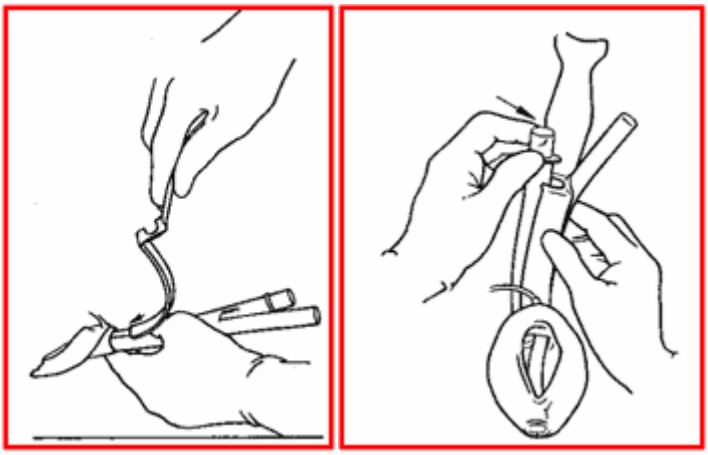
Insertion methods

To position the *LMA-ProSeal* correctly, the cuff tip must avoid entering the valleculae or the glottic opening and must not become caught up against the epiglottis or the arytenoids. The cuff must be deflated in the correct wedge shape (Figure) and should be kept pressed against the patient's posterior pharyngeal wall.

The *LMA-ProSeal* may be inserted using one of three methods. The *Introducer* may be used with the *LMA-ProSeal*, or insertion may be performed using the index finger or the thumb, in a similar manner to the *LMA-Classic*. All three techniques follow the same principles.

***Introducer* technique**

The following are the steps of introducer technique Place the tip of the *Introducer* into the strap at the rear of the cuff. Fold the tubes around the convex surface of the blade and fit the proximal end of the airway tube into the matching slot in the tool.



Place Introducer tip into strap at the junction of the cuff and two tubes Fold the tubes around the Introducer

The *LMA-ProSeal* is shown mounted in the *Introducer* in the figure

Under direct vision, press the tip of the cuff upward against he Hard palate and flatten the cuff against it (Figure 7). During insertion, the back of the mask should be in contact with the hard palate and the bowl of the mask should be facing the tongue. Verify the position of the mask and slide the cuff further inward against the palate (Figure 8). Push the jaw downward with the middle finger or instruct an assistant to pull the lower jaw downward momentarily. A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff has

not folded over.

Keeping the *Introducer* blade close to the chin, rotate the device inward in one smooth circular movement (Figure 9). During insertion, we have to follow the curve of the rigid insertion device. The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask. We should use the handle as a lever to force the mouth open. We should advance into the hypopharynx until a definite resistance is felt (Figure 10).

Before removing the insertion device, the non-dominant hand is brought from behind the patient's head to stabilize the airway tube (Figure 11). This prevents the *LMA-ProSeal* from being pulled out of place when the *Introducer* is removed. It also permits completion of insertion in the event that full insertion has not been achieved by the *Introducer* alone. At this point the *LMA-ProSeal* should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.

Figures 6-11: Insertion of the *LMA-ProSeal*™ using the *Introducer*.

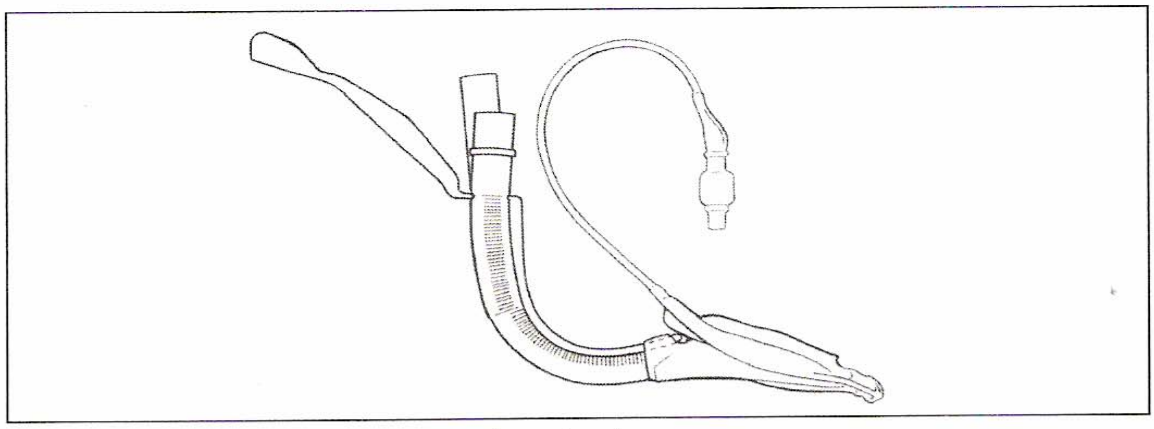


Figure 6: LMA-ProSeal™ *with the Introducer in place.*

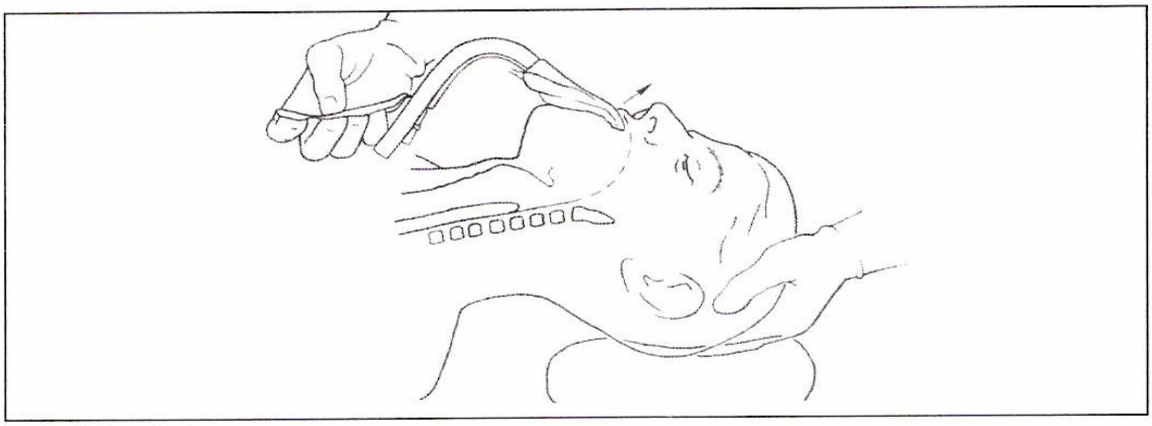


Figure 7: Press the tip of the cuff against the hard palate.

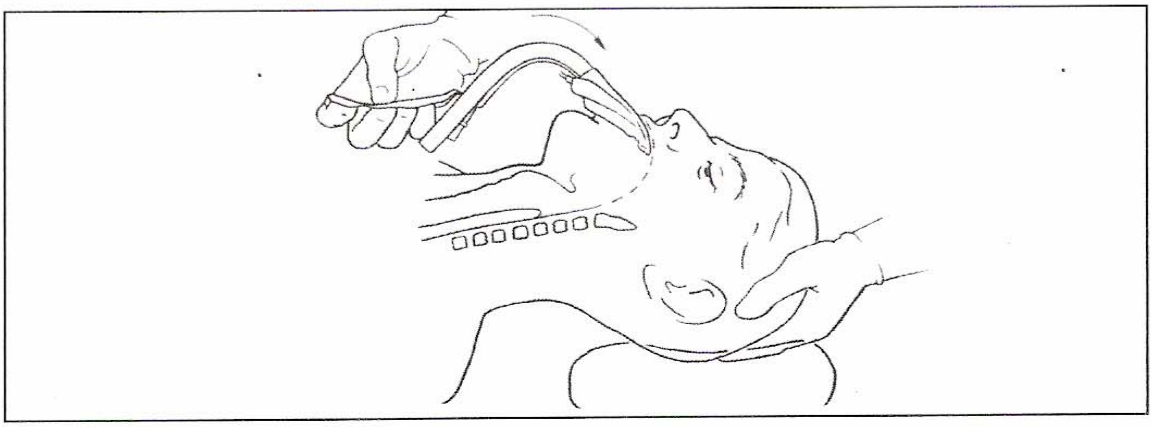


Figure 8: Press the cuff further into the mouth maintaining pressure against the palate.

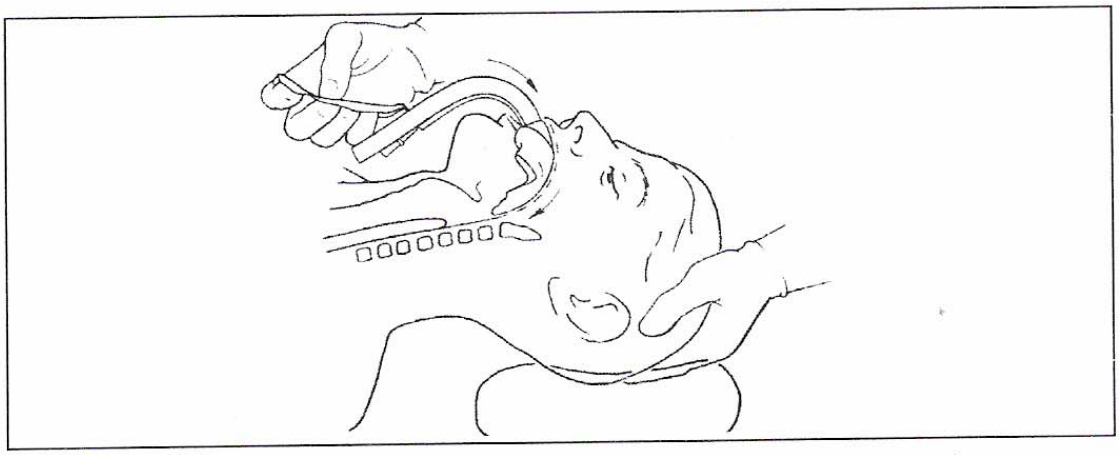


Figure 9: Swing the device inward with a circular motion, pressing against the contours of the hard and soft palate.

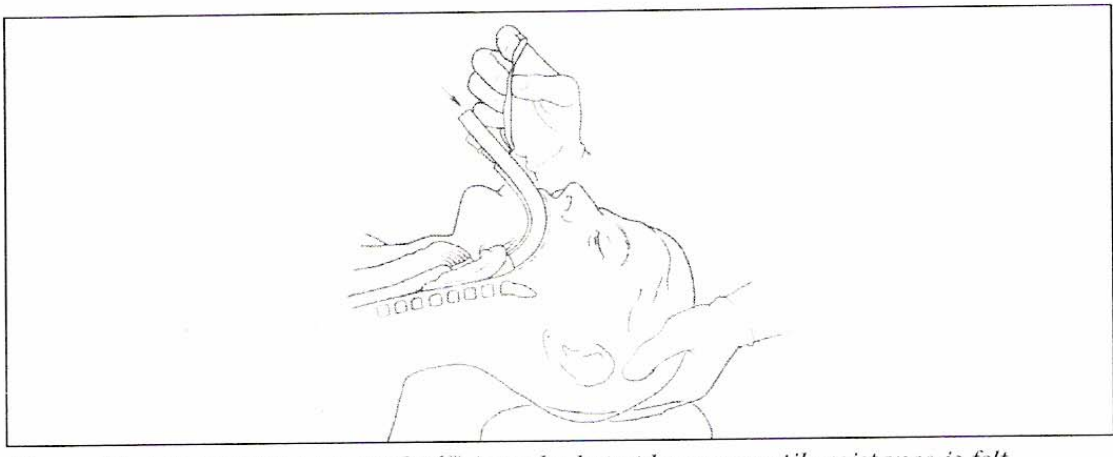


Figure 10: Advance the LMA-ProSeal™ *into the hypopharynx until resistance is felt.*

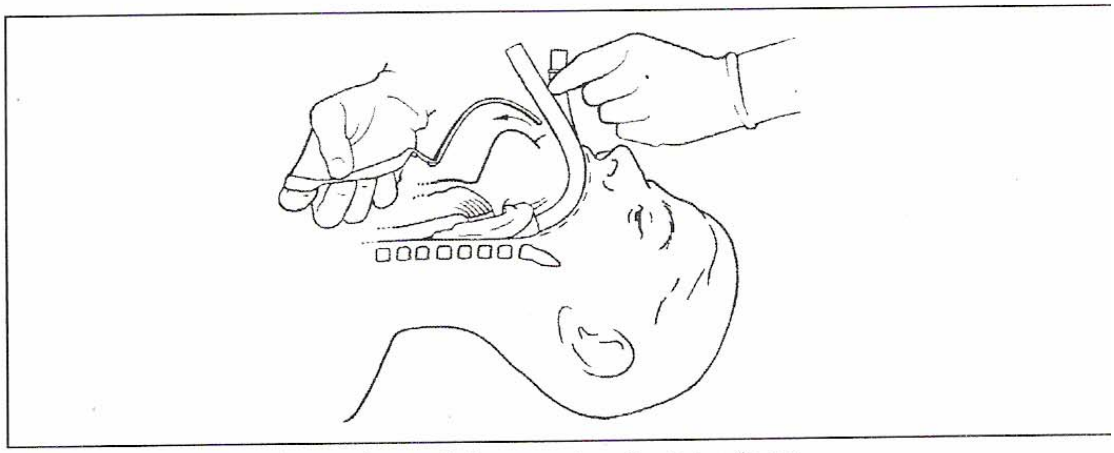


Figure 11: Hold the tube in place while removing the Introducer.

Index finger insertion technique

Step of this technique

We have to hold the *LMA-ProSeal like* a pen, with the index finger placed at the junction of the cuff and the two tubes, so that the fingertip is pushed into the *Introducer* strap. The position of the hand and wrist (Figure 12a & 12b).must be like that of one shown in the following figures

Under direct vision, we have to press the tip of the cuff upward against the hard palate and flatten the cuff against it (Figure 13) .A high arched palate may require a slightly lateral approach. We have to look carefully into the mouth to verify that the tip of the cuff is correctly flattened against the palate before proceeding.

As the index finger passes further into the mouth, the finger joint begins to extend (Figure 14).The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask. Further opening of the mouth makes it easier to verify the position of the mask. Then push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.Using the

index finger, press backward toward the other hand,which exerts counter-pressure (Figure 15). We should **not use excessive force.** We have to advance the device into the hypopharynx until a definite resistance is felt (Figure 16).

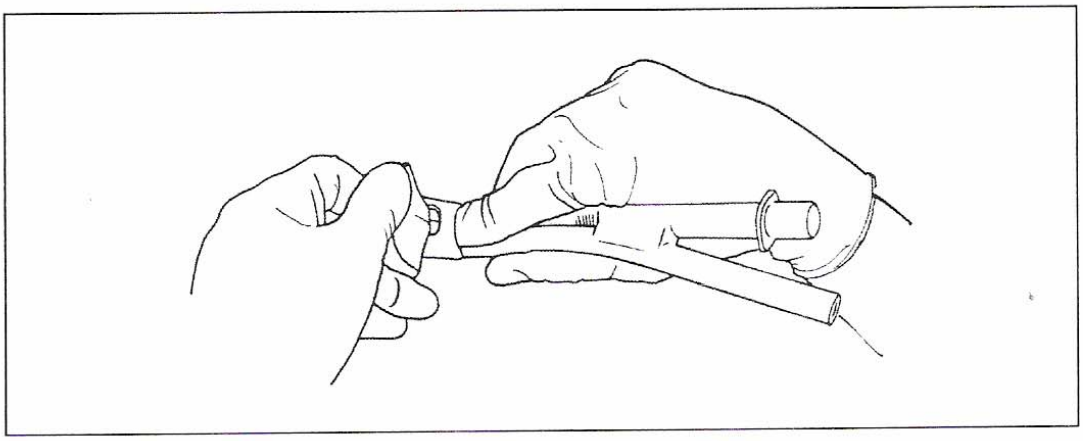
Depending on patient size, the finger may be inserted to its fullest extent into the oral cavity before resistance is encountered. Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube (Figure 17).This prevents the *LMA-ProSeal.* 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 *LMAProSeal* . should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.

The thumb insertion technique

The thumb insertion technique is useful if it is difficult to get access to the patient from behind. The thumb is inserted into the strap as shown in Figure 18. Insertion is similar to that using the index finger. As the thumb nears the mouth, the fingers are stretched forward over the patient's face. We have to advance the thumb to its fullest extent. The pushing action of the thumb

against the hard palate also serves to press the head into extension Figure 19 – 22.

Figures 12-17: Insertion of the *LMA-ProSeal*™ using the Index Finger Technique.



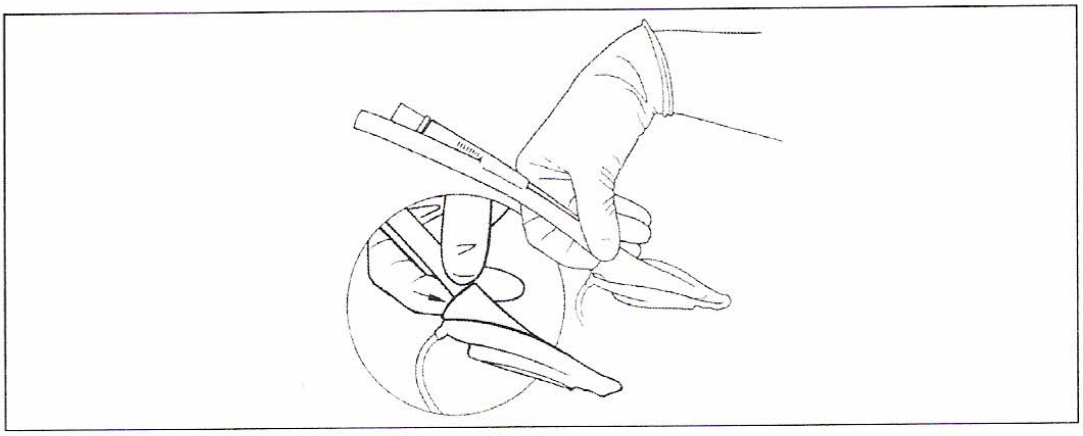


Figure 12a and 12b: Hold the LMA-ProSeal™ *with the index finger in the strap, note the flexed wrist.*

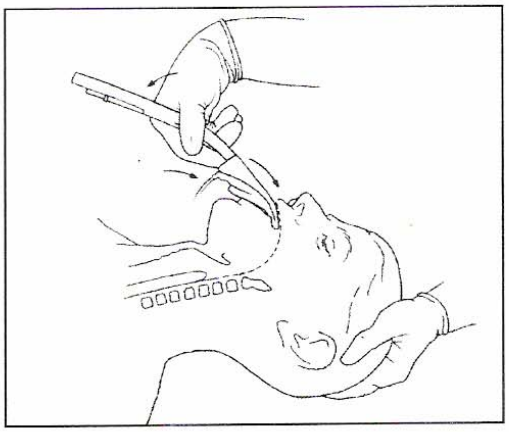


Figure 13: Press the mask up against the hard palate.

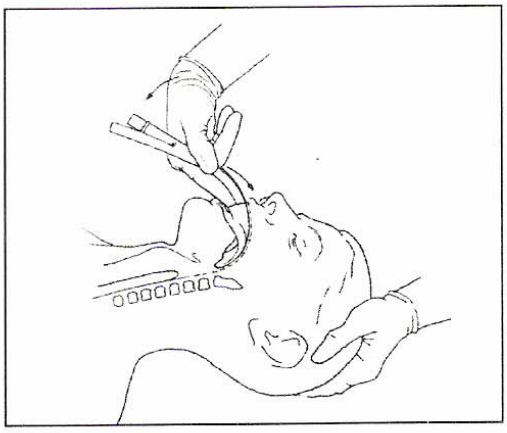


Figure 14: Slide the mask inward, extending the index finger.

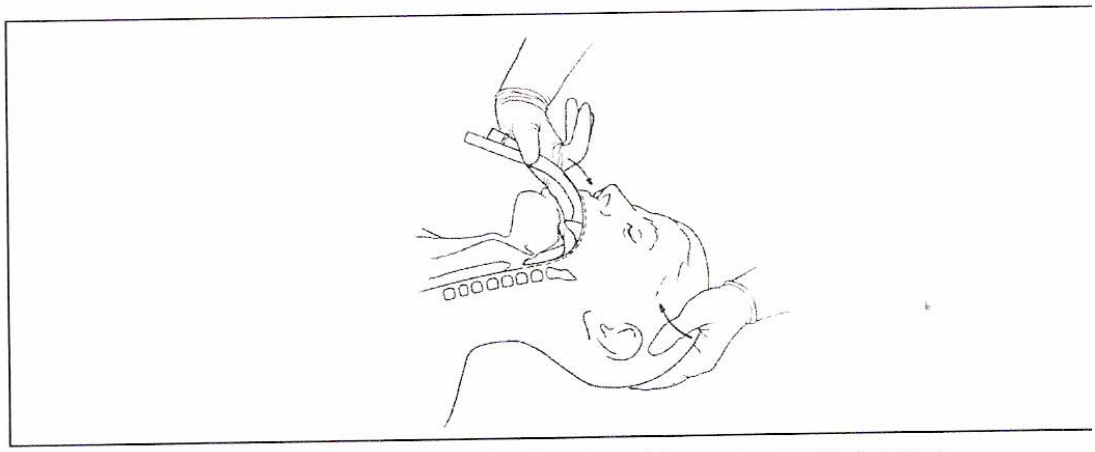


Figure 15: Press the finger towards the other hand, which exerts counter-pressure.

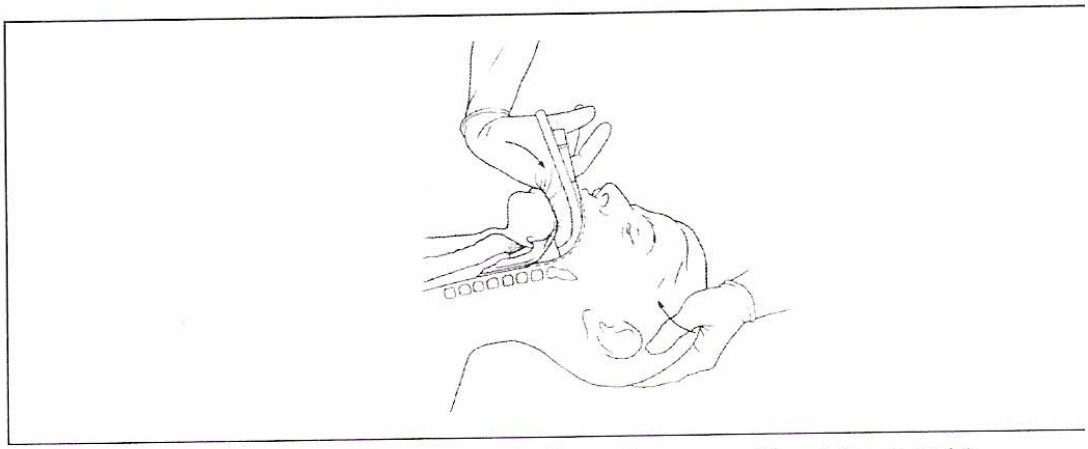


Figure 16: Advance the LMA-ProSeal™ *into the hypopharynx until resistance is felt.*

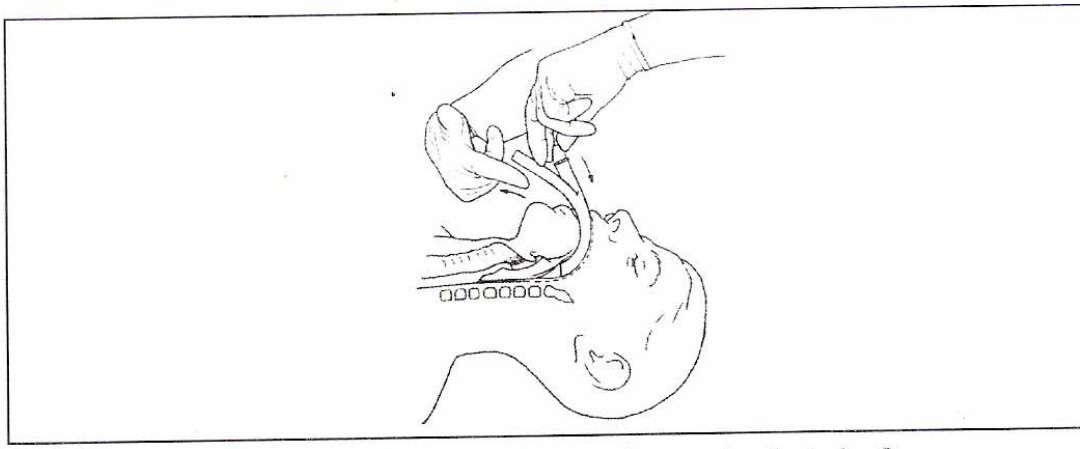


Figure 17: Hold the outer end of the airway tube while removing the index finger.

Figures: 18-22: Insertion of the *LMA-ProSeal*™ using the Thumb Technique.

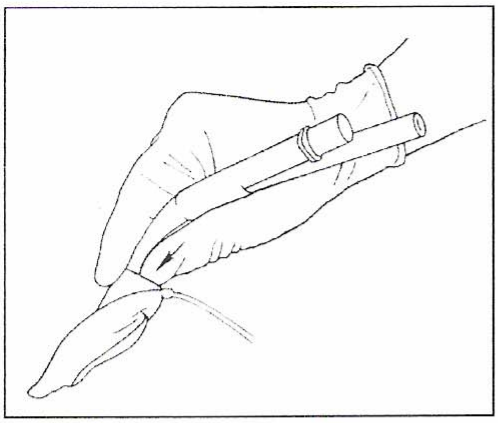


Figure 18: Hold the LMA-ProSeal™ *with the thumb in the strap.*

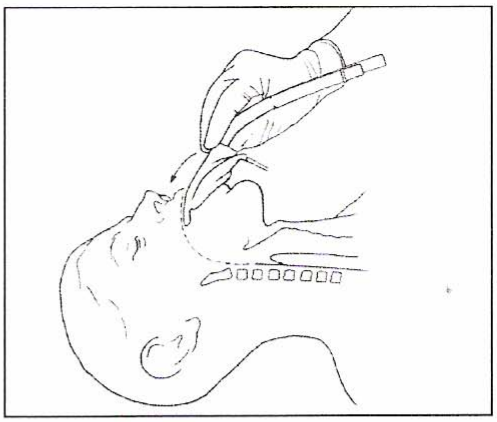


Figure 19: Place the mask against the palate.

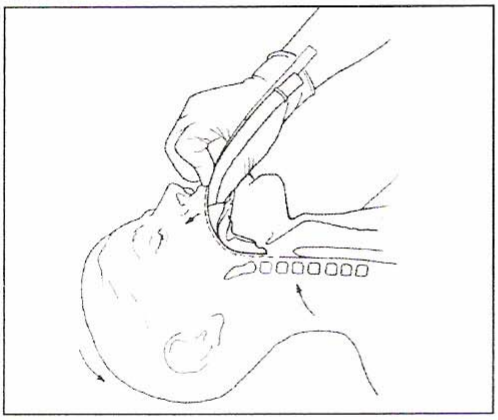


Figure 20: When the thumb is against the palate, press upward to extend head.

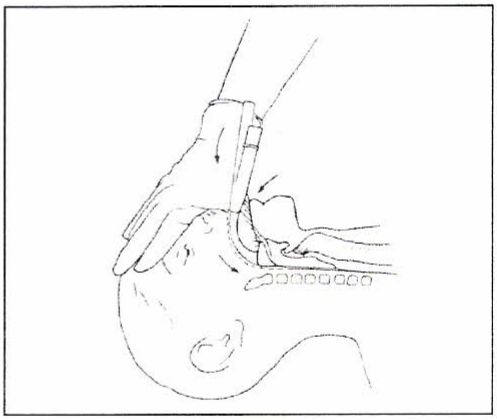


Figure 21: Extend fingers over head, allowing the thumb to pass inward.

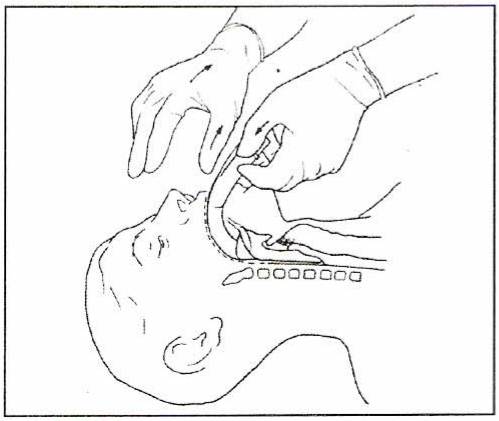


Figure 22: Use other hand to complete insertion as shown.

INSERTION PROBLEM

An inadequate depth of anesthesia may result in coughing and breath holding during insertion. If this occurs, anaesthesia should be deepened immediately with inhalational or intravenous agents and manual ventilation instituted. If the patient's mouth cannot be opened sufficiently to insert the mask, first ensure that the patient is adequately anesthetized. An assistant can be asked to pull the jaw downward. This maneuver makes it easier to see into the mouth and verify the position of the mask. However, do not maintain downward jaw traction once the mask has passed beyond the teeth.

The inserting finger must press the tube against the palate throughout the insertion maneuver, otherwise the tip may fold on itself or impact on an irregularity or swelling in the posterior pharynx (e.g., hypertrophied tonsils). If the cuff fails to flatten or begins to curl over as it is advanced, it is necessary to withdraw the mask and reinsert it. In case of tonsillar obstruction, a diagonal shift of the mask is often successful.

If difficulty persists with the chosen technique, one of the three techniques described above should be used.

Inflation

After insertion the tubes should emerge from the mouth directed caudally. Without holding the tubes, we have to inflate the cuff with just enough air to obtain a seal equivalent to a pressure of approximately 60 cm H2O (Figure 23). We should never over-inflate the cuff. We should avoid prolonged intra-cuff pressures greater than 60 cm H2O.

The initial cuff volume will vary according to the patient, size of device, head position, and anesthetic depth. 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 sometimes noted as the device seats itself in the hypopharynx.

The signs of correct placement may include one or more of the following: the slight outward movement of the tube upon inflation, the presence of a smooth oval swelling in the neck around the thyroid and cricoid area, or no cuff visible in the oral cavity.
We should never over-inflate the cuff after insertion.

Connecting to the anesthetic system

Taking care to avoid dislodgment, we should connect to the anesthetic circuit and employ gentle manual ventilation to inflate the lungs, noting whether there are any leaks. Capnography should be used to confirm adequate gas exchange. Auscultate in the anterolateral neck region to check for abnormal sounds that might indicate mild laryngeal spasm or light anesthesia.

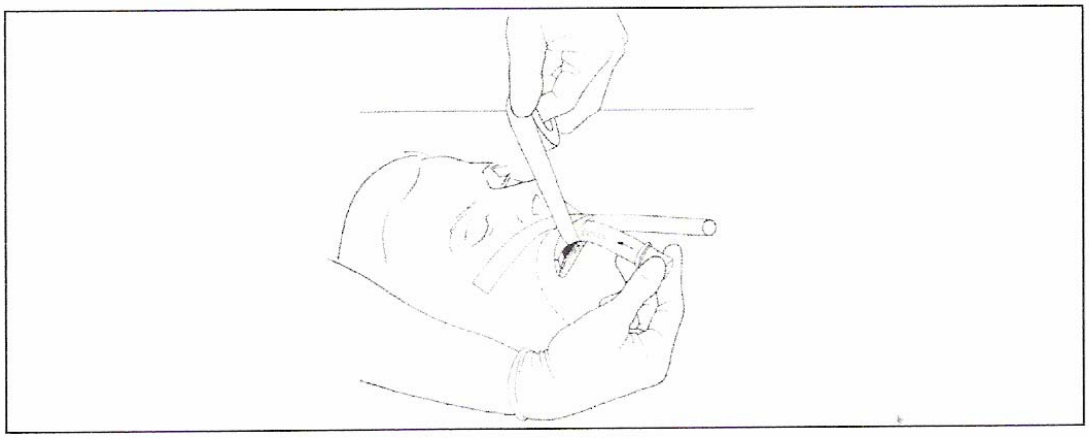


Figure 24: Fix the LMA-ProSeal™ *in place using adhesive tape.*

Fixation

The device should be fixed in place using adhesive tape

as shown in Figure 24. Apply gentle pressure to the outer end of the airway tube as it is fixed. This ensures that the tip of the mask is pressed securely against the upper esophageal sphincter.

Diagnosis of correct and incorrect mask position

When inserting and inflating the *LMA-ProSeal*, We should look carefully at the front of the neck to observe whether the cricoid cartilage moves forward, indicating correct passage of the mask tip behind it. Correct placement (Figure 25a) should produce a leak-free seal against the glottis with the mask tip wedged against the upper esophageal sphincter. The bite-block should lie between the teeth. If the mask lies too proximal as the result of incomplete insertion, gas will leak from the proximal end of the drain tube when the lungs are inflated (Figure 25b).This situation must be corrected by repositioning the mask. We should **not attempt to overcome the leak by occluding the drain tube.**

To facilitate the diagnosis of correct mask placement, We should place a small bolus (1-2 ml) of lubricant gel in the proximal end of the drain tube. In a properly placed mask, there should be a slight

up-down meniscus movement of the lubricant. If there is no movement or the bolus of lubricant is ejected, the mask may be incorrectly placed.

Occasionally a poorly deflated or inserted mask may enter the vestibule of the larynx (Figure 25c). In this situation, there may be some obstruction to ventilation and gas may leak from the proximal end of the drain tube. In spite of adequate anesthesia, obstruction worsens if the mask is pressed in further. The mask should be removed and reinserted.

Poor insertion or deflation may also cause the tip of the mask to fold back on itself in the hypopharynx, causing the drain tube to become obstructed (Figure 25d). If the tip is folded back there may be a lack of meniscus movement in the lubricant gel. A simple, noninvasive method to test for this problem would be to pass a gastric tube down to the end of the mask tip to verify that the drainage tube is patent. If the gastric tube cannot reach the distal end of the drain tube, the mask tip is likely folded over. Alternatively, this may be confirmed with a fiberoptic scope. The mask should be removed and reinserted.

To distinguish between the mask lying too high and having entered the glottis (Figure 25c), press the mask further inwards.

This overcomes a leak if the mask is too high, but causes increased obstruction to ventilation if the mask tip has entered the glottis. If leaks occur from the drain tube even though the device is correctly positioned, this may indicate a damaged device (e.g., a torn or perforated internal drain tube). If the device is damaged in any way, it should not be used.

An incorrectly placed mask may result in obstruction to ventilation or failure of the drain tube to channel fluids or gasses from the stomach and may increase the likelihood of gastric insufflations if used with PPV. Always We should check for proper placement after insertion.

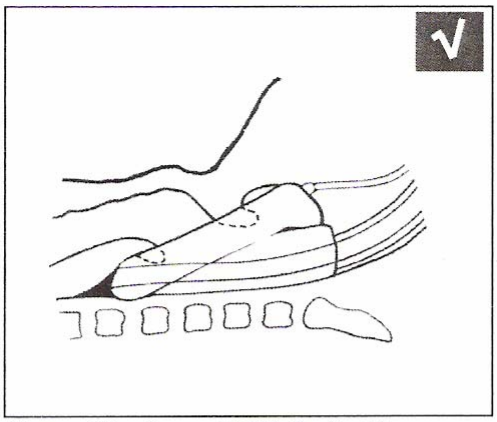


Figure 25a: Correct LMA-ProSeal™ *placement. Good seals at glottis and upper esophageal sphincter.*

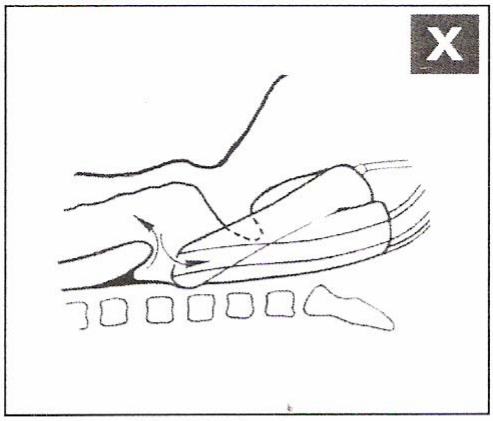


Figure 25b: Incorrect placement. LMA-ProSeal™ *placed too high in pharynx, poor seal allowing gas and fluid to pass in directions shown by arrows; can be eliminated by pressing the mask in further.*

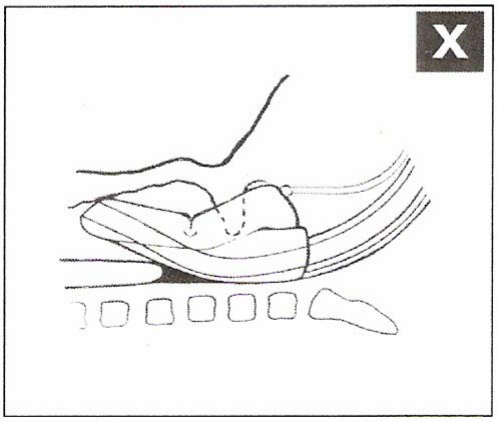


Figure 25c: Incorrect placement. LMA-ProSeal™ *incorrectly placed with tip in laryngeal vestibule; ventilation is obstructed and deteriorates if mask is pressed in further.*

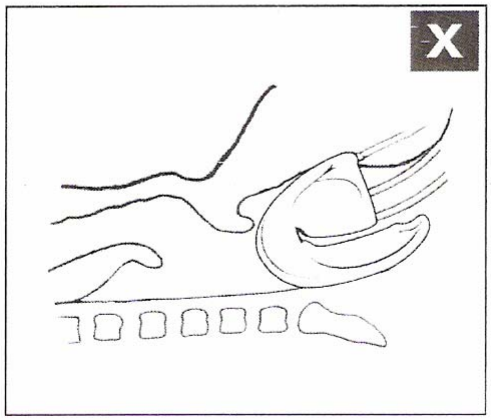


Figure 25d: Incorrect placement. LMA-ProSeal™ *mask folded back on itself in the hypopharynx, causing the drain tube to become obstructed.*

AIRWAY MAINTANANCE AND RECOVERY

As with other methods of airway management, the use of pulse oximetry and capnography is recommended when using the *LMA-ProSeal.*. The *LMA-ProSeal* may be used for either spontaneous

or controlled ventilation.

Spontaneous ventilation

The *LMA-ProSeal* is well tolerated in spontaneously breathing patients when used with volatile agents or intravenous anesthesia provided anesthesia is adequate to match the level of surgical stimulus and the cuff is not overinflated.

Coughing, breath holding, or movement may result if the induction agent is allowed to wear off before adequate levels of anesthesia for maintenance have been obtained. This is particularly likely to occur following the introduction of an external stimulus such as surgery or turning the patient when the level of anesthesia has been misjudged.

Ventilation should be assisted gently until breathing returns.

Positive pressure ventilation (PPV)

Although it may be used in spontaneously breathing patients, the *LMA-ProSeal* has been designed for use with PPV, with and without muscle relaxants.

When a relaxant technique is chosen, the relaxant drug may be given either before or after insertion. Alternatively, if a change in the surgical or diagnostic procedure requires conversion to a relaxant technique, a muscle relaxant can be given at any time.

The softer cuff material, deeper mask bowl, and special cuff shape of the *LMA-ProSeal* permit a more effective seal against the laryngeal inlet at lower mucosal pressures when compared to the *LMA-Classic*. Tidal volumes should still not exceed 8 ml/kg, and peak inspiratory pressures should be kept within the maximum airway seal pressure, which will be found to vary between individual patients, but is, on average, 10 cm H2O higher than the *LMA-Classic*. Should air leakage through the drain tube be observed during PPV, even though anesthesia is adequate, this may be due to the mask having migrated proximally. Ensure the securing tape is still in place and readjust as necessary while pressing the tubes downward to relocate the mask tip against the upper esophageal sphincter.

Use of drain tube

In addition to its diagnostic function, the drain tube facilitates channeling of fluids and gases out of the patient and/or the insertion of standard gastric (nasogastric or orogastric) tubes into the stomach at any time during the anesthetic procedure Fig.26.

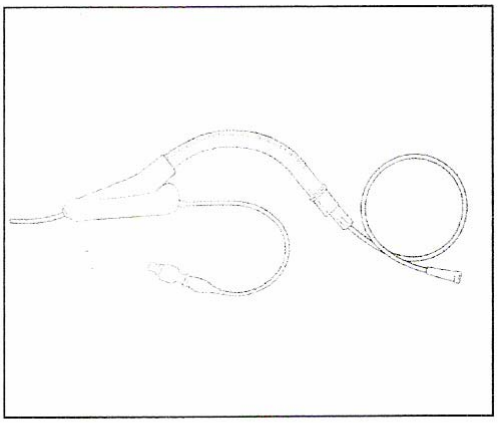


Figure 26: LMA-ProSeal™ *with gastric tube.*

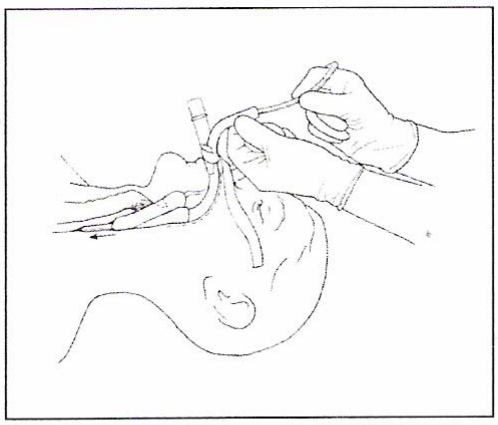


Figure 27: Passage of gastric tube through LMA-ProSeal™ *and through upper esophageal sphincter.*

We should not attempt to pass a gastric tube through the drain tube in the presence of known or suspected esophageal damage.

If it is clinically indicated to pass a gastric tube into the stomach, suction should not be performed until the gastric tube has reached the stomach. Suction should not be applied directly to the end of the drain tube, as this may cause the drain tube to collapse and cause possible injury to the upper esophageal sphincter.

To prevent injury to the upper esophageal sphincter, we should not apply suction directly to the end of the drain tube.

The gastric tube should be well lubricated and passed slowly and carefully. When such tubes are used in conjunction with the *LMA-ProSeal,* it is important to avoid the potential for trauma

associated with excessive tube rigidity. For this reason, we should not use gastric tubes which have been stiffened by refrigeration.

We should ensure that the tube is at or above room temperature. Some resistance is often detected as the tip of the gastric tube is pressed gently against the upper esophageal sphincter. **Force must never be used.** If a tube of appropriate size fails to pass (Table 3), the mask may be kinked or malpositioned. In these cases the mask should be removed and reinserted. We should not try to force the tube through (Figure 27).

To avoid trauma, force should not be used at any time during insertion of the *LMA-ProSeal* or insertion of a gastric tube through the drain tube.

Problems after insertion Inadequate level of anesthesia

The most common problem following insertion is failure to maintain an adequate level of anesthesia. Administer an additional bolus of induction agent and/or increase the concentration of volatile agent, while gently assisting ventilation.

Nitrous oxide diffusion

Nitrous oxide diffuses into the cuff causing a rise in intra-cuff pressure. Diffusion rate and resulting peak pressure

may vary with the initial volume of air injected into the cuff, the type of gasses used to inflate the cuff, the percentage of nitrous oxide in the inhaled mixture, and the size of the device. The incidence of post-operative sore throat may increase if cuff pressure becomes excessive. To reduce the risk of sore throat, the cuff pressure should be periodically checked, either by monitoring with a pressure transducer or simply by feeling the tension in the inflation indicator balloon. At an intracuff pressure of 60 cm H2O, the inflation balloon should feel very compliant. If the inflation indicator balloon becomes stiff or olive-shaped, this indicates excessive pressure. Cuff volume should be reduced to maintain a pressure close to 60 cm H2O.

Unexpected regurgitation

Even in fasted patients, some regurgitation may occur, for example, if anesthesia becomes inadequate, resulting in fluid emerging from the drain tube. It has been shown in cadavers that fluids pass up the drain tube without laryngeal contamination when the mask has been correctly placed. Therefore, if regurgitation occurs, provided that oxygen saturation remains at

acceptable levels, the *LMA-ProSeal* should not be removed. We should verify that anesthetic depth is adequate and deepen anesthesia intravenously, if appropriate, a gastric tube may be inserted to complete drainage if the presence of further gastric contents is suspected.

If reflux occurs in association with poor mask placement, aspiration is possible. In the event of suspected aspiration, the patient should immediately be tilted head down. Momentarily disconnect the anesthetic circuit so that gastric contents are not forced into the lungs. Verify that anesthetic depth is adequate and deepen anesthesia intravenously, if appropriate. reposition the device to ensure the distal end is lying against the upper esophageal sphincter and secure it in place using the fixation method described earlier.

Suction should then be applied through the airway tube. Suction of the tracheobronchial tree using a fiberoptic bronchoscope through the airway tube may be employed if the airway reflexes are adequately obtunded.

Provided oxygen saturation is maintained at an acceptable

level, the *LMA-ProSeal* should not be removed. If clinically indicated, commence preparation for immediate tracheal intubation of the patient. If aspiration has occurred, the patient should receive a chest X-ray and be treated, as clinically appropriate, with antibiotics, physiotherapy, and tracheal suction.

Emergence from anesthesia and removal

If applicable, reverse the neuromuscular block or allow the block to wear off before switching off the anesthetic agents at the end of the surgical or diagnostic procedure. With gentle assisted ventilation, the patient should be allowed to start breathing spontaneously.

At this stage it is advisable to check the intracuff pressure. The correctly placed *LMA-ProSeal* is well tolerated until the return of protective reflexes, provided that intra-cuff pressures are kept around 60 cm H2O.This means that a clear airway can be maintained until the patient is able to swallow and cough effectively. Removal should always be carried out in an area where suction equipment and the space for rapid tracheal intubation are present. The following procedure should be followed:

Patient monitoring should continue throughout the recovery stage. Oxygen should be continuously administered through the anesthetic circuit or via a T-piece. If suction is required around the oral cavity or down the airway tube, it should be carried out prior to recovery of reflexes.

Leave the patient undisturbed until reflexes are restored, except to administer oxygen and perform monitoring procedures. It

is not advisable to move the patient from the supine to the lateral recumbent position unless there is urgent reason to do so, such as regurgitation or vomiting. If the patient needs to be awakened in the lateral position, the patient must be turned in this position under adequate anesthesia.

Avoid suctioning the airway tube with the *LMA-ProSeal* in place. The inflated cuff protects the larynx from oral secretions and suctioning is not likely to be required. Suctioning and physical stimulation may provoke laryngeal spasm if anesthesia is light.

Watch for signs of swallowing. It is usually safe and convenient to remove adhesive tape when swallowing begins. However, the interval between the beginning of swallowing and the ability to open the mouth varies from patient to patient according to the length and type of anesthesia.

Deflate the cuff and simultaneously remove the device only when the patient can open the mouth on command. If the cuff is deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm.Verify airway patency and respiratory depth. Oral suctioning may now be performed, if required.

If the *LMA-ProSeal* is to be removed in a Post-Anesthesia Care Unit (PACU), recovery room staff should receive training in all aspects of *LMA-ProSeal* management. An anesthesiologist should always be readily available if the device is to be removed away from the operating room.

USES

The following procedures may be appropriate for use with the LMA ProSeal, LMA Unique., LMA Flexible., LMA Classic. , LMA CTrach., and/or LMA Fastrach..

When first gaining experience with LMA. airways, its use is recommended in the following:

- Short (< 1 hour), elective procedures
- ASA 1-2 patients
- Spontaneously breathing
- Supine position

Examples of basic/routine uses:

OPERATING ROOM - BASIC/ROUTINE USES

GENERAL SURGERY:

Central line placement/removal	LMA ProSeal LMA Unique. LMA Classic.
Cutaneous/subcutaneous lesions	
Inguinal or femoral herniorrhaphy	
Rectal surgery (lithotomy)	
Vascular shunt revisions	

GYNECOLOGY:

Cone biopsy	LMA ProSeal LMA Unique. LMA Classic.
Condylomata therapy	
D & C	
Examination under anesthesia	
Hysteroscopy	
Hysterectomy (vaginal)	

OPHTHALMOLOGY:

	Preferred	**Others**
Cryotherapy	LMA Flexible.	LMA ProSeal LMA Unique. LMA Classic.
Electroretinography		
Examination under anesthesia		
Eyelid repair		
Foreign body removal		
Intraocular pressure measurement		
Nasolacrimal duct exploration		
Strabismus repair		

ORTHOPEDICS:

Arthroplasty	LMA ProSeal LMA Unique. LMA Classic.
Arthroscopy	
Carpal tunnel release	
Closed/open reductions	
Hand and foot procedures	
Hardware removal	

Rotator cuff repair	
Tendon/ligament repair	

OTHER HEAD AND NECK:

	Preferred	**Others**
Cranioplasty	LMA Flexible.	LMA ProSeal LMA Unique. LMA Classic.
Facial plastics		
Mastoid surgery		
Myringotomy		
Scalp procedures		
Ear tube placement		

OTHER PLASTIC SURGERY PROCEDURES:

Breast biopsy/augmentation/reduction	LMA ProSeal LMA Unique. LMA Classic. LMA Flexible.
Burn dressings	
Skin grafts	
Varicose vein procedures	
Wound debridement	

UROLOGY:

Circumcision	LMA ProSeal LMA Unique. LMA Classic.
Cystoscopy	
Hypospadias repair	
Orchiectomy	
Orchiopexy	
Penile plastics	
Stent placement	
TURP	
Urethral meatotomy	
Vasectomy	

Examples of advanced procedures that may be done by experienced LMA. airway users are:

OPERATING ROOM - ADVANCED USES

ABDOMINAL/PELVIC:

	Preferred	**Others**
Femoral popliteal bypass	LMA ProSeal	LMA Unique. LMA Classic.
Gynecologic laparoscopy		
Laparoscopy cholecystectomy		

Radical retropubic prostatectomy		
Total abdominal hysterectomy		
Ventral hernia repair		

DENTAL AND ORAL:

	Preferred	**Others**
Cleft palate repair	LMA Flexible.	LMA ProSeal LMA Unique. LMA Classic.
Removal of tongue tumor or cyst		
Tooth extraction		
Tooth implant		

DIAGNOSTIC TESTS:

Bone marrow biopsy	LMA ProSeal LMA Unique. LMA Classic.
Bronchoscopy	
Colonoscopy	
*CT scan	
*MRI	

* LMA ProSeal wire-reinforced airway may affect image if near area of interest

EYE/EAR/NOSE/THROAT:

	Preferred	Others
Adenotonsillectomy	LMA Flexible.	LMA ProSeal LMA Unique. LMA Classic.
Antral washouts		
Cataract surgery with or without lens implant		
Intraocular surgery		
Myringoplasty		
Nasal polypectomy		
Reduction of nasal fractures		
Rhinoplasty		
Septoplasty		
Submucosal resection		
Tympanoplasty		

OTHER CLINICAL SITUATIONS:

Procedures/patients where access to alimentary tract is desired/anticipated			LMA ProSeal
Moderate obesity			
Prolonged surgery (> 2 hours)	LMA Unique. LMA Classic.	LMA Flexible.	
Non-supine position (jack-knife, lateral, prone, lithotomy, Trendelenburg)			
Remote anesthesia for radiotherapy			
Patients where peak inspiratory pressures are expected to be > 20 cm H_2O			

	Preferred	Others
Difficult Airways	LMA Fastrach. LMA CTrach.	LMA ProSeal LMA Unique. LMA Classic. LMA Flexible.

OTHER HEAD AND NECK:

Carotid endarterectomy	LMA ProSeal LMA Unique. LMA Classic. LMA Flexible.	
Cervical node biopsy		
Excision of bronchial cyst		
Micro laryngeal surgery		
Neurosurgery with or without stereo tactic frame		
Thyroid/parathyroid surgery		
Tracheal/carinal surgery		
Tracheotomy		LMA Fastrach. LMA CTrach.

EMERGENCY DEPAR.ENT & CPR/RESUSCITATION

Difficult airway	LMA Unique. LMA Classic. LMA Fastrach. LMA CTrach.
Resuscitative situation	

MATERIALS & METHOD

This is a prospective, randomized study conducted at Government Rajaji Hospital, attached to Madurai Medical College.

This prospective study comprised 100 patients between the ages of 18-85 years, of either sex, belonging to physical status ASA I-II

To compare the use of the PLMA & Endotracheal tube as a ventilatory device in anaesthetised, paralysed patients for various elective laparoscopic procedures in terms of

(a) Haemodynamic response to insertion of the PLMA and endotracheal tube intubation.

(b) Ventilatory parameters.

(c) Postoperative complications.

(d) Ease of gastric tube Placement

(e) Episodes of gastric insufflations

METHODS

With institutional ethical committee approval, written informed consent was obtained from 100 patients of physical status ASA I – III, aged 18-85 years of either sex, scheduled for elective laparoscopic surgery. It was a prospective study conducted over a period of three months.

Patients with a known difficult airway, cervical spine disease, body mass index >35 kgm-2, mouth opening <2.5 cm and patients who were at risk of aspiration: full stomach, hiatus hernia or gastro-esophageal reflux disease were excluded from the study.

Routine elective laparoscopic surgical procedures included for the study were: cholecystectomy, appendecectomy, diagnostic laparoscopy, laparoscopic sterilisation.

PREMEDICATION

All the patients were premedicated with the following drugs

1. Inj.Pentazocine 6mg/kg (I.M, 45 mts before surgery)
2. Inj.Atropine 0.02mg/kg (I.M, 45 mts before surgery)
3. Ranitidine 50mg (I.V, 30 mts before surgery)
4. Metoclopramide 10mg (I.V, 30 mts before surgery)

The following parameters were monitored: electrocardiogram, pulse oximetery, respiratory gases, blood pressure (non invasive), and airway pressures. All the patients received injection glycopyrrolate 0.2 mg, ranitidine 50 mg and metoclopramide 10 mg intravenously 45 min before surgery.

Anaesthesia was induced with propofol 2-3 mgkg-1/or Thiopentone sodium 3-5 mgkg-1. Insertion facilitated by Succinyl choline 1-2mg/kg Maintenance of anaesthesia was achieved with 66% nitrous oxide with oxygen.

Neuromuscular blockade was achieved with Injection Atracurium. A size 3 PLMA was used. The mask was inserted using the index finger or the introducer tool as recommended by the manufacturer. Closed circle breathing system with soda lime was used.

Correct placement of the device was confirmed by:

• Manual ventilation

• No audible leak from the drain tube with peak airway pressures less than 20 cm H_2O. A leak below 20 cm H_2O was taken as significant and suggested a malposition.

• The gel displacement test, done by placing a blob of gel at the tip of the drain tube and noting the airway pressure at which it was ejected. Positive pressure ventilation was started. A maximum of three insertion attempts were allowed before the placement of the

device was considered a failure. An alternative device a tracheal tube was used in such a situation and the number of attempts to secure the airway was noted.

Oropharyngeal seal pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 5 litre min-1 and recording the airway pressure at which equilibrium was reached. The airway pressure was not allowed to exceed 40 cm H2O.

A gastric tube, whenever needed, (Size 14-16) was then passed through the drain tube. Ease of placement of the gastric tube was recorded and its correct placement confirmed by injection of air and epigastric auscultation.

Presence or absence of any gastric contents and its pH was recorded. Ease of insertion of the device was also recorded. An easy 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.

Intraoperatively the following parameters were noted:

• Heart rate, systolic, diastolic and mean blood pressure before induction, and at 1 and 5 min after insertion of device and after achieving carboperitoneum / insufflating carbon dioxide and then at every 5 min intervals.

• Saturation (SpO_2)

Protocol to maintain SpO_2 > 95% observed by adjusting the FIO_2, respiratory rate and the tidal volume. If SpO_2 fell below 97%

FIO_2 was increased and if the SpO_2 did not improve, the tidal volume was increased.

• Peak airway pressures were recorded once the abdominal pressure reached 15 mmHg. For most abdominal laparoscopic procedures, the intra-abdominal pressures were kept between 12 to 14 mmHg.

•Ease of placement of gastric tube through the drain tube.

•Episodes of gastric insufflations noted during the

laparoscopic procedure by the surgeon was recorded.

Intraoperative analgesia was achieved with intravenous pentazocine boluses of 6 mg and intramuscular diclofenac sodium (50–75 mg). The following intraoperative complications were

documented: aspiration,regurgitation, hypoxia (SpO_2 < 90%), hypercarbia, bronchospasm, airway obstruction, gastric insufflation, blood staining of the device, and tongue-lip-dental trauma.

Residual blockade was reversed with0.02 mg/kg atropine and 0.04-mg/kg neostigmine. After the completion of procedure, the PLMA was removed when the patient was able to open the mouth on command. Any blood detected on the device on removal and duration of anaesthesia was recorded. Secretions, if present, over both the ventral and dorsal aspect of the PLMA were noted and pH tested with a litmus paper sensitive to pH changes postoperatively, the patients were monitored for heart rate, blood pressure, SpO_2 and respiratory rate, and any incidence of nausea and vomiting.

Patients were questioned directly about sore throat in the recovery room. Enquiry about the same was made 24 hrs later.

OBSERVATION & RESULTS

Table – 1

Type of procedure		
Procedure	**Number of cases (%) (PLMA)**	**Number of cases (%) (ENTOTRACHEAL TUBE)**
Cholecystectomy	15	18
Appendecectomy	15	20
Diagnostic Laparoscopic (General surgery,Gynaecological surgery)	10	10
Laparoscopic sterilisation	10	2

Table – 2

PLMA Placement	
Size: 3	**50**
Insertion attempts: 1/2/3 (n)	**49,1**
Failed insertions: PLMA	**1**
Easy	**47**
Difficult	**3**

ET TUBE Placement	
Intubation attempts: 1/2/3 (n)	**50**
Failed intubation: ET	**Nil**
Easy	**50**
Difficult	**Nil**

Table 3 Age

Age group	**Number of cases in**					
	PLMA GROUP		**ETT GROUP**		**TOTAL**	
	No	**%**	No	**%**	**No**	**%**
< 20	13	26	5	10	18	18
21 – 30	24	48	24	48	48	18
31 – 40	8	16	13	26	21	21
41 – 50	4	8	4	8	8	8
> 50	1	2	4	8	5	5
Total	50	100	50	100	100	100
Mean	31.4		26.8		29.1	
S.D	10.9		10.0		10.7	

There is no significant difference in the age composition of the two groups selected for the study.

Table 4 Sex

Sex	Number of cases in					
	PLMA GROUP		ETT GROUP		TOTAL	
	No	%	No	%	No	%
M	12	24	20	40	32	32
F	38	76	30	60	68	68

Table 5

Pulse rate and Mean arterial pressure before insertion of PLMA and before intubion of ET tube.

Pulse rate					P
	PLMA GROUP		ETT GROUP		
	Mean	S.D	Mean	S.D	
Pulse rate	83.9	10.4	78.9	14.3	0.146
M.A.P	92.4	9.1	90.1	11.1	0.2047

There is no significant difference in the resting pulse rate, blood pressure of the two groups.

Table 6 Weight

Weight	**PLMA**	**ETT**	**P**
Mean	50.5	51.1	0.8921
S.D	6.3	5.9	

There is no significant difference in the physical status of the two groups

Table 7 Pulse Rate

Events	**PLMA** (after PLMA insertion)		**ETT** (after ETT intubation)		**P**
	Mean	**S.D**	**Mean**	**S.D**	
Before LMA insertion	83.9	10.4	78.9	14.3	0.146

1 minute	80.9	9.4	84.2	17.5	**0.0349**
5 minutes	79.5	9.4	79.1	13.3	0.8465

Table 8

Mean Arterial Pressure

Events	**PLMA**		**ETT**		**p**
	Mean	S.D	**Mean**	**S.D**	
Before LMA	92.4	9.1	90.1	11.1	0.2047
1 minute (after PLMA insertion)	92.9	8.9	103.0	20.9	**0.0001**
5 minutes (after ETT intubation)	83.5	5.9	87.0	9.5	0.0767

There is minimal hemodynamic response to PLMA insertion compared to ETT intubation.

DISCUSSION

The laryngeal mask airway introduced in 1983 has revolutionised the management of patients who would previously have received anaesthesia by face mask, enabling the anaesthetist to keep both hands free. Since its commercial introduction in 1988, the use of laryngeal mask airway during surgery has increased exponentially. The use of laryngeal mask airway has challenged the assumption that tracheal intubation is the only acceptable way to maintain clear airway and positive pressure ventilation.

Relatively a new device, the PLMA is an improved version of the Classic LMA and offers some added safety features over the Classic LMA such as providing a better glottic seal at low mucosal pressures and a drain tube to vent out air and regurgitant material from the stomach.

We studied the ProSeal LMA in 50 patients undergoing laparoscopic surgery. The PLMA was easy to insert with a high success rate on the first attempt. Size 3 is appropriate for most of our female population. The insertion success rates, insertion time, and ease of placement of gastric tube were in conformity with

earlier reported studies. There were minimum haemodynamic responses to insertion.

We used the PLMA in varied surgical procedures,following peritoneal insufflation, CO_2 is absorbed transperitoneally, and the rate at which this occurs depends on the gas solubility, the perfusion of the peritoneal cavity, and the duration of the pneumoperitoneum. Mullet and colleagues found that end-tidal CO_2 and pulmonary CO_2 elimination increased between the eighth and tenth minutes, regardless of site and duration of insufflation. The CO_2 absorption is more following extraperitoneal rather than intraperitoneal insufflation. Increasing the minute ventilation by 15-25% is necessary to maintain normocarbia under well functioning physiological mechanisms.

The PLMA formed an effective seal around the glottis as reported by previous workers, allowing adequate oxygenation before and after CO_2 insufflation in all patients.

A maximum number of patients in our study achieved peak airway pressures between 20-29 cm of H_2O. Maltby and colleagues, as well as other workers have reported adequate airway management and ventilation with the use of the Classic LMA during carboperitoneum for laparoscopic cholecystectomy whereas

Lu et al do not recommend the use of the Classic LMA for the same. In another comparative study of the PLMA as an alternative to the tracheal tube for laparoscopic cholecystectomy, Maltby et al reported that both the devices (LMA & PLMA) provided equally effective pulmonary ventilation without clinically significant gastric distension in their non- obese patients.

None of these patients had reflux disease and therefore were not at risk of aspiration. All our patients, none of whom had a history of reflux disease, received metoclopramide, a prokinetic agent which markedly increases lower oesophageal sphincter tone. Brimacombe recommends its use in cases of difficult insertions and also where displacement of the mask can occur intraoperatively. The Classic LMA, though popular in short gynaecological laparoscopic procedures, does not offer protection to the trachea against aspiration of regurgitated material. Gastric insufflation was noted in 3 patients. Similar instances have been noted by Maltby and other workers who reported an equal incidence of gastric insufflation in paralysed intubated patients and in those who were managed with either the Classic LMA or the ProSeal PLMA as the airway device. Stix et al noted oesophageal insufflation and gastric

distension in two cases and cautioned that this can occur as a consequence of breach of the PLMA-UOS seal by PPV.

Patients undergoing laparoscopy might be considered to be at risk of developing the acid aspiration syndrome. However, the increased intra-abdominal pressure results in increase in the tone of the lower esophageal sphincter, which allows maintenance of the pressure gradient across the gastro- esophageal junction, and which might therefore reduce the risk of regurgitation Regurgitation of gastric contents through the drain tube was noted in patients but there were no cases of regurgitation into the bowl of the PLMA as detected by the litmus paper technique. There was no case of pulmonary aspiration. Furthermore, the head-down position used in these cases should help prevent any regurgitated fluid from entering the airway.

SUMMARY & CONCLUSION

Tracheal intubation and controlled ventilation is the gold standard for the anaesthetic management of a patient undergoing laparoscopic surgery. The ProSeal laryngeal mask airway (PLMA), a modified version of the Classic laryngeal mask airway (LMA),
Is being considered as an alternative airway device for wide range of laparoscopic surgical procedures. The aim of the study was

To compare the use of the PLMA & Endotracheal tube as a ventilatory device in anaesthetised, paralysed patients for various elective laparoscopic procedures in terms of

(a) Haemodynamic response to insertion of the PLMA and endotracheal tube intubation.
(b) Ventilatory parameters.
(c) Postoperative complications.

(d) Ease of gastric tube Placement

(f) Episodes of gastric insufflations

This study comprised 100 patients between the ages of 18-85 years, of either sex, belonging to physical status ASA I – II.

We assessed haemodynamic responses to insertion of the PLMA, ventilatory parameters, ease of gastric tube placement, gastric insufflation and any postoperative complications. The statistically analysed results showed that the PLMA caused minimum haemodynamic responses to insertion, was a reliable airway management device ensuring adequate ventilation and providing an effective glottic seal in all but one patient. It allowed easy passage of gastric tube. There were three cases of oesophageal regurgitation but no incidence of pulmonary aspiration. Sore throat was reported in patients.

CONCLUSION

Most anaesthesiologists, definitely have more experience and confidence in tracheal intubation. The PLMA is emerging as an effective alternative to tracheal intubation; its applications and safety are still being evaluated. It is likely that the successful first time insertion of the PLMA will increase with more frequent use of the device. We suggest that the experienced anaesthesiologists use the PLMA and correct position of the device must be ensured before embarking on the surgical procedure. There should be no hesitation in using an alternative device in case there is a problem regarding adequate ventilation or oxygenation. It has a special role in patients with difficult intubation coming for elective surgery where its use will avoid unnecessary trauma to the airway. Our data showed that the PLMA is a safe airway device in patients undergoing laparoscopic surgery as judged by stable haemodynamics, good oxygenation and adequate ventilation. We consider that residual gastric fluid should be removed by gastric aspiration.

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DEPARTMENT OF ANESTHESIOLOGY

GOVERNEMNT RAJAJI HOSPITAL, MADURAI

PROFORMA

COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VS ENDROTRACHEAL TUBE AS A VENTILATORY DEVICE IN ANAESTHETIZED PARALYZED PATIENTS FOR VARIOUS ELECTIVE LABAROSCOPIC PROCEDURES.

LMA Proseal Group

NAME	:	
AGE	:	
SEX	:	
WEIGHT	:	
IPNO	:	
DIAGNOSIS	:	
SURGERY	:	
PHYSICAL STATUS	:	
PRE MEDICATION	:	
INDUCTION	:	
INSERTION	:	1) Facilitated By 2) Method 3) No of Attempts
Cuff Volume	:	
CIRCUIT	:	Closed circle breathing system
MAINTENANCE	:	1) Oxygen 33% + Nitous oxide 66% 2) Non deploraising muscle relaxants –
ANALGESIA	:	
REVERSAL	:	
DURATION	:	PARAMETERS

Heamodynamical parameters

BI	Heart rate	systolic.BP	diastolic. BP	Mean. BP
1min				
3min				
Carboperitonium				
5min				
5min				
5min				
5min				
5min				
5min				
5min				
5min				

Ventilatory Parameters

SaO_2

3) Episodes of gastric insuflation:

COMPLICATIONS:

1) Aspiration & Regurgitation
2) Hypoxia
3) Bronchospasm, Airway obstruction,Ginuric insufflation
4) Airway Truma
5) pH – 1) Vorsal Secretion
   2) Ventral Secretions

6) Sore throat

DEPARTMENT OF ANESTHESIOLOGY

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PROFORMA

COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VS ENDROTRACHEAL TUBE AS A VENTILATORY DEVICE IN ANAESTHETIZED PARALYZED PATIENTS FOR VARIOUS ELECTIVE LABAROSCOPIC PROCEDURES.

Cuffed Endotracheal Tube Group

NAME	:	
AGE	:	
SEX	:	
WEIGHT	:	
IPNO	:	
DIAGNOSIS	:	
SURGERY	:	
PHYSICAL STATUS	:	
PRE MEDICATION	:	
INDUCTION	:	
INTUBATION	:	1) Facilitated by 2) Method 3) No of Attempts
Cuff Volume	:	
CIRCUIT	:	closed circle breathing system
MAINTENANCE	:	1) Oxygen 33% + nitous oxide 66% 2) Non deplorisign muscle relaxants
ANALGESIA	:	
REVERSAL	:	
DURATION	:	PARAMETERS

Heamodynamical parameters

BI Heart rate systolic.BP diastolic. BP Mean. BP

1min

3min

Carboperitonium

5min

5min

5min

5min

5min

5min

5min

5min

Ventilatory Parameters

SaO_2

3) Episodes of gastric insuflation:

COMPLICATIONS:

1) Aspiration & Regurgitation
2) Hypoxia
3) Bronchospasm, Airway obstruction,Ginuric insufflation
4) Airway Truma
5) pH – 1) Vorsal Secretion
   2) Ventral Secretions

6) Sore throat