“A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL”.

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This is to certify that the dissertation entitled **"A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL".** is a bonafide research work done by **(REG NO. BA0114004).**

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ABBREVIATIONS

LMA or Clma	-	Laryngeal Mask Airway i.e. classic LMA
PLMA	-	Proseal Laryngeal Mask Airway
SpO2	-	Peripheral oxygen saturation
D.T	-	Drain Tube
UES	-	Upper Esophageal Spinchter
GEB	-	Gum Elastic Bougie
E.T	-	Endotracheal Tube
PPV	-	Positive Pressure Ventilation
S.D	-	Standard Deviation
ASA	-	American Society of Anesthesiologists
MP grade	-	Mallampati grade
C.I	-	Confidence Interval

ABSTRACT

TITLE :

"A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL".

INTRODUCTION :

ProSeal laryngeal mask airway is not easy to be inserted due to its larger cuff especially in Indian population .The 90 degrees rotation technique for inserting the PLMA is reported to be better than the standard index finger insertion technique to improve the insertion success rate

The objective of this study was to evaluate and compare the ease of insertion through the rotational and standard insertion technique in terms of number of attempts, insertion time,airway sealing pressure,fiberoptic glottis view and hemodynamic changes.

METHODS:

120 adult patients were allocated to either a standard technique or a rotation technique group with 60 patients in each group. In the rotation technique group the entire cuff of the PLMA was placed in the patient's mouth in a midline approach without finger insertion, rotated 90 degrees counter clockwise around the patient's tongue, advanced and then rotated back until resistance was felt. The outcomes measured were success

rate at first insertion, insertion time,airway sealing pressure,fiberoptic glottis view and haemodynamic changes.

RESULTS:

For the rotation technique group the success rate at first insertion was greater (98% vs 78%, respectively; P = 0.001), and less time for insertion was required (11.88 +/- 3.62 sec vs 25.98 +/- 10.92 sec, respectively; P <0.0001). Airway sealing pressure ,fiberoptic glotic view were similar and changes in haemodynamic parameters were not clinically significant.

CONCLUSION:

The 90 degrees rotation technique for inserting the PLMA has a higher success rate at first insertion than the standard index finger insertion technique with lesser insertion time & fewer side effects.

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INTRODUCTION

In spite of colossal advances in modern anaesthetic practice, airway management continues to be of cardinal importance. The cuffed endotracheal tube was considered as the gold standard for laparoscopic procedures under general anaesthesia for providing a safe glottic seal[1.] The hindrance of tracheal intubation, which entails rigid laryngoscopy, leads to haemodynamic responses, damage to the oropharyngeal structures at insertion and postoperative sore throat is also a serious concern. This interdicts the utility of the tracheal tube and requires a better alternative[2.]

Failure to intubate can cause mortality and account for 30% of overall brain damage and death in general surgical population [3].

In some cases, inability to secure an airway with an endotracheal tube, with other disadvantages like exaggerated pressor responses and trauma to the oral structures and vocal cords had raised many questions regarding our overdependence on this device until Dr. Archie Brain in the year 1983 came up with a new device Laryngeal mask airway(LMA). Though, it was shown to have some distinct advantages, like no trauma to vocal cords, avoidance of laryngoscopy and minimal pressure responses, it clearly offered no protection against regurgitation of gastric contents into respiratory tract, and was[4] not suitable for effective positive pressure ventilation [5] which made it as a second choice to the endotracheal tube. The role of an LMA, being limited to the difficult airway algorithms and a few other selective cases, Dr. Archie Brain came up with a modification of the Laryngeal Mask Airway (LMA) in year 2001.This device was called the Proseal-Laryngeal mask airway[6].

This double lumen, double cuff LMA has some advantages over its predecessor. ProSeal laryngeal mask airway provides a channel for regurgitated fluid and gastric tube and has modified cuff for better seal . The double cuff of the P-LMA gave a better seal around the glottis [6,7] , hence establishing its superiority in IPPV.

These properties of P-LMA will aid in patients who are more prone for aspiration.

Correct placement of laryngeal mask airway requires some expertise and if LMA insertion is improper, it can cause partial or complete airway obstruction.

Standard Brain's LMA insertion technique is a bit complex[8]. While inserting LMA mask may deflect into back of the mouth and requires excessive force to place LMA at proper position which leads to multiple attempts, prolongs time required for insertion,airway trauma and LMA insertion failure.

Large number of LMA insertion techniques have been studied with regard to ease of insertion in all age groups, but standard Brain's insertion technique has not been replaced [9,10]. However, complications rate is reduced with alternative techniques ,67-90% with standard LMA insertion technique[11,12],with rotational insertion technique, it is 86% in adults[5] and 99% in children[8].

Rotational insertion technique has not been extensively studied in adult populations with regard to success rate and ease of LMA insertion[13,14].The rotational technique avoided the anterior pharyngeal structures and slided along the posterior palatopharyngeal curve without buckling the tip of LMA[8]. The objective of this study was to evaluate and compare the ease of LMA insertion through the rotational and standard LMA insertion technique in terms of number of LMA insertion compared to Brain's technique, in terms of number of LMA insertion attempts, time duration of LMA insertion,airway sealing pressure,fiberoptic glottis view and hemodynamic changes.

AIMS & OBJECTIVES

Comparison of effectiveness between standard and rotational techniques regarding.

1. Ease of insertion.
    - Time of insertion and number of insertion attempts.
    - Airway sealing pressure.
    - Fiber-optic glottis view.
2. Hemodynamic changes.

REVIEW OF LITERATURE

A study by **JEON YT et al**[15] compared two methods of insertion of ProSeal laryngeal mask airway (PLMA) in anaesthetized and paralyzed patients. They compared 90 degrees rotation technique with the index finger insertion technique.

One hundred and twenty Asian adult patients were recruited into the study and were assigned to a standard technique group or a rotation technique group. Men were inserted with a PLMA of size 5 whereas women were inserted with size 4. The index finger was used in the group of subjects allocated to standard technique group (n=60).In the second group in which PMLA was inserted using a rotational technique, the PMLA was first placed in the patient's mouth in the midline, with the entire cuff resting on the tongue and was rotated 90 degrees counter clockwise around the tongue. The study primarily assessed the success at first insertion. It also measured insertion time and complications as the secondary outcome.

It showed that the rotation technique had a higher success rate at first insertion than the group where standard technique was applied (100% vs 83%, respectively; P = 0.003), and less time was required (11 +/- 3 sec vs 19 +/- 16 sec, respectively; P = 0.03).

The study concluded that 90 degrees rotation technique for inserting the PLMA is more successful than the standard index finger insertion technique.

Kim M et al[16] studied the rotational insertion technique for size 3 of ProSeal laryngeal mask airway (PLMA) and concluded that it produces lesser complications in non-paralyzed adult female patients.Large size PLMA is recommended during positive pressure ventilation for effective sealing. The aim of this study was to see the effectiveness of rotational technique with larger size of PLMA (size 4 in female, size 5 in male) in paralyzed anesthetized patients.

A total of 94 male and female patients undergoing laparoscopic surgery were randomly allocated to the standard or rotational technique groups. In the standard technique group (n = 47), PLMA was inserted according to the manufacturer's instructions. In rotational technique group (n=47), PLMA was inserted into the mouth and rotated 90 degrees counterclockwise. PLMA was advanced and rotated back until the resistance of the hypopharynx was felt. Insertion success rates, sealing pressure were compared.

In rotational technique group, first-attempt insertion success rates were higher (100 vs. 81%, P = 0.003) and less time was required to achieve and effective airway (11 ± 3 vs. 19 ± 15 sec, P = 0.002). Sealing pressure was similar in both groups (26 cmH_2O, 25 cmH_2O).

The rotational technique is useful for large size of PLMA in paralyzed, anesthetized patients

Hwang JW et al[17] compared two insertion techniques of ProSeal laryngeal mask airway.

A total of 160 female patients (American Society of Anesthesiologists physical status I or II; age 18-80 yrs) undergoing gynecologic surgery were randomly allocated to the standard or rotational technique groups. In the standard technique group (n = 80), ProSeal laryngeal mask airway insertion was performed by a single experienced user using digital manipulation. In the rotational technique group (n =

80), the ProSeal laryngeal mask airway was rotated counter clockwise through 90 degrees in the mouth and advanced until the resistance of the hypopharynx was felt, and then straightened out in the hypopharynx (n = 80). The ease of insertion was assessed by the success rate at the first attempt. Heart rate and mean blood pressure were recorded 1 min before and 1 min after insertion. Postoperative complications were noted.

The success rate of insertion at the first attempt was higher for the rotational technique (100% vs. 85%, $P < 0.001$). The overall success rate, i.e., successful insertion within three attempts, was 94% for the standard technique versus 100% for the rotational technique. There was no significant change in heart rate, but mean blood pressure increased significantly with the standard technique ($P = 0.001$).The rotational technique is more successful than the standard technique.

M Yun et al[18] compared two insertion techniques of the ProSeal laryngeal mask airway in pediatric patients.

A total of 92 pediatric patients (American Society of Anesthesiologists physical status I or II; age 3 to 12 years) undergoing ophthalmologic surgery were randomly allocated to the standard or rotational technique groups. In the standard technique group (n = 46), ProSeal laryngeal mask airway insertion was performed by a single experienced user using digital manipulation. In the rotational technique group (n = 46), the ProSeal laryngeal mask airway was rotated counter-clockwise through 90° in the mouth and advanced until the resistance of the hypopharynx was felt, and then straightened out in the hypopharynx (n = 80). The ease of insertion was assessed by the success rate at the first attempt. Heart rate and mean blood pressure were recorded 1 minute before and 1 minute after insertion. Postoperative complications were noted.

The success rate of insertion at the first attempt was higher for the rotational technique (95.7% vs 76.1%, $P < 0.001$). The overall success rate - that is, successful insertion within three attempts - was 100% for the both techniques. Systolic, diastolic and mean blood pressure and heart rate increased significantly with the standard technique ($P < 0.001$). Systolic blood pressure and heart rate increased significantly with the rotational technique **(**$P < 0.01$). The incidence of blood staining (8.7% vs 23.9%, $\boldsymbol{P} = 0.048$) was lower with the rotational technique.

The rotational technique is more successful than the standard technique.

Dileep Kumar, Mueenullah Khan and Muhammad Ishaq[19] compared the ease of insertion between rotational laryngeal mask airway (LMA) insertion and Brain's LMA insertion technique in terms of number of LMA insertion attempts, time duration of LMA insertion and complications: trauma, laryngospasm, and hypoxaemia.

One hundred ASA I and II adults undergoing short elective surgical procedures requiring general anaesthesia with spontaneous breathing were enrolled. Following pre-oxygenation, anaesthesia was induced with propofol 2 mg/kg and fentanyl 2 µg/kg. Patients were randomly assigned into one of the study groups: rotational-(R) and standard-(S). LMA insertion was performed when patients became apnoeic and adequate LMA insertion depth achieved.

Successful placement was confirmed by chest expansion, reservoir bag movement and appearance of capnographic tracing in both spontaneously breathing patients and in apnoeic patients with assisted ventilation.

Significant differences were not seen in patient's demographics, Mallampati score, ASA status and pre-operative vital signs. Statistically insignificant difference was found for the time duration and number of LMA insertion attempts. The incidence of trauma was significantly noted in standard insertion technique (28%) compared to (6%) in rotational insertion technique (p = 0.003). The hypoxaemia and laryngospasm was not reported among the groups.

The rotational technique was practically easy while negotiating the back of mouth and it requires little efforts with lowest complication rate. This technique can be considered in adults when encountering difficulty and repetitive failures with standard LMA insertion technique

Yun MJ et al[20]A previous study using a 180° rotation to insert the ProSeal™ laryngeal mask airway (LMA ProSeal) in children did not show improvement over the standard technique. We used a 90° rotation technique to insert the LMA ProSeal in pediatric patients and compared ease of insertion and pharyngeal trauma with the standard technique.

This prospective randomized controlled study included 126 patients aged three to nine years. Anesthesia was induced with thiopental and rocuronium, and the LMA ProSeal used in the study ranged in size from 2 to 3 depending on the patient's body weight. In the control group (n = 63), the LMA ProSeal was inserted using the index finger. In the rotation group (n = 63), the entire cuff of the LMA ProSeal was placed in the patient's mouth without finger insertion and rotated 90° counter clockwise around the tongue. The LMA ProSeal was then advanced and rotated back until resistance was felt. The primary outcome was the insertion success rate at first attempt.

The success rate of insertion at first attempt was higher with the rotation technique than with the standard technique (97% vs 70%, respectively; $P < 0.001$) and the insertion time was shorter (16 ± 6 sec vs 30 ± 24 sec, respectively; $P < 0.001$). Mean blood pressure after LMA ProSeal insertion increased significantly in the control group (62 ± 12 to 69 ± 17 mmHg; $P = 0.01$), but not in the rotation group. The 90° rotation technique improves ease of insertion of the LMA ProSeal in children, and it decreases the risk of pharyngeal trauma.

Nakayama S, **Osaka Y**, **Yamashita M**[21] compared the ease of insertion of the laryngeal mask airway (LMA) with a partially inflated cuff using the standard 'nonrotational' technique versus the rotational technique.

One hundred and forty-five children undergoing anaesthesia using the LMA were randomly assigned to either method. The cuff was partially inflated in both groups. The ease of insertion was assessed by the time taken to complete the LMA insertion, the number of attempts before successful placement and the occurrence of complications.

The success rate of insertion at the first attempt was higher in the rotational technique group (99% versus 79%, $P < 0.05$). All patients in the rotational group had the mask inserted within two attempts. On the other hand, three patients had the mask inserted on the first attempt with the rotational technique after three unsuccessful attempts by an anaesthesiologist with the standard 'nonrotational' technique. Insertion technique made no difference on insertion time.

The rotational technique was associated with a higher success rate for insertion and a lower incidence of complications in children. Using the rotational technique with a partially inflated cuff could be the first-choice approach in paediatric patient

Ghai B, Ram J, Makkar JK, Wig J.[22] compared fiber-optic assessment of laryngeal mask airway (LMA) position in children using two LMA insertion techniques, i.e., standard and rotational.

Seventy-eight ASA I children, aged 2.5 months to 10 years, undergoing elective cataract surgery were included in this study. LMA was inserted in random order using either standard or rotational technique, removed, and thereafter crossed over to alternate technique. Positioning of LMA was assessed using fiber-optic bronchoscope with each technique. Change in the incidence of fiber-optic assessment grades 1 and 2 between two insertion techniques was measured as the primary outcome. Secondary outcome measures studied were first-attempt success rate, overall success rate, time for successful insertion, visual analogue scale for placement, complications, and maneuvers used to relieve airway obstruction.

Incidence of fiber-optic grades 1 and 2 was 61.5% with standard technique and increased to 92.3% with rotational technique ($P < 0.001$, McNemar's test) (RR 3.0, 95% CI 2.2-4.2). Median (IQR) fiber-optic grading was significantly better with rotational technique [2 (1-2)] as compared to standard technique [2 (2-3)], ($P < 0.001$, Wilcoxon signed rank test). First-attempt success rate was significantly higher (96.2%) with rotational technique compared with standard technique (80.7%) ($P = 0.04$, McNemar's test). Overall success rate (i.e., successful insertion with two attempts) was 100% with rotational technique compared with 89.7% with standard technique ($P = 0.003$, Fischer's exact test). Time for successful insertion and incidence of complications were significantly lesser with rotational technique.

Rotational technique of LMA insertion in children is associated with better seating of LMA (as observed on fiber-optic assessment) compared with the standard technique. Also, it is associated with higher success rate and lower incidence of complications.

BASIC SCIENCES

ANATOMY OF UPPER AIRWAY

MOUTH

The mouth is made up of the vestibule and the mouth cavity, the former communicating with the latter through the aperture of the mouth.

The **vestibule** is formed by the lips and cheeks without and by the gums and teeth within. An important feature is the opening of the *parotid duct* on a small papilla opposite the 2nd upper molar tooth. Normally the walls of the vestibule are kept together by the tone of the facial muscles; a characteristic feature of a facial (VII) nerve paralysis is that the cheek falls away from the teeth and gums, enabling food and drink to collect in, and dribble out of, the now patulous vestibule.

The **mouth cavity** is bounded by the alveolar arch of the maxilla and the mandible, and teeth in front, the hard and soft palate above, the anterior two-thirds of the tongue and the reflection of its mucosa forward onto the mandible below, and the oropharyngeal isthmus behind. The mucosa of the floor of the mouth between the tongue and mandible bears the median *frenulum linguae*, on either side of which are the orifices of the

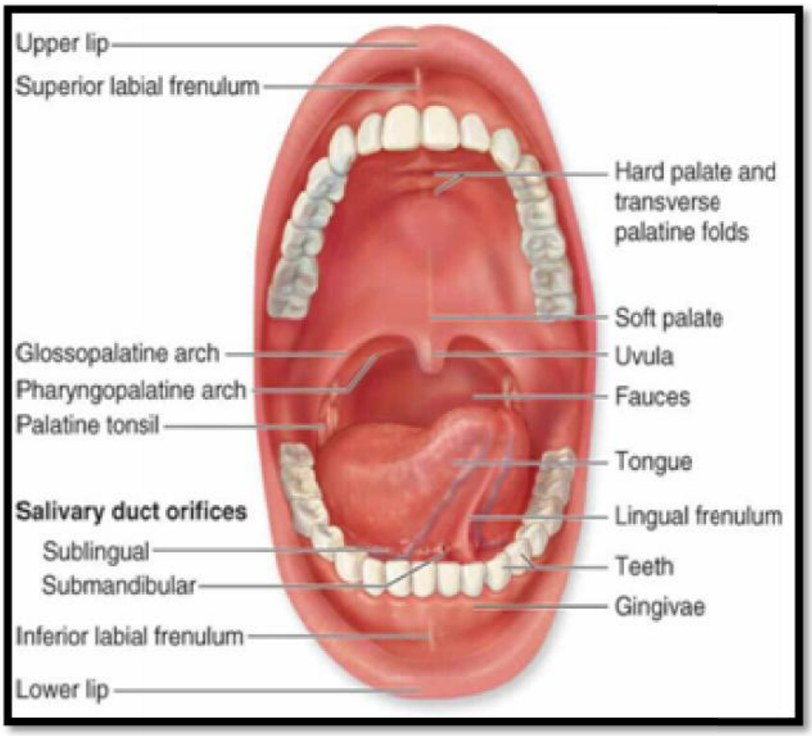


Fig. 1 Oral cavity

Submandibular salivary glands (Fig. 1). Backwards and outwards from these ducts extend the sublingual folds that cover the sublingual glands on each side (Fig. 1); the majority of the ducts of these glands open as a series of tiny orifices along the overlying fold, but some drain into the duct of the submandibular gland (Wharton's duct).

The palate

The **hard palate** is made up of the palatine processes of the maxillae and the horizontal plates of the palatine bones. The mucous membrane covering the hard palate is peculiar in that the stratified squamous mucosa is closely connected o the underlying periosteum, so that the two dissect away at operation as a single sheet termed the mucoperiosteum. This is thin in the midline, but thicker more laterally due to the presence of numerous small palatine salivary glands, an uncommon but well-recognized site for the development of mixed salivary tumours.

The **soft palate** hangs like a curtain suspended from the posterior edge of the hard palate. Its free border bears the *uvula* centrally and blends on either side with the pharyngeal wall. The anterior aspect of this curtain faces the mouth cavity and is covered by a stratified squamous epithelium. The posterior aspect is part of the nasopharynx and is lined by a ciliated columnar epithelium under which is a thick stratum of mucous and serous glands embedded in lymphoid tissue. The 'skeleton' of the soft palate is a tough fibrous sheet termed the *palatine aponeurosis*, which is attached to the posterior edge of the hard palate. The aponeurosis is continuous on each side with the tendon of tensor palati and may, in fact, represent an expansion of this tendon.

The **muscles of the soft palate** are five in number: the tensor palati, the levator palati, the palatoglossus, the palatopharyngeus and the musculus uvulae

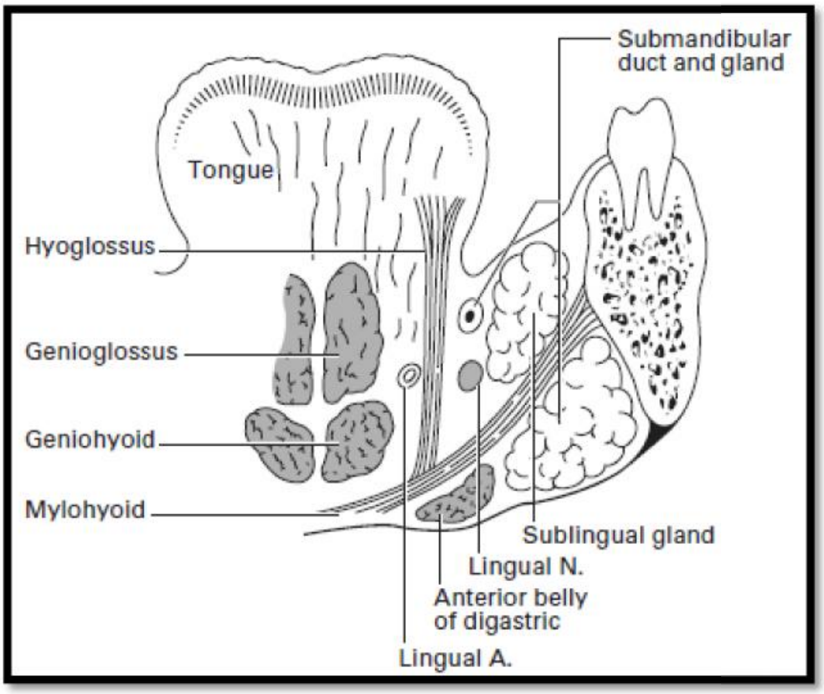


Fig. 2 Tongue

The *tensor palati* (tensor veli palatini) arises from the scaphoid fossa at the root of the medial pterygoid plate, from the lateral side of the Eustachian cartilage and the medial side of the spine of the sphenoid. Its fibres descend laterally to the superior constrictor and the medial pterygoid plate to end in a tendon that pierces the pharynx, loops medially around the hook of the hamulus to be inserted into the palatine aponeurosis. Its action is to tighten and flatten the soft palate.

The *levator palati* (levator veli palatini) arises from the undersurface of the petrous temporal bone and from the medial side of the Eustachian tube, enters the upper surface of the soft palate and meets its fellow of the opposite side. It elevates the soft palate.

The *palatoglossus* arises in the soft palate, descends in the palatoglossal fold and blends with the side of the tongue. It approximates the palatoglossal folds.

The *palatopharyngeus* descends from the soft palate in the palatopharyngeal fold to merge into the side wall of the pharynx: some fibres become inserted along the posterior border of the thyroid cartilage. It approximates the palatopharyngeal folds.

The *musculus uvulae* takes origin from the palatine aponeurosis at the posterior nasal spine of the palatine bone and is inserted into the uvula. Injury to the cranial root of the accessory nerve, which supplies this muscle via the vagus nerve, results in the uvula becoming drawn across and upwards towards the opposite side.

The tensor palati is innervated by the mandibular branch of the trigeminal nerve via the otic ganglion. The other palatine muscles are supplied by the pharyngeal plexus, which transmits cranial fibres of the accessory nerve via the vagus The palatine muscles help to close off the nasopharynx from the mouth in deglutition and phonation. In this, they are aided by contraction of the upper part of the superior constrictor, which produces a transverse ridge on the back and side walls of the pharynx at the level of the 2nd cervical vertebra termed the *ridge of Passavant*.

Paralysis of the palatine muscles results (just as surely as a severe degree of cleft palate deformity) in a typical nasal speech and in regurgitation of food through the nose.

NOSE

The airway functionally begins at the nares and the mouth, where air first enters the body. Phylogenetically, breathing was intended to occur through the nose. This arrangement not only enables the animal to smell danger but also permits uninterrupted conditioning of the inspired air while feeding. Resistance to airflow through the nasal passages is twice the resistance that occurs through the mouth. Therefore, during exercise or respiratory distress, mouth breathing occurs to facilitate a reduction in airway resistance and increased airflow.

The nose serves a number of functions: respiratory, olfaction, humidification, filtration, and phonation. In the adult human, the two nasal fossae extend 10 to 14 cm from the nostrils to the nasopharynx. The two fossae are divided mainly by a midline quadrilateral cartilaginous septum together with the two extreme medial portions of the lateral cartilages. The nasal septum is composed mainly of the perpendicular plate of the ethmoid bone descending from the cribriform plate, septal cartilage, and the vomer. Disruption of the cribriform plate secondary to facial trauma or head injury may allow direct communication with the anterior fossa. The use of positive-pressure mask ventilation in this scenario may lead to the entry of bacteria or foreign material leading to meningitis or sepsis. In addition, nasal airways, nasotracheal tubes, and nasogastric tubes may be inadvertently introduced into the subarachnoid space.

Each nasal fossa is convoluted and provides approximately 60 cm^2 surface area per side for warming and humidifying the inspired air. The nasal fossa is bounded laterally by inferior, middle, and superior turbinate bones (conchae), which divide the fossa into scroll-like spaces called the inferior, middle, and superior meatuses (Fig. 3). The inferior turbinate usually limits the size of the nasotracheal tube that can be passed through the nose. Thus, damage to the lateral walls may occur as a result of vigorous attempts during nasotracheal intubation. The arterial supply to the nasal cavity is mainly from the ethmoid branches of the ophthalmic artery, sphenopalatine and greater palatine branches of the maxillary artery, and superior labial and lateral nasal branches of the facial artery. Kiesselbach's plexus, where these vessels anastomose, is situated in Little's area on the anterior-inferior portion of the nasal septum. This is a common source of clinically significant epistaxis. The vascular mucous membrane overlying the turbinates can be damaged easily, leading to profuse hemorrhage. The paranasal sinuses, named for the bone in which they are located, are the sphenoid, ethmoid, maxillary, and frontal. They drain through apertures into the lateral wall of the nose. Prolonged nasotracheal intubation has most often been associated with infection of the maxillary sinus as its drainage is hindered by the location of the ostia superiorly in the sinus promoting a chronic infectious process

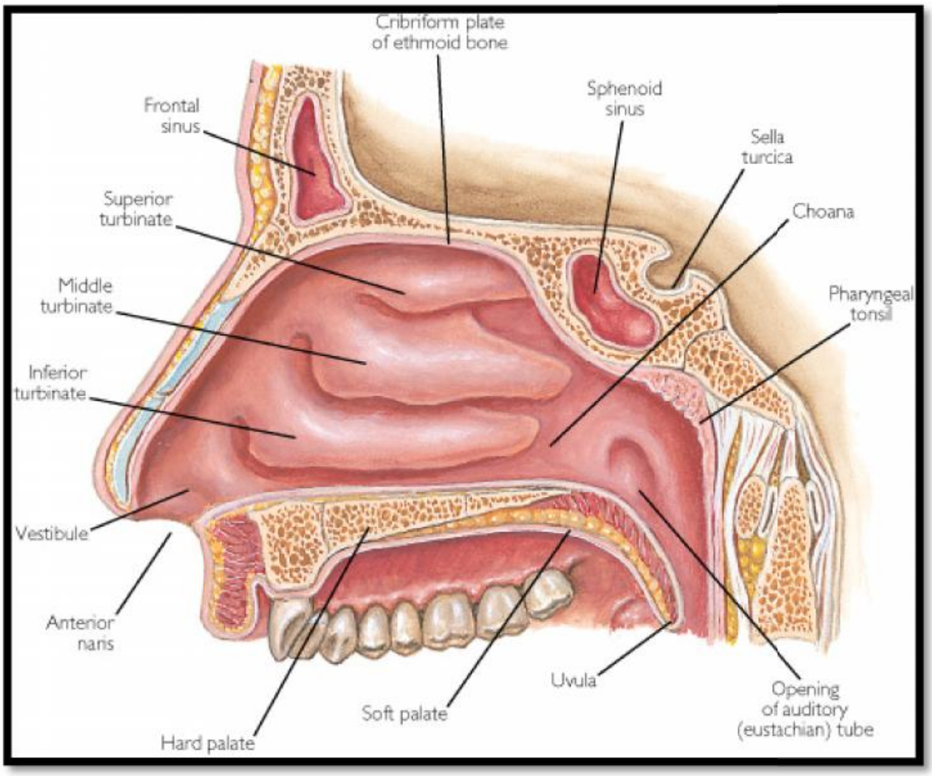


Fig. 3: Nasal cavity

The olfactory area is located in the upper third of the nasal fossa and consists of the middle and upper septum and the superior turbinate bone. The respiratory portion is located in the lower third of the nasal fossa. The respiratory mucous membrane consists of ciliated columnar cells containing goblet cells and nonciliated columnar cells with microvilli and basal cells. The olfactory cells have specialized hairlike processes, called the olfactory hair, innervated by the olfactory nerve. The nonolfactory sensory nerve supply to the nasal mucosa is derived from the first two divisions of the trigeminal nerve. The parasympathetic autonomic nerves reach the mucosa from the facial nerve after relay through the sphenopalatine ganglion, and sympathetic fibers are derived from the plexus surrounding the internal carotid artery through the vidian nerve.

Approximately 10,000 L of ambient air passes through the nasal airway per day, and 1 L of moisture is added to this air in the processThe moisture is derived partly from transudation of fluid through the mucosal epithelium and from secretions produced by glands and goblet cells. These secretions have significant bacteriocidal properties. Foreign body invasion is further minimized by the stiff hairs (vibrissae), the ciliated epithelium, and the extensive lymphatic drainage of the area.

A series of complex autonomic reflexes controls the blood supply to the nasal mucosa and allows it to shrink and swell quickly. Reflex arcs also connect this area with other parts of the body. For example, the Kratschmer reflex leads to bronchiolar constriction upon stimulation of the anterior nasal septum in animals. A demonstration of this reflex may be seen in the postoperative period when a patient becomes agitated when the nasal passage is packed.

PHARYNX

The pharynx, 12 to 15 cm long, extends from the base of the skull to the level of the cricoid cartilage anteriorly and the inferior border of the sixth cervical vertebrae posteriorly. It is widest at the level of the hyoid bone (5 cm) and narrowest at the level of the esophagus (1.5 cm), which is the most common site for obstruction after foreign body aspiration. It is further subdivided into the nasopharynx, oropharynx, and laryngopharynx. The nasopharynx, which primarily has a respiratory function, lies posterior to the termination of the turbinates and nasal septum and extends to the soft palate. The oropharynx has primarily a digestive function, starts below the soft palate, and extends to the superior edge of the epiglottis. The laryngopharynx (hypopharynx) lies between the fourth and sixth cervical vertebrae, starts at the superior border of the epiglottis, and extends to the inferior border of the cricoid cartilage, where it narrows and becomes continuous with the esophagus (Fig.4). The eustachian tubes open into the lateral walls of the nasopharynx. In the lateral walls of the oropharynx are situated the tonsillar pillars of the fauces. The anterior pillar contains the glossopharyngeus muscle and the posterior pillar the palatoglossus muscle. The wall of the pharynx consists of two layers of muscles, an external circular and an internal longitudinal. Each layer is composed of three paired muscles. The stylopharyngeus, the salpingopharyngeus, and the palatopharyngeus form the internal layer (Fig. 5). They elevate the pharynx and shorten the larynx during deglutition. The superior, middle, and inferior constrictors form the external layer, and they advance the food in a coordinated fashion from the oropharynx into the esophagus.

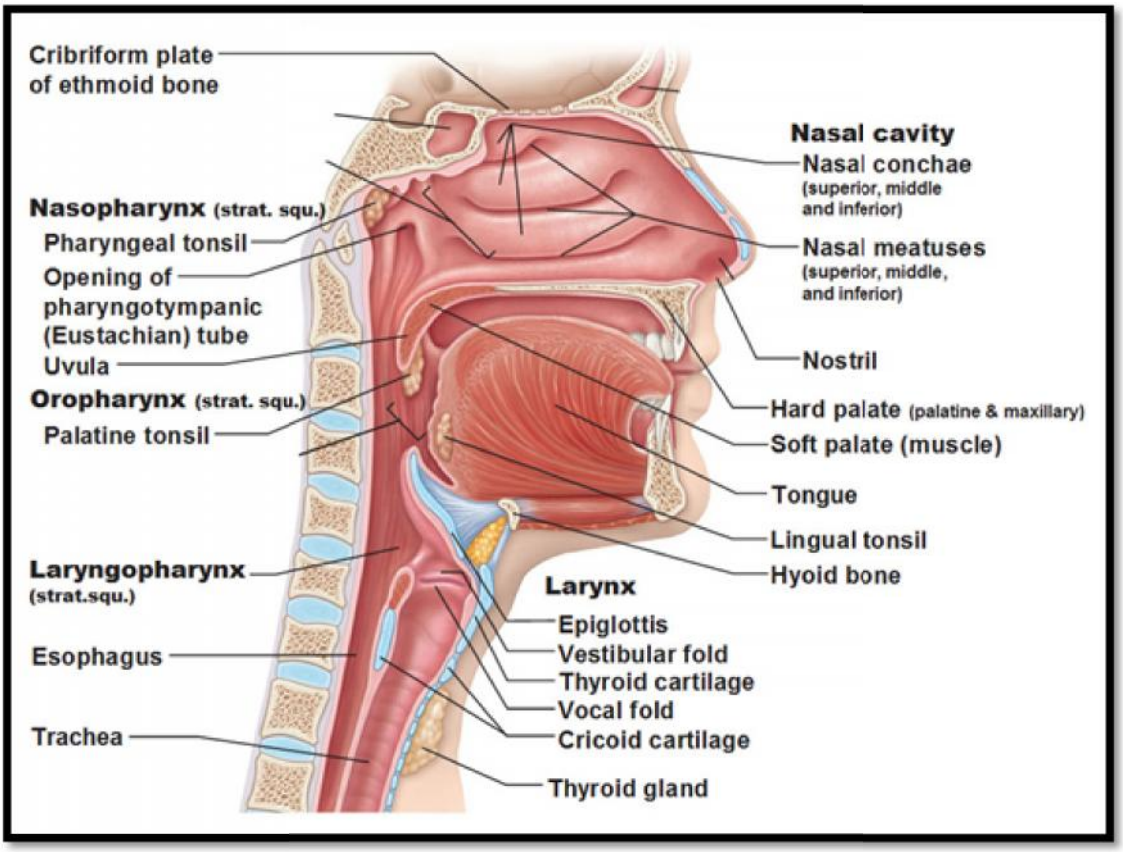


Fig. 4: Airway

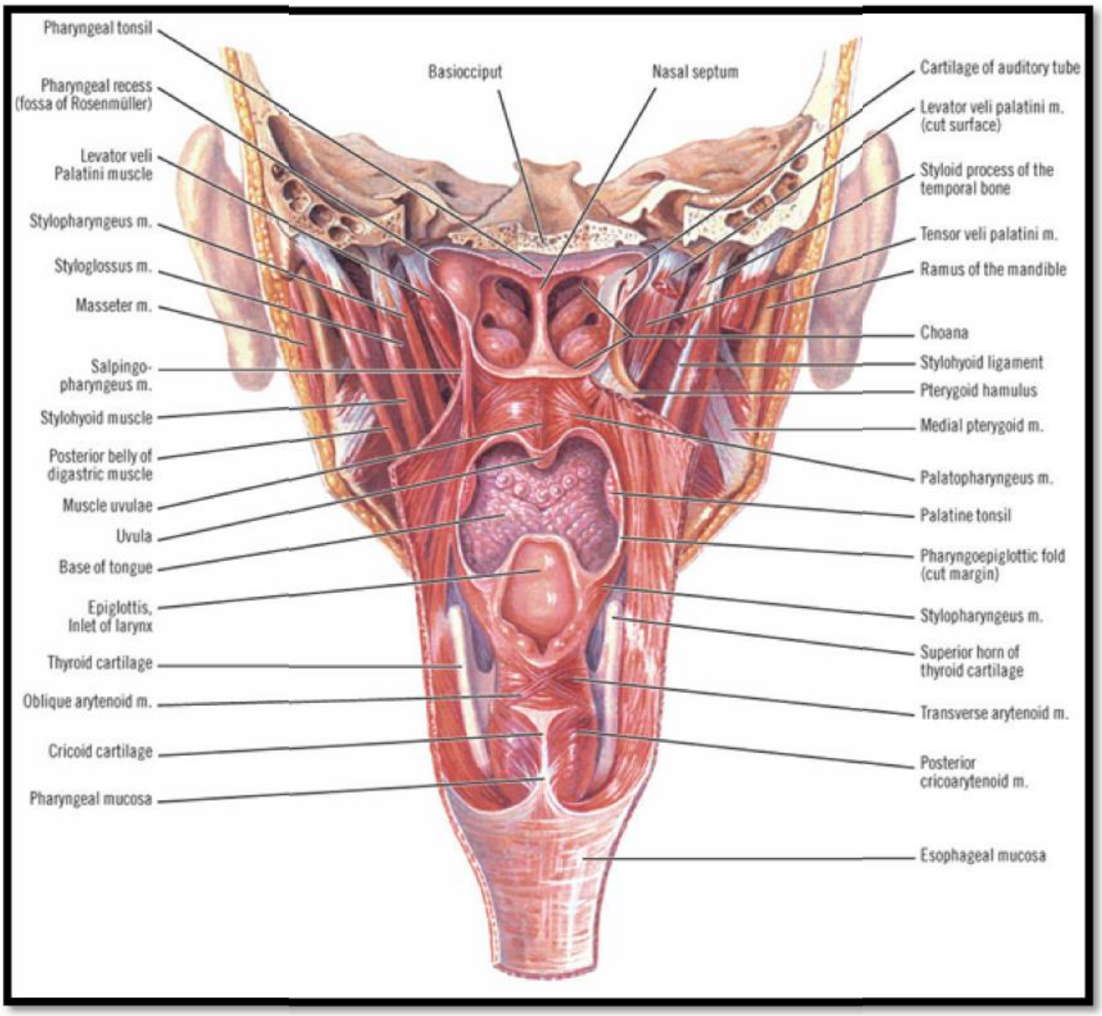


Fig. 5: Pharynx

The constrictors are innervated by filaments arising out of the pharyngeal plexus (formed by motor and sensory branches from the vagus, the glossopharyngeal, and the external branch of the superior laryngeal nerves). The inferior constrictor is additionally innervated by branches from recurrent laryngeal and external laryngeal nerves. The internal layer is innervated by the glossopharyngeal nerve.

LARYNX

The larynx, which lies in the adult neck opposite the third through sixth cervical vertebrae, is situated at the crossroads between the food and air passages (or conduits). It is made up of cartilages forming the skeletal framework, ligaments, membranes, and muscles. Its primary function is to serve as the “watchdog” of the respiratory tract, allowing passage only to air and preventing secretions, food, or foreign bodies from entering the trachea. In addition, it functions as the organ of phonation. The larynx may be somewhat higher in females and children. Until puberty, no differences in the laryngeal sizes exist between males and females. At puberty, the larynx develops more rapidly in males than females, nearly doubling in the anteroposterior diameter. The female larynx is smaller and more cephalad. The measurements of the adult male and female larynx length, transverse diameter, and sagittal diameter are 44 and 36 mm, 43 and 41 mm, and 36 and 26 mm, respectively. Most larynxes develop somewhat asymmetrically. The inlet to the larynx is bounded anteriorly by the upper edge of the epiglottis, posteriorly by a fold of mucous membrane stretched between the two arytenoid cartilages, and laterally by the aryepiglottic folds.

1. Bones of the Larynx

The hyoid bone suspends and anchors the larynx during respiratory and phonatory movement. It is U shaped, as its name is derived from the Greek word *hyoeides*, meaning shaped like the letter upsilon (Fig. 6). It has a body, which is 2.5 cm wide by 1 cm thick, and greater and lesser horns (cornu). This bone does not articulate with any other bone. It is attached to the styloid processes of the temporal bones by the stylohyoid ligament and to the thyroid cartilage by the thyrohyoid membrane and muscle. Intrinsic tongue muscles originate on the hyoid, and the pharyngeal constrictors are attached here as well.

2. Cartilages of the Larynx

Nine cartilages provide the framework of the larynx (Fig. 7). These are the unpaired thyroid, cricoid, and epiglottis and the paired arytenoids, corniculates, and cuneiforms. They are connected and supported by membranes, synovial joints, and ligaments. The ligaments, when covered by mucous membranes, are called folds.

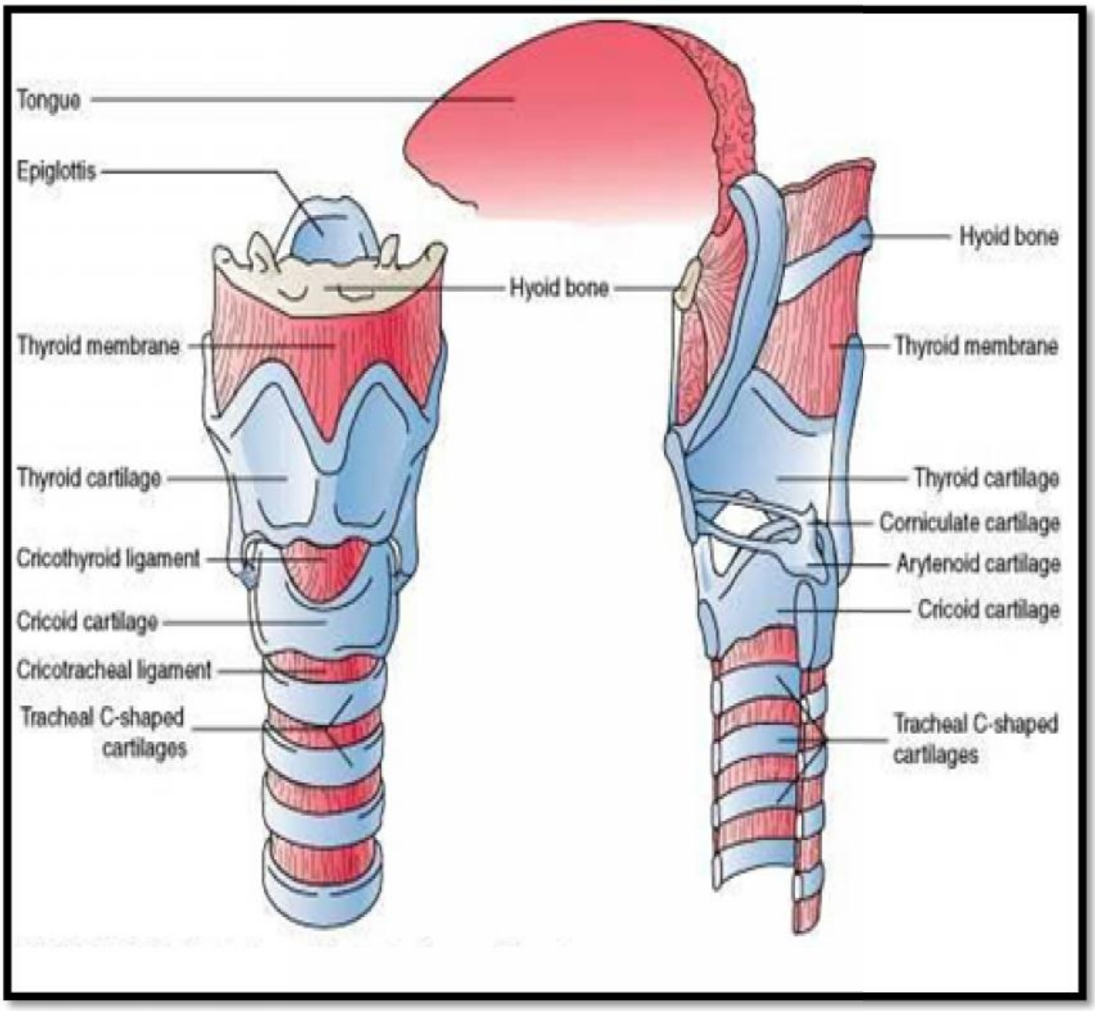


Fig. 6: Larynx

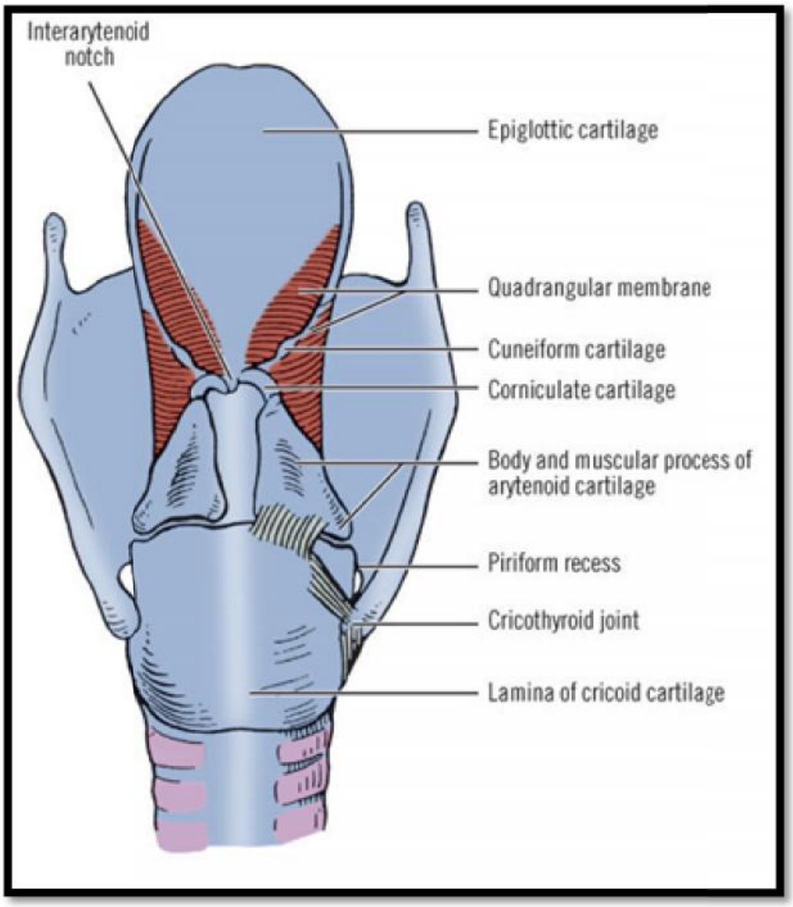


Fig. 7: Thyroid cartilage

a. Thyroid Cartilage

The thyroid cartilage, the longest laryngeal cartilage and largest structure in the larynx, acquires its shieldlike shape from the embryologic midline fusion of the two distinct quadrilateral laminae. In females, the sides join at approximately 120 degrees, and in males at closer to 90 degrees. This smaller thyroid angle explains the greater laryngeal prominence in males (the "Adam's apple"), the longer vocal cords, and the lower pitched voice. The thyroid notch lies in the midline at the top of the fusion site of the two laminae. On the inner side of this fusion line are attached the vestibular ligaments and, below them, the vocal ligaments (Fig. 6). The superior (greater) and inferior (lesser) cornu of the thyroid are the slender posteriorly directed extensions of the edges of the lamina. The lateral thyrohyoid ligament attaches the superior cornu to the hyoid bone, and the cricoid cartilage articulates with the inferior cornu at the cricothyroid joint. The movements of this joint are rotatory and gliding, which leads to changes in the length of the vocal folds.

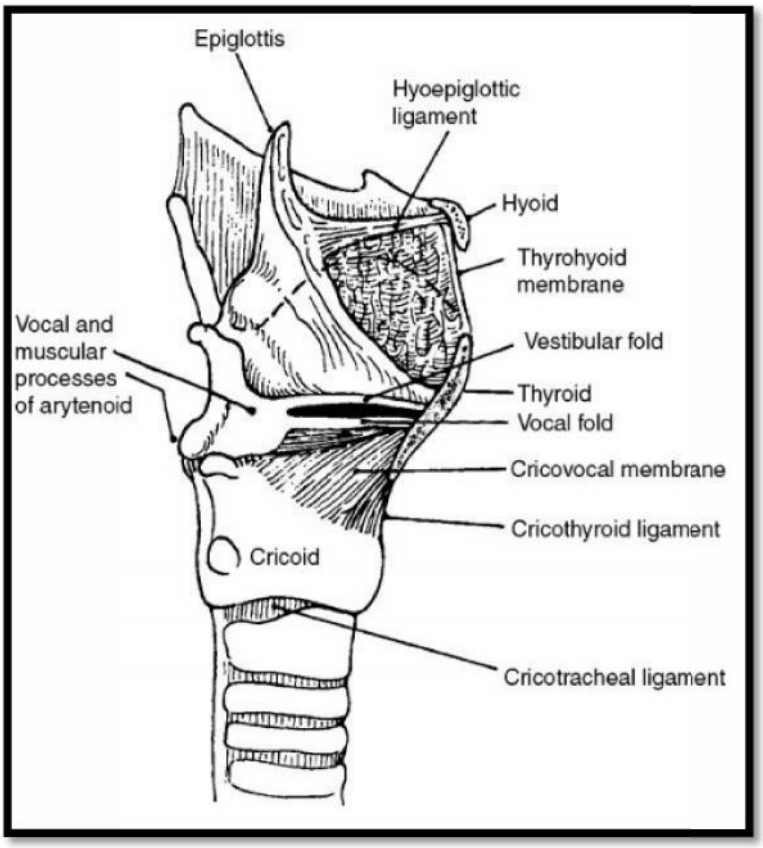


Fig. 8: Cricoid cartilage

b. Cricoid Cartilage

The cricoid cartilage represents the anatomic lower limit of the larynx and helps support it. It is thicker and stronger than the thyroid cartilage and represents the only complete cartilaginous ring in the airway. Thus, cautious downward pressure on the cricoid cartilage to prevent passive regurgitation is possible without subsequent airway obstruction. The name cricoid is derived from the Greek words krikos and eidos, meaning shaped like a ring, hence its frequent reference to a signet ring shape.

The bulky portion or laminae are located posteriorly. The tracheal rings connect to the cricoid by ligaments and muscles. The cricoid lamina has ball and socket synovial articulations with the arytenoids posterosuperiorly and the thyroid cartilage more inferolaterally and anteriorly. It also attaches to the thyroid cartilage by the cricothyroid membrane, a relatively avascular and easily palpated landmark in most adults.(Fig. 6-8)

Attempts have been made to measure the inner diameters of the cricoid cartilage in cadaveric specimens, with great variability noted. Randestad and colleagues reported that the smallest diameter is in the frontal plane in females, ranging from 8.9 to 17.0 mm (mean 11.6), and that in males ranged from 11.0 to 21.5 mm (mean 15.0 mm). They further noted that placement of a standard size ET (7 mm inner diameter for females and 8 mm inner diameter for males) through the cricoid cartilage while preventing mucosal necrosis may be difficult in certain individuals. The cricothyroid membrane represents an important identifiable landmark, providing access to the airway by percutaneous or surgical cricothyroidotomy. The various dimensions of the cricothyroid membrane have been identified in cadaveric specimens. However the actual methodology of obtaining the anatomic measurements varies, making comparisons difficult to interpret. Caparosa and Zavatsky described the cricothyroid membrane as a trapezoid with a width ranging from 27 to 32 mm, representing the actual anatomic limit of the membrane, and a height of 5 to 12 mm.(Fig. 11). Bennett and coauthors reported the dimensions as a width of 9 to 19 mm and a height of 8 to 19 mm, and Dover and coworkers reported a width of 6.0 to 11.0 mm and a height of 7.5 to 13.0 mm, using the distance between the cricothyroid muscles as their horizontal limit. In females it was reported that the width and height of the membrane are smaller than in males. Anteriorly vascular structures overlie the membrane and pose a risk of hemorrhage. Cadaveric studies have noted the presence of a transverse cricothyroid artery, a branch of the superior thyroid artery, traversing the upper half of the membrane. Thus, a transverse incision in the lower third of the membrane is recommended. The superior thyroid artery was noted to course along the lateral edge of the membrane as well. Also, various branches of the superior and inferior thyroid veins and the jugular veins were reported to traverse the membrane.

c. Arytenoids

The two light arytenoid cartilages are shaped like three-sided pyramids, and they lie in the posterior aspect of the larynx. The arytenoid's medial surface is flat and covered with only a firm, tight layer of mucoperichondrium. The base of the arytenoid is concave and articulates by a true diarthrodial joint with the superior lateral aspect of the posterior lamina of the cricoid cartilage. It is described as a ball and socket with three movements, rocking or rotating, gliding, and pivoting, controlling adduction and abduction of the vocal cords. All such synovial joints can be affected by rheumatoid arthritis. Cricoarytenoid arthritis, noted to be present in a majority of these patients, has been identified as a cause of life-threatening upper airway obstruction. Cricoarytenoid arthropathy has also been reported as a rare but potentially fatal cause of acute upper airway obstruction in patients with systemic lupus erythematosus.

The lateral extension of the arytenoid base is called the muscular process. Important intrinsic laryngeal muscles, lateral and posterior cricoarytenoids, originate here. The medial extension of the arytenoid base is called the vocal process. Vocal ligaments, the bases of the true vocal folds, extend from the vocal process to the midline of the inner surface of the thyroid lamina (Fig. 6-8). The fibrous membrane that connects the vocal ligament to the thyroid cartilage actually penetrates the body of the thyroid. This membrane is called Broyles' ligament. This ligament contains lymphatics and blood vessels and therefore can act as an avenue for extension of laryngeal cancer outside the larynx. The relationship between the anterior commissure of the larynx and the inner aspect of the thyroid cartilage is important to otolaryngologists, who perform thyroplasties and supraglottic laryngectomies on the basis of its location. A study of cadavers reported that the anterior commissure of the larynx can usually be found above the midpoint of the vertical midline fusion of the thyroid cartilage ala.

d. Epiglottis

The epiglottis is considered to be vestigial by many authorities. Composed primarily of fibroelastic cartilage, the epiglottis does not ossify and maintains some flexibility throughout life. It is shaped like a leaf or a tear and is found between the larynx and the base of the tongue (Fig. 6-8). In approximately 1% of the population, the tip and posterior aspect of the epiglottis are visible during a pharyngoscopic view with the mouth opened and tongue protruded. Contrary to reports, this does not always predict ease of intubation. The upper border of the epiglottis is attached by its narrow tip or petiole to the midline of the thyroid cartilage by the thyroepiglottic ligament. The hyoepiglottic ligament connects the epiglottis to the back of the body of the hyoid bone. The mucous membrane that covers the anterior aspect of the epiglottis sweeps forward to the tongue as the median glossoepiglottic fold and to the pharynx as the paired lateral pharyngoepiglottic folds. The pouchlike areas found between the median and lateral folds are the valleculae. The tip of a properly placed Macintosh laryngoscope blade rests in this area. The vallecula is a common site of impaction of foreign bodies, such as fish bones, in the upper airway.

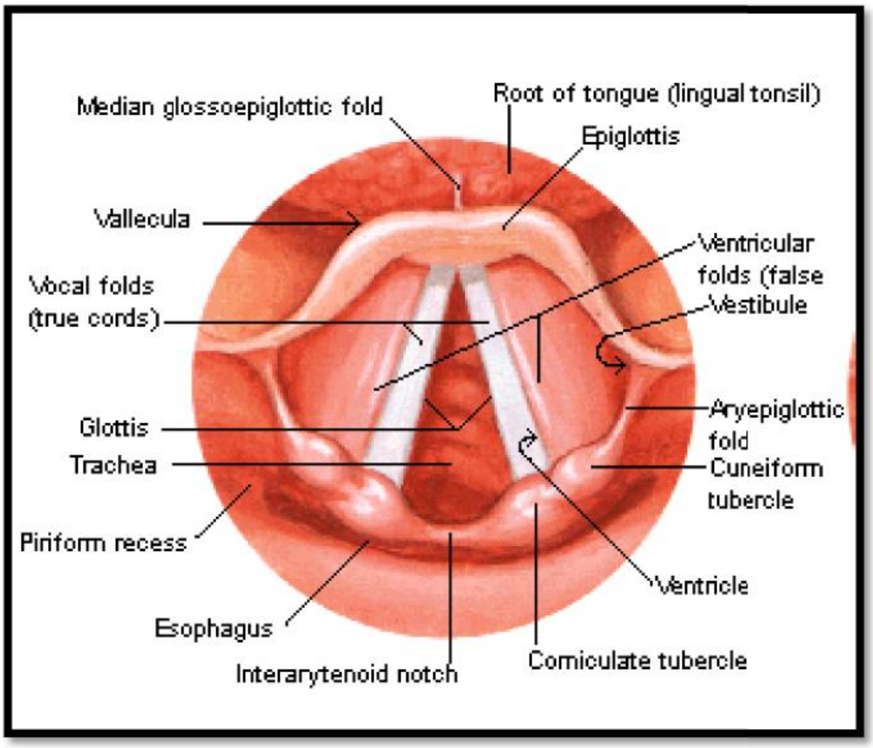


Fig. 9: Vocal cords

e. Cuneiform and Corniculate Cartilages

The epiglottis is connected to the arytenoid cartilages by the laterally placed aryepiglottic ligaments and folds (Fig. 7 &13). Two sets of paired fibroelastic cartilages are embedded in each aryepiglottic fold. The sesamoid cuneiform cartilage is roughly cylindrical and lies anterosuperior to the corniculate in the fold. The cuneiform may be seen laryngoscopically as a whitish elevation through the mucosa. The corniculate is a small triangular object visible directly over the arytenoid cartilage. The cuneiform and corniculate cartilages reinforce and support the aryepiglottic folds and may help the arytenoids move.

f. False and True Vocal Cords

The thyrohyoid membrane (Figs 9, 10 & 12), attaching the superior edge of the thyroid cartilage to the hyoid bone, provides cranial support and suspension. It is separated from the hyoid body by a bursa that facilitates movement of the larynx during deglutition. The thicker median section of the thyrohyoid membrane is the thyrohyoid ligament and its thinner lateral edges are pierced by the internal branches of the superior laryngeal nerves.

Beneath the laryngeal mucosa is a fibrous sheet containing many elastic fibers, the fibroelastic membrane of the larynx. Its upper area, the quadrangular membrane, extends in the aryepiglottic fold between the arytenoids and the epiglottis. The lower free border of the membrane is called the vestibular ligament and forms the vestibular folds, or false cords

The cricothyroid membrane joins the cricoid and thyroid cartilages. The thickened median area of this fibrous tissue, the "conus elasticus," extends up inside the thyroid lamina to the anterior commissure and continues and blends with the vocal ligament. The cricothyroid ligament thus connects the cricoid, thyroid, and arytenoid cartilages. The thickened inner edges of the cricothyroid ligament, called the vocal ligament, form the basis of the vocal folds.

g. Laryngeal Cavity

The laryngeal cavity (Fig. 9) extends from the laryngeal inlet to the lower border of the cricoid cartilage. Viewed laryngoscopically from above, two paired inward projections of tissue are visible in the laryngeal cavity the superiorly placed vestibular folds, or false cords, and the more inferiorly placed vocal folds, or true vocal. The space between the true cords is called the rima glottidis, or the glottis. The glottis is divided into two parts. The anterior intermembranous section is situated between the two vocal folds. The two vocal folds meet at the anterior commissure of the larynx. The posterior intercartilaginous part passes between the two arytenoid cartilages and the mucosa, stretching between them in the midline posteriorly, forming the posterior commissure of the larynx. At rest the vocal processes are approximately 8 mm apart. The area extending from the laryngeal inlet to the vestibular folds is known as the vestibule or supraglottic larynx. The laryngeal space from the free border of the cords to the cricoid cartilage is called the subglottic or infraglottic larynx. On the basis of cadaver studies, the measurements of the subglottis have been identified. Understanding the anatomic relationships between the cricothyroid space and the vocal folds is important to minimize complications after cricothyrotomy. Bennett and colleagues reported this distance as 9.78 mm. The region between the vestibular folds and the glottis is termed the ventricle or the sinus. The ventricle may expand anterolaterally to a pouchlike area with many lubricating mucous glands called the laryngeal saccule. The saccule is believed to help in voice resonance in apes. The pyriform sinus lies laterally to the aryepiglottic fold within the inner surface of the thyroid cartilage

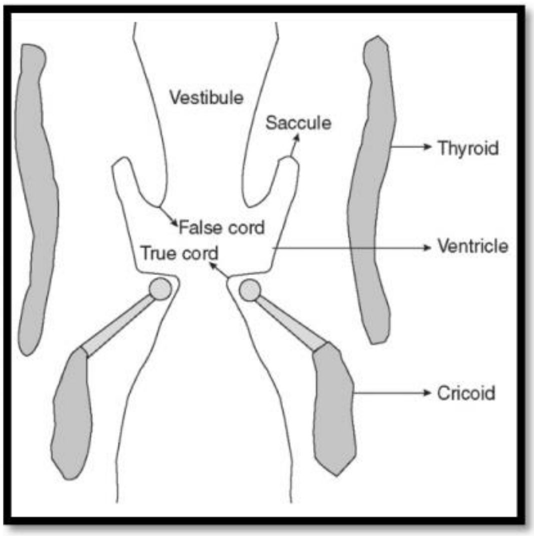


Fig. 10: Laryngeal cavity

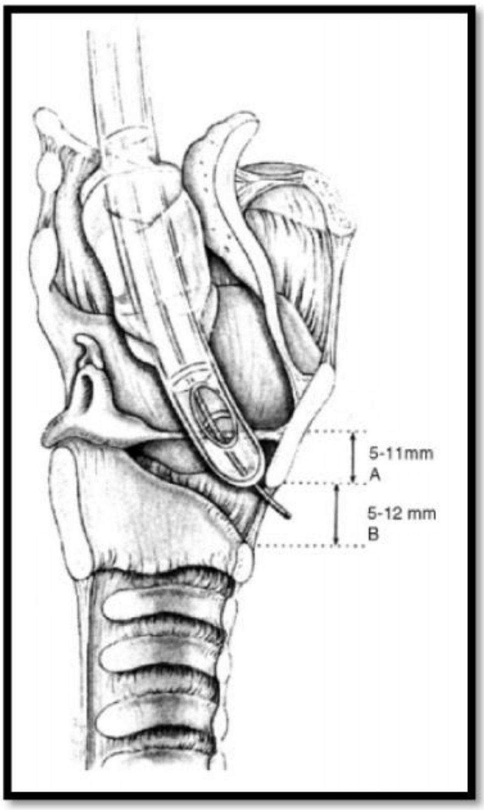


Fig. 11: Laryngeal cavity

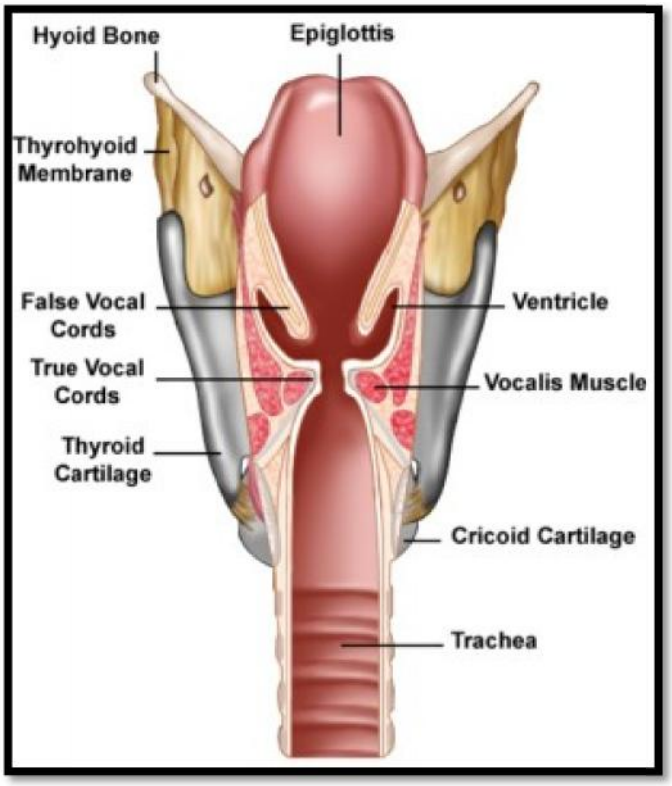


Fig. 12: Cross section of larynx

The epithelium of the vestibular folds is the ciliated-pseudostratified variety (respiratory), whereas the epithelium of the vocal folds is the nonkeratinized squamous type. Thus, the entire interior of the larynx is covered with respiratory epithelium except the vocal folds.

Airway protection is enhanced by the orientation of the cords. The false cords are directed inferiorly at their free border. This position can help to stop egress of air during a Valsalva maneuver. The true cords are oriented slightly superiorly. This prevents air or matter from entering the lungs. Great pressure is needed to separate adducted true cords. Air trapped in the ventricle during closure pushes each false cord and true cord more tightly together

3. Muscles of the Larynx

The complex and delicate functions of the larynx are made possible by an intricate group of small muscles. These muscles can be divided into the extrinsic and the intrinsic groups. The extrinsic group connects the larynx with its anatomic neighbors, such as the hyoid bone, and modifies the position and movement of the larynx. The intrinsic group facilitates the movements of the laryngeal cartilages against one another and directly affects glottic movement.

A. Extrinsic Muscles of the Larynx

The suprahyoid muscles attach the larynx to the hyoid bone and elevate the larynx. These muscles are the stylohyoid, geniohyoid, mylohyoid, thyrohyoid, digastric, and stylopharyngeus muscles. In the infrahyoid muscle group are the omohyoid, sternothyroid, thyrohyoid, and sternohyoid muscles. These “strap” muscles, in addition to lowering the larynx, can modify the internal relationship of laryngeal cartilages and folds to one another. The inferior constrictor of the pharynx primarily assists in deglutition (Table 1 & Fig. 13)

Table. 1 Extrinsic muscles of larynx

Extrinsic muscles of larynx		
Muscle	**Function**	**Innervation**
Sternohyoid	Indirect depressor of the larynx	Cervical plexus Ansa hypoglossi C1, C2, C3
Sternothyroid	Depresses the larynx Modifies the thyrohyoid & aryepiglottic folds	Same as above
Thyrohyoid	Same as above	Cervical plexus Hypoglossal nerve C1, C2
Thyroepiglottic	Mucosal inversion of aryepiglottic fold	Recurrent laryngeal nerve
Stylopharyngeus	Assists folding of thyroid cartilage	Glossopharyngeal
Inferior pharyngeal constrictor	Assists in swallowing	Vagus, pharyngeal plexus

B. Intrinsic Muscles of the Larynx

The function of the intrinsic musculature is threefold: (1) open the vocal cords during inspiration, (2) close the cords and the laryngeal inlet during deglutition, and (3) alter the tension of the cords during phonation. The larynx can close at three levels: the aryepiglottic folds close by the contraction of the aryepiglottic and oblique arytenoid muscles, the false vocal cords close by the action of the lateral thyroarytenoids, and the true vocal cords close by the contraction of interarytenoids, lateral cricoarytenoids, and the cricothyroid.[51] The intrinsic muscles include the aryepiglottic and thyroepiglottic, thyroarytenoid and vocalis, oblique and transverse arytenoids, lateral and posterior cricoarytenoids, and cricothyroids (Fig. 13). All but the transverse arytenoids are paired.

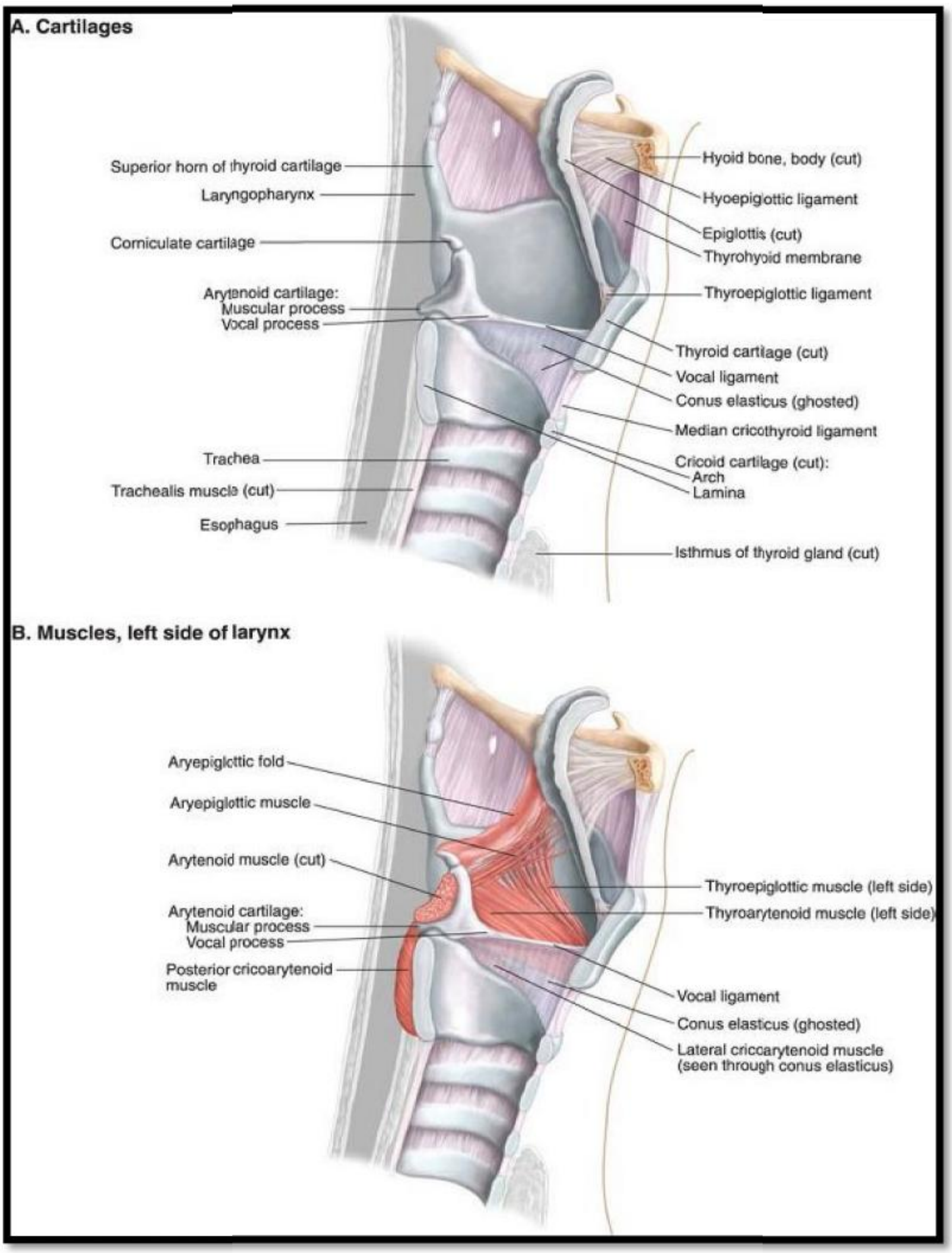


Fig. 13: Cartilages & Muscles of Larynx

Some authors consider the cricothyroid muscle to be both an extrinsic and intrinsic muscle of the larynx because its actions affect both laryngeal movements and the glottic structures. It is the only intrinsic muscle found external to the larynx itself. The paired cricothyroid muscles join the cricoid cartilage and the thyroid cartilage (Fig.13). The muscle has two parts. A larger, ventral section runs vertically between the cricoid and the inferior thyroid border. The smaller oblique segment attaches to the posterior inner thyroid border and the lesser cornu of the thyroid. During swallowing, the muscle contracts and the ventral head draws the anterior part of the cricoid cartilage toward the relatively fixed lower border of the thyroid cartilage. The oblique head of the muscle rocks the cricoid lamina posteriorly. Because the arytenoids do not move, the vocal ligaments are tensed and the glottic length is increased 30%

The thick posterior cricoarytenoid muscle originates near the entire posterior midline of the cricoid cartilage. Muscle fibers run superiorly and laterally to the posterior area of the muscular process of the arytenoid cartilage. Upon contraction, the posterior cricoarytenoid rotates the arytenoids and moves the vocal folds laterally.

The posterior cricoarytenoid is the only true abductor of the vocal folds.

The lateral cricoarytenoid muscle joins the superior border of the lateral cricoid cartilage and the muscular process of the arytenoid. This muscle rotates the arytenoids medially, adducting the true vocal folds. The unpaired transverse arytenoid muscle joins the posterolateral aspects of the arytenoids. The muscle, covered anteriorly by a mucous membrane, forms the posterior commissure of the larynx. Contraction of this muscle brings the arytenoids together and ensures posterior adduction of the glottis.

The oblique arytenoids (see Fig.13) ascend diagonally from the muscular processes posteriorly across the cartilage to the opposite superior arytenoid and help close the glottis. Fibers of the oblique arytenoid may continue from the apex through the aryepiglottic fold as the aryepiglottic muscle, which attaches itself to the lateral aspect of the epiglottis. The aryepiglottic muscle and the oblique arytenoid act as a "purse-string" sphincter during deglutition.

The thyroarytenoid muscle (see Fig.13) is broad and sometimes divided into three parts. It is among the fastest contracting striated muscles. The muscle arises along the entire lower border of the thyroid cartilage. It passes posteriorly, superiorly, and laterally to attach to the anterolateral surface and the vocal process of the arytenoid.

The segment of thyroarytenoid muscle that lies adjacent to the vocal ligament (and frequently surrounds it) is called the vocalis muscle. The vocalis is the major tensor of vocal fold and can "thin" the fold to achieve a high pitch. Beneath the mucosa of the fold, extending from the anterior commissure back to the vocal process, is a potential space called Reinke's space. This area can become edematous if traumatized. The more laterally attached fibers of the thyroarytenoid function as the prime adductor of the vocal folds.

The most lateral section of the muscle, sometimes called the thyroepiglottic muscle, attaches to the lateral aspects of arytenoids, the aryepiglottic fold, and even the epiglottis. When it contracts, the arytenoids are pulled medially, down, and forward. This shortens and relaxes the vocal ligament. The function and innervation of the extrinsic muscles are summarized in Table 1. Table 2 describes the intrinsic musculature of the larynx.

Table. 2: Intrinsic muscles of larynx

Intrinsic muscles of larynx		
Muscle	**Function**	**Innervation**
Posterior cricoarytenoid	Abductor of vocal cords	Recurrent laryngeal
Lateral cricoarytenoid	Adducts arytenoids closing glottis	Recurrent laryngeal
Transverse arytenoid	Adducts arytenoids	Recurrent laryngeal
Oblique arytenoid	Closes glottis	Recurrent laryngeal
Aryepiglottic	Closes glottis	Recurrent laryngeal
Vocalis	Relaxes the cords	Recurrent laryngeal
Thyroarytenoid	Relaxes tension cords	Recurrent laryngeal
Cricithyroid	Tensor of the cords	Superior laryngeal (external branch)

C. Innervation of the Larynx

The main nerves of the larynx are the recurrent laryngeal nerves and the internal and external branches of the superior laryngeal nerves. The external branch of the superior laryngeal nerve supplies motor innervation to the cricothyroid muscle. All other motor supply to the laryngeal musculature is provided by the recurrent laryngeal nerve (Fig.14). Both the superior and recurrent laryngeal nerves are derivatives of the vagus nerve.

The superior laryngeal nerve generally separates from the main trunk, off the inferior vagal ganglion, just outside the jugular foramen. At approximately the level of the hyoid bone, it divides into the smaller external and larger internal branches. The external branch travels below the superior thyroid artery to the cricothyroid muscle, giving off a branch to the inferior constrictor of the pharynx along the way. The internal branch travels along with the superior laryngeal artery and passes through the thyrohyoid membrane laterally between the greater cornu of the thyroid and hyoid. The nerve and artery together pass through the pyriform recess, where the nerve may be anesthetized intraorally. The nerve divides almost immediately into a series of sensory branches and provides sensory innervation from the posterior aspect of the tongue base to as far down as the vocal cords. Sensory innervation of the epiglottis is dense, and the true vocal folds are more heavily innervated posteriorly than anteriorly.

The left recurrent laryngeal nerve branches from the vagus in the thorax and courses cephalad after hooking around the arch of the aorta in close relation to the ligamentum arteriosum, at approximately the level of the fourth and fifth thoracic vertebrae. On the right, the nerve loops posteriorly beneath the subclavian artery, at approximately the first and second thoracic vertebrae, before following a cephalad course to the larynx. Both nerves ascend the neck in the tracheoesophageal groove before they reach the larynx. The nerves enter the larynx just posterior to, or sometimes anterior to, the cricothyroid articulation. The recurrent laryngeal nerve supplies all the intrinsic muscles of the larynx except the cricothyroid. The recurrent laryngeal nerve also provides sensory innervation to the larynx below the vocal cords. Parasympathetic fibers to the larynx travel along the laryngeal nerves, and the sympathetics from the superior cervical ganglion travel to the larynx with blood vessels. Tables 1 and 2 summarize the innervation of the laryngeal musculature.

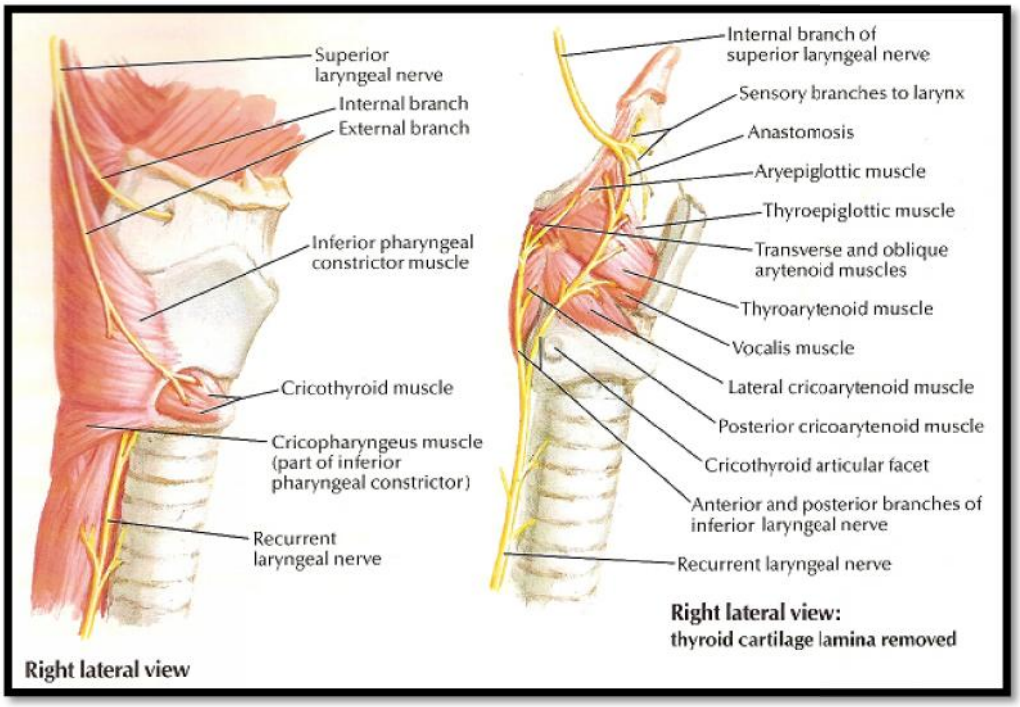


Fig. 14: Innervation of Larynx

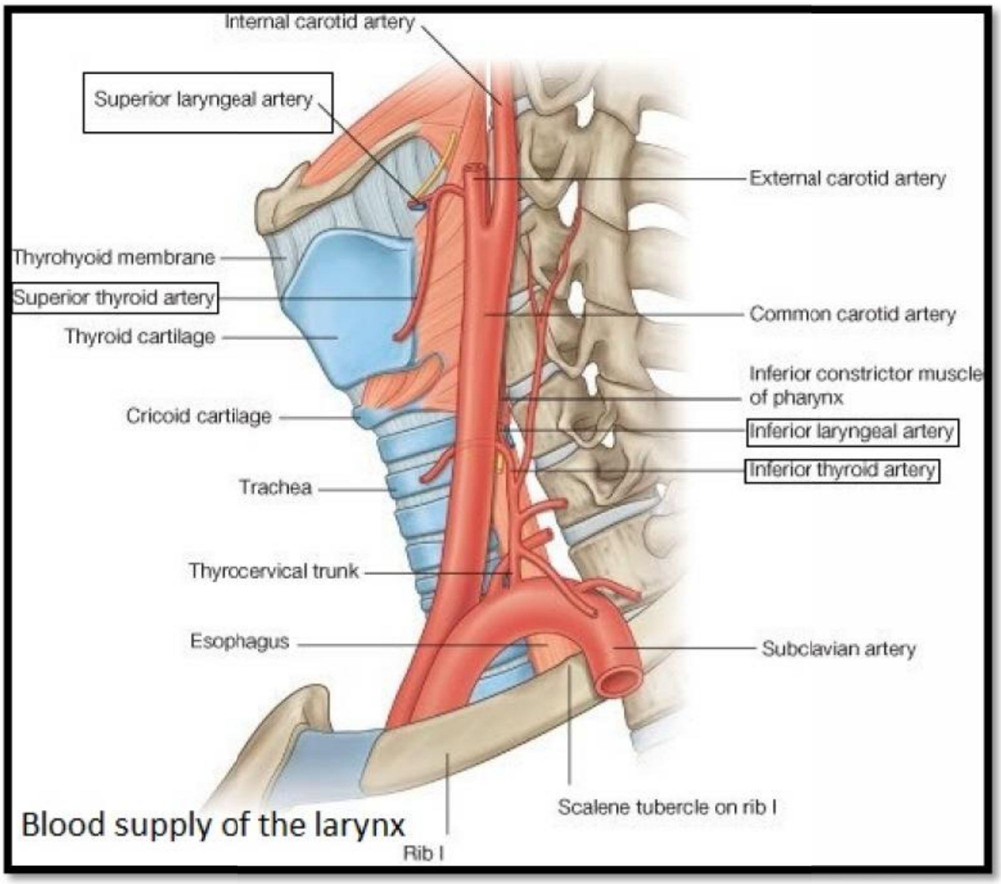


Fig. 15: Blood supply of Larynx

D. Blood Supply of the Larynx

Blood supply to the larynx is derived from the external carotid and the subclavian arteries. The external carotid gives rise to the superior thyroid artery, which bifurcates, forming the superior laryngeal artery.(Fig. 15). This artery courses with the superior laryngeal nerve through the thyrohyoid membrane to supply the supraglottic region. The inferior thyroid artery, derived from the thyrocervical trunk, terminates as the inferior laryngeal artery. This vessel travels in the tracheoesophageal groove with the recurrent laryngeal nerve and supplies the infraglottic larynx. There are extensive connections with the ipsilateral superior laryngeal artery and across the midline. A small cricothyroid artery may branch from the superior thyroid and cross the cricothyroid membrane. It most commonly travels near the inferior border of the thyroid cartilage

PROSEAL LMA

1. DEVICE DESCRIPTION

The LMA airway is an innovative supraglottic airway management device. Since its commercial introduction in 1988, the LMA airway has been used in over 200 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 LMA Classic. The LMA ProSeal is designed to provide additional benefits over the LMA Classic that extends the range of procedures for which an LMA airway is indicated. 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: mask, inflation line with pilot balloon, airway tube and drain tube (Fig. 16). The mask 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 the larger sizes also have a rear cuff which helps to increase the seal. Attached to the mask is an inflation line terminating in a pilot balloon and valve for mask inflation and deflation. A red plug is also fitted to the valve assembly to allow residual air in the mask to be vented during autoclaving. It prevents expansion of the cuff when left open during steam autoclaving. The plug must be detached before autoclaving and replaced before clinical use. Some older LMA ProSeal devices may not have a red plug fitted. A drain tube passes lateral to the airway tube and traverses the floor of the mask opening at the mask tip opposite the upper oesophageal sphincter. The airway tube is wire reinforced to prevent collapse and terminates with a standard 15mm connector. A malleable introducer tool (the LMA ProSeal Introducer) is available in adult and paediatric sizes to aid insertion if it is desirable to avoid placing a finger in the patient's mouth. It is supplied in the recommended curvature for immediate use but may be bent to any desired shape. A dedicated deflation device (LMA ProSeal Cuff-Deflator) is available to aid complete deflation for successful sterilisation, optimum insertion and positioning in the patient.

In order to accommodate the neonatal anatomy, the LMA ProSeal size 1 does not have the bite block (Fig 16). The LMA ProSeal size 1 also differs from the other sizes in that it has a relatively larger drain tube (8fr).

All components are not made with natural rubber latex. The Laryngeal Mask Company recommends that the LMA ProSeal be used a maximum of 40 times before being discarded. In addition to the well known characteristics of the LMA Classic™, the LMA ProSeal™ offers the following features:

- A softer cuff material, deeper mask bowl and special cuff shape allows a higher seal than the LMA Classic for a given intracuff pressure with the adult sizes.
- A revised cuff arrangement, which allows a higher seal than the LMA Classic™, for a given intracuff pressure.
- A channel (or drain tube) opening at the upper oesophageal sphincter to permit drainage of gastric secretions and access to the alimentary tract. The tube is also intended to prevent inadvertent gastric insufflation.
- A drain tube which allows for blind insertion of standard oro-gastric tubes, in any patient position, without the need to use Magill's forceps.
- A double tube arrangement which reduces the likelihood of mask rotation; the revised cuff profile, together with the flexible tubes, result in the device being more securely anchored in place.
- A built-in bite-block (except LMA ProSeal size 1) which reduces the danger of airway obstruction or tube damage
- A location strap for the LMA ProSeal Introducer (Fig. 17), which also accommodates the index finger or thumb for manual insertion.
- The position of the drain tube inside the cuff prevents the epiglottis occluding the airway tube This eliminates the need for aperture bars.

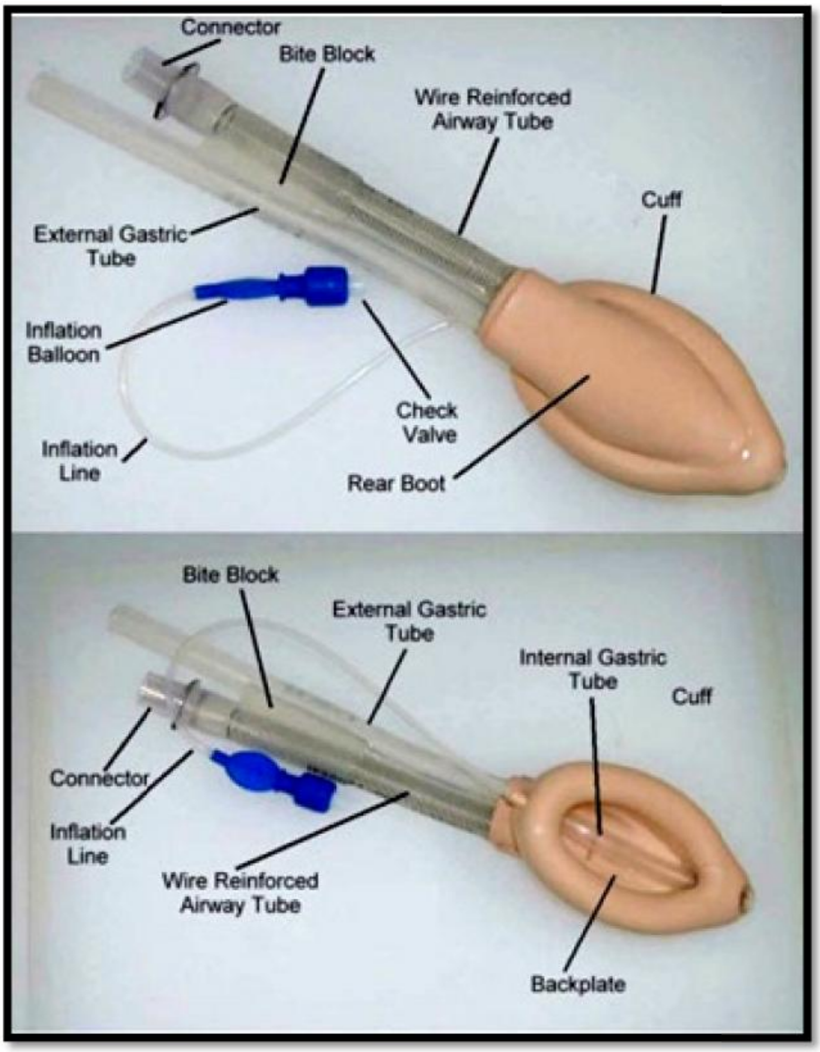


Fig. 16: PLMA

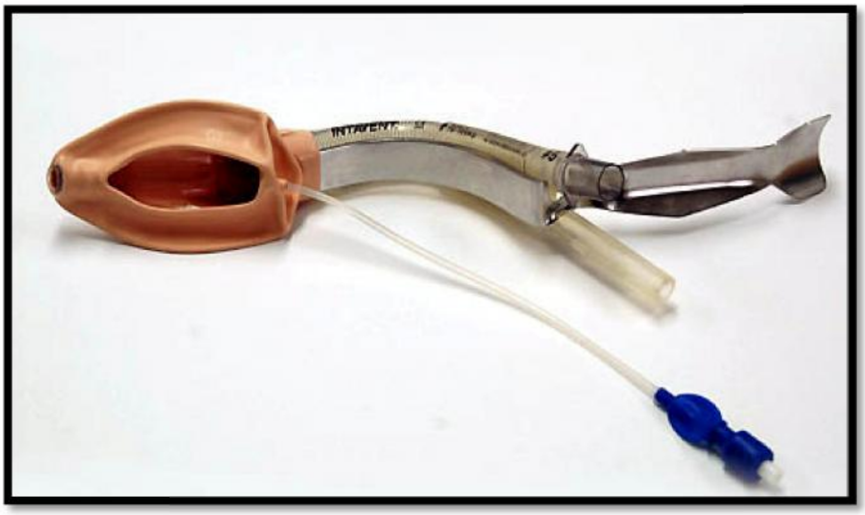


Fig. 17: Introducer of PLMA

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 cuff presses against the upper oesophageal sphincter. Its sides face into the pyriform fossae and the upper border rests against the base of the tongue (Fig. 18)

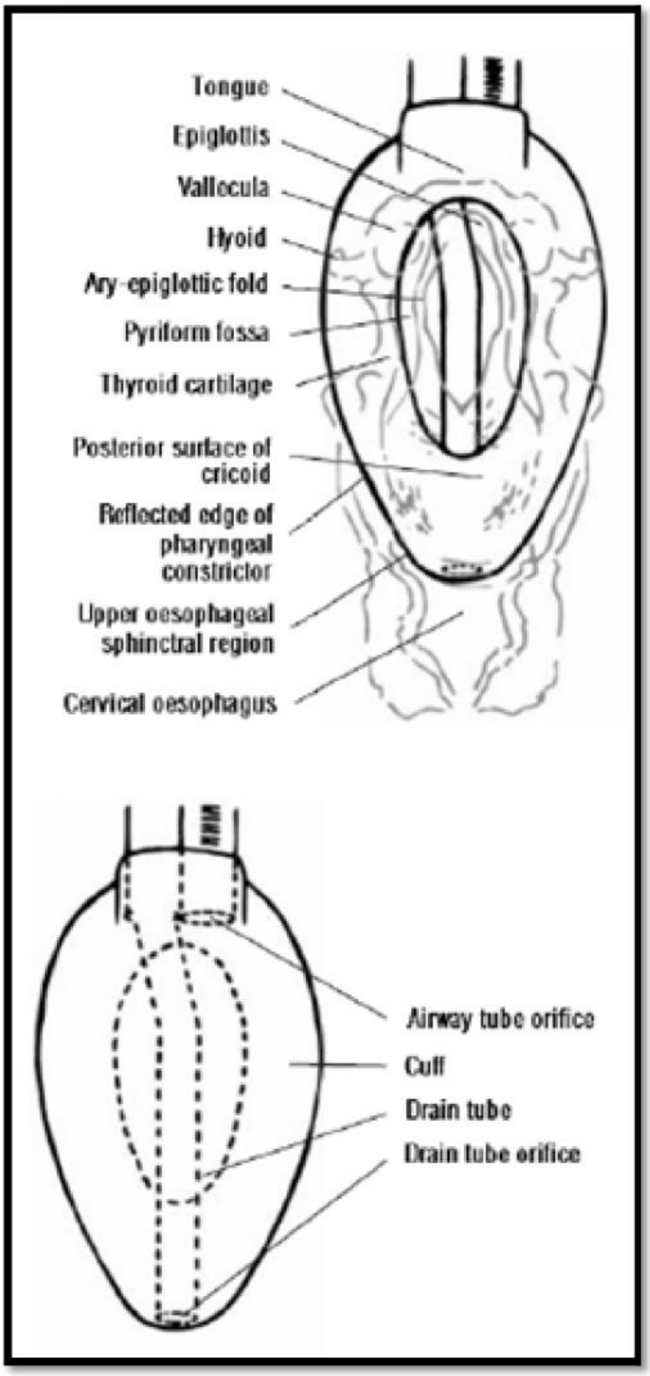


Fig. 18: Relations of PLMA mask

2. INDICATIONS FOR USE

The LMA ProSeal is indicated for use in achieving and maintaining control of airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or positive pressure ventilation. It is also indicated for securing the immediate airway in known or unexpected difficult airway situations.

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 may be used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes requiring artificial ventilation. In these cases, LMA ProSeal should be used only when tracheal intubation is not possible.

3. CONTRAINDICATIONS

Due to the potential risk of regurgitation and aspiration, do 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 airway forms a low-pressure seal around the larynx.
- Patients where the peak airway inspiratory pressures are anticipated to exceed 30 cm H2O with LMA ProSeal.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for use with LMA ProSeal

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.

4. WARNINGS & PRECAUTIONS

4.1 Warnings

- The LMA ProSeal does not protect the patient from the effects of regurgitation and aspiration.
- The presence of a gastric tube does not rule out the possibility of regurgitation and may even make regurgitation more likely because the gastric tube may make the lower esophageal sphincter incompetent.
- Should the device used in a fasted patient who is at risk of retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed. Examples of conditions

where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.

- In patients with severe oropharyngeal trauma, the device should only be used when all other attempts to establish an airway have failed.
- If airway problems persist or ventilation is inadequate, the device should be removed and an airway established by some other means.
- LMA ProSeal displays magnetic field interactions in the MRI environment. The appropriate fixation of this device is required to prevent possible movement due to magnetic field interactions.
- Used device shall be decontaminated first in accordance with local hospital procedures for handling of bio-hazard products and subsequently disposed of by incineration or landfill in accordance with all local and national regulations.
- Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.

4.2 Precautions:

- Do not immerse or soak the device in liquid prior to use.

5. ADVERSE EVENTS

Both minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration) following use of LMA airways have been reported in the published literature. Review of published literature shows the incidence of aspiration with the LMA airway is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anesthesia.

The incidence of sore throat following LMA airway use is approximately 13%, and is usually mild and short-lived; however, severe or prolonged sore throat, sometimes accompanied by dysphagia and tissue burns, has been reported in patients in whom an improperly cleaned or sterilized reusable mask has been used.

Infrequent neurovascular events reported with LMA airway use include cases of hypoglossal nerve injury, tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, recurrent laryngeal nerve injury, and vocal cord paralysis. These complications are most likely the result of malposition or excessive intracuff pressure, causing compression of nerves and/or blood vessels. Cuff malposition or excessive cuff pressure can be exacerbated by incorrect mask size, prolonged surgery, and use of nitrous oxide.

Adverse events reported with LMA airway use include airway obstruction, arytenoids dislocation, aspiration, bleeding, breath holding, bronchospasm, coughing, dental/denture damage, dry mouth/throat, dysarthria, dysphagia, dysphonia, dysrhythmia, ear pain, gagging, gastric dilatation/insufflation/rupture, glottic closure, head and neck edema, hearing impairment, hiccup, hoarseness, hypersalivation, hypoglossal nerve paralysis, hypoxia, laryngeal hematoma, laryngeal spasm, lingual nerve paralysis, mouth ulcer, myocardial ischemia, nausea, parotid gland swelling, pharyngeal dysesthesia, pharyngeal ulcer, pulmonary edema, recurrent laryngeal nerve injury, regurgitation, retching, sore jaw, sore mouth, sore throat, stridor, submandibular gland swelling, temporomandibular joint dislocation, tissue trauma (epiglottis, larynx, lip, mouth, posterior pharyngeal wall, soft palate, uvula, tonsils), tongue cyanosis, tongue macroglossia, vocal cord paralysis, and vomiting.

6. PREPARATION FOR USE

Warning:

With proper cleaning, sterilisation and handling, the LMA ProSeal can be safely used 40 times. Continued use beyond 40 uses is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure of the device.

LMA ProSeal is delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

The airway accessories, i.e., the LMA ProSeal Introducer and LMA ProSeal Cuff Deflator, should be cleaned and sterilized in the same manner as the LMA ProSeal.

Caution:

Careful handling is essential. The LMA ProSeal is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.

Use only syringe with standard luer taper tip for inflation or deflation.

Gloves should be worn during preparation and insertion to minimize contamination of the device.

6.1 Cleaning

Thoroughly wash the cuff, airway tube and drain tube in warm water using a dilute (8-10% v/v) sodium bicarbonate/water solution until all visible foreign matter is removed.

Caution :

Make sure the LMA ProSeal red plug is closed during cleaning to prevent exposure of the valve to any cleaning solution.

If moisture is noticed, the red plug should be opened and tapped against a towel to remove the excess moisture.

When cleaning the LMA ProSeal, ensure the areas behind the LMA ProSeal Introducer strap and under the internal drain tube are clean. Clean the tubes using a small soft bristle brush (approximately 1/4 inch or 6mm in diameter for adult size devices). Gently insert the brush through the proximal (outer) end of the drain tube, taking care not to damage the drain tube. Thoroughly rinse the cuff, airway tube and drain tube in warm, flowing tap water to remove cleaning residues. Carefully inspect the LMA ProSeal to ensure that all visible foreign matter has been removed. Care should be taken to ensure that water does not enter the device through the valve or the red plug.

Repeat the above as necessary.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer’s instructions. The cleaners must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA ProSeal use is Endozime.

Warning:

Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilize the airway. Such substances are absorbed by the materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use an airway that has been exposed to any of these substances.

Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.

Caution: Do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.

6.2 Sterilisation

Warning: Steam autoclaving is the only recommended method for sterilisation of the LMA ProSeal. Adherence to the following procedure is essential to ensure sterilisation without damage:

6.2.1 Sterilisation of LMA ProSeal (without red plug)

Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backward to obtain a vacuum in the cuff. Then disconnect the syringe while maintaining the vacuum.

For complete deflation, it is recommended that LMA Cuff-Deflator or LMA ProSeal Cuff-Deflator (available from authorized distributor) be used for this purpose. Ensure that both the syringe used to deflate the cuff and the valve is dry.

Do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port before autoclaving to avoid damage to the valve.

If the cuff of a deflated LMA ProSeal without manual vent immediately and spontaneously re inflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the cuff to re-inflate slowly over a period of several hours as the silicone rubber material is gas permeable.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.

6.2.2 Sterilisation of LMA ProSeal (with red plug)

For the LMA ProSeal with red plug, it is not necessary to deflate the cuff prior to steam autoclaving, so it is normal for the LMA ProSeal to be inflated upon removal from the autoclave, provided the manual vent is in the open position.

Caution: Make sure the LMA ProSeal manual vent is open during sterilisation to prevent herniation of the cuff.

6.2.3 Autoclave Settings

Always follow the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilisation, provided the maximum temperature does not exceed 135°C or 275°F.

Caution: The integrity of the device material may be adversely affected by exceeding sterilisation temperatures of 275oF or 135oC.

One steam sterilisation cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.

Autoclaves vary in design and performance characteristics. Cycle parameters should therefore always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare personnel are responsible for adhering to the appropriate sterilisation processes which have been specified. Failure to do so may invalidate the sterilisation process of the healthcare facility.

After autoclaving, allow the device to cool to room temperature before use.

6.3 Performance Tests

Warning:

All of the non-clinical tests described below must be conducted before each use of LMA ProSeal. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimizes contamination of the airway device before insertion. Failure of any one test indicates that the device has passed its useful life and should be replaced.

Do not use the LMA airway or any of the accessories if they are damaged in any way.

6.3.1 Performance Test 1: Visual Inspection

- Examine the surface of the airway tube, cuff and drain tube for damage, including cuts, tears, or scratches.
- Examine the interior of the airway tube, mask bowl and drain tube to ensure that they are free from blockages or loose particles. Any particles present in the tubes should be removed.
- Examine the transparency of the tubes. Reusable airway tubes will gradually discolor with age and re-use.

Warning:

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

Do not use the LMA ProSeal if it is damaged or if visible particles cannot be removed from inside the airway tube as they may be inhaled by the patient after insertion.

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

Ensure that it cannot easily be pulled off by hand using reasonable force. Do not use excessive force or twist the connector as this may break the seal.

Do not use the LMA ProSeal if the mask connector does not fit tightly into the outer end of the airway tube.

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

Examine the rear cuff of the LMA ProSeal, if present, for wrinkles or folds suggesting herniation.

6.3.2 Performance Test 2: Inflation and Deflation

- Carefully insert a syringe into the valve port and fully deflate the device so that the cuff walls are tightly flattened against each other. To deflate the LMA ProSeal, make sure the red plug is closed. Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other.

Warning: Do not use the device if the cuff walls reinflate immediately and spontaneously, even if only slightly.

Examine the fully deflated LMA ProSeal mask for wrinkles or folds suggesting herniation. If obvious wrinkles are apparent, the rear cuff may be severely herniated and the LMA ProSeal should not be used.

Inflate the cuff with 50% more air than the recommended maximum clinical inflation Volume. Any tendency of the cuff to deflate indicates the presence of a leak and should be evident within two minutes. Examine the symmetry of the inflated cuff.

There should be no uneven bulging at either end or sides.

Do not use the LMATM airway if cuff leakage is present or if there is uneven bulging of the cuff.

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

Do not use the LMATM airway if the inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.

While the device remains 50% over-inflated, inspect the interior of the LMA ProSeal drain tube from both ends of the mask. Ensure that the tube is not collapsed or perforated.

Use of an LMA ProSeal with a collapsed or occluded drain tube may prevent venting of the stomach or insertion of a gastric tube and may permit inflation of the stomach and possible regurgitation. Use of a perforated or torn drain tube may prevent the LMA ProSeal from being inflated or allow for escape of anesthetic gases.

6.4 Pre-insertion preparation

Prior to insertion of the device, the cuff should be fully deflated to a flattened wedge shape. The cuff walls should not have any wrinkles and the cuff should be straight at the distal end (figures 7a and 7b). This shape facilitates atraumatic insertion and correct positioning in the patient. It reduces the risk of entry of the distal end into the valledullae or glottis and avoids it becoming caught against the epiglottis or the arytenoids. The correct cuff shape can be accomplished through use of the LMA ProSeal Cuff- Deflator (Fig. 19 & 20), available from the distributor.

Prior to deflating the LMA ProSeal and during clinical use, make sure the red plug is closed.

Directions for use of the LMA ProSeal Cuff- Deflator:

- Squeeze the handles of the LMA ProSeal Cuff- Deflator to open the jaws
- Insert the LMA ProSeal, partially inflated, with its distal end exactly level with the tip of the indicating arrow on the cuff deflator
- The mask bowl should face the curved surface of the LMA ProSeal Cuff-Deflator
- Release the handles to compress the mask
- Use a syringe to deflate the cuff
- Whilst deflating, pull back gently on the inflation line to ensure all air is removed from the mask
- Deflate to a vacuum and disconnect the syringe whilst maintaining as high a vacuum as possible
- Squeeze the LMA ProSeal Cuff-Deflator handles again to release the LMA ProSeal
- Ensure that the back of the mask is straight, without any curvature of the distal end; the distal end should be maximally flattened.

If the distal end is not maximally flattened or there is evidence of air in the cuff, partially re-inflate the cuff and repeat the procedure.

Alternative methods of cuff deflation:

Alternatively, the device can be deflated manually by compressing the distal end between finger and thumb to obtain the correct cuff shape. The same principles and results apply in all methods of device deflation.

Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant. Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant. It is recommended that a bolus of lubricant be applied to the posterior tip of the deflated cuff. It is not necessary to spread the lubricant over the mask surface. A water soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone based lubricants as they degrade the LMA ProSeal components. Lubricants containing Lidocaine are not recommended. Lidocaine may delay the return of protective reflexes and may provoke an allergic reaction, or affect surrounding structures, including vocal cords.

Warning: Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.

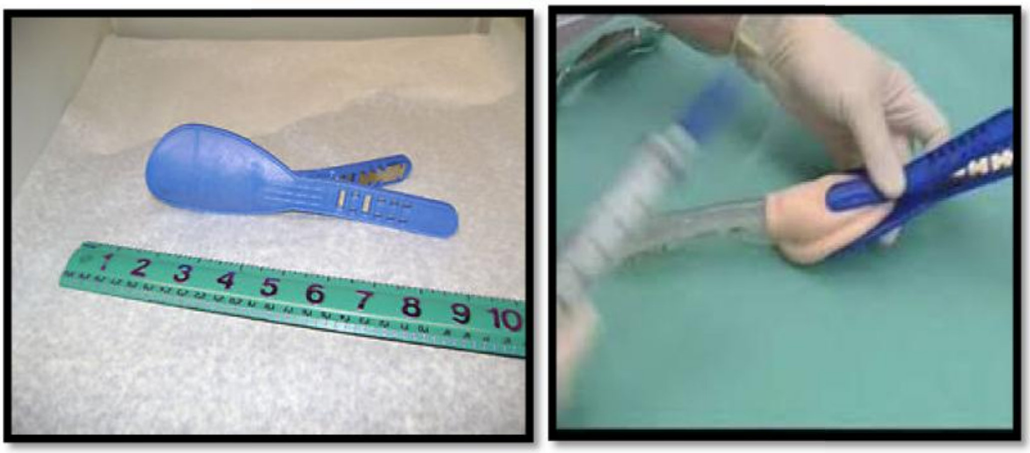


Fig. 19: PLMA cuff deflator

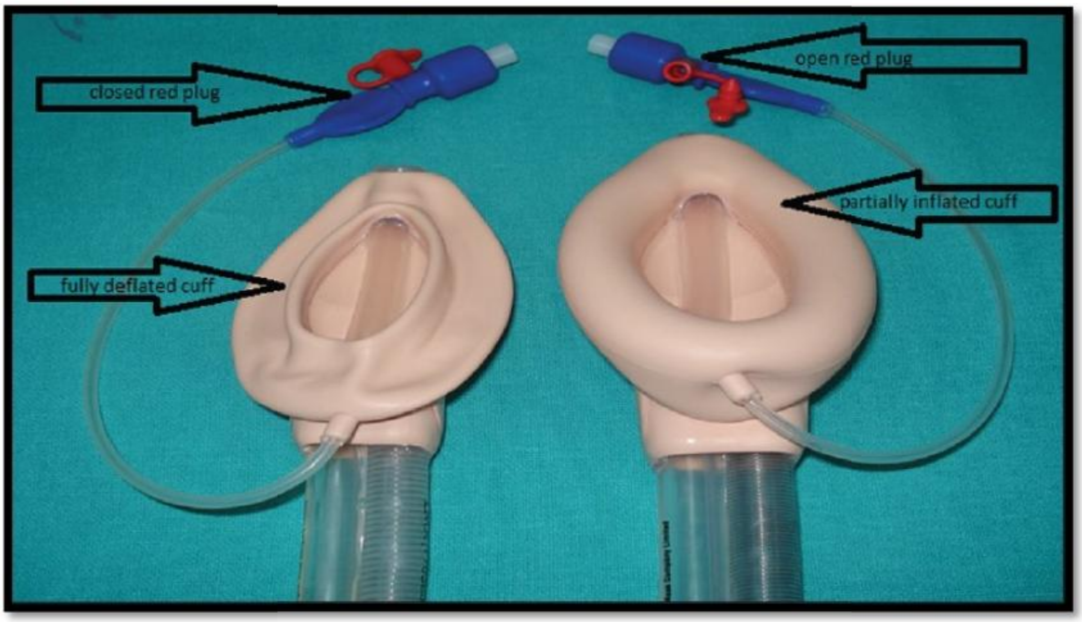


Fig. 20; PLMA cuff deflator

7 INSERTION

7.1 Introduction

Before using the LMA ProSeal , the user should be familiar with the instructions contained in this manual.

Warning:

An incorrectly placed mask may result in an unreliable or obstructed airway or failure of the LMA ProSeal drain tube to channel fluids or gases from the stomach and may increase the likelihood of gastric insufflations if used with PPV. Always check for proper placement after insertion.

Make sure the red plug is closed during clinical use to prevent deflation of cuff.

To avoid trauma, excessive force must be avoided at any time during insertion of the LMA ProSeal or insertion of a gastric tube through the LMA ProSeal drain tube.

Inadequate anaesthesia may lead to coughing, breath-holding or laryngeal spasm.

Before insertion it is important to note the following points:

- Check that the size of the device is appropriate for the patient (see Appendix at the back of manual). The ranges are approximate and clinical judgment should be used in selecting an appropriate size.
- The cuff must always be fully deflated by firmly pulling back on the deflating syringe and gently pulling on the inflation line.
- Check the shape of the cuff and its lubrication, as described previously.
- Have a spare sterile LMA airway ready and prepared for immediate use. Where possible, an alternative size of LMA airway should also be available.
- Pre-oxygenate and implement standard monitoring procedures.
- Achieve an adequate level of anesthesia before attempting insertion. Resistance or swallowing, biting or 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 LMA ProSeal Introducer, it may be possible to reduce or eliminate head and neck manipulation.

7.2 Induction Method

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.
- Inhalational induction: This provides excellent conditions for insertion in children and in some adults.
- Thiopentone or other barbiturate induction: Barbiturates on their own are not ideal induction agents for insertion.

7.3 Insertion Method

The LMA ProSeal may be inserted using the standard index finger or the thumb technique, depending on access to the patient.

The LMA ProSeal may also be inserted using the LMA ProSeal Introducer. The dedicated Introducer may provide a more useful method of insertion than the thumb/finger techniques, when using LMA ProSeal sizes 1 to 2½.

All three techniques follow the same principles. To position the LMA airway 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 and should be kept pressed against the patient's posterior pharyngeal wall. To avoid contact with anterior structures during insertion, the inserting finger must press the tube upwards (cranially) throughout the insertion maneuver.

7.4 Index Finger Insertion Technique

Hold the LMA ProSeal like a pen, with the index finger pushed into the Introducer strap (Fig. 21). Note the flexion and position of the hand and wrist.

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it. Note the position of the hand and wrist. A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff is correctly flattened against the palate before proceeding.

Further opening of the mouth makes it easier to verify the position of the mask. Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.

As the index finger passes further into the mouth, the finger joint begins to extend. 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.

Using the index finger to guide the device, press backward toward the other hand, which exerts counter pressure. Do not use excessive force. Advance the device into the hypopharynx until a definite resistance is felt. Full insertion is not possible unless the index finger is fully extended and the wrist is fully flexed.

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.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 LMA ProSeal should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.

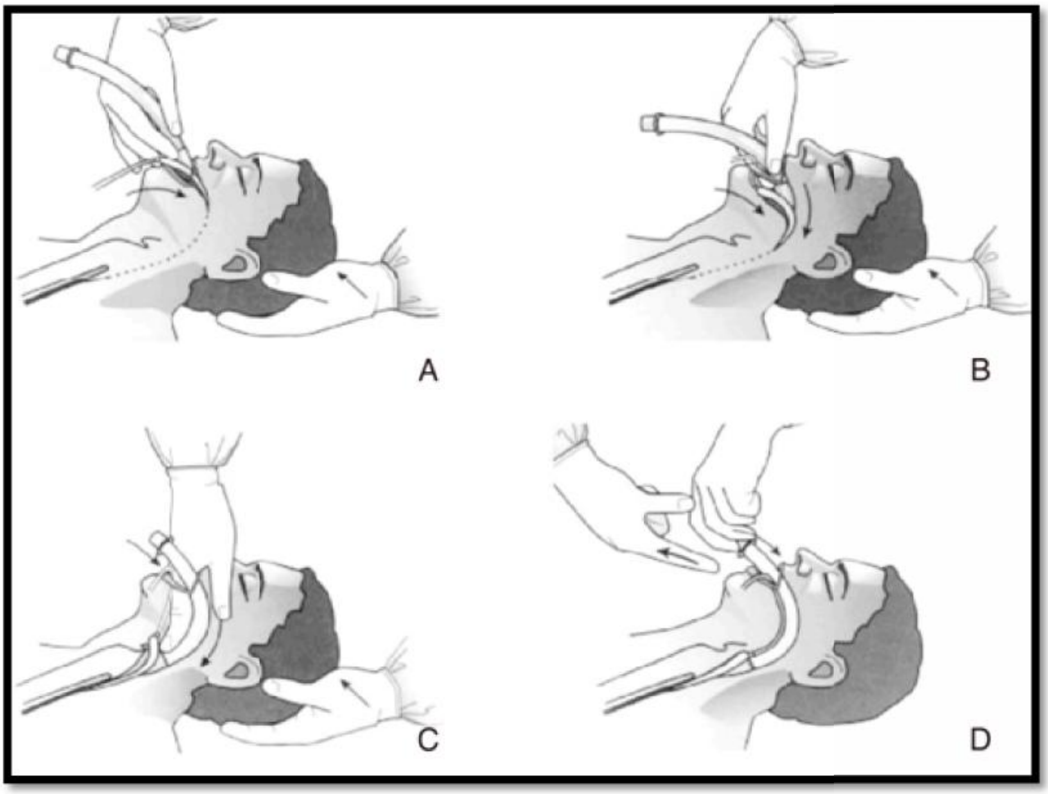


Fig. 21: Plma Cuff

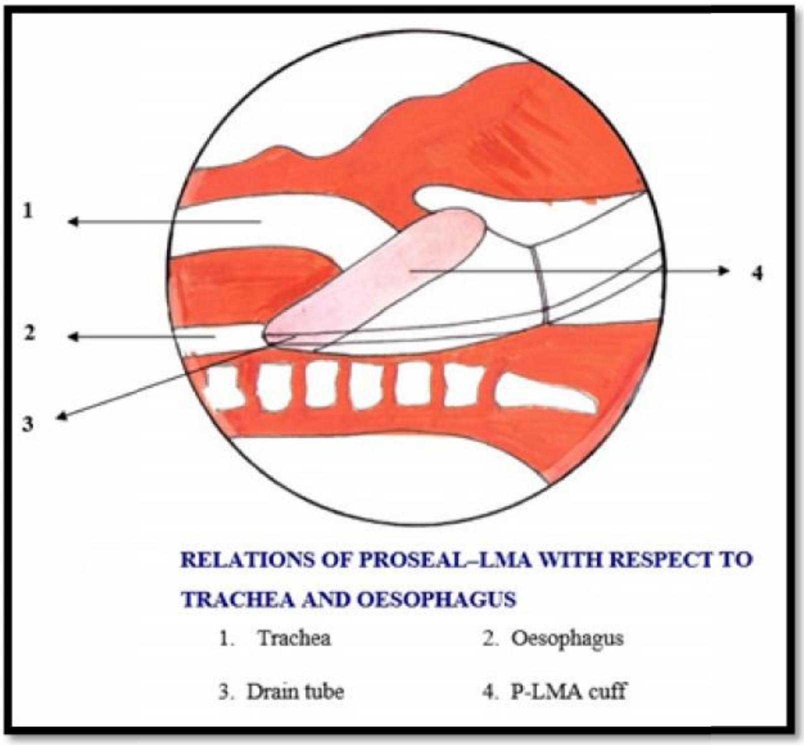


Fig. 22: Index finger insertion technique of PLMA

7.5 Insertion Problems

An inadequate depth of anesthesia may result in coughing and breath-holding during insertion. If this occurs, anesthesia 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 cuff 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 other techniques described above should be used.

7.6 Device Inflation

After insertion, the tubes should emerge from the mouth directed caudally. Without holding the tubes, inflate the cuff with just enough air to achieve an intracuff pressure of 60 cm H2O The inflation amounts shown in Appendix at the back of the manual are the maximum inflation volumes. Frequently, only half the maximum volumes are sufficient to obtain a seal and/or achieve 60 cm H2O intracuff pressure.

Warning:

Never overinflate the cuff after insertion. Avoid intracuff pressures greater than 60 cmH2O. The cuff is designed to be inflated to a low pressure (approximately 60 cmH2O). Over inflation may not improve the seal, may be associated with mucosal ischaemia, may cause the device to be dislodged and may cause the drain tube to collapse.

Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.

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.

7.7 Connecting to the anesthetic system

Taking care to avoid dislodgment, connect the device to the anesthetic circuit and employ gentle manual ventilation to inflate the lungs, noting whether there are any leaks. Auscultation and 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.

7.8 Diagnosis of correct or incorrect mask

When inserting and inflating the LMA ProSeal, 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 (Fig. 23a) should produce a leak-free seal against the glottis (seal 1) with the mask tip wedged against the upper esophageal sphincter (seal 2). 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 and there will be little protection in the event of gastric reflux (Fig.23c). This situation must be corrected by repositioning the mask. Do not attempt to overcome the leak by occluding the drain tube.

Occasionally a poorly deflated or inserted mask may enter the vestibule of the larynx (Fig.23d). 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. To facilitate diagnosis of correct mask placement or detection of incorrect placement, 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.

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 (Fig.23b). 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, 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.

Warning: 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.

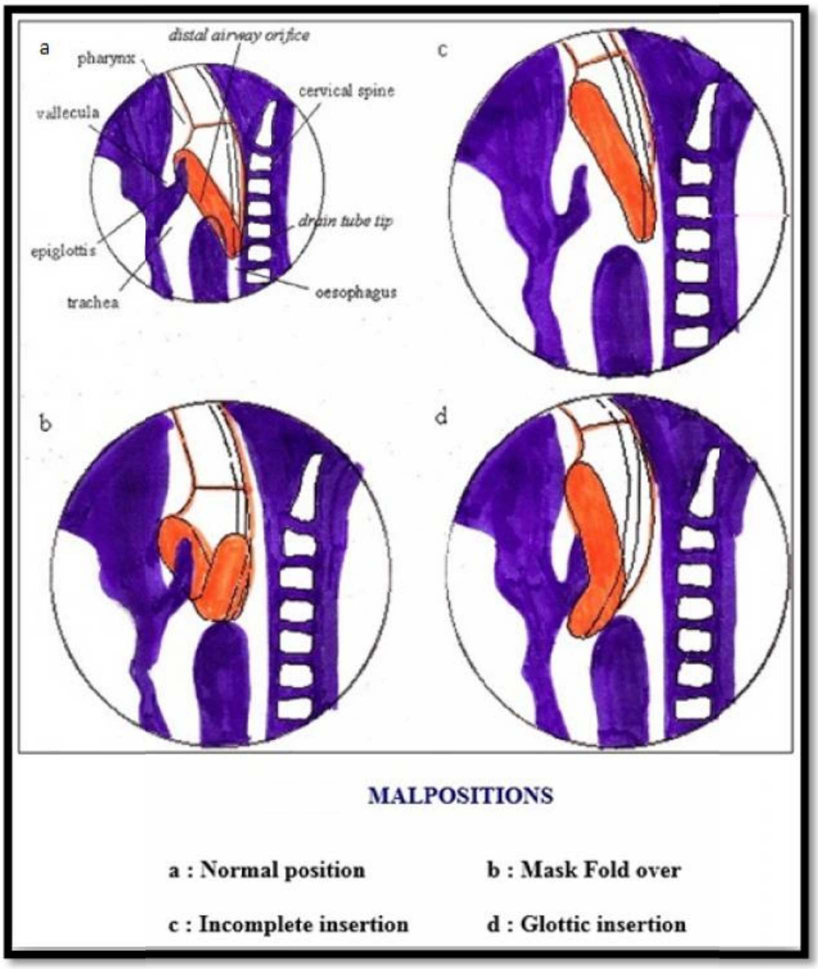


Fig. 23: Relations of PLMA

7.9 Device Fixation

All sizes of LMA ProSeal has a built-in bite-block except LMA ProSeal size 1. Once inflated, the device should be fixed in place using adhesive tape. Gentle pressure applied 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 oesophageal sphincter. To prevent the risk of device rotation, fix the device with the outer end extending over the chin in the mid-line

During use of LMA ProSeal size 1, take extra care during fixation of the airway to ensure that the cuff doesn't rotate and become displaced. Although the double tube design makes the airway tube more stable and less likely to rotate but the absence of the bite block requires extra caution.

8 ANAESTHESIA MAINTENANCE AND RECOVERY

As with other methods of airway management, the use of pulse oximetry and capnography is recommended when using the LMA ProSeal. It may be used for either spontaneous or controlled ventilation.

8.1 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 from inadequate anaesthesia 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

8.2 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 result in a gentler but also more effective seal against the laryngeal inlet when compared to the LMA Classic 1, 2.

The following points should be observed when using the LMA ProSealTM with PPV:

- The drain tube may also act as a relief conduit to prevent gastric insufflations during PPV. However, tidal volumes should not exceed 8ml/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 up to 30 cm H2O with the LMA Pro Seal TM which is 10 cm H2O higher than the LMA Classic TM.
- If leaks occur during PPV, this may be due to:

  Light anesthesia causing a degree of glottic closure,

  Inadequate neuromuscular blockade,

  Reduction in lung compliance related to the procedure or patient factors, or

  Displacement or migration of the cuff by head turning or traction.
- Should leakage through the drain tube be observed during PPV, even though anaesthesia is adequate, this may be due to the mask having migrated proximally. Ensure the securing tapes are still in place and readjust as necessary, while pressing the tubes inwards to relocate the mask tip against the upper oesophageal sphincter.

- In the event of a leak around the cuff, do not simply add more air to the cuff. This will not necessarily improve the seal pressure and may make the leak worse by adding tension to the normally soft cuff, pushing it away from the larynx.

8.3 Use of drain tube

Warning:

Do not attempt to pass a gastric tube through the LMA ProSeal drain tube if there is gas leaking through the drain tube and in the presence of known or suspected esophageal pathology or 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.(Fig. 24)

Suction should not be applied directly to the end of drain tube, as this may cause the drain tube to collapse and cause possible injury to the upper esophageal sphincter.

The primary function of the drain tube is to provide a separate conduit from and to the alimentary tract. It may direct gases or liquids from the patient and may also serve as a guide for blind insertion of an orogastric tube at any time during the anaesthetic. Refer to Appendix at the back of this manual for maximum gastric tube sizes.

The oro-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, Warning: do not use oro-gastric tubes which have been stiffened by refrigeration. Ensure the tube is at or above room temperature.

Upon insertion, some resistance is often detected as the tip of the catheter is pressed gently against the upper sphincter. Force must never be used. If a tube of appropriate size fails to pass, the mask may be kinked or malpositioned. In these cases, the mask should be removed and reinserted. Do not use excessive force. Clinical judgement should be used in deciding when the orogastric tube should be removed.

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

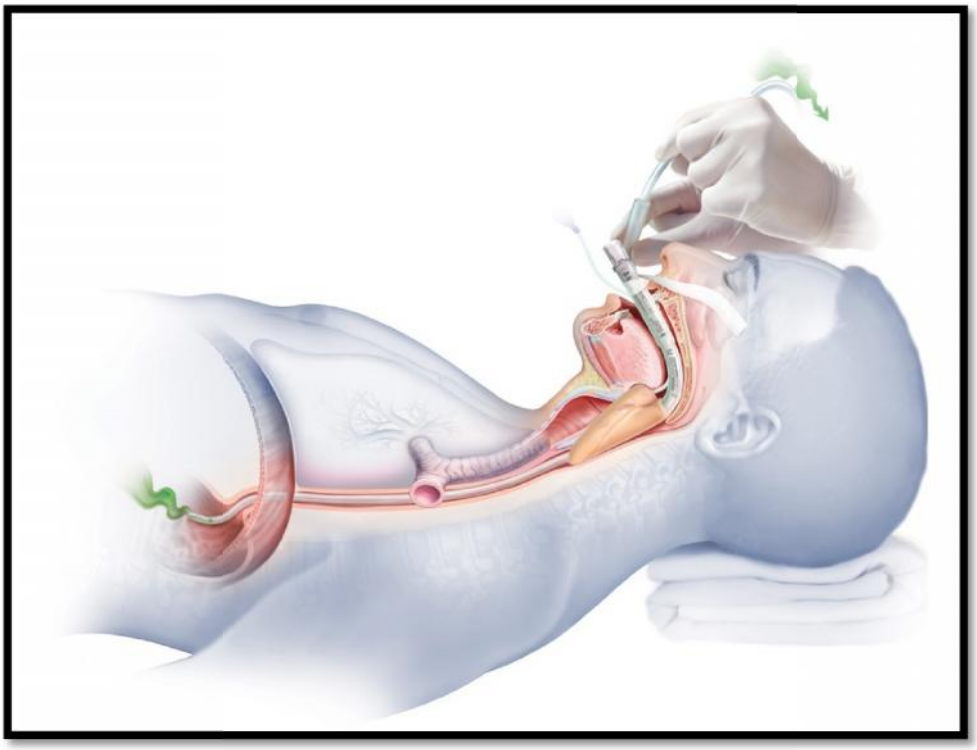


Fig. 24: Mannequin demonstration of 90 degree rotational insertion technique of PLMA

8.4 Potential problem 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 intracuff pressure. Diffusion rate and resulting peak pressure may vary with the initial volume of air injected into the cuff, the type of gases 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 intracuff pressure becomes excessive. To reduce the risk of a sore throat or possible neurovascular injury, the cuff pressure should be periodically checked and gas intermittently withdrawn to maintain 60 cm H2O intracuff pressure or the minimal "just seal" pressure. This can be achieved in several different ways. First, a pressure monitor or pressure transducer may be used. Pressure manometers are commercially available from Posey, Mallinckrodt, Portex, and VBM-Medical. Secondly, simply feeling the inflation indicator balloon can be performed. At 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 the initial control pressure.

Warning: Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.

Poor airway seal / Air leak

Should signs of a poor airway seal or air leak occur at the beginning or during a case, one or more of the following measures may be taken:

- Verify the depth of anesthesia is adequate and deepen if necessary.
- Check cuff pressures at start and periodically during a case, especially if using nitrous oxide.
- Ensure intracuff pressures are not >60 cm H2O; reduce intracuff pressure, if necessary, while maintaining an adequate seal.
- If the mask is seated too high in the pharynx, then press in further to confirm contact with the upper esophageal sphincter.
- Ensure proper fixation by applying palatal pressure while taping in place.
- Always confirm cuff integrity prior to placement.

Malposition of airway product

In general, malposition of the airway product can be assessed by capnography or by observation of changes in tidal volume, e.g., a reduced expired tidal volume. If malposition is suspected, check whether there is a smooth, oval neck swelling extending below the thyroid cartilage. If absent, it may indicate anterior misplacement of the mask tip into the laryngeal inlet, particularly if there is an unusually prolonged expiratory phase. If malposition is suspected, the airway product may be removed and reinserted once anesthetic depth is adequate for reinsertion. Check cuff pressure at the start and periodically during a case, verify cuff integrity prior to use and ensure proper fixation. If the LMA ProSealTM pops out of the mouth during insertion, the mask may be incorrectly positioned with the distal tip folded backward in the pharynx. Remove and reinsert or digitally sweep behind the tip.

Unexpected regurgitation

Even in fasted patients, regurgitation may occur for a variety of reasons (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 placed4.

If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the airway should not be removed. Verify that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate. If reflux occurs in association with a misplaced mask, aspiration is theoretically possible.

In the event of suspected aspiration when using the device, 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. 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.

If the presence of further gastric contents is suspected, an oro-gastric tube may be passed through the drain tube. Provided oxygen saturation is maintained at an acceptable level, the device 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.

Airway obstruction with the LMA ProSeal

There have been reports of airway obstruction occurring with the LMA ProSeal. Some of the reports were associated with noisy respiration and negative pressure, causing air to be drawn into the esophagus with inspiration. Other clinicians have reported an increased incidence of stridor with the LMA ProSeal. One proposed mechanism of the airway obstruction is pressure from the distal mask causing narrowing of the glottic inlet and subsequent mechanical closure of the vocal cords. Another mechanism is folding of the cuff wall medially, causing a physical airway obstruction. Should the patient show signs of airway obstruction, one or more of the following measures may be taken:

- Verify the depth of anesthesia is adequate and deepen if necessary.
- Ensure intracuff pressures are not >60 cm H2O; reduce intracuff pressure, if necessary, while maintaining an adequate seal.
- If the patient is spontaneously breathing, provide expiratory PEEP up to a clinically safe level or use PPV.
- Try placing the patient’s head and neck in a sniffing position (head extended and neck flexed).
- Consider fiberoptic examination to evaluate cuff position and vocal cord function.
- If all else fails, remove and reinsert.
- If appropriate, consider insertion of a smaller sized LMA ProSeal.

Warning: If airway problems persist or ventilation is inadequate, LMA ProSeal airway should be removed and an airway to be established by some other means.

8.5 Emergence from anaesthesia 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 intracuff 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 facilities 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 or drain 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 anaesthesia.

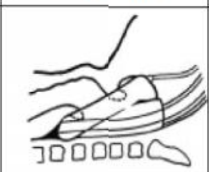
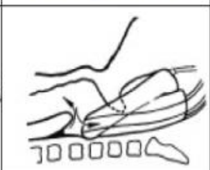
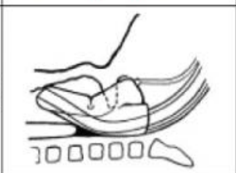
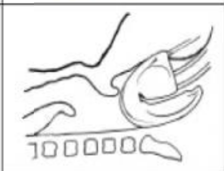
- Avoid suctioning the airway tube with the LMA ProSeal in place. The inflated cuff protects the larynx from oral secretions and suctioning is not likely to be required. Suctioning and physical stimulation may provoke laryngeal spasm if anesthesia is light.
- Watch for signs of swallowing. It is usually 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 airway is to be removed in a Post-Anaesthesia 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.

STEPS TO FACILITATE CORRECT MASK POSITION

- After insertion, inflate the cuff to no more than 60 cm H2O intracuff pressure.
- Connect to anesthesia circuit and check for leaks from the drain tube and airway tube.
- Verify position of bite block.
- Place a small bolus of lubricant gel on the proximal end of the drain tube and gently squeeze the bag to assess movement.
- If necessary, pass an orogastric tube to the end of the mask tip to verify the drain tube is patent.
- Once correctly positioned, apply palatal pressure to tubes while taping in place.

Table 3: Tips For Trouble Shooting Problems After Lma Proseal Insertion

	√ Correct placement	× Incorrect placement	× Incorrect placement	× Incorrect placement
				
Mask position	Tip behind arytenoid and cricoid cartilages	Tip too high in pharynx	Tip in laryngeal vestibule	Tip folded backwards
Gas leak from drain tube	No	Yes	Yes	No
Bite block	Approximately midway between teeth	Too high	Approximately midway between teeth	Too high
Lubricant test	Slight meniscus movement	May have movement depending on position	• Marked up/down movement • Ejection of lubricant or spontaneous bubble formation	No meniscus movement
Additional verification	Passing OG tube to mask mask tip demonstrates drain tube is patent	Pressing in further eliminates leak	Pressing in further increases obstruction	Dificulty passing OG tube indicates occluded drain tube

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TIPS FOR TROUBLE SHOOTING PROBLEMS AFTER LMA PROSEAL INSERTION

Problems after insertion	Possible cause(s)	Possible Solution(s)
Poor airway seal / air leak (audible air leak, poor ventilation	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Inadequate anaesthesia	Deepen anaesthesia
	Poor fixation	Ensure palatal pressure and proper fixation
	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O (adjust if necessary)
	Herniation of cuff	Confirm cuff integrity prior to use; deflate entirely prior to autoclaving
Gas leakage up to drain tube with or without PPV	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Open upper esophageal sphincter	Monitor
Airway obstruction (difficult ventilation, phonation, stridor)	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Distal tip of mask pressing on glottis inlet with mechanical closure of vocal cords	- Ensure adequate anaesthesia and correct cuff inflation pressures, - Place patient's head/neck in sniffing position - Try PPV or add PEEP
	Folding of cuff walls medially	- Consider insertion of one size smaller LMA ProSeal™ - Ensure correct cuff inflation pressures
Gastric insufflation	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
Migration/Rotation/Mask popping out of mouth	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O
	Herniation of cuff	Confirm cuff integrity prior to use
	Accidental displacement	Ensure proper fixation
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Poor fixation	Ensure palatal pressure and proper fixation
Resistance to OG tube insertion	Insufficient lubrication	Add lubricant and re-attempt passing OG tube
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Gross overinflation of cuff	Check off pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O

SPECIFICATIONS

Patient selection

The patient selection information in the accompanying table is for guidance purposes only. Research regarding the LMA Classic™ has indicated that a size 4 or 5 will suit most adults. However, when selecting the size of any medical device, clinical judgement should be used.

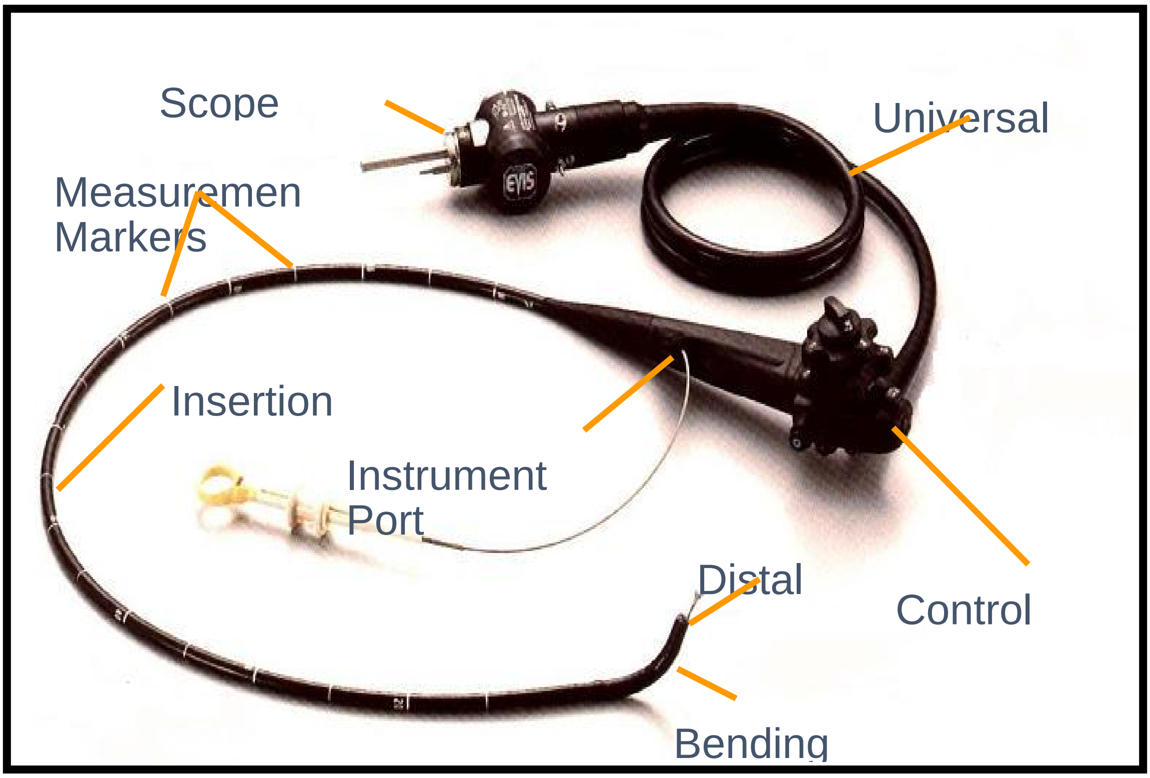
Inflation volume

The inflation volumes quoted in the table below are maximum values and should not be exceeded in use. After insertion, the cuff should be inflated until a “just seal” pressure is obtained.

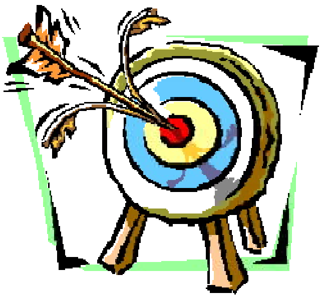
Table 5 : Lma Proseal Sizes And Cuff Volumes

LMA ProSeal™ size	Patient selection information	Maximum Inflation Volume	Maximum Diameter of Oro-gastric Tube	Introducer size
1	Neonates up to 5kg	4ml	2.7mm / 8fr	1 - 2½
1 ½	Infant 5-10kg	7ml	3.5mm / 10fr	1 - 2½
2	Child 10-20kg	10ml	3.5mm / 10fr	1 - 2½
2 ½	Child 20-30kg	14ml	4.9mm / 14fr	1 - 2½
3	Child 30-50kg	20ml	5.5mm / 16fr	3 - 5
4	Adult 50-70kg	30ml	5.5mm / 16fr	3 - 5
5	Adult 70-100kg	40ml	6.0mm / 18fr	3 - 5

This typically corresponds to an intra-cuff pressure of 60cm H2O. This pressure should not be exceeded. If a seal is not obtained after inflating the cuff to this pressure, then the device is either malpositioned or a larger size may be required. Where possible, it is recommended that the largest suitable size is used at a lower intra-cuff pressure, rather than the reverse.


Scope
Universal
Measuremen
Markers
Insertion
Instrument
Port
Distal
Control
Bending

Introduction



Objectives

Review of Literature

Basic Sciences

Methodology

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Discussion

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Summary

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Annexure-II

Annexure-III

Annexure-IV

Annexure-V

MATERIALS AND METHODS

The present study titled“A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL” was conducted at KLE’S Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Nehru Nagar, Belagavi on patients undergoing short elective surgical procedures requiring general anaesthesia between January 2015 to December 2015

Study design: RANDOMISED CLINICAL TRIAL

Selection Criteria:

Inclusion Criteria:

1. The subjects are adult surgical candidates aged 18-60 years.
2. ASA physical status I and II.
3. Mallampati grade I and II.
4. Short elective surgery who require general anesthesia in whom tracheal intubation is not necessary.
5. Both male and female patients will be included.

Exclusion Criteria:

1. Presence of any significant acute or chronic lung disease.
2. Pathology of the neck or upper respiratory tract.
3. Potential difficult intubation.

4. Increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux, or full stomach).
5. Pregnant women.
6. BMI >30.

Sample size :

A total sample size of 120 adult patients divided into 2 groups.

Group S : Standard insertion technique 60 cases

Group R : Rotational insertion technique 60 cases.

Sample size calculation:

With type I error rate $\alpha = 0.05$ and

type II error rate $\beta = 0.02$

with a power of 80% and using the formula-

$$n = \frac{2\,(Z\alpha + Z\beta)^2\,pq}{(p_0 - p_1)^2}$$

n = number of samples

$Z\alpha = 1.96$

$Z\beta = 0.84$

n= 60

Methodology:

Following departmental research committee and institutional ethical board approval, written informed consent will be obtained from 120 adult patients aged above 18 years, ASA I and II, scheduled for elective short surgical procedures requiring general anaesthesia. Standard anaesthesia monitors include Non invasive blood pressure, pulse oximeter, electrocardiogram and $EtCO_2$ (end-tidal carbon dioxide) are applied. Baseline blood pressure, heart rate and peripheral O2 saturation are recorded. Anaesthesia protocol will be standardized. Patients of both groups would be premedicated with Metoclopramide 10mg, Ranitidine 50mg intravenously 15 min before surgery. 3 sprays of 10% lignocaine given to the posterior oropharynx. Midazolam 0.02mg/kg, Fentanyl 1mcg/kg, Ketamine 0.5mg/kg are administered intravenously. Following pre-oxygenation for 2 minutes anaesthesia will be induced with propofol titrated to loss of verbal contact with the patient, loss of eyelash reflex and relaxation of jaw. If coughing, gagging or body movement occurs during insertion of device, propofol 1mg/kg will be added to achieve an adequate level of anaesthesia. For the safety reason of patients before the insertion of any of the devices after loss of verbal contact, the anaesthetist will check that hand-ventilation with a face mask is possible.

Once the patient becomes apnoeic and LMA insertion depth is achieved on the basis of clinical judgement, (i.e. jaw relaxation), the deflated ProSeal LMA size three in females and size four in males will be inserted. The patients will be assigned to their groups with a computer generated randomisation list (www.randomizer.org). i.e. standard and rotational insertion techniques. In standard technique (Group-S), LMA will be placed using the Brain's insertion technique. The patient's head is positioned with head extended at the atlanto-axial joint and flexed at the neck with non-dominant hand. The LMA is held like a pen and index finger placed at the junction of LMA tube and cuff. Index finger is used to press the LMA against hard palate and posterior pharyngeal wall until definite resistance is felt at the base of the hypopharynx. LMA is then held with nondominant hand and index finger is removed.

In the rotation technique (Group-R) the entire cuff of the PLMA is placed in the patient's mouth in a midline approach without finger insertion, rotated 90 degrees counter clockwise around the patient's tongue, advanced and then rotated back until resistance is felt.Following LMA insertion in both techniques, LMA will be inflated with 20 ml of air in size 3 and 30 ml in size 4 LMA and seal obtained. Successful placement is checked by chest expansion, reservoir bag movement and appearance of capnographic tracing. The depth of anaesthesia was increased so that the patient becomes apneic then the patient was placed on closed circuit and fresh gas flow kept at 3litre/hr and the airway pressure on the monitor at which the airleak is present or when the airway pressure doesn't increase beyond a certain pressure is noted as the airway seal pressure. The position of the LMA was graded in accordance with the fiber-optic scoring system :

Grade 1= only vocal cords visible.

Grade 2= vocal cords and posterior epiglottis visible.

Grade 3=vocal cords and anterior epiglottis visible.

Grade 4= vocal cords not seen.

Anaesthesia will be maintained with Sevoflurane, oxygen plus nitrous oxide spontaneously. Patients are intraoperatively monitored for heart rate, noninvasive blood pressure and SpO_2. All LMAs are removed in deep plane of anaesthesia. All study variables are recorded by other anaesthesiologists who are neither involved in study nor aware of the nature of study. The surgeon is requested not to clean, drape or position the patient until five minutes has elapsed after placement of the supraglottic device so as to avoid any stimuli likely to interfere with the findings.

RESULT

This one year randomized clinical trail was conducted in the Department of Anaesthesiology, during the period of January 2015 to December 2015 at KLES Dr Prabhakar Kore Charitable Hospital,Belagavi attached to Jawaharlal Nehru Medical College, Belagavi.

A total sample size of 120 adult patients divided into 2 groups.

Group S : Standard insertion technique 60 cases

Group R : Rotational insertion technique 60 cases.

TABLE 6 A : COMPARISON OF AGE DISTRIBUTION

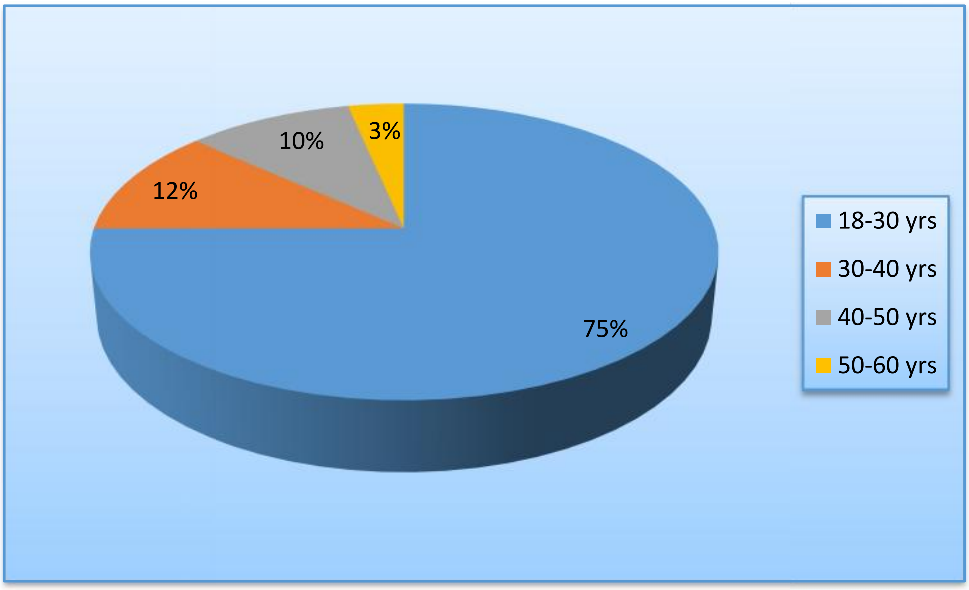
AGE (yrs)	GROUP S	GROUP R
18-30	45 (75%)	46 (77%)
30-40	7 (12%)	7 (11%)
40-50	6 (10%)	4 (7%)
50-60	2 (3%)	3 (5%)

TABLE 6 B : COMPARISON OF AGE DISTRIBUTION

GROUP	Mean ± S.D
S	28.88 ± 10.05
R	28.75 ± 9.16

P Value : 0.94 . No statistical difference between two groups Statistical test : Unpaired t test

GRAPH 1 : AGE DISTRIBUTION OF GROUP S



GRAPH 2 : AGE DISTRIBUTION OF GROUP R

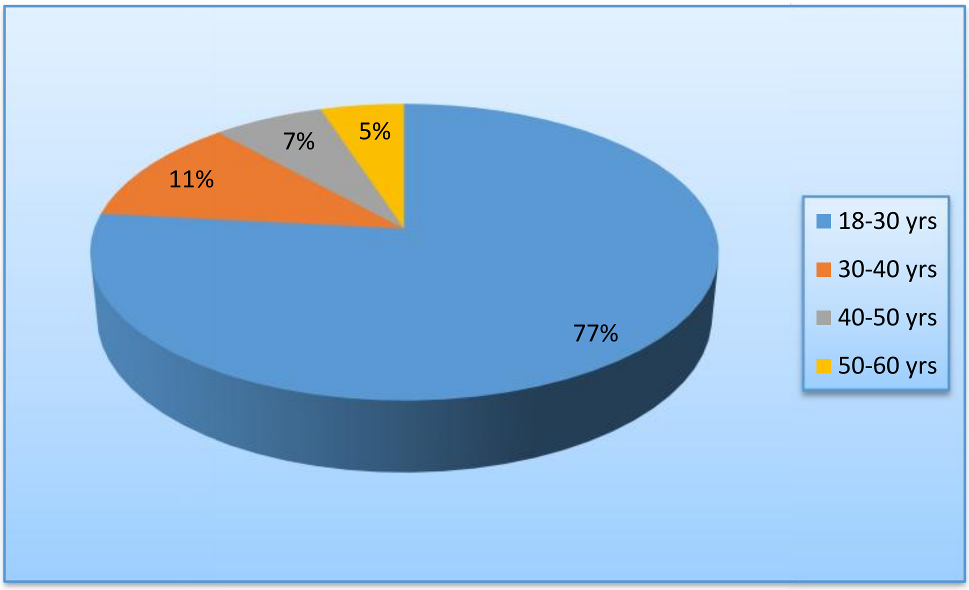
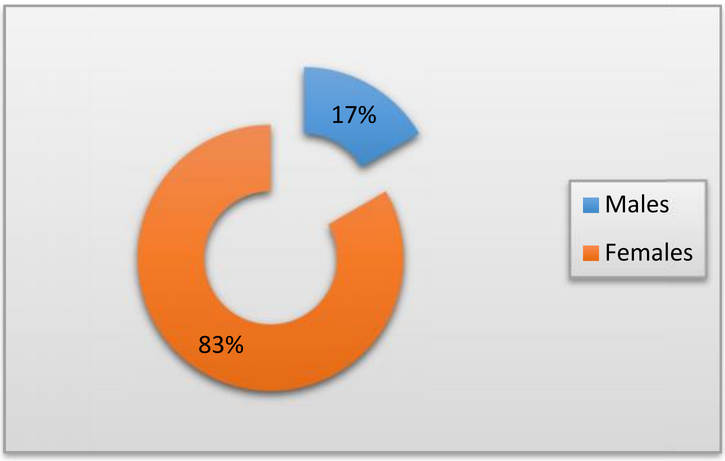


TABLE 7 : COMPARISON OF GENDER DISTRIBUTION

GROUP	MALES	FEMALES
S	10 (17%)	50 (83%)
R	9 (15%)	51 (85%)

P Value : 1. No statistical difference between two groups Statistical test – Fisher’s exact test

GRAPH 3 : GENDER DISTRIBUTION OF GROUP S



GRAPH 4 : GENDER DISTRIBUTION OF GROUP S

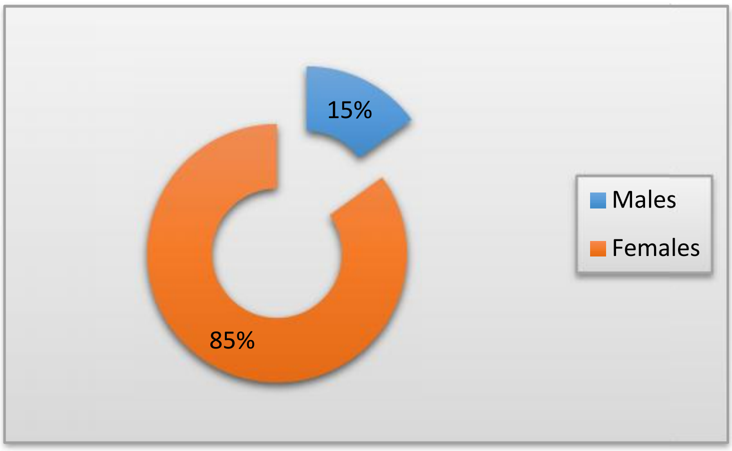


TABLE 8 : COMPARISON OF ATTEMPTS OF INSERTION

GROUP	1 Attempt	> 1 Attempt
S	47 (78%)	13 (22%)
R	59 (98%)	1 (2%)

P Value : 0.001. Shows significant statistical difference between the two groups

Statistical test – Fisher's exact test

GRAPH 5 : COMPARISON OF ATTEMPTS OF INSERTION

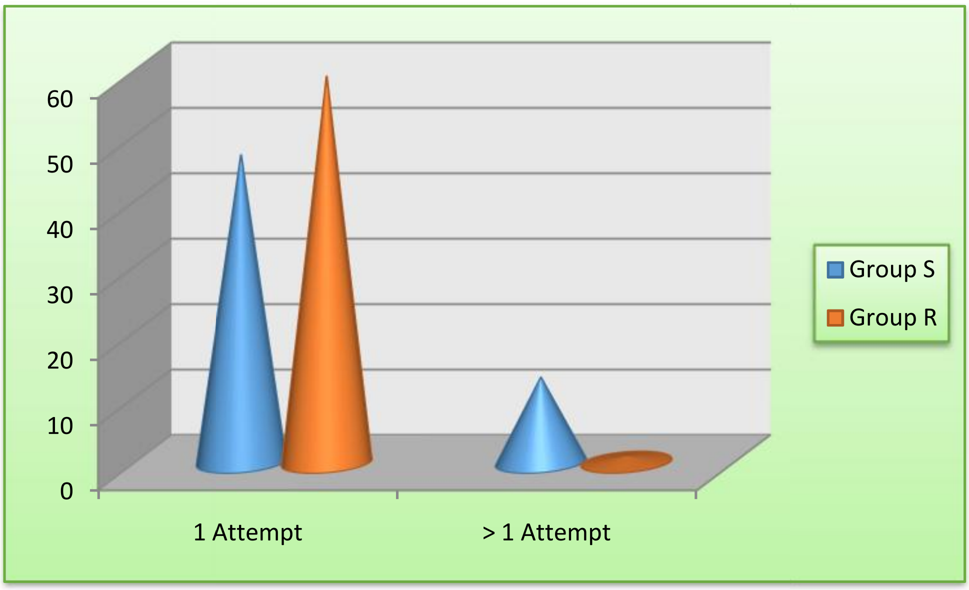


TABLE 9 : COMPARISON OF INSERTION TIME

GROUP	Mean (secs) ± S.D
S	25.98 ± 10.92
R	11.88 ± 3.62

P value : <0.0001. Shows significant statistical difference between the two groups

Statistical test – Unpaired t test

GRAPH 6 : COMPARISON OF INSERTION TIME

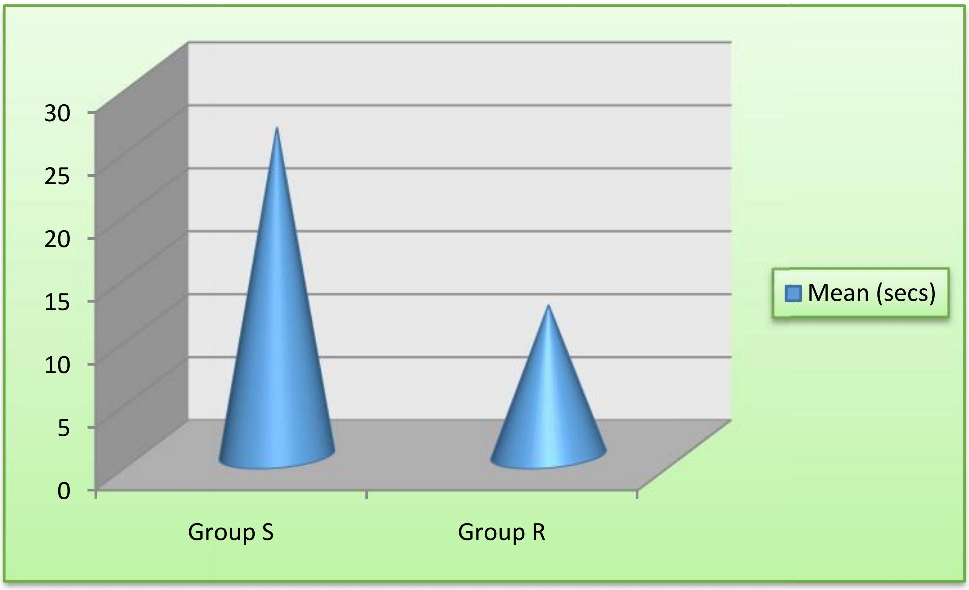


TABLE 10 : COMPARISON OF FIBEROPTIC GRADING

	Grade I	Grade II	Grade III	GradeIV
Group S	2(3.33%)	58(96.66%)	0	0
Group R	2(3.33%)	58(96.66%)	0	0

P Value : 1. No significant difference between the two groups Statistical test – Chi – squared test

GRAPH 7 : COMPARISON OF FIBEROPTIC GRADING

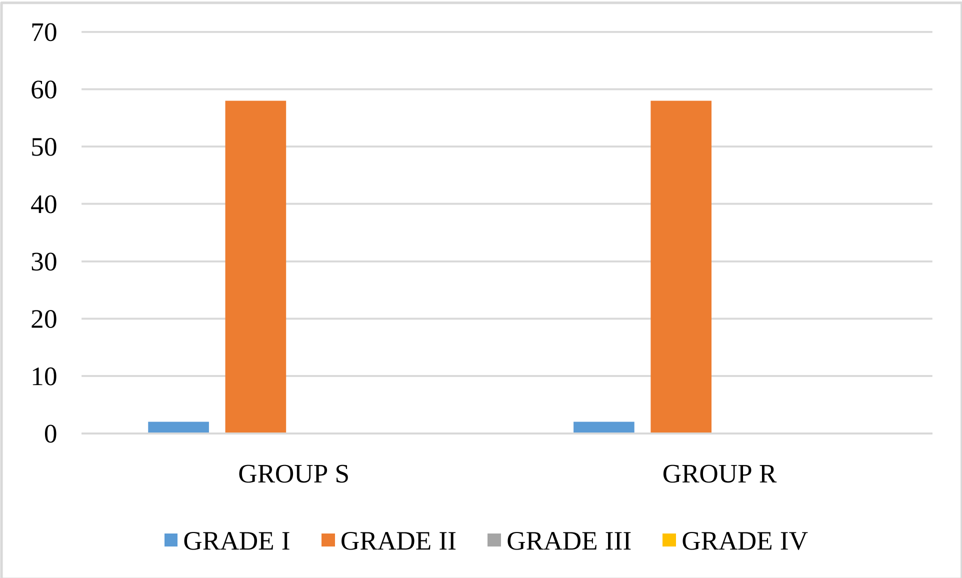


TABLE 14 : COMPARISON OF HEART RATE AT DIFFERENT LEVELS

	Group S		Group R		P Value
	Mean	**S.D**	**Mean**	**S.D**	
Before Insertion	**75.57**	**9.53**	**79.38**	**11.75**	**0.053**
At Insertion	**83.38**	**13.01**	**81.43**	**9.19**	**0.345**
2 minutes	**80.43**	**8.89**	**85.02**	**13.59**	**0.031**
5 minutes	**77.05**	**10.37**	**80.4**	**12.14**	**0.107**

There is a significant difference between the two groups at 2 minutes after insertion

GRAPH 8 : COMPARISON OF HEART RATE AT DIFFERENT LEVELS

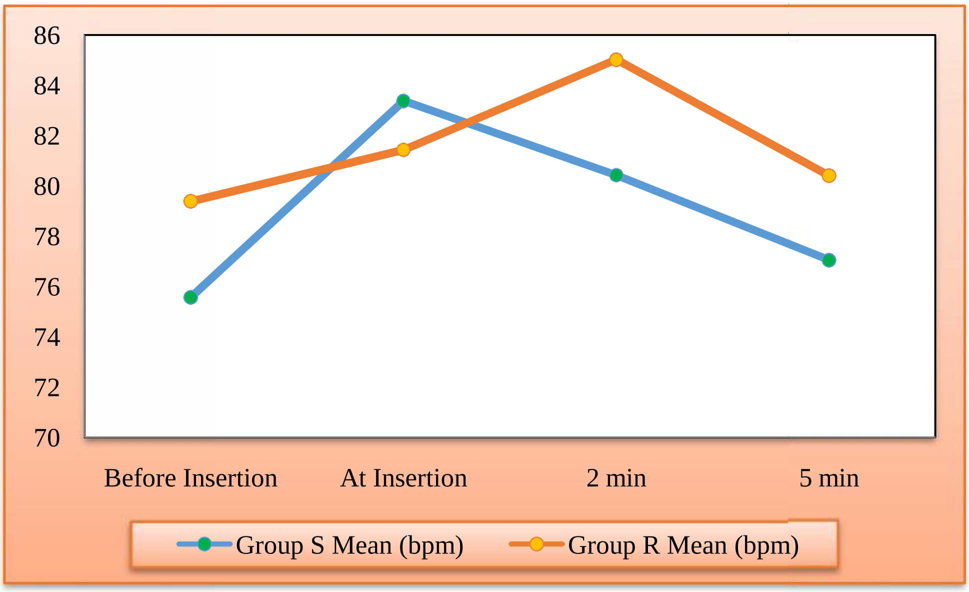


TABLE 15 : COMPARISON OF MEAN ARTERIAL PRESSURE AT DIFFERENT LEVELS

	Group S		Group R		P Value
	Mean	**S.D**	**Mean**	**S.D**	
Before Insertion	**92.5**	**7.33**	**89.52**	**6.25**	**0.018**
At Insertion	**99.8**	**12.34**	**90.77**	**7.34**	**0.000**
2 minutes	**101.78**	**12.37**	**91.77**	**7.34**	**0.000**
5 minutes	**95.33**	**6.71**	**94.08**	**9.01**	**0.39**

There is a significant difference between the two groups during insertion & at 2 minutes after insertion

GRAPH 9 : COMPARISON OF MEAN ARTERIAL PRESSURE AT DIFFERENT LEVELS

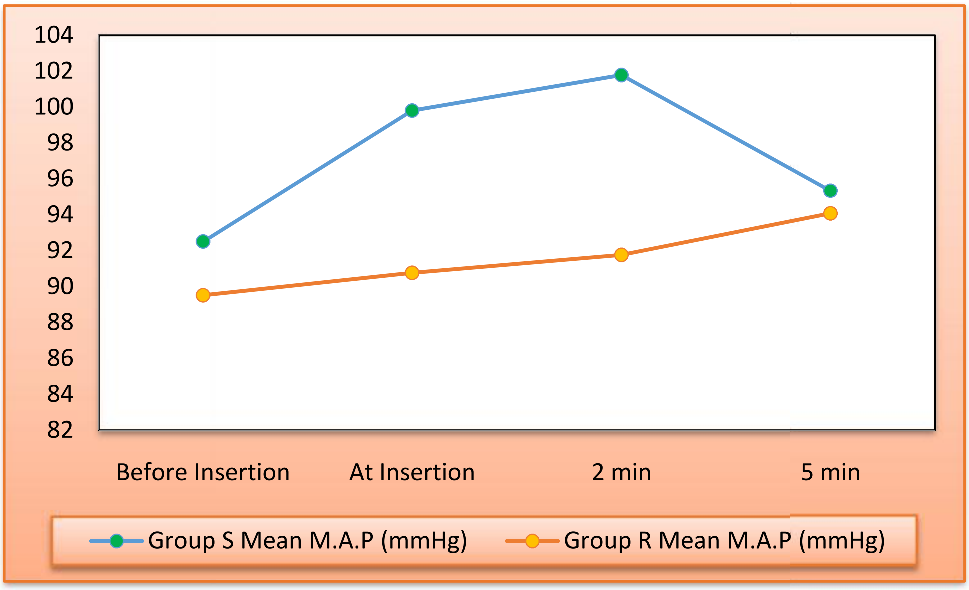


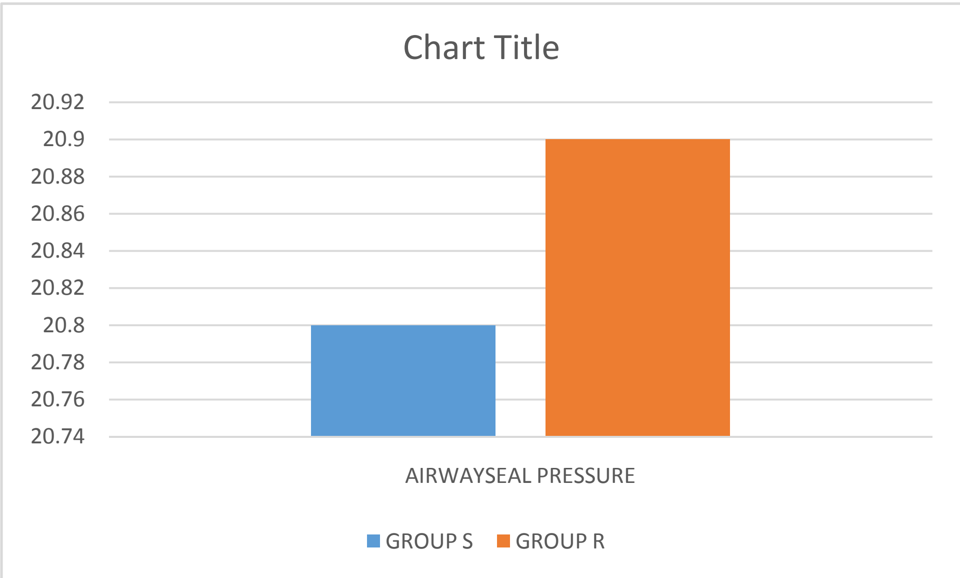
TABLE 16 : COMPARISION OF AIRWAYSEAL PRESSURE

	GROUP S (MEAN±SD)	GROUP R (MEAN±SD)	P VALUE
AIRWAYSEAL PRESSURE	**20.8±0.42**	**20.9±0.32**	**0.466**

P Value : 0.466. Shows no significant statistical difference between the two groups

Statistical test – Fisher's exact test

GRAPH 10 : COMPARISION OF AIRWAYSEAL PRESSURE



DISCUSSION

Airway management is the obligatory skill in Anaesthesiology and the most common reasons for major anaesthesia related morbidities and mortalities is inability to secure the airway . Laryngeal mask airway (LMA) has a recognised role in modern anaesthesia practice. Its frequently used for airway management of spontaneously breathing patients undergoing elective short surgical procedures.To provide emergency ventilation in difficult airway scenarios LMA Proseal is used in recent times.The LMA ProSeal is an advanced form of LMA airway that may be used for the same indications as the LMA Classic.

The LMA ProSeal is devised to gain additional benefits over the LMA Classic that extends the range of procedures for which an LMA airway is indicated. LMA Classic is used with low-pressure positive pressure ventilation (PPV), the LMA ProSeal is specifically devised for use with PPV with and without muscle relaxants at higher airway pressures. Some degree of skill is required for correct placement of laryngeal mask airway and if LMA insertion is sub-optimal, it can cause partial or complete airway obstruction. Standard Brain's LMA insertion technique difficult to execute. Problems are usually encountered when getting the tip of LMA mask to deflect or buckle into back of the mouth and requires excessive force to place LMA at proper position which results in multiple insertion attempts, prolonged insertion time, trauma to airway and failure of LMA insertion.

Nevertheless, the manufacturer's instructions is strictly followed, but still it is difficult to negotiate the LMA through the pharynx posteriorly. Complications like failure insertion attempts, hypoxaemia, laryngospasm and oral trauma are frequently observed with the standard LMA insertion technique.[21] Brodrik has mentioned LMA insertion failure due to down-folding of epiglottis and backward rotation of LMA mask in 10% of his study population with standard Brain's LMA insertion technique.[29] Rotational insertion technique has not been broadly investigated in adult populations with regard to success rate and ease of LMA insertion. Less number of studies have been done regarding the rotational LMA insertion as an alternative method of LMA insertion in adult population.[13,14,30]

This study demonstrates that the 90 degree rotation technique has advantages over the standard technique for insertion of PLMAs in anesthetized patients. The ProSeal LMA was reportedly more difficult to insert than the Classic LMA.[23,24] Its larger cuff makes it difficult to place in the oral cavity and leaves narrow space for insertion of an index finger or thumb. The 90 degree rotation technique does not require the insertion of a finger, avoids finger trauma and glove contamination with blood or saliva. Many techniques have been proposed to improve the success rate of PLMA insertion.[25]

The 90 degree rotation insertion technique is suitable because it does not require additional devices ,consists of insertion of the PLMA into the oral cavity, rotation around the tongue, and advancement. We were initially concerned that it may be problematic to rotate the large cuff in the mouth but it was so and we never failed to insert PLMAs using the rotation insertion technique. In this study, The rotation technique causes less pharyngeal trauma. The decreased incidence of complications may be associated with reduced resistance between the tip of the PLMA head and the pharyngeal wall.

In our study we have compared the effectiveness of two techniques of insertion of LMA ProSeal with respect to

1) Ease of insertion.
    - Time of insertion and number of insertion attempts.
    - Airway sealing pressure.
    - Fiber-optic glottis view.
2) Hemodynamic changes in 120 adult patients with 60 patients in each group of insertion technique presenting for short surgical procedure requiring general anaesthesia in whom tracheal intubation is not necessary.

There was significant statistical difference between standard technique & 90 degree rotational technique of insertion of ProSeal LMA with respect to attempts of insertion, insertion time, heart rate & mean arterial pressure.

In a study conducted by Jeon YT et al[15] where they have compared standard technique with 90 degree rotational technique of insertion of ProSeal LMA in 120 adult patients. Their rotational technique of insertion is identical ours. Their success rate at first insertion was greater for the rotation technique group than for the standard technique group (100% vs 83%, respectively; P = 0.003) whereas in our study also the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs 78%, respectively; P = 0.001) which is statistically significant. In their study less time was required for PLMA insertion in rotational group as compared to standard group (11 +/- 3 sec vs 19 +/- 16 sec, respectively; P = 0.03) whereas in our study (11.88 ± 3.62 secs vs 25.98 ± 10.92 ; P = <0.0001) which is statistically significant. In their study the blood pressure change showed group-insertion interaction effect (P < 0.001). In our study the blood pressure change was statistically significant during insertion & at 2 minutes after insertion, during insertion for rotational group compared to standard group was (90.77 ± 7.34 mmHg vs 99.8 ± 12.34 mmHg) & at 2 minutes after insertion for rotational group compared to standard group was (91.77 ± 7.34 mmHg vs 101.78 ± 12.37 mmHg).

In another study conducted by Kim, M.; Hwang, J.; Jeon, Y. T.; Na, H. S.[16] where they have compared standard technique with 90 degree rotational technique of insertion of ProSeal LMA in total 94 adult patients. Again their rotational technique of insertion is identical to that of ours. Their success rate at first insertion was greater for the rotation technique group than for the standard technique group (100 vs. 81%, P = 0.003) whereas in our study also the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs 78%, respectively; P = 0.001) which is statistically significant. In their study less time was required for PLMA insertion in rotational group as compared to standard group (11 ± 3 vs. 19 ± 15 sec, P = 0.002) whereas in our study (11.88 ± 3.62 secs vs 25.98 ± 10.92 ; P = <0.0001) which is statistically significant.

In another study conducted by M Yun et al[26] where they have compared standard technique with 90 degree rotational technique of insertion of ProSeal LMA in total 92 paediatric patients. Their rotational technique of insertion is identical to that of ours. Their success rate at first insertion was greater for the rotation technique group than for the standard technique group (95.7 vs. 76.1%, P < 0.001) whereas in our study also the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs 78%, respectively; P = 0.001) which is statistically significant. The overall success rate - that is, successful insertion within three attempts - was 100% for the both techniques which is identical to our study. In their study Systolic, diastolic and mean blood pressure and heart rate increased significantly with the standard technique (P <0.001). In our study heart rate & mean arterial pressure increased significantly with standard technique (P < 0.05).

In a study conducted by Mi-Ja Yun et al[27] where they have compared standard technique with 90 degree rotational technique of insertion of ProSeal LMA in total 126 paediatric patients aged 3 to 9 years. Their rotational technique of insertion is identical to that of ours. Their success rate at first insertion was greater for the rotation technique group than for the standard technique group (97 vs. 70%, P < 0.001) whereas in our study also the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs 78%, respectively; P = 0.001) which is statistically significant. The insertion time was shorter (16 ± 6 sec *vs* 30 ± 24 sec, respectively; *P* < 0.001). In our study it was (11.88 ± 3.62 secs vs 25.98 ± 10.92 ; P = <0.0001) which is statistically significant. In their study the blood staining of PLMA was less with rotation technique group compared to standard group (10% vs. 25%, P = 0.03 In their study mean blood pressure increased significantly with the standard technique (62 ± 12 to 69 ± 17 mmHg; *P* = 0.01). In our study heart rate & mean arterial pressure increased significantly with standard technique (P < 0.05).

In a study conducted by Dileep Kumar, Mueenullah Khan and Muhammad Ishaq[28] where they have compared standard technique with 90 degree rotational technique of insertion of ProSeal LMA in total 100 adult patients. Again their rotational technique of insertion is identical to that of ours. The frequency of LMA insertion attempts were observed at first attempt (84%), at second attempt (96%) and at third attempt (100%) with both the standard and rotational LMA insertion techniques. Statistically insignificant differences were detected for the time duration of LMA insertion among the study groups which is in contrast to our study where the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs 78%, respectively; P = 0.001) which is statistically significant. In their study the rotational LMA insertion technique was found to be completed in less than 30 seconds duration in 86% compared to 78% with standard LMA insertion technique which was not statistically significant (P = 0.456) which is in contrast to our study (11.88 ± 3.62 secs vs 25.98 ± 10.92 ; P = <0.0001) which is statistically significant.

In another study conducted by Haghighi M, Mohammadzadeh A, Naderi B, Seddighinejad A, Movahedi H where they have compared two methods of LMA insertion classic versus simplified (AIRWAY) method in 100 patients of ASA grades I & II. In the AIRWAY group, the deflated LMA is entered into the mouth in a 180 degree insideout position compared to the classic method without using fingers and is proceeded until it enters the pharynx (sudden loss of resistance) and then returned 180 degree back to its normal position to be fixed in the right place. The attempt numbers, time to insertion, complications such as laryngospasm, blood stained LMA and gastric inflation is being investigated. Successful first attempt in AIRWAY group (86%) had no meaningful statistic difference with the classic group (80%) (p>0.05) which is in contrast to our study where the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs 78%, respectively; P = 0.001) which is statistically significant. The time for successful insertion was meaningfully less in the group compared to the classic one (p<0.0001). In our study it was (11.88 ± 3.62 secs vs 25.98 ± 10.92 ; P = <0.0001) which is statistically significant.

Our study has some limitations. First it was impossible to blind the anesthesiologists to the insertion technique, which may have been a source of bias even though assessment of insertion time, blood pressure change, airway sealing pressure and fiberoptic glottis view was conducted by another person blinded to the insertion method.

CONCLUSION

From our study we conclude that :

- The chance of insertion at first attempt is greater with 90 degree rotational technique compared to standard technique of insertion of ProSeal LMA.
- Time required for insertion of ProSeal LMA is less with 90 degree rotational technique compared to standard technique of insertion of ProSeal LMA.
- Airway sealing pressure with 90 degree rotational technique is similar to standard technique of insertion
- Fiberoptic glottis view with 90 degree rotational technique is similar to standard technique of insertion.
- Haemodynamic changes with respect to increase in heart rate & mean arterial pressure are more for standard technique compared to 90 degree rotational technique of insertion of ProSeal LMA.

SUMMARY

In this present study titled "A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL".we have compared the effectiveness between two insertion techniques regarding insertion time, number of insertion attempt,airwayseal pressure,fiberoptic glottis view and haemodynamic changes.

The study was conducted in 120 adult patients aged 18-60 years of ASA grades I & II undergoing short surgical procedures requiring general anaesthesia. Patients were randomly allocated into standard technique & 90 degree rotational technique group. Each group contained 60 patients.

Intravenous premedication was given to patients. Following induction PLMA was inserted based on the random allocation of the standard technique or rotational technique group.

The success rate at first insertion was higher for rotational group & insertion time was less for rotational group which was statistically significant. Haemodynamic changes with respect to increase in heart rate & mean arterial pressure was more for standard technique compared to 90 degree rotational technique which showed significant statistical difference,airway sealing pressure and fiberoptic glottis view was similar in both groups.

Hence it was concluded that 90 degree rotational technique of insertion of PLMA was better than standard technique of insertion.

BIBLIOGRAPHY

1. Sharma B, Sahai C, Bhattacharya A, Kumar VP, Sood J. ProSeal laryngeal mask airway: A study of 100 consecutive cases of laparoscopic surgery. Indian J Anaesth 2003;47:467-72.
2. Misra MN, Ramamurthy B. The Pro-Seal LMAtm and the tracheal tube: A comparison of events at insertion of the airway device. Internet J Anesthesiol 2008. Vol. 16. [Last accessed on 2010 Jul 9].
3. Lunn JN, Mushin WW. Morbidity associated with anaesthesia. London: Nuffield Provincial Hospitals Trust, Associations of Anesthesiologists of Great Britain and Ireland(Annual report).1982 ;50 :70-84.
4. Brimacombe J, Brain AIJ, Berry A. The laryngeal mask airway: Review and practical guide. London : WB Saunders, 1997.
5. Bimla Sharma, Chand Sahai, Abhijit Bhattacharya, V.P. Kumra, Jayashree Sood. Proseal Laryngeal mask airway : A study of 100 consecutive cases of laproscopic surgery. Indian J Anaesth. 2003;47, 467-472.
6. Brain AIJ, Verghese C, Strube PJ. The LMA 'Proseal' – A laryngeal mask with an oesophageal vent. Br J Anaesth 2000; 84:650-654.
7. Keller C, Brimacombe J. Mucosal pressure and oropharyngeal leak pressure with the proseal versus the classic laryngeal mask airway in anaesthetized paralysed patients. Br J Anaesth 2000; 85:262-266.
8. Nakayama S, Osaka Y, Yamashita M. The rotational technique with a partially inflated laryngeal mask airway improves the ease of insertion in children. *Paediatr Anaesth* 2002; **12**:416-9

9. Koay CK, Yoong CS, Kok P. A randomized trial comparing two laryngeal mask airway insertion techniques. *Anaesth Intensive Care* 2001; **29**:613-5.
10. Soh CR, Ng ASB. Laryngeal mask airway insertion in paediatric anesthesia: comparison between the reverse and standard techniques. *Anaesth Intense Care* 2001; **29**:515-519.
11. Matta BF, Marsh DS, Nevin M. Laryngeal mask airway: more successful method of insertion. *J Clin Anesth* 1995; **7**:132-5.
12. Wakeling HG, Butler PJ, Baxter PJ. The laryngeal mask airway: a comparison between two insertion techniques. *Anaesth Analg* 1997; **85**:687-90.
13. Haghighi M, Mohammadzadeh A, Naderi B, Seddighinejad A, Movahedi H. Comparing two methods of LMA insertion; classic versus simplified (airway). *MEJ Anesth* 2010; **20**:509-14.
14. Brimacombe J, Berry A. Insertion of the laryngeal mask airway. Aprospective study of four techniques. *Anaesth Intense Care* 1993; **21**:89-92.
15. Jeon YT, Na HS, Park SH, Oh AY, Park HP, Yun MJ, Kim JH, Hwang JW. Insertion of the ProSeal laryngeal mask airway is more successful with the 90 degrees rotation technique. Can J Anaesth. 2010 Mar;57(3):211-5.
16. Kim, M.; Hwang, J.; Jeon, Y. T.; Na, H. S. Comparison of two insertion techniques of ProSeal(TM) laryngeal mask airway in paralyzed, anesthetized patients: Standard versus 90-degree rotation. European journal of anaesthesiology 2010 Jun:27(47):256
17. Hwang JW, Park HP, Lim YJ, Do SH, Lee SC, Jeon YT. Comparison of two insertion techniques of ProSeal laryngeal mask airway: standard versus 90-degree rotation.

18. M Yun, J Hwang, A Oh, M Han, H Kim, H Na and S Lee. Comparison of two insertion techniques of the ProSeal laryngeal mask airway: standard versus 90° rotation in pediatric patients. Critical Care 2010, 14(Suppl 1):P215
19. Dileep Kumar, Mueenullah Khan and Muhammad Ishaq. Rotational vs. Standard Smooth Laryngeal Mask Airway Insertion in Adults. Journal of the College of Physicians and Surgeons Pakistan 2012, Vol. 22 (5): 275-279
20. Yun MJ, Hwang JW, Park SH, Han SH, Park HP, Kim JH, Jeon YT, Lee SC. The 90° rotation technique improves the ease of insertion of the ProSeal™ laryngeal mask airway in children. Can J Anaesth. 2011 Apr;58(4):379-83
21. Nakayama S, Osaka Y, Yamashita M. The rotational technique with a partially inflated laryngeal mask airway improves the ease of insertion in children. Paediatr Anaesth. 2002 Jun;12(5):416-9.
22. Ghai B, Ram J, Makkar JK, Wig J. Fiber-optic assessment of LMA position in children: a randomized crossover comparison of two techniques. Paediatr Anaesth. 2011 Nov;21(11):1142-7
23. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology 2000; 93: 104–9.
24. Brimacombe J, Keller C, Fullekrug B, et al. A multicenter study comparing the ProSeal and Classic laryngeal mask airway in anesthetized, nonparalyzed patients. Anesthesiology 2002; 96:289–95.
25. Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: a review of the literature. Can J Anesth 2005; 52: 739–60.

26. M Yun, **Hwang, A Oh, M Han, H Kim, H Na** and **S Lee.** Comparison of two insertion techniques of the ProSeal laryngeal mask airway: standard versus 90° rotation in pediatric patients. Critical Care 2010, 14(Suppl 1):P215

27. Mi-Ja Yun, Jung-Won Hwang, Sang-Heon Park, Sung-Hee Han and Hee-Pyoung Park, et al.The 90° rotation technique improves the ease of insertion of the ProSeal™ laryngeal mask airway in children. Canadian Journal of Anesthesia / Journal canadien d'anesthésie, 2011, Volume 58, Number 4, Pages 379-383

28. Dileep Kumar, Mueenullah Khan and Muhammad Ishaq. Rotational vs. Standard Smooth Laryngeal Mask Airway Insertion in Adults. Journal of the College of Physicians and Surgeons Pakistan 2012, Vol. 22 (5): 275-279

29. Brodrik PM, Webster NR, Nunn JF. The laryngeal mask airway. A study of 100 patients during spontaneous breathing. *Anesthesia* 1989; **44**:238-41.

30. Monem A, Khan F. Laryngeal mask airway insertion anesthesia and insertion techniques. *J Pak Med Assoc* 2007; **57**:607-11.

31. Joshi S, Sciacca RR, Solanki DR, Young WL, Mathru MM. A Prospective evaluation of clinical tests for placement of laryngeal mask airway. *Anesthesiology* 1998; **89**:1141-6.

ANNEXURE-I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. ______________________________ we are requesting you toenroll yourself in **"A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL",** Department of Anaesthesiology, J.N. Medical College, Belagavi under KLE university, Belagavi.

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of the research is to evaluate effectiveness between two insertion techniques regarding time of insertion and number of insertion attempts,gastric insufflation and leak around the cuff,hemodynamicchanges,airway trauma & post-operative airway morbidity.

Procedure Involved:

If you agree to enroll yourself in my study,youwill be premedicated with Metoclopramide 10mg, Ranitidine 50mg intravenously 15 min before surgery. 3 sprays of 10% lignocaine givento the posterior oropharynx. Midazolam0.02mg/kg, Fentanyl 1mcg/kg, Ketamine 0.5mg/kg are administered intravenously. Following pre-oxygenation for 2 minutes. anaesthesia will be induced with propofol titrated to loss of verbal contact with the patient, loss of eyelash reflex and relaxation of jaw. If coughing, gagging or body movement occurs during insertion of device, propofol 1mg/kg will be added to achieve an adequate level of anaesthesia. For the safety reason of patients before the insertion of any of the devices after loss of verbal contact, the anaesthetist will check that hand-ventilation with a face mask is possible. Once the patient becomes apnoeic and LMA insertion depth is achieved on the basis of clinical judgement, (i.e. jaw relaxation), the deflated ProSeal LMA size three in females and size four in males will be inserted. The patients will be assigned to their groups with a computer generated randomisation list (www.randomizer.org). i.e. standard and rotational insertion techniques.

Benefits and Risks

These airway devices have become very popular because of their ability to maintain an airway without perturbing the trachea and can be used in patients without muscle relaxation who are only lightly anesthetized.There is incidence of postoperative sore throat and blood staining on the PLMA.

Voluntary participation / Withdrawal

Taking part in the study is voluntary; you may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at Dr. PrabhakarKore Hospital.

Alternatives

Even if you decline the participation in the study, you will get the routine line of management.

Confidentiality

All information collected about you during the course of the study will be kept confidential. The code numbers will identify you in this study records and the information from this study may be published but youridentity will be confidential in any publication. The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

- In emergency to protect your rights and welfare.
- If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research.

Compensation

In the event of injury, related to the study, treatment will be made available at Dr. PrabhakarKore Hospital and MRC, Belagavi. No reimbursement, compensation or free medical care will be given by law.

Queries/ Contact details

If you have any queries about your right as a study subject, you may call Dr. Ganga Pilli, Prof. & Head of Pathology as Chairman of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No.9448863866 or Extension-4052 at J. N. Medical College, Belagavi

Consent for participation in research trial

I, ____ voluntarily agree to participateas a subject for the study. By signing this consent form I am not giving up any of my legal rights, I may withdraw myself from the study anytime. I am signing the consent form after having read or been read form inmy own vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : ____

Signature or the Left Thumb Print :________________

Date: ____________

Witness Name : _________________________

Signature:_____________ Date:

Investigators Name: ______________________

Signature:_____________

Date:_______ Place:______

ANNEXURE-II

PROFORMA

"A COMPARISON OF STANDARD AND ROTATIONAL TECHNIQUES FOR EASE OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL".

Patient Name: IP No.:

Age: Gender: Female

Date of Operation: Occupation:

Address: Anaesthesiologist:

Preanesthetic Evaluation:

1. Chief Complaints:
2. Past History: HTN / DM / Asthma / Epilepsy / Rx allergy/Other relevant history
3. Treatment / Drug intake history :
4. History of previous surgeries and anaesthetic exposure
5. Family history

General physical examination

Pallor / Icterus / Clubbing / Cyanosis / Lymphadenopathy / Edema

Pulse Rate :   BP :

Respiratory Rate :   Temperature :

Systemic Examination

RS :   CNS :

CVS :   Abdomen :

Airway examination :

Jaw movements :   Teeth :

Airway assessment :   Spine :

Investigations

Hb :   Total Leucocyte Count :

Platelet count :   Serum Urea :

Serum.Creatinine: RBS:

ECG :   Chest X-Ray:

Urine R/M :   Others :

ASA GRADE : I   II   III   IV   V   E

Diagnosis :

Proposed Surgery :

Preoperative baseline values :

Pulse: BP:

Monitors attached :

Pulse oximetry :NIBP :

ECG :

- **Group of study belongs to :**

Standard insertion technique group :

Rotational insertion technique group :

Study Parameters:

The ease or smooth LMA insertion is the outcome of study and is recorded on the basis of number of LMA insertion attempts, LMA insertion time from removal of face mask to confirmation of chest expansion and capnographic appearance. Airsealing pressure. Haemodynamic parameters such as heart rate, systolic and diastolic blood pressure as well as SpO_2 will be recorded before and during LMA insertion, then every 1min upto 5min after insertion and during removal.Fibre-optic glottic view is graded.

Definition of variables :

- Ease of insertion : subjective
- Insertion time : The time interval between holding the airway device to confirmation of correct placement by bilateral air entry on chest auscultation.
- Airway seal pressure:the airway pressure on the monitor at which the airleak is present or when the airway pressure doesn't increase beyond a certain pressure is noted as the airway seal pressure.
- Failed insertion of the LMA is defined as the inability to position the device within 60 seconds.
- Hypoxaemia is $SpO_2 < 90\%$.

The position of the LMA was graded in accordancewith the fiber-optic scoring system :

Grade 1= only vocal cords visible.

Grade 2= vocal cords and posterior epiglottis visible.

Grade 3=vocal cords and anterior epiglottis visible.

Grade 4= vocal cords not seen.

Inclusion Criteria:

The subjects are adult surgical candidates aged 18-60 years.

ASA physical status I and II.

Mallampati grade I and II.

Short elective surgery who require general anesthesia in whom tracheal intubation is not necessary.

Both male and female patients will be included.

Exclusion Criteria:

Presence of any significant acute or chronic lung disease.

Pathology of the neck or upper respiratory tract.

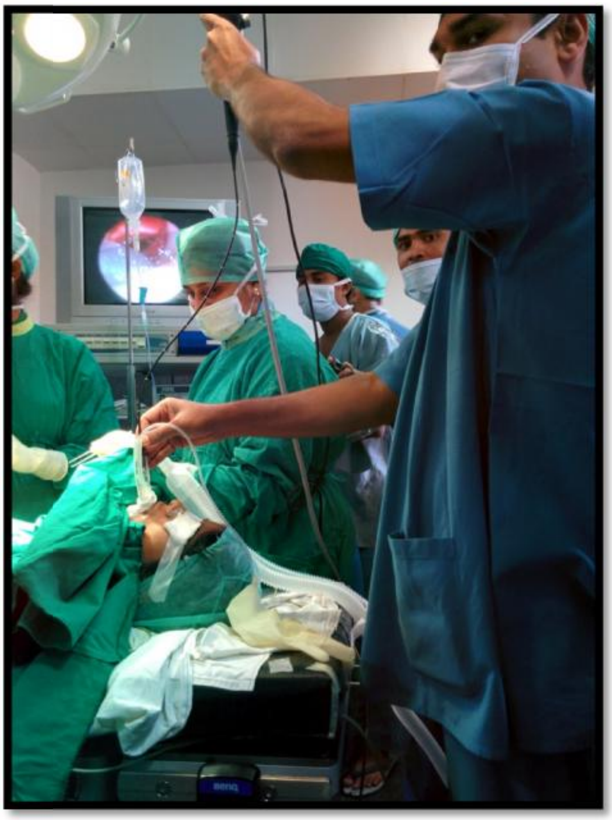
Potential difficult intubation.

Increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux, or full stomach).

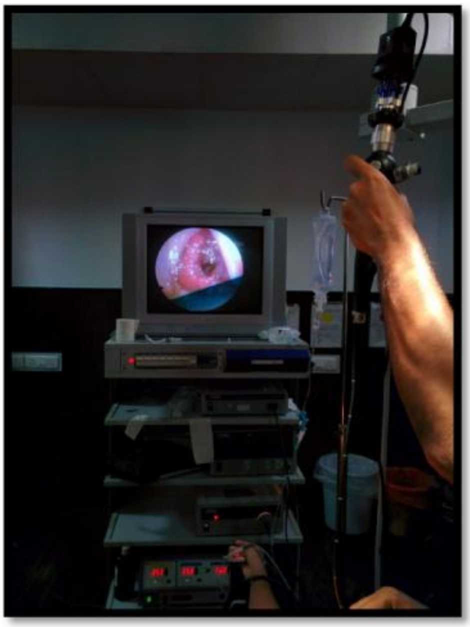
Pregnant women.

BMI >30.

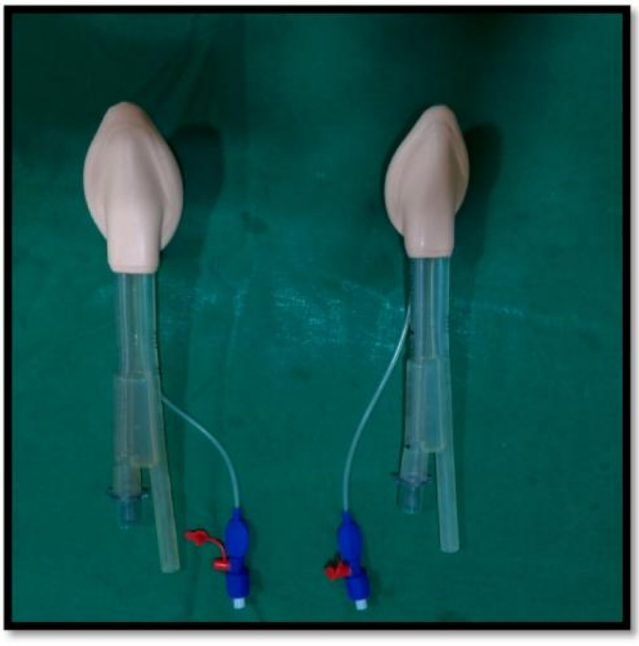
ANNEXURE III – PHOTOGRAPHS



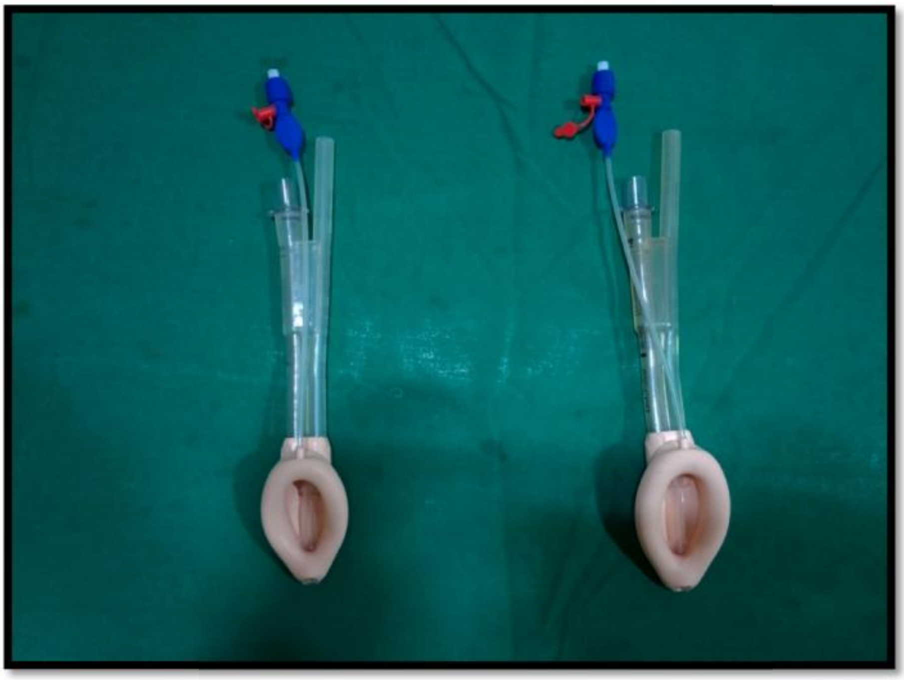
Photographs :1 Fiberoptic confirmation of Proseal LMA



Photographs : 2 Glottic view



Photographs :3 Proseal LMA size 3 and 4



Photographs :4 Proseal LMA size 3 and 4

Photographs :5 Fiberoptic bronchoscope

KEY TO MASTER CHART

ASA – American Society of Anaesthesiologists

Attempts of insertion -

- 1 - One attempt
- 2 - Two attempts
- 3 - Three attempts

Fiberoptic grading

Grade 1= only vocal cords visible.

Grade 2= vocal cords and posterior epiglottis visible.

Grade 3=vocal cords and anterior epiglottis visible.

Grade 4= vocal cords not seen.

M – Male

F – Female

H.R – Heart rate

S.B.P – Systolic blood pressure

D.B.P – Diastolic blood pressure

M.A.P – Mean arterial pressure

SpO2 – Peripheral oxygen saturation