“A RANDOMIZED CLINICAL TRIAL OF TWO INSERTION TECHNIQUES OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULTS-INDEX FINGER INSERTION TECHNIQUE VERSUS 90 DEGREE ROTATIONAL TECHNIQUE”

By

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Dissertation submitted to the

B. L. D. E. U’S SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE,VIJAYAPUR.KARNATAKA

In partial fulfillment of the requirements for the degree of

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IN

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Under the guidance of

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LIST OF ABBREVIATIONS

- LMA or cLMA - Laryngeal Mask Airway i.e. classic LMA
- PLMA - Proseal Laryngeal Mask Airway
- SpO_2 - 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 randomized clinical trial for comparison of two techniques of insertion of Proseal laryngeal mask airway in adults – index finger insertion technique versus 90 degree rotational technique.

Introduction

Proseal laryngeal mask airway (PLMA) is not easy to insert due to its larger cuff especially in Indian population .The 90 degrees rotation technique for inserting the PLMA (which does not involve use of introducer or aids or finger insertion) 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 90 degree rotational and standard insertion technique in terms of number of attempts, duration of insertion and occurrence of complications.

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, hemodynamic changes and complications.

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). The incidence of postoperative sore throat was lower (15% vs. 38.34%, respectively; P = 0.0067), and blood staining on the PLMA was less (11.7% vs. 45%, respectively; P < 0.0001). Haemodynamic changes with respect to increase in mean arterial pressure was more for standard technique compared to 90 degree rotational technique which showed statistical significance.

Conclusion

The 90 degrees rotation technique for inserting the ProSeal LMA (which does not involve use of introducer or aids or finger insertion) has a higher success rate at first insertion than the index finger insertion technique with lesser insertion time and fewer side effects.

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INTRODUCTION

In spite of tremendous advances in contemporary anaesthetic practice, airway management continues to be of paramount importance to anaesthesiologist. Till date, the cuffed tracheal tube was considered as the gold standard for providing a safe glottic seal.[1] The disadvantages of tracheal intubation, which involves rigid laryngoscopy, are in terms of concomitant haemodynamic responses and damage to the oropharyngeal structures at insertion. Postoperative sore throat is also a serious concern. This precludes the global utility of the tracheal tube and requires a better alternative.[2] Over a period of time, newer airway devices have been added to the anaesthesiologist‘s armamentarium.

Failure to intubate can cause mortality and account for 30% of overall anaesthetic brain damage and death in general surgical population.[3] This inability to secure an airway with an endotracheal tube, in some of such cases, coupled with other disadvantages like exaggerated pressor response and trauma to the oral structures and vocal cords, had raised many questions over our overdependence on this device until Dr. Archie Brain in the year 1983 described a new device called the Laryngeal Mask Airway (cLMA). 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. Also, its unpopularity for effective positive pressure ventilation saw it being a second choice to the endotracheal tube.[4,5] With the role of an cLMA, being restricted to the difficult airway algorithms and a few other selective cases, Dr. Archie Brain came up with a new invention, or rather a modification of the cLMA in the year 2001.

This device was called the Proseal-Laryngeal mask airway (PLMA).[6] This double lumen, double cuff PLMA has some clear advantages over its predecessor. The double tube design separated the respiratory and alimentary tracts, providing a safe escape channel for the regurgitated fluids. The double cuff of the PLMA gave a better seal around the glottis, hence establishing its superiority in IPPV.[6,7] These properties increase the suitability of PLMA in a group of patients who are more prone for aspiration.

Correct placement of laryngeal mask airway requires some degree of skill and if cLMA insertion is sub-optimal, it can cause partial or complete airway obstruction. Standard Brain's cLMA insertion technique is somewhat difficult.[8] Problems are usually encountered when getting the tip of cLMA mask to deflect or buckle into back of the mouth and it requires excessive force to place cLMA at proper position which results in multiple insertion attempts, prolonged insertion time, trauma to airway and failure of cLMA insertion.

Various cLMA insertion techniques have been tested with regard to ease of insertion in all age groups, but still none of them have been standardized to replace the Brain's insertion technique.[9,10] However, there was a reduction in complications rate with alternative techniques compared to Brain's technique.[11,12] The reported first attempt success rate is between 67-90% with standard cLMA 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 broadly investigated in adult populations with regard to success rate and ease of cLMA insertion.[13,14] However, the rotational technique was found to be effective because it avoided the anterior pharyngeal structures and slid along the posterior palato-pharyngeal curve without deflecting or buckling the tip of cLMA.[8] The objective of this study was to evaluate and compare the ease of PLMA insertion through the rotational or standard PLMA insertion technique in terms of number of attempts, insertion time, airway morbidity and haemodynamic changes.

AIMS AND OBJECTIVES

Comparison of effectiveness between two insertion techniques i.e. index finger insertion technique (henceforth referred to as standard technique) and 90 degree rotational technique regarding

a) Time of insertion and number of insertion attempts.

b) Gastric insufflation and leak around the cuff.

c) Haemodynamic changes.

d) Airway trauma and post-operative airway morbidity.

REVIEW OF LITERATURE

The birth of PLMA

The cLMA has a clearly established role as an airway device in elective setting when neither the patient nor the procedure requires tracheal intubation. Perhaps more importantly, the cLMA also has been proved extremely useful in managing the difficult airway.[15]

A quest to find out an alternative device for airway management other than endotracheal tube resulted in the invention of laryngeal mask airway by Dr. Archie Brain a British anaesthetist. Dr. Brain developed cLMA in 1981 at the Royal Berkshire Hospital, White Chapel in East End, London and introduced the device to clinical practice in 1988 after a development effort spanning the years from 1981 to 1988.[16]

His invention was based on plaster of paris cast models of hypopharynx. Brain confirmed it on cadavers that the prototype mask was long enough to encircle the laryngeal inlet. His prototype was used on a human patient in 1981 followed by a successful pilot study on 23 patients. Soon careful observations and clinical experience lead to changes in designing. In the first paper on the cLMA, published in the British journal of anaesthesia in 1983, Dr Brain described the device as an alternative to either the endotracheal tube or the face mask with either spontaneous or positive pressure ventilation.[17] It has become very popular in routine medicine practice during past decade.[18,19,20] In 1996 it entered the American Society of Anesthesiologists‘ difficult airway algorithm in five different places, both as a ventilatory device (airway) and a conduit for endotracheal intubation.[19,23,24]

Although the correctly placed cLMA tip lies against the upper esophageal sphincter, the cLMA does not isolate the respiratory tract from the gastrointestinal tract and does not protect the lungs from regurgitated gastric contents. The glottic seal is usually lost at peak airway pressures above 20 cm H_2O.[19]

Aspiration with cLMA is a possibility.[19] In 1983, Brain noted that even if a second tube was placed in the long axis of the mask, with a distal opening at the mask tip and open proximally to the atmosphere, still an effective seal could not be achieved against the larynx unless the distal end of the mask, with its open second tube, was sealed against the upper esophageal sphincter (UES). An effective seal around the larynx indicated an effective seal of the second tube at the UES, as otherwise gases would escape through the second tube. As such leakage was easily detected; this double-tube design seemed desirable because it could indicate poor mask position.

The second tube in the device allows a second sealed junction against the upper esophageal sphincter, giving continuity with the alimentary tract and isolating it from the airway. Theoretically this should give (i) some channeling of regurgitated gastric contents; (ii) in consequence, less need for effective occlusion of the esophageal sphincter by the mask tip in the event of regurgitation; (iii) the opportunity to pass a gastric tube through the drainage tube; and (iv) avoidance of gastric insufflation during positive pressure ventilation.

Brain developed crude prototype of the LMA-Proseal TM (PLMA; IntaventOrthofix, Maidenhead, UK), based on the classic laryngeal mask airway (cLMA) in 1995 and later refined it and released for clinical use by 2000.[6] The

PLMA has established its superiority over cLMA in IPPV. Its properties increase the suitability of PLMA in patients who are more prone for aspiration.

PLMA concept and design

The PLMA is made from medical-grade silicone and is reusable. The inventor‘s aims of the modifications are: 1) avoidance of gastric inflation during controlled ventilation; 2) less need for tight occlusion of the UES by the mask tip in the event of regurgitation, because of the presence of the drainage tube (DT); 3) opportunity to pass an orogastric tube (OGT); 4) channeling of regurgitated stomach contents.[6] Changes were also designed to improve airway seal. The functional separation of the respiratory and gastrointestinal tracts is important in understanding potential advantages of the PLMA over the cLMA and other supra-glottic airway devices (SAD). In this regard one might consider the PLMA to act as an ‘artificial larynx”, rather than simply an airway tube.[25] It may be a better alternative for any elective surgery where cLMA is used with controlled ventilation and also for cardiopulmonary resuscitation.[26,27]

Insertion techniques

The principles of PLMA insertion are similar to the cLMA. Conventionally cLMA is fully deflated and lubricated with water based jelly on its posterior surface and pressed along the palato-pharyngeal curve using the index finger. It is finally pushed further down till resistance is felt. Many a time difficulties are encountered with the classical technique. Various modifications have been evaluated. The semi-flexible double tube is too floppy to push the cuff around the oro-pharyngeal inlet into the laryngo-pharynx but sufficiently stiff to push it into the hypo-pharynx once it has entered the laryngo-pharynx. The lack of a back plate makes the cuff more likely to fold over. The bulkier deflated cuff reduces the space in the mouth for digital manipulation and makes epiglotticdownfolding more likely.

There are three primary insertion techniques for the PLMA: 1) digital insertion, which is similar to the cLMA; 2) introducer-guided insertion, which allows the PLMA to be inserted like the intubating LMA, but the head and neck are in the‘sniffing’ rather than the neutral position; and 3) gum elastic bougie guided insertion, which guides the PLMA around the oropharyngeal inlet and into the hypopharynx.[22,24,26]

Insertion is recommended with head extended and lower neck flexed, and may be performed with or without an introducer. Insertion without an introducer is similar to cLMA insertion The index finger is placed in the retaining strap, this is made easier by lateral compression of the body of the mask to bow the strap outward. The PLMA is pressed against the hard palate and advanced into the hypopharynx until resistance is felt. The finger in the retaining strap is pushed towards the occiput, while the other hand exerts counter-pressure to maintain the ‘sniffing’ position.

Presently a silicone coated, malleable metal introducer is provided with each PLMA. The distal end locates in the retaining strap and the proximal end in the notch between airway tube and DT. The PLMA then resembles the intubating laryngeal mask airway (ILMA) and insertion technique is very similar except ideal head and neck position is ‘sniffing’ for the PLMA insertion, and ‘neutral’ for the ILMA.[29] The bowl is placed into the mouth, guided against the hard palate and advanced in a smooth arc with the handle, until resistance is encountered. The introducer is then removed, taking care to avoid dental damage. After insertion the cuff is inflated. A defined volume of air can be used, but inflation to an intracuff pressure of 60 cm H_2O is preferred as this minimizes pharyngeal mucosal pressure. [6,7]

Correct placement produces a leak-free seal with the mask tip wedged against the UES. If positioned correctly atleast 50% of the bite block usually disappears beyond the upper incisors. Where the entire bite block is visible the device is almost certainly misplaced.[31] Inward force while the PLMA is secured reduces extrusion and misplacement.[32] Several studies have not reported significant differences in insertion success between digital and introducer techniques. Several studies have been done using standard LMA and PLMA in both paralysed and unparalysed anaesthetized patients.[33,34,35]

An alternative technique involves placing a gum elastic bougie (GEB) into the esophagus using a laryngoscope and railroading the PLMA over this. This technique prevents folding of the mask tip and increases correct placement of the PLMA.[36] In 100 paralyzed patients first time insertion success, correct positioning (assessed clinically) and OGT passage were all 100% without evidence of increased complications or airway trauma.[37] In 240 patients with three insertion techniques (a: digital, b: introducer and c: GEB-guided railroading) the railroading technique was most successful.[38] Some authors have reported more than 3,000 GEB-guided insertions without mask folding.[39] GEB guided insertion requires laryngoscopy and intentional GEB insertion into the esophagus. It is therefore unlikely to be the routine first choice technique, but is useful if difficulties are encountered with conventional methods.

Insertion success

Direct comparison studies of 1,436 patients reported first time PLMA insert success of 85% and for the cLMA 93%. Success increases when three attempts are allowed.[6,7,40,34,41,42,43,44,45] PLMA insertion time is longer than the cLMA. PLMA insertion difficulty may be caused by the larger, deeper, softer bowl and the non-linear leading edge formed by the DT. It has been suggested the PLMA requires 20 to 30 insertions before achieving competence.[34]

Most comparisons of cLMA with PLMA involved operators with greater experience with cLMA than PLMA. After training by lecture and manikin, nurses naive to both devices (using digital insertion technique) achieved comparable insertion time and success rates with both devices. Use of a GEB-guided technique, might increase this further.[38]

The PLMA is more difficult to insert at first attempt than the cLMA, [46,47,48,49] as mentioned earlier. Several techniques have been described to improve the insertion success rate. i.e. the use of a gastric tube, fiberoscopy, gum elastic bougie and suction catheter.[50,51,52,53] However, these techniques are only recommended to be used as backup when the digital or introducer tool techniques fail. The main cause of failed insertion is impaction at the back of the mouth,[46] A slight lateral approach has been described if tactile resistance was felt at the back of the mouth.[54]

A rotational technique involving inserting the mask back-to-front like a Guedel airway and then rotating it 180 degrees as it is pushed into the hypopharynx has been used to improve the ease and success of laryngeal mask airway insertion in children and adults. However, this 180-degree rotational technique results in some residual rotation in the coronal plane in adults and did not improve the ease of insertion of PLMAs in children.[10,8,55,56] The 180-degree rotation of the PLMA in the hypopharynx can be difficult because of its large cuff.

A 90-degree rotational technique has been described which is more successful than the standard technique and is associated with less pharyngeal mucosal trauma, as evidenced by a lower incidence of sore throat and mucosal bleeding.[57] It is a simple technique and does not involve the use of additional introducer aids.

Cuff inflation and fixation

The cuff volume required to form an effective seal with the respiratory tract is lower for the PLMA than the cLMA. A properly placed PLMA can withstand peak inflation pressure of approximately 35 cms H_2O without leak as compared to 25 cms H_2O offered by the cLMA.[24,26]

Mucosal injury and sore throat

In a study involving 1,235 patients the reported mucosal injury, recognized by blood on the PLMA after removal, ranged from 3 to 28%: with a mean of 10.2%.[58,59,60,38,43,44,45] The observed incidence of sore throat after 1,586 PLMA uses ranged from 2 to 49%, with mean of 18%.[37,38,61,62] One potential cause of sore throat is pressure exerted on the pharyngeal mucosa by the PLMA.[7]

The relationship between cuff volume, mucosal and airway seal pressures was studied in 32 patients with PLMA and cLMA. Intra-cuff pressures were lower and airway seal pressure higher with the PLMA for any given intracuff volume.[7] The pressure exerted on the mucosa was below that considered critical for mucosal perfusion. Therefore, the PLMA forms a more effective seal without an increase in mucosal pressure. The intubating LMA (ILMA) exerts higher mucosal pressures than thecLMA or PLMA[7,63].Thus, when using recommended intracuffvolumes/pressures, the PLMA is the least likely of the LMA devices to impair mucosal perfusion.[7]

Airway trauma (blood on the device after removal), is higher for PLMA than cLMA in several comparative studies but reached statistical significance in only one study. Blood was detected in 9 to 18% of cases, which is comparable to larger reports with cLMA. Incidence of sore throat in comparative studies is similar to the cLMA or lower ranging from 5 to 23% compared to 5.8% to 34% after cLMA use.[34,43,44,45]

The 90^{o} rotational technique

Jeon YT et al [64]studied the 90 degrees rotation technique for inserting the PLMA in anesthetized paralyzed patients i.e. 120 Asian adult patients. This technique was compared with the index finger insertion technique. 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 primary outcome was success at first insertion. Secondary outcome measures were insertion time and complications. The success rate at first insertion was greater for the rotation technique group than for the standard technique group (100% vs 83%, respectively; $P = 0.003$), and less time was required for insertion (11 ± 3 sec vs 19 ± 16 sec, respectively; $P = 0.03$). The incidence of postoperative sore throat was lower (12% vs33%, respectively; $P = 0.009$), and blood staining on the PLMA was less (8% vs 40%, respectively; $P < 0.001$). The conclusions are the 90 degrees rotation technique for inserting the PLMA is more successful than the standard index finger insertion technique. It is associated with fewer side effects, such as blood on the PLMA and sore throat, which suggests it causes less pharyngeal trauma.

Kim M et al [65] studied the effectiveness of rotational technique with larger size of PLMA (size 4 in female, size 5 in male) in paralyzed, anesthetized patients (total 94 patients undergoing laparoscopy). In rotational technique group, first-attempt insertion success rates were higher (100 vs. 81%, $P = 0.003$) and less time was required for insertion (11 ± 3 vs. 19 ± 15 sec, $P = 0.002$). There was low incidence of postoperative sore throat (11 vs. 34%, $P = 0.007$) and blood stain on PLMA was less (9 vs. 40%, $P <0.001$) for rotational technique. 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 [66] compared two insertion techniques of PLMA in a total of 160 female patients undergoing gynecologic surgery 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 incidence of blood staining (9% vs. 36%, $P < 0.001$) and sore throat (8% vs. 25%, $P = 0.005$) was lower with the rotational technique. The authors opine that the rotational technique is more successful than the standard technique and is associated with less pharyngeal mucosal trauma, as evidenced by a lower incidence of sore throat and mucosal bleeding.

M Yun et al [67] compared two insertion techniques of the PLMA in pediatric patients. A total of 92 pediatric patients (age range 3 to 12 years) undergoing ophthalmologic surgery were randomly allocated to the standard or rotational technique groups. 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 i.e. 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 ($P<0.001$). The incidence of blood staining (8.7% vs 23.9%, $P = 0.048$) was lower with the rotational technique. The conclusion was, the rotational technique is more successful than the standard technique and is associated with less pharyngeal mucosal trauma, as evidenced by a lower incidence of mucosal bleeding.

Dileep Kumar, Mueenullah Khan and Muhammad Ishaq[68] compared the ease of insertion between rotational cLMA insertion and standard insertion technique in terms of number of cLMA insertion attempts, time duration of cLMA 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. The higher incidence of trauma was noted in standard insertion technique (28%) compared to (6%) rotational insertion technique ($p = 0.003$). 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 cLMA insertion technique.

Yun MJ et al[69] used a 90° rotation technique to insert the PLMA in pediatric patients and compared ease of insertion and pharyngeal trauma with the standard technique in 126 patients aged 3 to 9 years. Anesthesia was induced with Thiopental and Rocuronium, and the PLMA used in the study ranged in size from 2 to 3 depending on the patient's body weight. The success rate of insertion at first attempt was higher with the rotation 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 PLMA insertion increased significantly in the control group ($P = 0.01$), but not in the rotation group. The incidence of blood staining was lower in the rotation group than in the control group (10% vs 25%, respectively; $P = 0.03$), but the incidence of sore throat was not significantly different (24% vs 22%, respectively; $P = 0.9$). They have concluded that the 90° rotation technique improves ease of insertion of the PLMA in children, and it decreases the risk of pharyngeal trauma.

Nakayama S, Osaka Y, Yamashita M[8] compared the ease of insertion of the laryngeal mask airway (cLMA) with a partially inflated cuff using the standard 'nonrotational' technique versus the rotational technique in 145 children. The success rate of insertion at the first attempt was higher in the rotational technique group (99% versus 79%, $P < 0.05$). However they did not find difference in insertion time. They opine that 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.[70] compared fiber-optic assessment of cLMA position in 78 children of age range 2.5 months to 10 years, undergoing elective cataract surgery using two cLMA insertion techniques, i.e., standard and rotational, a crossover study. Incidence of fiber-optic grades 1 and 2 was 61.5% with standard technique and increased to 92.3% with rotational technique ($P < 0.001$,) (RR

3.0, 95% CI 2.2-4.2). Median Inter Quartile Range fiber-optic grading was significantly better with rotational technique as compared to standard technique ($P < 0.001$,). First-attempt success rate was significantly higher (96.2%) with rotational technique (80.7%) ($P = 0.04$,). Overall success rate (i.e., successful insertion with two attempts) was 100% with rotational technique compared with 89.7% with standard technique ($P = 0.003$,). Time for successful insertion and incidence of complications were significantly lesser with rotational technique. Rotational technique of cLMA insertion in children is associated with better seating of cLMA (as observed on fiber-optic assessment) compared with the standard technique. Also, it is associated with higher success rate and lower incidence of complications.

OUR STUDY HYPOTHESIS

We presumed that the insertion of PLMA with 90-degree rotational technique which is simple technique and does not involve use of introducer or aids or finger insertion would reduce the contact surface resulting in lesser friction between the PLMA and the pharyngeal wall and make it easy to advance the PLMA over the smooth angle against the posterior pharyngeal wall.

Our hypothesis is that the success rate with 90 degree rotational technique is higher and airway morbidity is lower as compared to the standard insertion technique. We planned the study to compare the success rate and incidence of complications of the standard technique with the rotational technique.

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 submandibular salivary glands(Fig. 1).

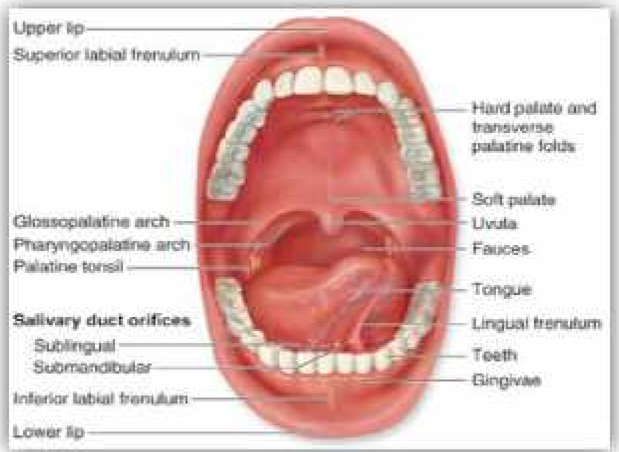


Fig. 1

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 levatorpalati, the palatoglossus, the palatopharyngeus and the musculus uvulae.

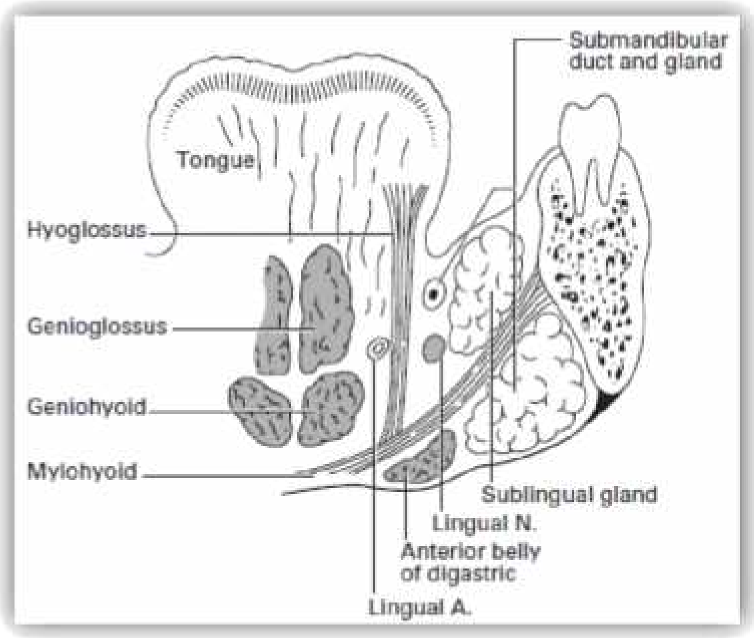


Fig. 2

The tensor palati (tensor velipalatini) 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 levatorpalati (levatorvelipalatini) 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 musculusuvulae 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 vagusThe 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

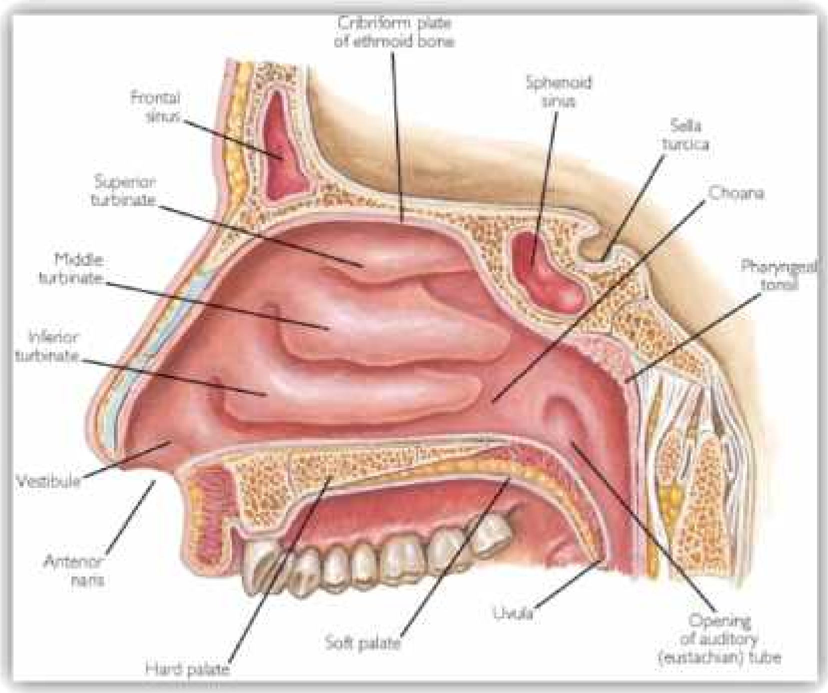


Fig. 3

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 process. The 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.

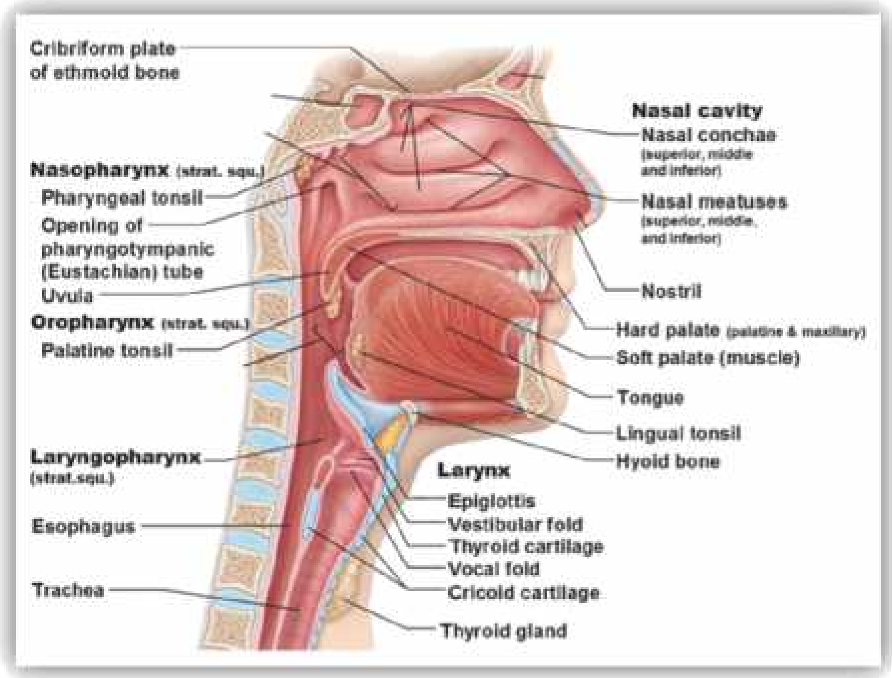

Cribriform plate
of ethmoid bone
Nasal cavity
Nasal conchae
(superior, middle
and inferior)
Nasopharynx (strat. squ.)
Pharyngeal tonsil
Opening of
pharyngotympanic
(Eustachian) tube
Nasal meatuses
(superior, middle,
and inferior)
Uvula
Nostril
Oropharynx (strat. squ.)
Hard palate (palatine & maxillary)
Palatine tonsil
Soft palate (muscle)
Tongue
Lingual tonsil
Laryngopharynx
(strat.squ.)
Hyoid bone
Larynx
Epiglottis
Vestibular fold
Esophagus
Thyroid cartilage
Vocal fold
Trachea
Cricoid cartilage
Thyroid gland

Fig. 4

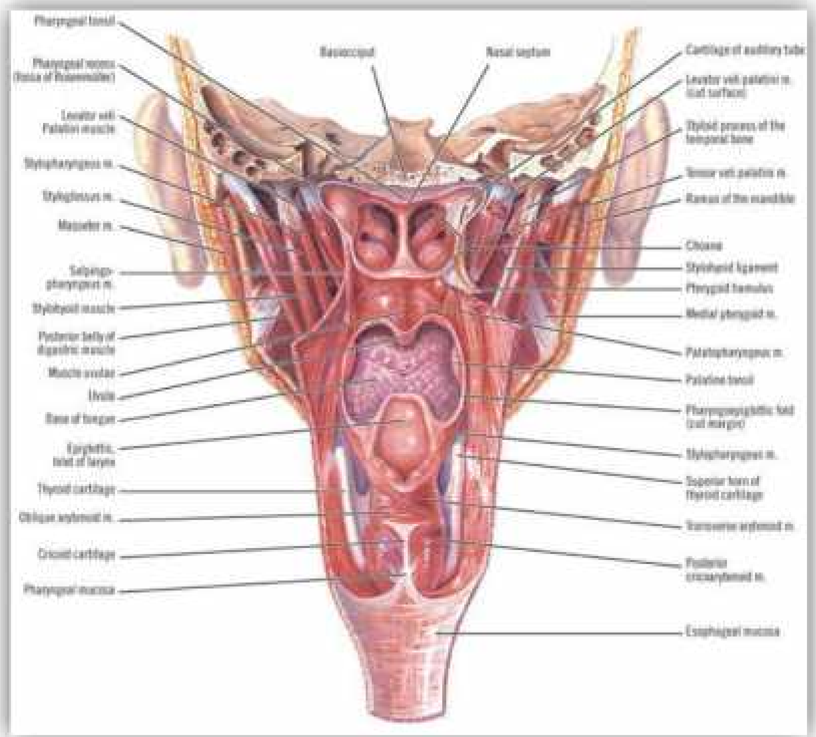

Pharyngeal tonsil
Basiocciput
Nasal septum
Stylopharyngeus m.
Styloglossus m.
Masseter m.
Uvula
Base of tongue
Thyroid cartilage
Cricoid cartilage
Pharyngeal mucosa
Ramus of the mandible
Choana
Medial pterygoid m.
Palatine tonsil
Esophageal mucosa

Fig. 5

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.

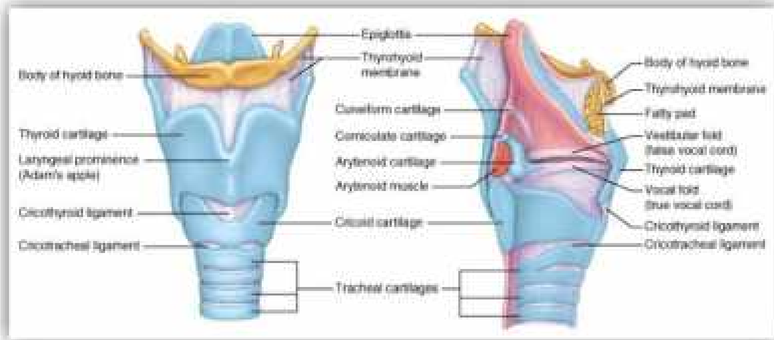


Fig. 6

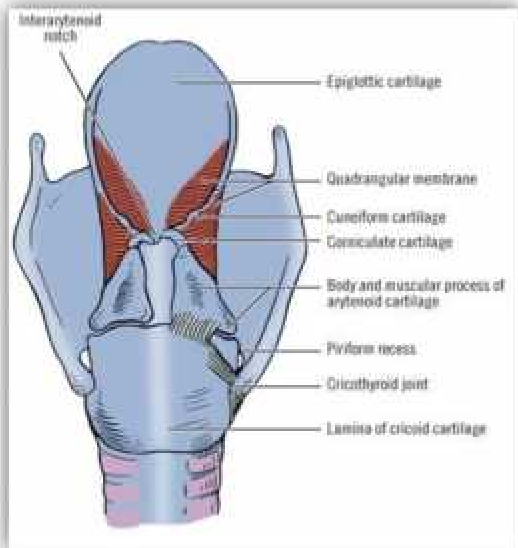


Fig. 7

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.

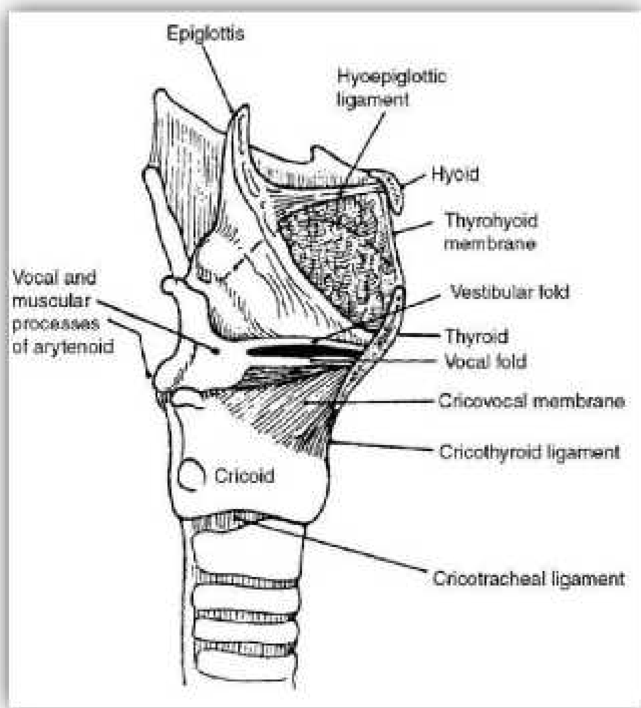


Fig. 8

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 thelarynx 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.

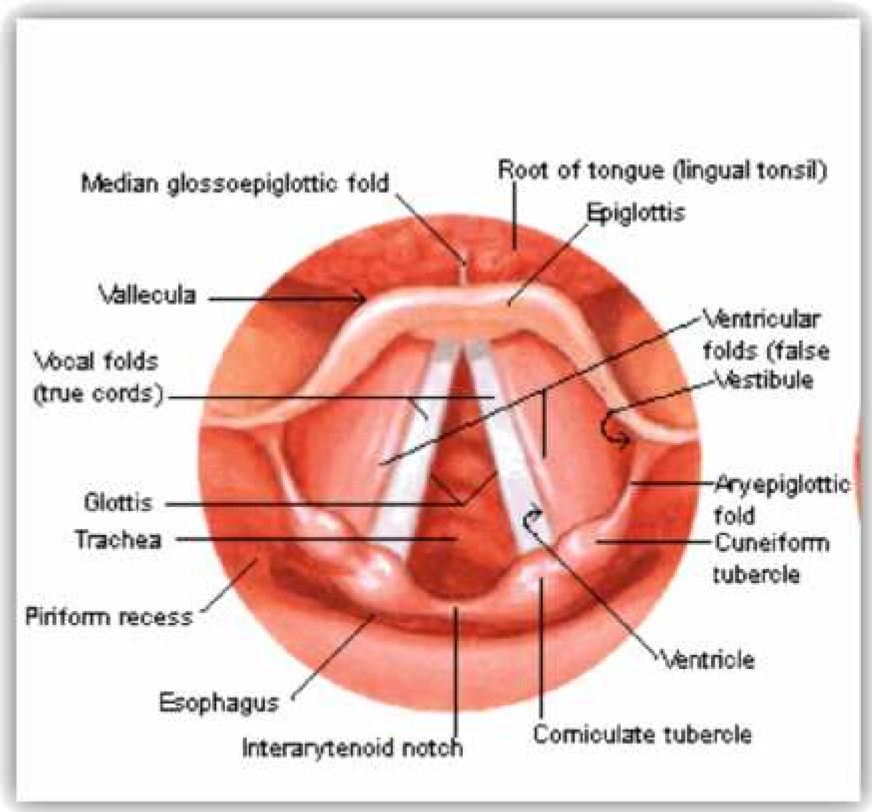


Fig. 9

E. Cuneiform and Corniculate Cartilages

The epiglottis is connected to the arytenoid cartilages by the laterally placed aryepiglottic ligaments and folds (Fig. 7 and 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 and 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 ‘conuselasticus’, 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 rimaglottidis, 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

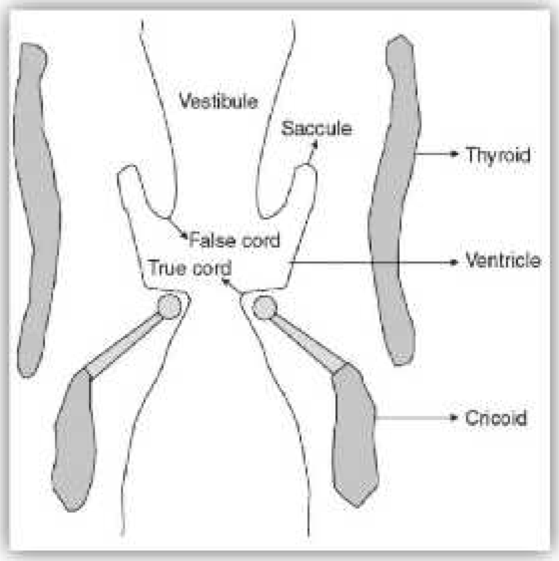

Vestibule
Saccule
Thyroid
False cord
True cord
Ventricle
Cricoid

Fig. 11

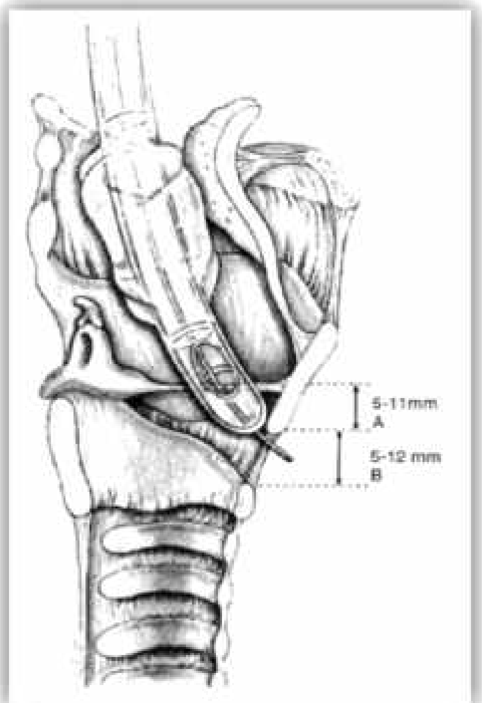

5-11mm
A
5-12 mm
B

Fig. 12

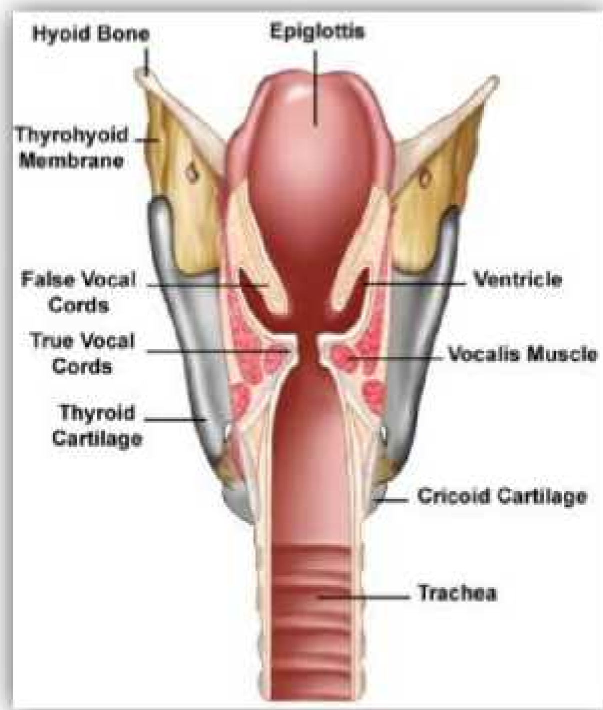


Fig. 13

The epithelium of the vestibular folds is the ciliated-pseudostratified variety (respiratory), whereas the epithelium of the vocal folds is the non keratinized 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 and Fig. 13).

Table . 1Extrinsic muscles of larynx

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

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. 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.

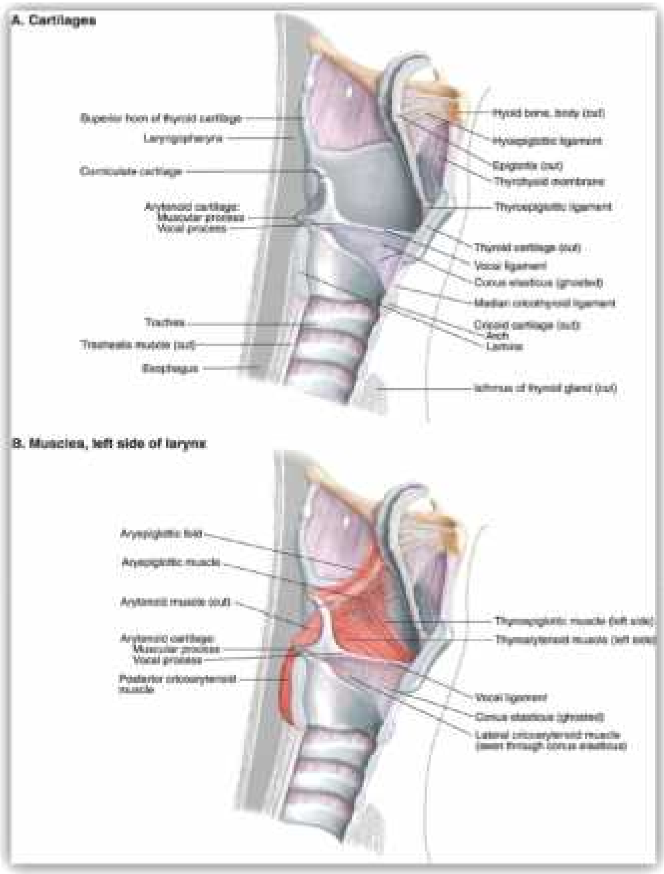


Fig. 14

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

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

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 ligamentumarteriosum, 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

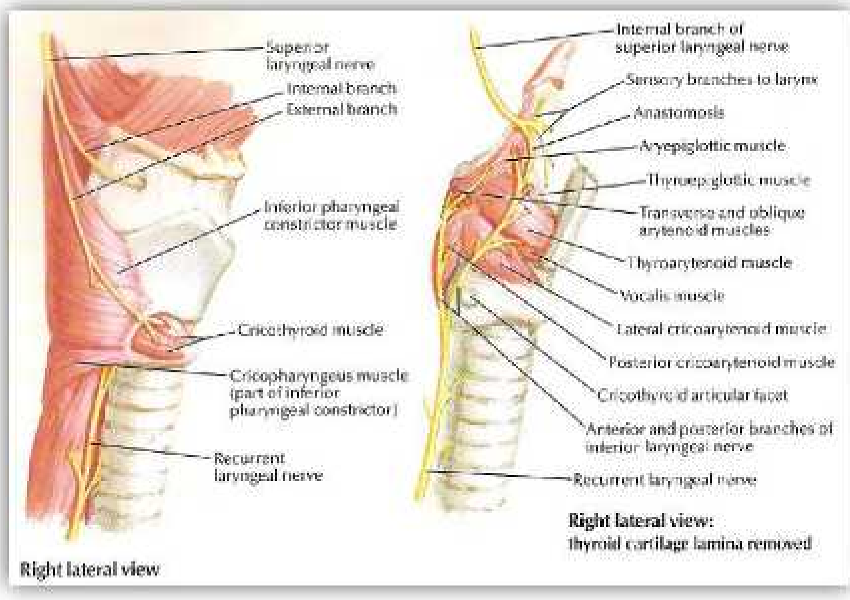


Fig. 15

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.

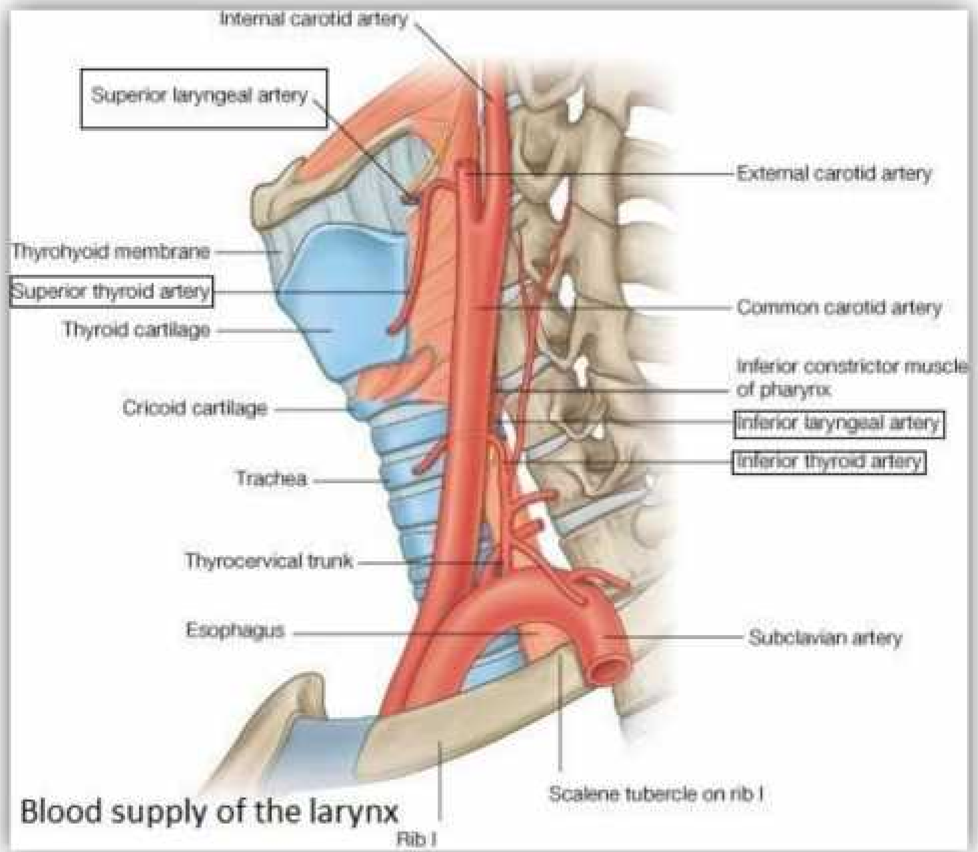


Fig. 16

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[29]

Device description

The cLMA is an innovative supraglottic airway management device. Since its commercial introduction in 1988, the cLMA has been used in over 200 million patients for routine and emergency procedures.

The PLMA is an advanced form of LMA that may be used for the same indications as the LMA Classic. The PLMA is designed to provide additional benefits over the cLMA that extends the range of procedures for which an LMA is indicated. While the cLMA may be used with low-pressure positive pressure ventilation (PPV), the PLMA has been specifically designed for use with PPV with and without muscle relaxants at higher airway pressures.

The PLMA 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 PLMA 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 PLMA 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 (PLMA 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 PLMA size 1 does not have the bite block (Fig 16). The PLMA 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 PLMA be used a maximum of 40 times before being discarded. In addition to the well known characteristics of the cLMA, the PLMA offers the following features.

- A softer cuff material, deeper mask bowl and special cuff shape allows a higher seal than the cLMA for a given intracuff pressure with the adult sizes.
- A revised cuff arrangement, which allows a higher seal than the cLMA, 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 insufflations.
- 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 PLMA size 1) which reduces the danger of airway obstruction or tube damage.
- A location strap for the PLMA 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.

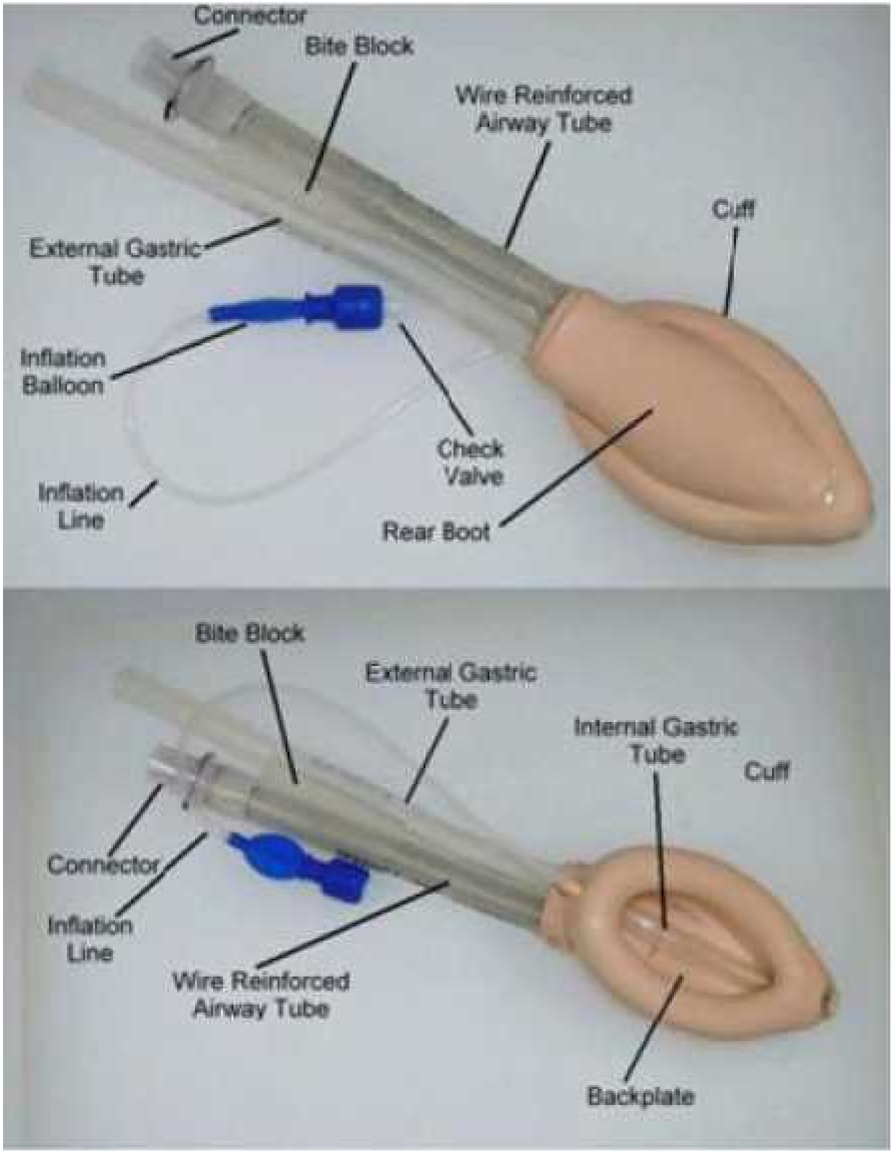


Fig. 16

Fig. 17

The PLMA 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 .

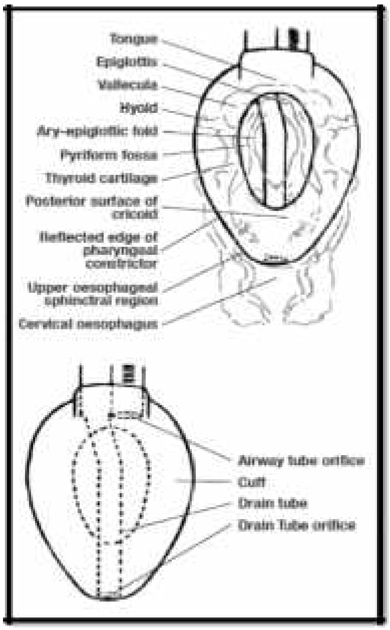


Fig. 18

Indications for use

The PLMA 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 PLMA 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 PLMA 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, PLMA should be used only when tracheal intubation is not possible.

Contraindications

Due to the potential risk of regurgitation and aspiration, do not use the PLMA 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 PLMA 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 H_2O with PLMA.
- 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 PLMA.

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 anairway.

Adverse events:

- The incidence of intraoperative complications and postoperative sore throat are similar between cLMA & PLMA.
- Aspiration of gastric contents - less likely with the PLMA, although aspiration may result if the tube is not correctly placed.
- Gastric distention - incidence increases with increasing airway pressure and tidal volume but is unlikely to occur at airway pressures of less than 20 cm H_2O (30 cm H_2O for the PLMA) if the PLMA is properly positioned.
- Trauma - injuries to the epiglottis, posterior pharyngeal wall, uvula, soft palate, tongue and tonsils, hematoma above the vocal cords in a patient with a bleeding diathesis, arytenoid and temporomandibular joint dislocation, tongue cyanosis, and complete disruption of a cleft soft palate repair.
- Sore throat – incidence following PLMA use is between 0% & 70%.
- Blood on the laryngeal mask occurs less often if the laryngeal mask is removed deflated, dysphagia is seen more frequently after PLMA use.
- Nerve injury - palsies of the hypoglossal, recurrent laryngeal and lingual nerves
- Bronchospasm
- Others - transient salivary glands and tongue swelling and sialadenopathy.

Performance Tests

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.

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 PLMA, 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.

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. This shape facilitates atraumatic insertion and correct positioning in the patient. It reduces the risk of entry of the distal end into the vallecullae or glottis and avoids it becoming caught against the epiglottis or the arytenoids. The correct cuff shape can be accomplished through use of the PLMA Cuff- Deflator (Fig. 19 and 20), available from the distributor. Prior to deflating the PLMA and during clinical use, make sure the red plug is closed.

Directions for use of the PLMA Cuff- Deflator

- Squeeze the handles of the PLMA Cuff- Deflator to open the jaws.
- Insert the PLMA, 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 PLMA 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 PLMA Cuff-Deflator handles again to release the PLMA.
- 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 PLMA 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

Fig. 19

Fig. 20

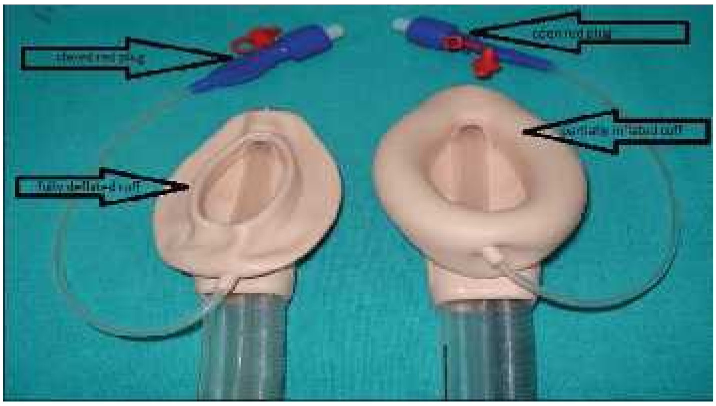


Fig. 21

Insertion

Before insertion it is important to note the following points:

- Check that the size of the device is appropriate for the patient. The ranges are approximate and clinical judgment should be used in selecting anappropriate 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 PLMA ready and prepared for immediate use. Where possible, an alternative size of PLMA 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 PLMA Introducer, it may be possible to reduce or eliminate head and neck manipulation.

Induction Method

The following induction methods are compatible with the insertion of the PLMA :

- 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.

Insertion Method

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

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

All three techniques follow the same principles. To position the PLMA 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.

Index Finger Insertion Technique (Fig. 22)

Hold the PLMA like a pen, with the index finger pushed into the Introducer strap. 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 PLMA from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point the PLMA should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.

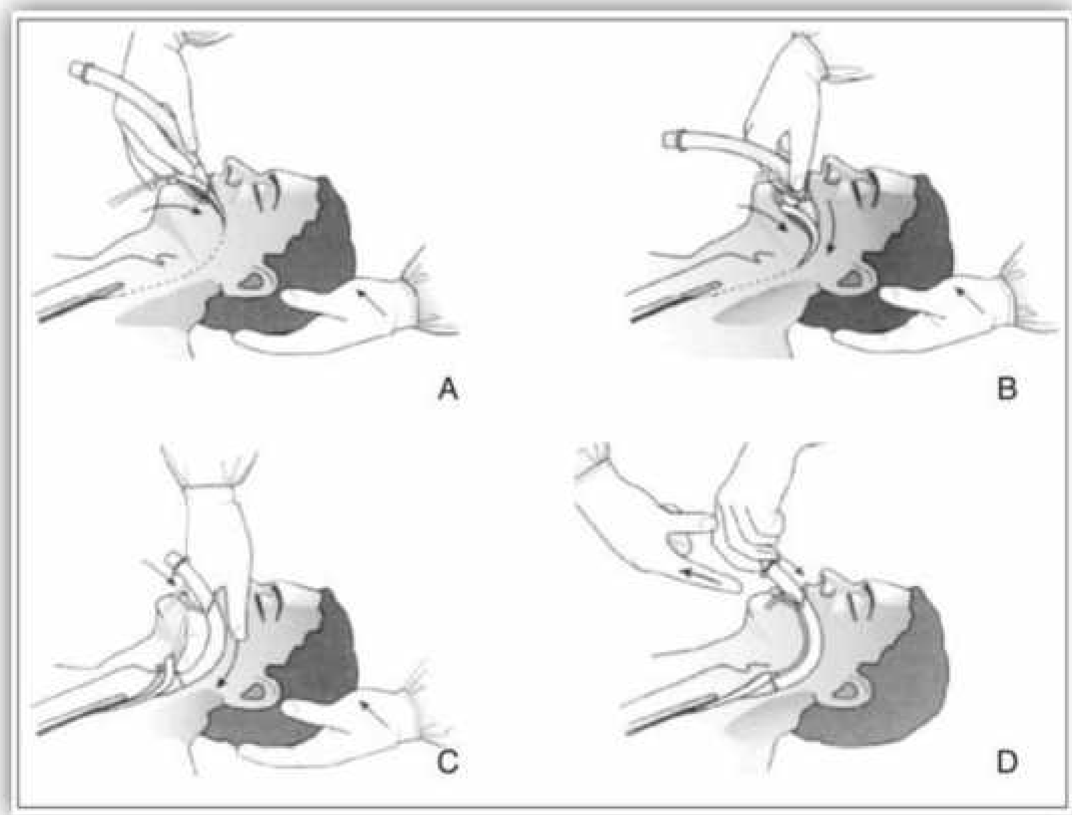

A
B
C
D

Fig. 22

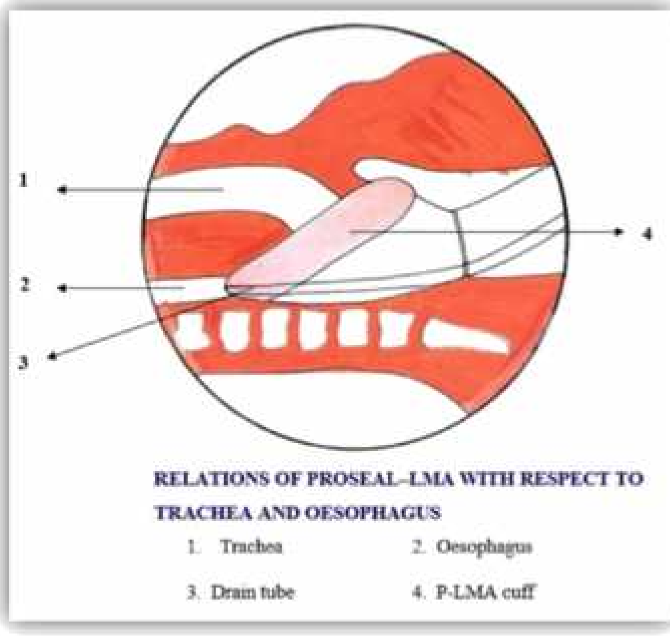

1
2
3
4
RELATIONS OF PROSEAL-LMA WITH RESPECT TO TRACHEA AND OESOPHAGUS
1. Trachea
2. Oesophagus
3. Drain tube
4. P-LMA cuff

Fig. 23

Rotational insertion technique of PLMA[64](Fig. 24a to 24e)

- Holding the midportion of the airway tube of the PLMA, the entire cuff is placed into the patient's mouth via the midline approach without finger insertion.
- The airway tube is rotated 90^{o} counter-clockwise from outside the mouth so that the cuff is turned around the tongue to come to rest to the right side of the tongue.
- The PLMA is then advanced into the hypopharynx until resistance is felt.
- During advancement, the PLMA is rotated back to the midline.
- Confirmation of correct placement and device Inflation.

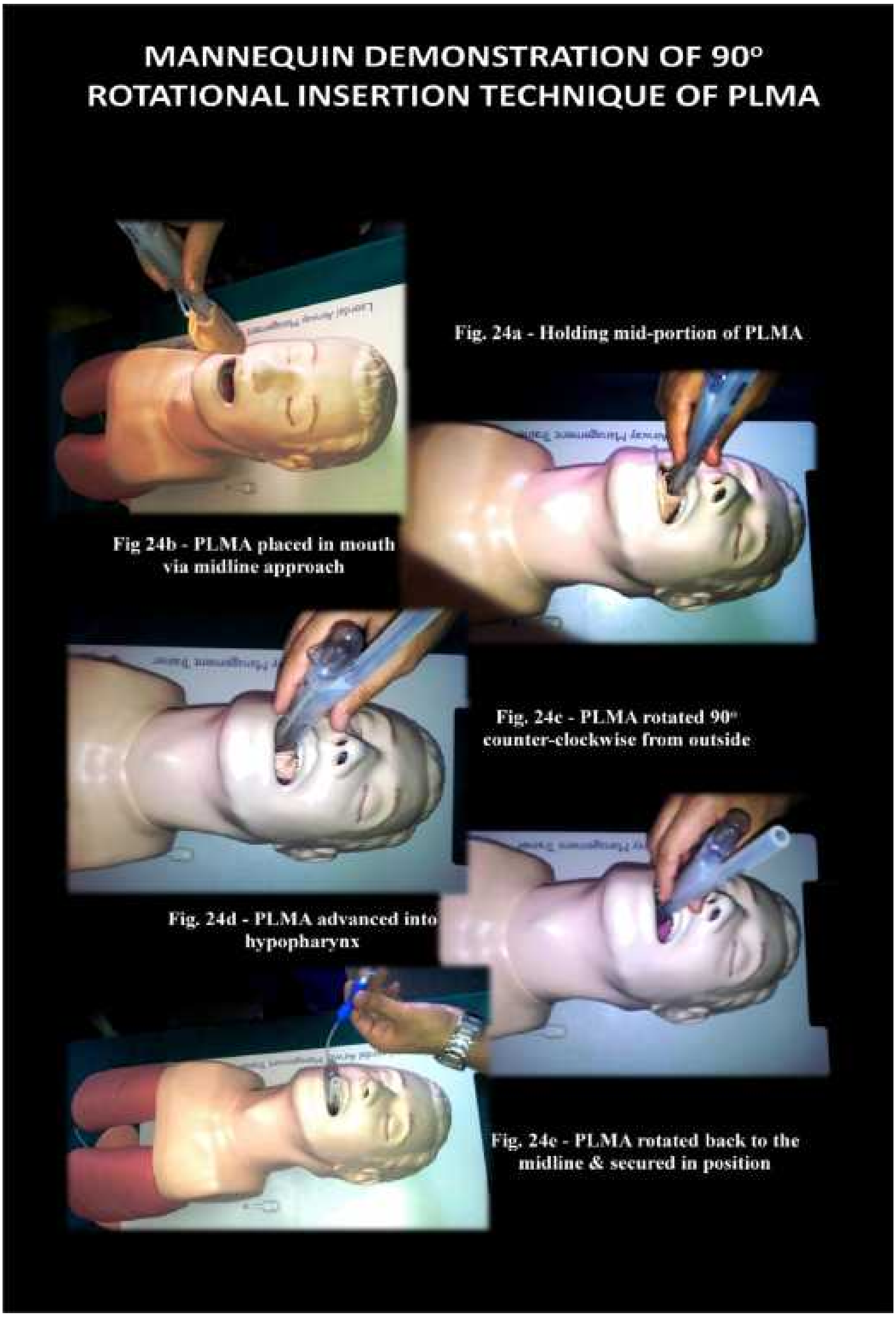

MANNEQUIN DEMONSTRATION OF 90°
ROTATIONAL INSERTION TECHNIQUE OF PLMA
Fig. 24a - Holding mid-portion of PLMA
Fig 24b - PLMA placed in mouth via midline approach
Fig. 24c - PLMA rotated 90° counter-clockwise from outside
Fig. 24d - PLMA advanced into hypopharynx
Fig. 24e - PLMA rotated back to the midline & secured in position

Fig. 24

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 H_2O 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 H_2O intracuff pressure.

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.

Diagnosis of correct or incorrect mask

When inserting and inflating the PLMA, 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. 25a) 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.25c). 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.25d). 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.25b). 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.

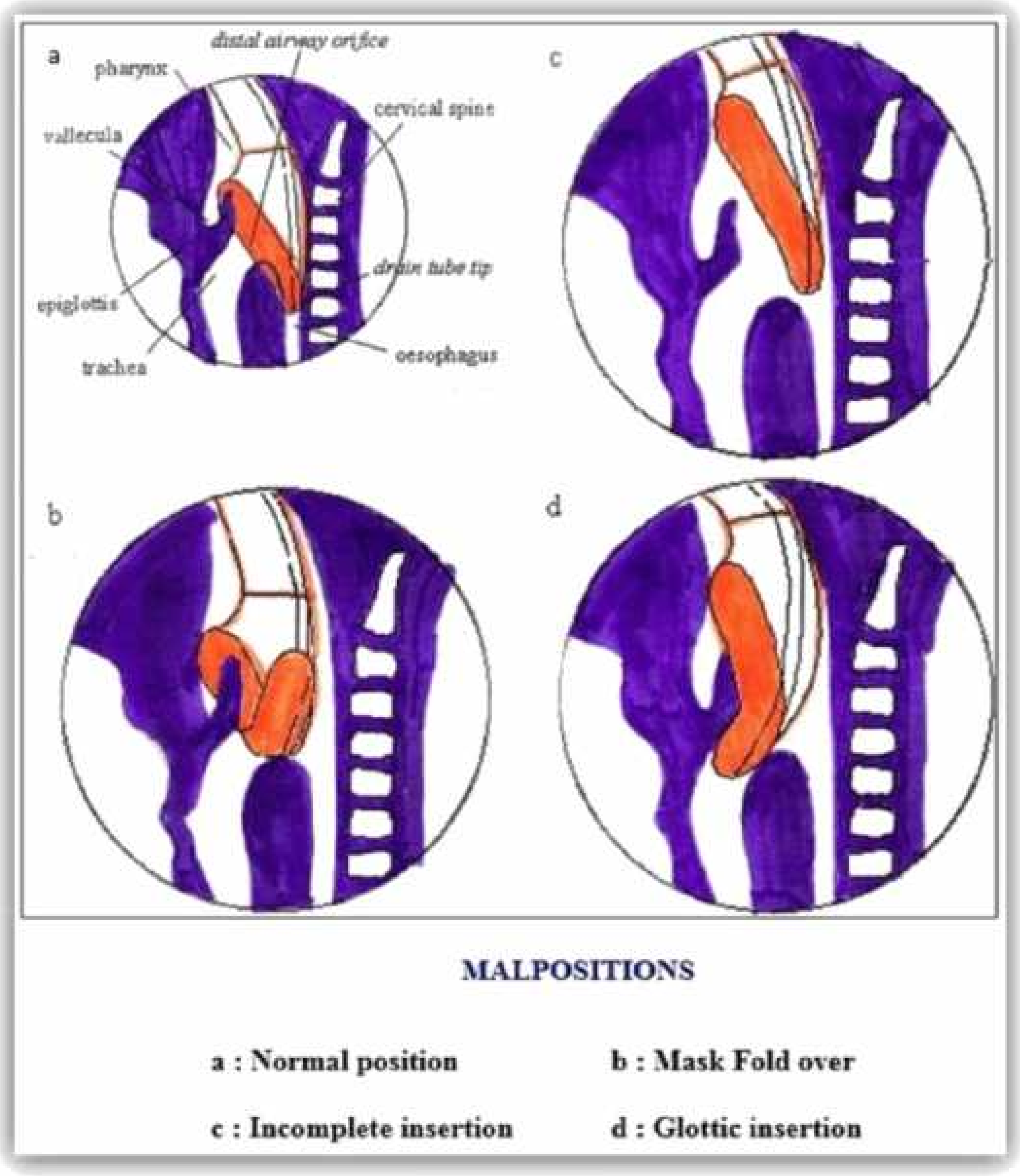

a
distal airway orifice
pharynx
vallecula
cervical spine
epiglottis
drain tube tip
trachea
oesophagus
c
b
d
MALPOSITIONS
a : Normal position
b : Mask Fold over
c : Incomplete insertion
d : Glottic insertion

Fig. 25

Device Fixation

All sizes of PLMA has a built-in bite-block except PLMA 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 PLMA 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.

Anaesthesia maintenance and recovery

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

Spontaneous ventilation

The PLMA 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

Positive Pressure Ventilation (PPV)

Although it may be used in spontaneously breathing patients, the PLMA 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 PLMA result in a gentler but also more effective seal against the laryngeal inlet when compared to the cLMA.

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

- The drain tube may also act as a relief conduit to prevent gastric insufflation during PPV. However, tidal volumes should not exceed 8ml/kg and peak inspiratory pressures should be kept within the maximum airway seal pressurewhich will be found to vary between individual patients, but is on average up to 30 cm H_2O with the PLMA which is 10 cm H_2O higher than the cLMA.
- 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.

Use of drain tube (Fig. 26)

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 PLMA, 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 PLMA drain tube.

Fig. 26

Steps to facilitate correct mask position

- After insertion, inflate the cuff to no more than 60 cm H_2O 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.

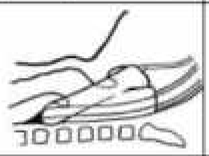
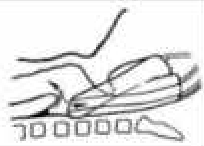
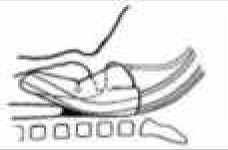
	√ Correct placement	× Incorrect placement	× Incorrect placement	× Incorrect placement
				
Mask position	Tip behind arytenoid and cricoid cartilages	Tip too high in pharynx	Tip in laryngeal vestibule	Tip folded backwards
Gas leak from drain tube	No	Yes	Yes	No
Bite block	Approximately midway between teeth	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	Difficulty passing OG tube indicates occluded drain tube

Table 3

Specifications

Patient selection

The patient selection information in the accompanying table is for guidance purposes only. Research regarding the cLMA 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.

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

Table 4

This typically corresponds to an intra-cuff pressure of 60cm H_2O. 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.

MATERIALS AND METHODS

Source of Data (Sample)

The randomized study was conducted for a period of 1 year, at BLDEU's Shri.B.M.Patil Medical College Hospital and Research center, Vijayapur on patients undergoing short elective surgical procedures requiring general anaesthesia.

The study has been conducted after obtaining clearance from ethical committee of the institution. Informed consent was taken from all the patients who participated within the study.

Design of the study

Randomized clinical trial.

Inclusion Criteria

1. The subjects are adult surgical candidates aged 18-60 years, ASA I or II,Mallampati I or II, presenting for short elective surgery who required general anesthesia in whom tracheal intubation was not necessary.
2. Both male and female patients.

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-esophageal reflux, or full stomach)
5. Pregnant women
6. BMI >30

Pre-anaesthetic evaluation

Patients included in the study underwent thorough pre-operative evaluation which included the following:

History

History of underlying medical illnesses, previous history of surgery and anaesthesia, hospitalization was noted.

Physical examination

- General condition of the patient.
- Vital signs – heart rate, blood pressure, respiratory rate, height and weight.
- Examination of cardiovascular system, respiratory system, central nervous system and the vertebral column.
- Airway assessment - Mallampati grading and rule of 1- 2- 3.

Investigations

Complete blood count, urine routine, blood sugar level if indicated, ECG if indicated, chest X- ray if indicated were done.

Patients who satisfied the inclusion criteria were explained about the nature of the study and the anaesthetic procedure. The study was conducted at operation theatre of BLDEU'sShri B. M. Patil medical college, Vijayapur. Informed consent was taken from the patients regarding the procedure.

Premedication

All patients received tablet diazepam 10mg orally night before the surgery for anxiolysis.

Method of collection of Data

120 adult patients of each gender, randomly divided into two groups of 60 each (by computer generated random numbers) were included in the study:

Group S - Standard index finger insertion technique

Group R - Rotational insertion technique

Following departmental research committee and institutional ethical board approval, written informed consent was obtained from 120 adult patients aged above 18 years, ASA I and II, scheduled for elective short surgical procedures requiring general anaesthesia. In the operation theatre intravenous line was established with 20G cannula. Standard anaesthesia monitors included non invasive blood pressure, pulse oximeter, electrocardiogram and end-tidal carbon dioxide ($EtCO_2$). Baseline blood pressure, heart rate and peripheral O_2 saturation were recorded. Anaesthesia protocol was standardized. Patients of both groups were premedicated with metoclopramide 10mg, ranitidine 50mg intravenously 15 min before surgery. 3 sprays of 10% lignocaine were given to the posterior oro-pharynx. Midazolam 0.02mg/kg, fentanyl 1mcg/kg were administered intravenously. Following pre-oxygenation for 2 minutes anaesthesia was 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 occurred during insertion of device, propofol 1mg/kg was added to achieve an adequate level of anaesthesia. For the safety concerns before the insertion of any of the devices after loss of verbal contact, we checked that hand-ventilation with a face mask was possible. Once the patient became apnoeic and adequate depth of anaesthesia was achieved on the basis of clinical judgment, (i.e. jaw relaxation), the deflated PLMA size three in females and size four in males was inserted. The patients were assigned to their groups with a computer generated randomization list (www.randomizer.org) into standard and rotational insertion techniques. . After randomization was determined by using random number generator, the assignments were concealed in opaque envelopes until immediately before induction.

In standard technique (Group-S), PLMA was placed using the Brain's insertion technique. The patient's head was positioned with head extended at the atlanto-axial joint and flexed at the neck with non-dominant hand. The PLMA was held like a pen and index finger placed at the junction of PLMA tube and cuff. Index finger was used to press the PLMA against hard palate and posterior pharyngeal wall until definite resistance was felt at the base of the hypopharynx. PLMA was then held with nondominant hand and index finger was removed.

In the rotation technique (Group-R) 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.

Following PLMA insertion in both techniques, PLMA was inflated with 20 ml of air in size 3 and 30 ml in size 4 PLMA and seal was obtained. Successful placement was checked by chest expansion, reservoir bag movement and appearance of capnographic tracing. The end point of each insertion was taken when there was bilateral chest movement, a square wave on a capnograph and SpO_2> 95%. The surgeon was requested not to clean, drape or position the patient until five minutes elapsed after placement of the supraglottic device so as to avoid any stimuli likely to interfere with the findings. Anaesthesia was maintained with sevoflurane, oxygen plus nitrous oxide. Patients were intraoperatively monitored for heart rate, noninvasive blood pressure and SpO_2.At the end of surgery the PLMA was removed in deep plane of anaesthesia. All study variables as listed below were recorded by the anesthesiology colleague who was neither involved in study nor aware of the nature of study.

Study Parameters

Attempts of insertion – Number of attempts taken to insert PLMA

Insertion time[77] (sec) - The time interval between holding the airway device up toconfirmation of correct placement by bilateral air entry on chest auscultation. The end point of each insertion was taken when there was bilateral chest movement, a square wave on a capnograph and SpO_2> 95%[77].

Oropharyngeal leak[13] (grade) - signifies malposition of the device. It is detectedby giving 20 CmH_2O pressure and divided into :-

Grade 1: no leak

Grade 2: palpable leak

Grade 3: just audible leak with appropriate ventilation

Grade 4: audible leak with inappropriate ventilation

Grade 5: complete obstruction with no ventilation.

Hemodynamic changes like heart rate (HR), systolic blood pressure (SBP),diastolic blood pressure (DBP), mean arterial pressure (MAP) and peripheral oxygen saturation (SpO_2) at following time points : before insertion, just after insertion, 2 minutes and 5 minutes after insertion.

Complications :

- Incidence of intraoperative gastric insufflations
- Incidence of blood staining of device at removal
- Incidence of post-operative sore throat

Statistics

Sample Size: Total of 120 patients to detect 17% difference in the success rate at firstinsertion attempt(based on literature review[64]) between the two groups for an α value of 0.05 and power of 80% were included and randomly divided into 2 groups.

Randomization: Patients were allocated to the two insertion techniques randomly bycomputer generated random numbers.

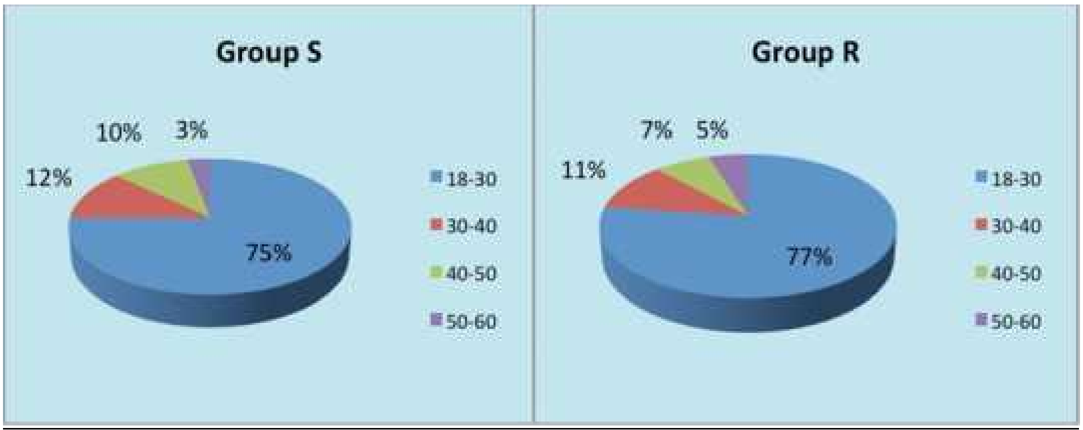
Data was analyzed using Student t test for independent parametric data, General Linear Model for repeated measure parametric data, Chi –square test or Fisher‘s exact test – for non - parametric data.

OBSERVATION AND RESULTS

Table 5

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%)
Mean ±S.D	28.88 ± 10.05	28.75 ± 9.16
p value– 0.94		



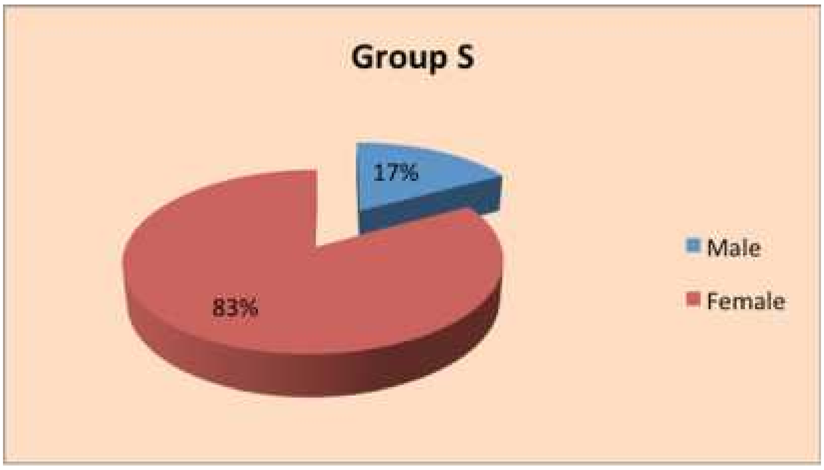
Graph 1 : Group S Graph 2 : Group R

Age distribution was comparable between the two groups (p value:0.94) Statistical test : Unpaired t test with statistical software Graph Pad In Stat 3.06.

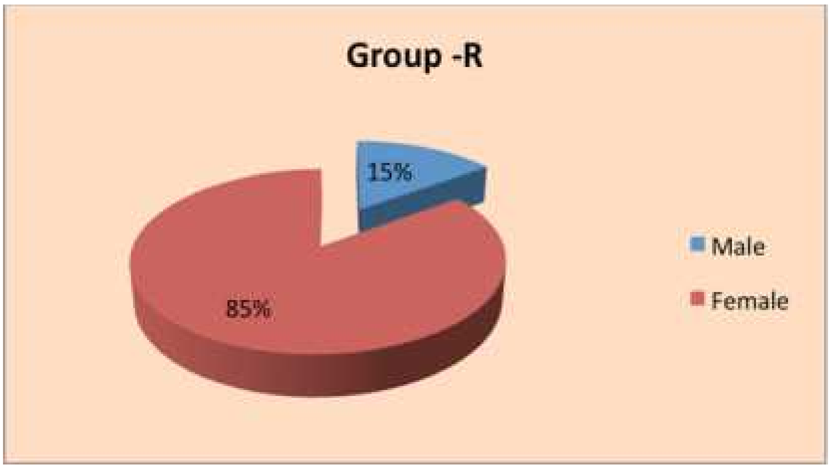
Table 6

GENDER DISTRIBUTION

Group	Male	Female
S	10 (17%)	50 (83%)
R	9 (15%)	51 (85%)
p value- 1		



Graph 3



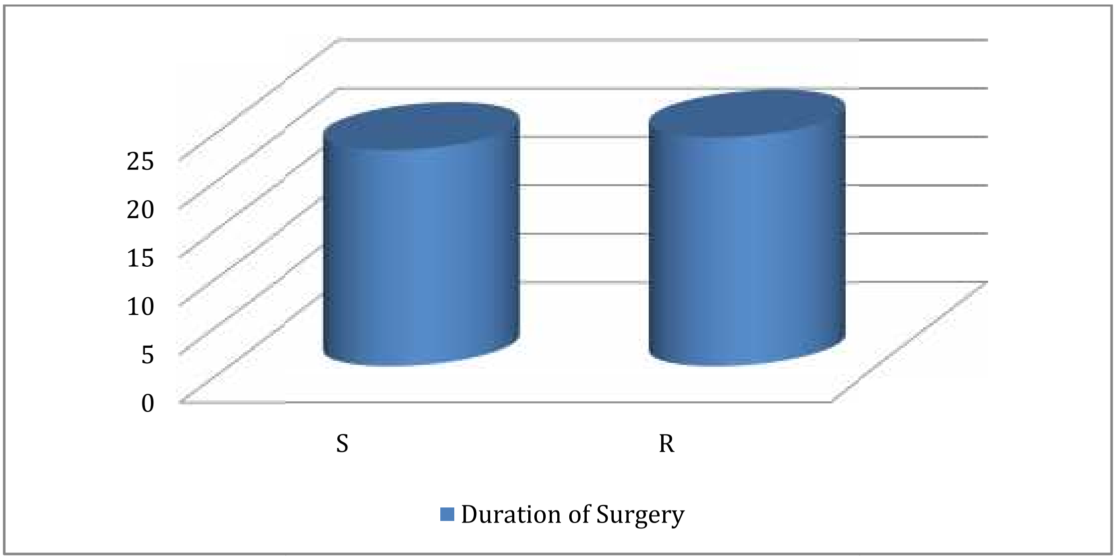
Graph 4

The gender distribution was comparable between two groups (p value: 1) Statistical test – Fisher‘s exact test with statistical software Graph Pad In Stat 3.06

Table 7

DURATION OF SURGERY

Group	Duration of Surgery Mean(min)±S.D
S	22.3 ± 5.9
R	23.6 ± 6.4
p value– 0.12	



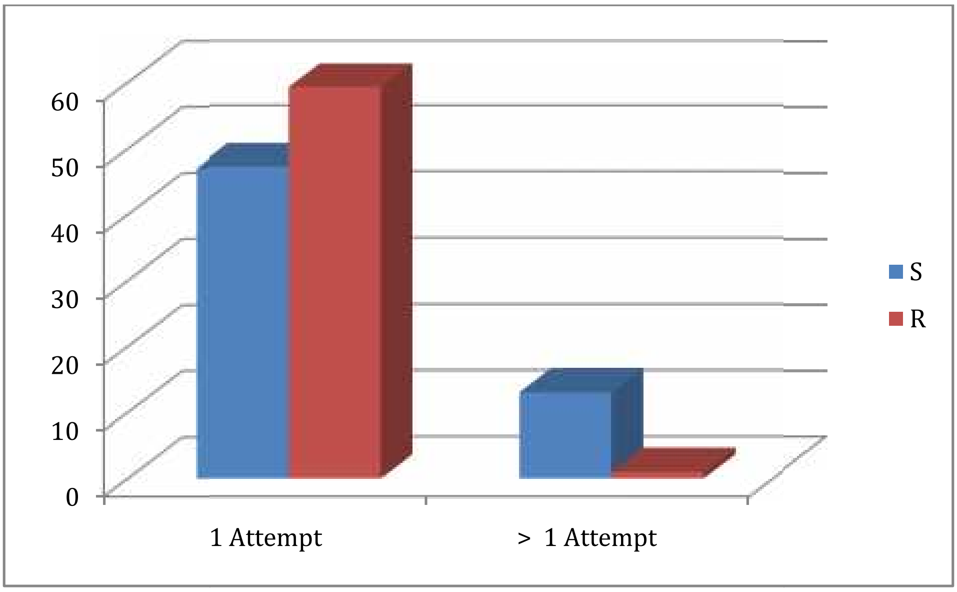
Graph 5

The duration of surgery distribution was comparable between two groups (p value: 0.12) Statistical test – Unpaired t test with statistical software Graph Pad In Stat 3.06.

Table - 8

ATTEMPTS OF INSERTION

Group	1 Attempt	> 1 Attempt
S	47 (78%)	13 (22%)
R	59 (98%)	1 (2%)
p value– 0.001		



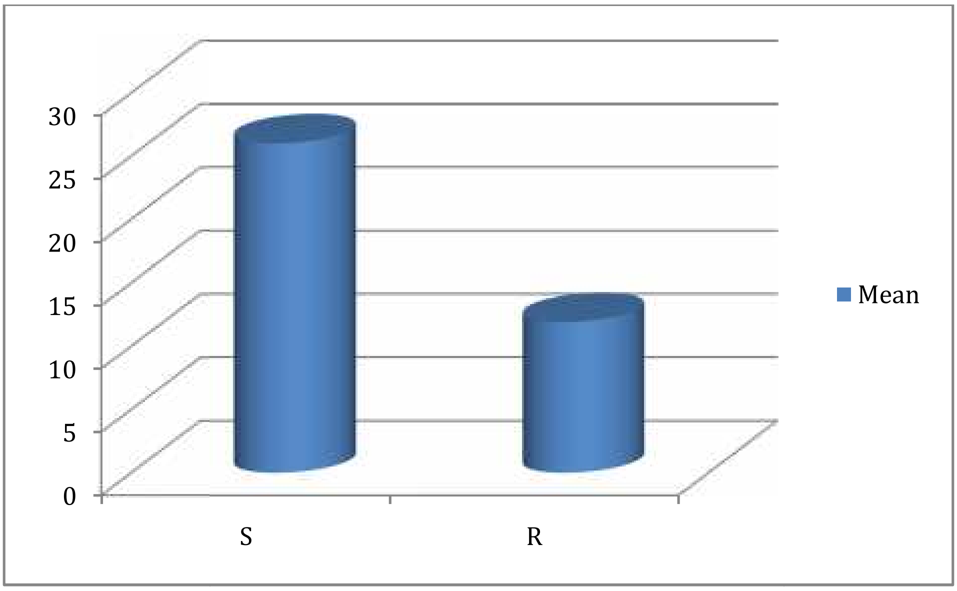
Graph 6

The rotation group exhibited 98% success at first insertion versus 78% in standard technique with a significant statistical difference between the two groups (p value: 0.001) Statistical test – Fisher‘s exact test with statistical software Graph Pad In Stat 3.06.

Table 9

INSERTION TIME

Group	Mean (Secs) ± S. D.	95% confidence interval for difference
S	25.98 ± 10.92	11.157 to 17.043
R	11.88 ± 3.62	
p value < 0.0001		



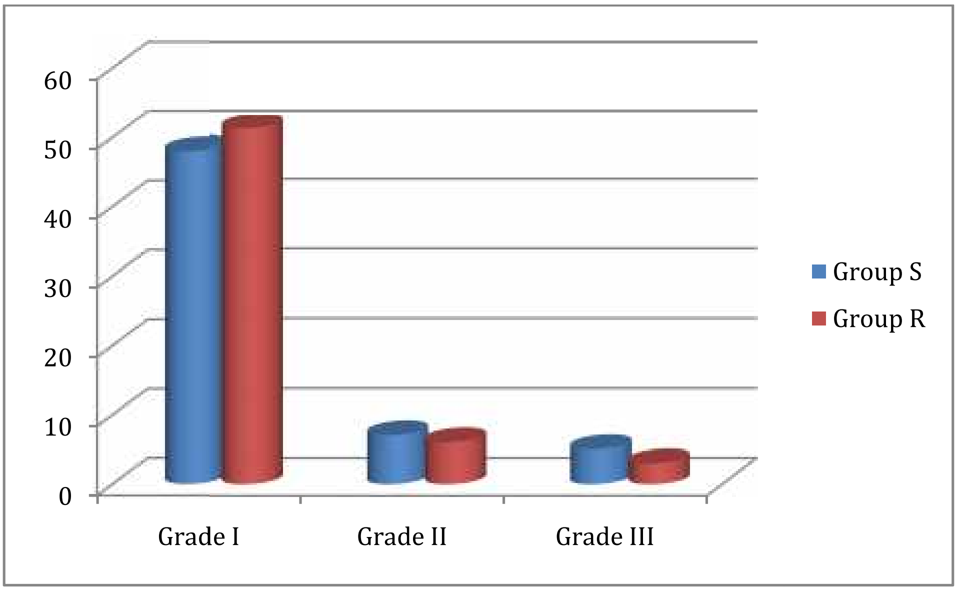
Graph 7

The insertion time was significantly less with rotational technique as compared to the standard technique (11.88 sec vs 25.98 sec) (p value: < 0.0001) Statistical test – Unpaired t test with statistical software Graph Pad In Stat 3.06.

Table 10

OROPHARYNGEAL LEAK

	Grade I	Grade II	Grade III
Group S	48 (80%)	7 (11.67%)	5 (8.33%)
Group R	51 (85%)	6 (10%)	3 (5%)
p value– 0.716			



Graph 8

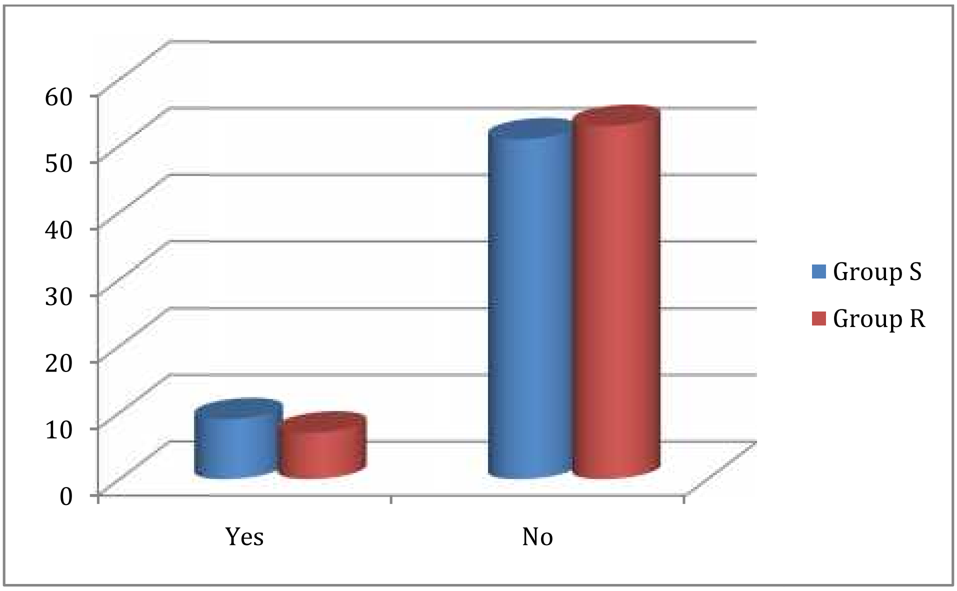
Incidence of oropharyngeal leak was similar in the two groups (p value: 0.716)

Statistical test – Chi – squared test with statistical software Graph Pad In Stat 3.06.

Table 11

GASTRIC INSUFFLATION

	Yes	No
Group S	9 (15%)	51 (85%)
Group R	7 (11.67%)	53 (88.33%)
p value– 0.789		



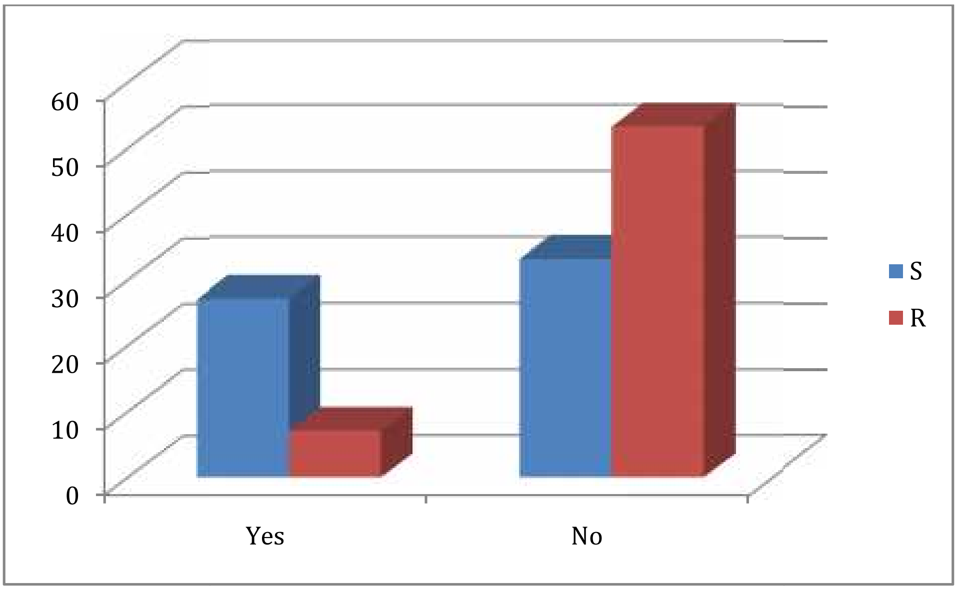
Graph 9

The two groups showed no significant difference in the incidence of gastric insufflations (p value: 0.789) Statistical test – Fisher‘s exact test with statistical software Graph Pad In Stat 3.06.

Table – 12

BLOOD STAINING OF PLMA

Group	Yes	No
S	27 (45%)	33 (55%)
R	7 (11.7%)	53 (88.3%)
p value- < 0.0001		



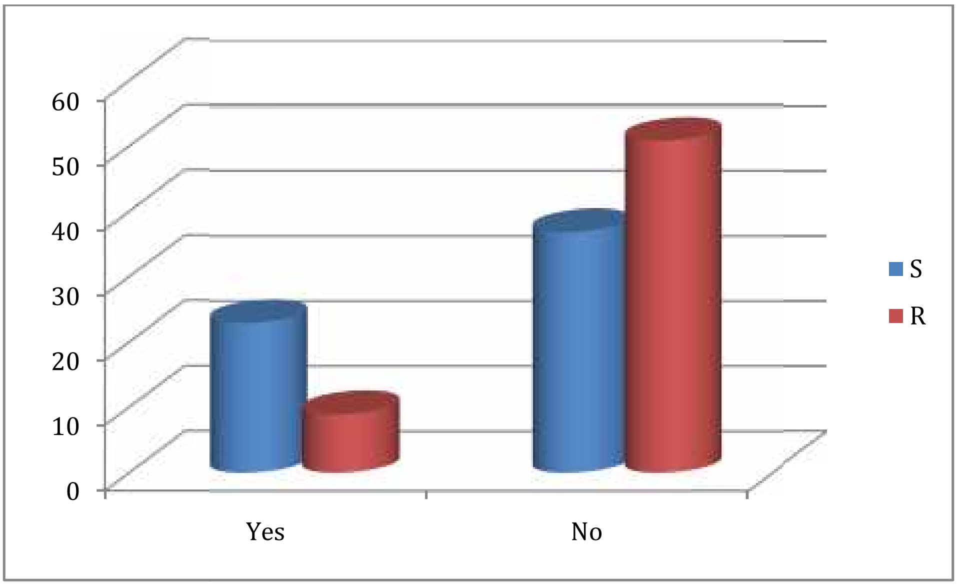
Graph 10

We observed higher percentage of blood staining of PLMA with standard technique as compared to rotational technique (45% versus 11.7%) (p value: < 0.0001) Statistical test – Fisher's exact test with statistical software Graph Pad In Stat 3.06.

Table 13

SORE THROAT

Group	Yes	No
S	23 (38.34%)	37 (61.66%)
R	9 (15%)	51 (85%)
p value– 0.0067		



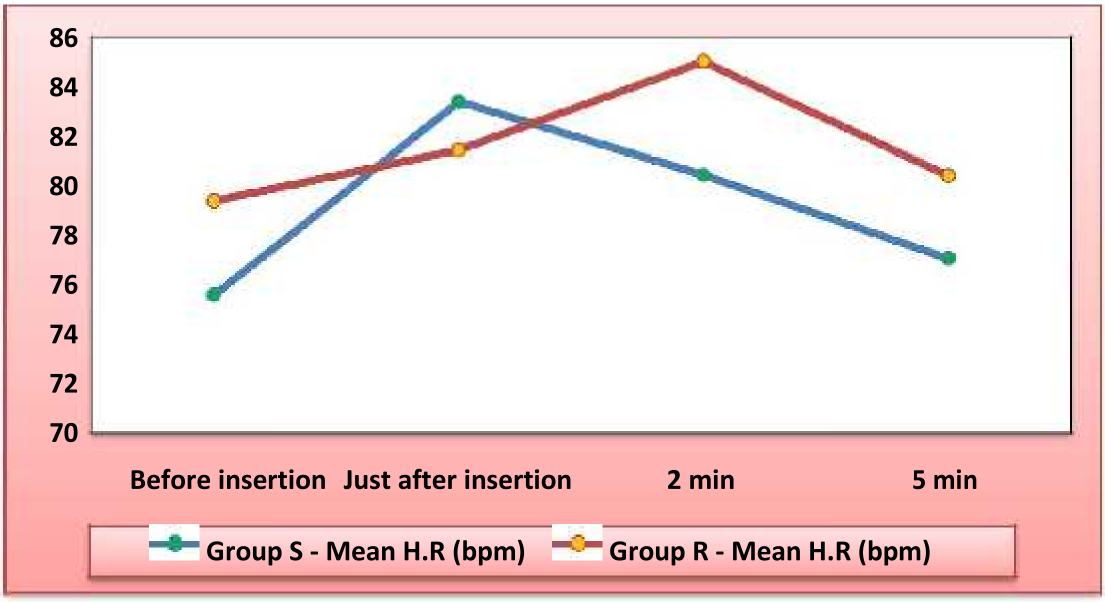
Graph 11

Lesser number of patients in the rotation technique had post operative sore throat as compared to standard technique (15% vs 38.34%) (p value: 0.0067) Statistical test – Fisher‘s exact test with statistical software Graph Pad In Stat 3.06.

Table 14

HEART RATE AT DIFFERENT LEVELS

	Group S		Group R		p value
	Mean (bpm)	S.D	Mean (bpm)	S.D	
Before insertion	75.57	9.53	79.38	11.75	0.053
Just after insertion	83.38	13.01	81.43	9.19	0.345
2 Minutes	80.43	8.89	85.02	13.59	0.051
5 Minutes	77.05	10.37	80.4	12.14	0.107



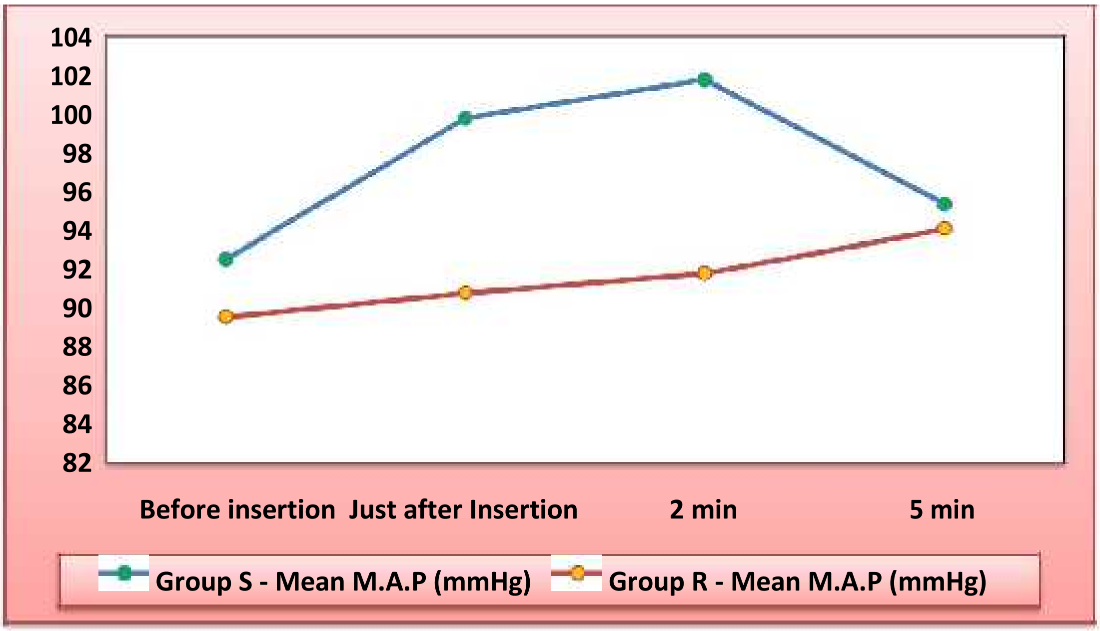
Graph 12

There is no significant statistical difference between the two groups statistical test : General linear model for repeated measures with statistical software SPSS 20.0.

TABLE 15

MEAN ARTERIAL PRESSURE AT DIFFERENT LEVELS

	Group S		Group R		p value
	Mean (bpm)	S.D	Mean (bpm)	S.D	
Before insertion	92.5	7.33	89.52	6.25	0.018
Just after 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



Graph 13

MAP showed significant rise with standard technique after insertion and at 2 minutes after insertion as compared to rotational techniqueStatistical test: General linear model for repeated measures with statistical software SPSS 20.0

DISCUSSION

This study demonstrates that the 90 degree rotation technique was superior and has advantages over the standard technique with respect to attempts of insertion, insertion time, blood staining of PLMA, sore throat and it is associated with lesser hemodynamic disturbances at insertion.

Airway management is the most essential skill in Anaesthesiology and inability to secure the airway is one of the most common reasons for major anaesthesia related morbidities and mortalities. LMA also called LMA classic (cLMA) has established role in modern anaesthesia practice. It is frequently used for airway maintenance of spontaneously breathing patients undergoing elective short surgical procedures. cLMA has gained popularity as a backup device to provide the emergency ventilation in difficult airway scenarios. The PLMA is an advanced form of cLMA airway that may be used for the same indications as the cLMA. The PLMA is designed to provide additional benefits over the cLMA that extends the range of procedures for which a cLMA is indicated. While the cLMA may be used with low-pressure positive pressure ventilation (PPV), the PLMA has been specifically designed for use with PPV with and without muscle relaxants at higher airway pressures. Correct placement of PLMA requires some degree of skill and if insertion is sub-optimal, it can cause partial or complete airway obstruction. The PLMA is inserted with one of several techniques. All the techniques except the standard technique involve use of various additional aids. Standard Brain‘s insertion technique is somewhat difficult. Problems are usually encountered while getting the tip of the mask to deflect or buckle into back of the mouth and it requires excessive force to place PLMA at proper position which results in multiple insertion attempts, prolonged insertion time, trauma to airway and failure of PLMA insertion. Also the standard Brain's insertion technique is somewhat less easy in adults. Nevertheless, even if the manufacturer's instructions are strictly followed, it is difficult to negotiate the PLMA through the pharynx posteriorly. In consequence of that the number of failures in insertion attempts, hypoxemia, laryngospasm and oral trauma are often observed with the standard insertion technique.[8] Brodrik[71] has mentioned the reason of placement difficulty and LMA insertion failure due to down-folding of epiglottis and backward rotation of LMA mask in 10% of his study population with recommended standard Brain's insertion technique. Rotational insertion technique has not been broadly investigated in adult populations with regard to success rate and ease of PLMA insertion. Very few studies have been done regarding the rotational insertion as an alternative method of insertion in adult population.[13, 14, 72]

The PLMA is reportedly more difficult to insert than the Classic LMA.[73, 74] Its larger cuff makes it difficult to place in the oral cavity and leaves little room for insertion of an index finger or thumb. The 90 degree rotation technique does not require the insertion of a finger, which avoids finger trauma and glove contamination with blood or saliva. Many techniques have been proposed to improve the success rate of PLMA insertion.[75] The introducer tool was no more successful than the standard digital technique.[38] The 90 degree rotation insertion technique is convenient because it does not require additional devices. Insertion simply consists of insertion of the PLMA into the oral cavity, rotation around the tongue, and advancement.[64] We were initially concerned that it would be difficult to rotate the large cuff in the mouth.

However, this proved not to be problematic, and we never failed to insert PLMAs using the rotation insertion technique.

Many studies have been conducted to determine the optimal sizes for the cLMA and the PLMA. Grady et al.[78] suggested that a small LMA (size 4) decreases the incidence of sore throat in spontaneously breathing male patients. They reported that a large LMA increased the risk of sore throat fourfold. Kihara et al.[59] showed that selection of PLMA size according to sex was more appropriate than selection according to the manufacturer‘s weight-based guidelines (size 3, 30–70 kg; size 4,>70–90 kg; and size 5,>90 kg). For patients of Indian subcontinent size 3 in females and size 4 in males are used.[68]

In our study we have compared the effectiveness of two techniques of insertion of PLMA, standard versus 90^{o} rotational with respect to a) time of insertion and number of insertion attempts b) gastric insufflation and leak around the cuff c) hemodynamic changes d) airway trauma and post-operative airway morbidity, 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.

In our study the success rate at first insertion was greater for the rotation technique group than for the standard technique group (98% vs. 78% respectively with a mean difference of 20%; p=0.001).

The study demonstrated that less time was required for PLMA insertion in rotational group as compared to standard group (11.88 ± 3.62 sec vs. 25.98 ± 10.92 sec; 95% C.I – 11.157 to 17.043; p = <0.0001). The technique is also beneficial in that it involves lesser morbidity in the form of lower incidence of postoperative sore throat (15% vs. 38.34%; p = 0.0067), blood staining of PLMA (11.7% vs. 45%; p= <0.0001) compared with the standard technique.

In our study mean arterial pressure increased significantly with standard technique ($p < 0.05$, during insertion 99.8 ± 12.34 mmHg vs. 90.77 ± 7.34 mmHg and at 2 minutes after insertion 101.78 ± 12.37 mmHg vs. 91.77 ± 7.34 mmHg).

Jeon YT et al[64] have compared standard technique with 90 degree rotational technique of insertion of PLMA in 120 adult patients. 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).Our result is similar to this study. The blood pressure change showed group-insertion interaction effect ($p < 0.001$). Although they claim that the blood pressure effect was statistically significant the quantum of mean change was trivial and of no clinical relevance.

Kim, M et al.[65] have compared standard technique with 90 degree rotational technique of insertion of PLMA in total 94 adult patients. 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). Our results are comparable with this study

M Yun et al[67] in their study compared standard technique with 90 degree rotational technique of insertion of PLMA in total 92 pediatric patients. Systolic, diastolic and mean blood pressure and heart rate increased significantly with the standard technique ($p<0.001$). Although our patients are adults the results are similar.Mi-Ja Yun et al[76] in a study involving total 126 pediatric patients aged 3 to 9 years compared standard technique with 90 degree rotational technique of insertion of

PLMA concluded that the incidence of sore throat was not significantly different (24% vs. 22%, respectively; p = 0.9) which is in contrast to our study. Our incidence of sore throat was less with rotational technique (15% vs. 38.34%, respectively; p= 0.0067). We presume that age; prior oro-pharyngeal hygiene can be confounding factors.

However our results agree with the findings of Dileep Kumar, Mueenullah Khan and Muhammad Ishaq. Although the study was with cLMA, the technique used by them is the same as our technique; hence it is of interest to study their findings. In their study they compared standard technique with 90 degree rotational technique of insertion of cLMA in total 100 adult patients. [68] The incidence of trauma (blood stained LMA on removal) with standard insertion technique was 28% compared to 6% with rotational LMA. They have remarked that insertion time was similar in the two techniques as the rotational cLMA insertion technique was found to be completed in less than 30 seconds duration in 86% compared to 78% with standard cLMA insertion technique which was not statistically significant (p = 0.456) which is in contrast to our study. They did find the difference however although not statistically significant. Further it can be argued that their definition of insertion time is different. They further claim that frequency of insertion attempts were similar with both the standard and rotational cLMA insertion techniques which were statistically not significant which is in contrast to our study. However their sample size is less robust than ours.

Another type of rotation technique i.e. the standard airway insertion technique i.e. 180 degree insertion technique like what we do with age-old oro-pharyngeal airway is also described. In a study conducted by Haghighi M et al[13] where they have compared two methods of cLMA insertion, ‘classic’ versus ‘simplified’ (AIRWAY). Successful first attempt in AIRWAY group (86%) had no meaningful statistical difference with the classic group (80%, $p > 0.05$). In the classic group 32% of cLMAs became blood stained compared to 16% in the AIRWAY group, the difference being not meaningful (P value- 0.06) which is in contrast to our technique where the blood staining of PLMA was less with 90 degree rotation technique group. In their study theincidences of gastric insufflation & leak around the cuff in ‘simplified’ (AIRWAY) versus ‘classic’cLMA insertion techniques were respectively (10% vs. 22%) and grade 1 leak (44% vs. 40%), grade 2 leak (44% vs. 36%) & grade 3 leak (12% vs. 24%) which were statistically not significant. The results are comparable to our study. It should be noted that their study was on classic LMA and ours is on PLMA. Our purpose in mentioning this study is it involved rotational technique although of different kind. This 180 degree rotation technique moreover involves greater rotation and the device can be associated with higher torsion and more friction. It is our firm opinion that the 90 degree rotation technique hence is more advantageous especially for PLMA insertion.

Our study has its share of limitations. First it was impossible to blind the anesthesiologists to the insertion technique, which may have been a source of bias. However assessment of insertion time, blood pressure change, and postoperative complications was conducted by another person blinded to the insertion method. Second we did not assess the position of the PLMA directly using a bronchoscope, and correct positioning was confirmed by clinical assessment only. It is noteworthy that, the clinical judgment has been considered enough to confirm correct PLMA placement and fiberoptic evaluation is considered unnecessary in routine practice.[11, 31]

SUMMARY

In this present study titled “A randomised clinical trial for comparison of two techniques of insertion of ProSeal laryngeal mask airway in adults
– index finger insertion technique versus 90 degree rotational technique”I we have compared the effectiveness between two insertion techniques regarding insertion time, number of insertion attempts, gastric insufflations, leak around the cuff, haemodynamic changes, airway trauma and postoperative airway morbidity.

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

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). The incidence of postoperative sore throat was lower (15% vs. 38.34%, respectively; p = 0.0067), and blood staining on the PLMA was less (11.7% vs. 45%, respectively; p< 0.0001). Haemodynamic changes with respect to increase in mean arterial pressure was more for standard technique compared to 90 degree rotational technique which showed statistical significance.

Hence it was concluded that 90 degree rotational technique of insertion of ProSeal LMA (which does not involve use of introducer or aids or finger insertion) was better than standard technique of insertion.

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 (PLMA).
- Time required for insertion of PLMA is less with 90 degree rotational techniquecompared to standard technique of insertion of PLMA.
- Incidence of complications like blood staining of PLMA at removal and sorethroat postoperatively is less for 90 degree rotational technique compared to standard technique of insertion of PLMA.

Hemodynamic changes with respect to increase in mean arterial pressure is more for standard technique compared to 90 degree rotational technique of insertion of PLMA.

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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

B.L.D.E. UNIVERSITY'S

SHRI B.M.PATIL MEDICAL COLLEGE, BIJAPUR – 586103

INSTITUTIONAL ETHICAL COMMITTEE No/552/15 30/11/15

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 17/11/2015 at 03 pm to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.

Title "A randomized clinical trial of two insertion techniques of proseal laryngeal mask airway in adults - Index finger insertion techniques versus 90 degree rotational technique"

Name of P.G. Student : Dr Gowri Geetha
Dept of Anaesthesiology

Name of Guide/Co-investigator : Dr. D.G. Talikoti
Prof & HOD. Anaesthesiology.

DR.TEJASWINI VALLABHA
CHAIRMAN
CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College, BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization
1) Copy of Synopsis/Research Project
2) Copy of informed consent form
3) Any other relevant documents.

ANNEXURE II

CONSENT FORM

TITLE OF THE PROJECT : **"A RANDOMISED CLINICAL TRIAL FOR COMPARISON OF TWO TECHNIQUES OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULTS – INDEX FINGER INSERTION TECHNIQUE VERSUS 90 DEGREE ROTATIONAL TECHNIQUE"**

PRINCIPAL INVESTIGATOR : **Dr. Gowni Geetha**

Department of Anaesthesiology
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PG GUIDE : **Dr.D.G.Talikoti**

Professor and HOD, Dept of Anaesthesiology
BLDE University's Shri B.M. Patil
Medical College Hospital & Research
Centre,Sholapur Road Vijayapur-03

PURPOSE OF RESEARCH:

I have been informed that this study is **:" A RANDOMISED CLINICAL TRIAL FOR COMPARISON OF TWO TECHNIQUES OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULTS – INDEX FINGER INSERTION TECHNIQUE VERSUS 90 DEGREE ROTATIONAL TECHNIQUE".**

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

I understand that I will be doing**:"A RANDOMISED CLINICAL TRIAL FOR COMPARISON OF TWO TECHNIQUES OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULTS – INDEX FINGER INSERTION TECHNIQUE VERSUS 90 DEGREE ROTATIONAL TECHNIQUE".**

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain while intubating and I understand that necessary measures will be taken to reduce these complications as and when they arise.

BENEFITS:

I understand that my/my wards participation in this study will help in finding out:"A RANDOMISED CLINICAL TRIAL FOR COMPARISON OF TWO TECHNIQUES OF INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY IN ADULTS – INDEX FINGER INSERTION TECHNIQUE VERSUS 90 DEGREE ROTATIONAL TECHNIQUE".

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. **Dr. Gowni Geetha** is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me for keep for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr.Gowni Geetha will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to ____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:	Dr. D.G.Talikoti	Dr. GowniGeetha
	(Guide)	(Investigator)

STUDY SUBJECT CONSENT FORM:

I confirm that **DR.GOWNI GEETHA** has explained to me the purpose of research, the study procedure, that I will undergo and the possible discomforts as well as benefits that I may experience. I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give consent to participate as a subject in this research project.

________________________ ____________________

(Participant) Date

____________________ ____________________

(witness to signature) Date

ANNEXURE III

PROFORMA

I. Name : Age/Sex : I.P No. :

Ward : Group allotted by randomization : Group S / Group R

II. 1. Type of the surgery : Duration of surgery (min.) :

2. Indication :

III. Significant History :

IV. General physical examination

Pallor Icterus Cyanosis Clubbing Koilonychia Lymphadenopathy

Oedema

V. Vital parameters

Pulse : Blood Pressure : Respiratory Rate : Temperature :

VI. Systemic examination

1. CVS :
2. RS :
3. CNS :

VII. Airway Assessment : MP Grade ……….. ASA Grade……….

VIII. Investigation

1. Routine :
2. Special (if any) :

IX. Procedure

1. Premedication :

Metoclopramide 10mg,

Ranitidine 50mg intravenously 15 min before surgery.

3 sprays of 10% lignocaine to the posterior oropharynx.

Midazolam 0.02mg/kg Fentanyl 1mcg/kg

2. Induction : 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.
3. Insertion of PLMA of appropriate size by standard or rotational insertion technique
4. Maintenance of Anaesthesia : Sevoflurane, oxygen plus nitrous oxide
5. Airway management device removed post-operatively.
6. Thorough intra-operative monitoring carried out and complications looked for post-operatively

X. Parameters

Airway device details	**Group : S / R**
Attempts of insertion	
1	
2	
3	
Insertion time (seconds)	
Oropharyngeal leak (grade)	
I	
II	
III	
IV	
V	**Group S / R**

Intraoperative :

Gastric insufflations (%)

At removal

Blood staining of device (%)

Postoperative

Sore throat (%)

DATE : STAFF SIGNATURE :

ANNEXURE IV

KEY TO MASTER CHART

- IPD No. – Inpatient department number
- ASA – American Society of Anaesthesiologists Attempts of insertion
- 1 - One attempt
- 2 - Two attempts
- 3 - Three attempts
- Oropharyngeal leak (grade) - 1 – Yes
- Gastric insufflations, blood staining of device, sore throat - 1 - Yes
- 0 – No
- 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
- SpO_2 – Peripheral oxygen saturation

MASTER CHART

GROUP S																																							
									Airway device details								Intraoperative	At Removal	Postoperative	Parameter																			
											Oropharyngeal leak (grade) (%)									Before insertion					Just after insertion					After insertion									
																														2 min					5 min				
Sl No	Name	IPD No	Age	Gender	Weight	Height(cms)	ASA(%)	Mallampad Grading (%)	Duration of Surgery (min)	Attempts of insertion	Insertion time(Secs)	I	II	III	IV	V	Gastric insufflations (%)	Blood staining of device (%)	Sore throat (%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)
1	Vijayalkshmi K	415430	28	F	50	152	2	2	20	1	38	1					0	1	0	63	99	58	71	98	71	100	58	74	100	94	104	60	75	99	87	99	61	74	98
2	Yasmin	415977	28	F	46	149	2	1	22	1	35	1					1	0	1	70	104	88	93	99	77	126	80	95	100	89	128	82	97	99	61	119	90	100	98
3	Lingamma	420753	22	F	44	150	2	1	18	1	28	1					0	0	0	58	112	81	91	97	62	136	88	104	99	94	138	90	106	98	70	127	73	91	98
4	Chaya Chitra	422648	25	F	47	147	2	1	15	2	22	1					0	1	0	79	122	79	93	99	107	146	98	114	100	63	148	100	116	99	68	136	79	98	98
5	Yallawwa	430523	22	F	51	156	1	1	24	1	39	1					0	1	1	70	129	64	85	97	79	149	100	117	100	77	151	103	119	100	81	138	90	106	99
6	Mallamma	438881	22	F	45	145	1	1	20	2	38		1				0	0	0	70	118	73	88	98	90	133	85	101	99	84	135	87	103	99	62	125	87	100	99
7	Jayashree	441343	25	F	52	160	1	1	16	1	30	1					1	0	0	67	129	79	95	100	87	139	91	107	100	77	141	93	109	100	88	130	86	101	100
8	Sunitha	443918	42	F	55	162	2	2	17	1	25	1					0	1	1	64	106	67	80	100	88	118	70	86	100	68	120	72	88	100	88	113	63	80	100
9	Lakshmi bai	449175	26	F	49	152	1	1	19	3	40	1					0	0	1	57	127	80	96	99	79	141	83	109	100	94	143	95	111	100	89	131	85	100	100
10	Rajashree	452687	28	F	55	159	2	1	22	1	15	1					0	1	0	83	113	79	90	99	92	125	77	93	100	80	127	79	95	99	92	118	77	91	99
11	Saraswati Indi	420555	36	F	50	165	2	1	21	1	16		1	1			0	0	0	80	128	88	101	97	86	138	90	106	100	84	140	92	108	100	78	129	90	103	100
12	Mahananda	420796	21	F	46	151	2	1	16	1	23						0	1	1	98	146	92	110	99	62	98	68	78	100	69	100	70	80	100	91	96	98	97	100
13	Rajeshwari Tikota	474698	27	F	54	160	2	1	18	2	32	1					0	0	0	88	124	81	95	97	95	127	79	95	100	71	129	81	97	100	70	120	88	98	99
14	Renuka Rathod	682	30	F	58	165	2	1	18	1	39	1					0	0	1	87	122	74	90	99	74	134	86	102	99	86	136	88	104	99	77	125	80	95	99
15	Mamatha umarani	7547	22	F	60	155	2	1	20	1	30	1					0	1	0	91	118	74	89	98	79	116	68	84	100	95	118	70	86	100	90	111	81	91	100
16	Rajeshwari Utnal	19114	25	F	45	150	1	1	26	3	32	1					1	0	0	64	119	76	90	97	81	139	91	107	100	82	141	93	109	100	59	129	88	102	100

17	Renuka Sindagi	33304	22	F	53	160	2	2	30	1	31	1					0	1	1	81	110	73	86	98	68	125	77	93	100	76	127	79	95	100	84	118	71	87	99
18	Savitri Mallappa	3665	33	F	65	164	2	2	35	2	27	1					1	0	1	70	103	89	94	98	114	137	89	105	100	71	139	91	107	98	68	128	86	100	96
19	Kasturi Sankrappa	4565	24	F	48	157	2	2	28	1	14	1					0	0	0	61	127	84	99	98	76	122	74	90	100	93	124	76	92	99	74	116	81	93	98
20	Jayashree Mane	60017	23	F	59	158	2	1	30	1	23	1					0	1	1	93	115	86	96	100	78	129	81	97	100	78	131	83	99	100	86	122	81	94	99
21	Rohini Udapudi	6058	34	F	62	156	2	1	20	1	23	1					0	1	0	58	121	81	94	99	97	156	108	124	99	66	158	110	126	99	70	143	90	108	99
22	Pawan Pujari	5785	23	M	66	165	1	1	22	1	31	1					0	0	0	85	114	69	84	98	96	153	106	121	100	63	155	108	123	100	81	141	90	107	99
23	Sridevi Kumbar	6637	18	F	47	150	1	1	17	1	11			1			0	1	0	69	122	89	100	97	91	112	67	82	100	86	114	69	84	100	94	107	80	89	100
24	Iravva Pandu	7296	26	F	51	158	2	1	19	1	11	1					0	0	1	83	113	90	98	98	108	126	84	98	99	88	128	86	100	100	72	119	82	94	100
25	Anushree Patil	87798	22	F	57	154	2	1	20	1	42	1					0	1	1	69	111	95	100	98	100	135	87	103	99	83	137	89	105	100	69	126	78	94	100
26	Gouramma Patil	8590	27	F	56	155	2	1	22	3	21	1					1	0	0	84	130	74	93	97	70	119	76	90	100	89	121	78	92	98	83	113	79	90	98
27	Maheshwari	9499	40	F	49	148	2	2	35	1	32	1					0	0	0	65	135	85	102	97	84	129	86	100	100	80	131	88	102	100	89	122	84	97	100
28	Kanya Kumari	9969	24	F	50	152	2	2	21	1	39		1				0	1	0	79	118	72	88	99	76	128	80	96	99	94	130	82	98	99	74	121	77	91	99
29	Shakunatala Pattar	10281	24	F	54	158	1	1	24	1	25	1					0	0	1	89	130	76	94	97	83	146	98	114	100	101	148	100	116	98	70	135	70	91	98
30	Gouramma Patil	10762	30	F	51	149	1	1	16	1	10	1					0	0	0	74	113	64	80	98	83	129	94	106	100	84	131	96	108	100	84	122	82	95	100
31	Kavitha	12299	23	F	58	159	1	1	18	2	39	1					0	1	0	81	115	68	84	98	88	118	76	90	100	63	120	78	92	100	80	113	75	88	100
32	Chandramma	12628	21	F	48	150	1	1	25	1	31	1					0	0	0	79	123	80	94	97	81	158	110	126	100	88	160	112	128	100	90	145	78	100	100
33	Padmika Karam	146638	60	F	55	154	1	2	15	3	36	1					0	1	1	92	123	66	85	97	101	143	98	113	100	80	145	100	115	100	72	133	74	94	100
34	Shantabai	12722	21	F	50	152	1	1	25	1	10	1					0	0	0	83	106	75	85	98	100	150	102	118	100	68	152	104	120	100	61	138	89	106	100
35	Shaila	151746	24	F	56	157	2	1	18	1	21	1					0	1	1	87	125	72	90	98	66	107	66	80	100	73	109	68	82	98	72	104	87	93	98
36	Pooja Bijjaragi	14655	26	F	58	149	2	1	28	1	35	1					1	0	0	64	125	95	105	97	84	121	82	95	100	79	123	84	97	99	67	115	82	93	99
37	Sumathi	160992	50	F	60	162	1	2	18	2	29		1				0	1	0	76	147	87	107	97	90	136	92	107	100	80	138	94	109	100	61	127	85	99	100
38	Vaishnavi	168473	21	F	46	149	2	1	27	1	26	1					0	1	1	66	111	91	98	97	74	125	84	98	100	83	127	86	100	100	68	119	97	104	100
39	Basanna Patil	16233	24	M	65	168	1	1	35	1	38	1					1	0	0	79	118	80	93	98	77	141	93	109	100	83	143	95	111	98	82	131	77	95	98
40	Uday Singh	173494	24	M	68	164	2	1	15	1	8			1			0	1	0	76	124	71	89	98	82	126	78	94	100	73	128	80	96	100	80	119	82	95	100
41	Lakshmi Pujari	16443	29	F	50	154	1	1	18	1	38	1					0	0	1	70	119	72	87	97	109	116	73	87	100	75	118	75	89	100	70	111	95	100	100
42	Mallappa	16968	19	M	50	160	2	1	15	3	20	1					0	0	0	73	134	74	94	97	75	110	66	81	100	78	112	68	83	100	63	106	82	90	100
43	Gangappa	16963	40	M	70	162	2	2	22	1	24	1					0	1	1	76	117	67	84	98	78	124	75	92	100	78	126	77	94	100	69	117	76	89	99
44	Vijayalaxmi	17193	20	F	49	151	2	1	30	1	42			1			0	0	0	72	123	80	95	98	90	126	78	94	99	74	128	80	96	99	77	119	74	89	99
45	Vaishali	187705	40	F	52	158	1	2	18	1	8		1				0	0	0	84	121	90	100	98	96	122	80	94	100	79	124	82	96	100	63	116	90	99	100
46	Asha	18146	19	F	45	153	1	1	15	1	10	1					0	1	1	61	105	79	88	97	60	120	76	91	100	83	122	78	93	100	67	114	88	96	100
47	Sharada Rajmani	18701	24	F	53	148	2	1	23	1	21	1					0	0	0	81	117	73	88	100	90	121	74	90	100	83	123	76	92	98	69	115	78	91	98

48	Veena	18732	21	F	50	155	1	1	35	2	22	1					1	1	0	70	123	86	98	97	85	128	80	96	100	83	130	82	98	100	78	121	76	91	100
49	Chandrappa	17784	48	M	69	168	2	1	25	1	13	1					0	0	1	64	117	88	98	98	82	137	93	108	99	79	139	95	110	99	82	128	81	96	99
50	Jaganath Kumar	19658	19	M	58	160	1	1	20	1	34	1					0	1	0	75	119	95	103	98	96	124	82	96	100	76	126	84	98	100	77	118	76	90	100
51	Bagyashree	19707	50	F	50	154	2	1	25	1	34	1					0	0	1	75	136	74	95	97	78	128	86	100	100	87	130	88	102	100	72	121	93	102	100
52	Rajeshwari	21315	27	F	55	159	2	2	15	2	39	1					0	1	0	80	123	75	91	98	104	163	116	131	99	86	165	118	133	99	83	149	87	108	99
53	Sreedhar	21192	40	M	72	169	1	1	30	1	16	1					0	0	0	78	124	77	92	98	68	143	96	111	100	81	145	98	113	100	72	133	93	107	100
54	Padma	230723	25	F	52	157	1	1	20	1	9			1			1	0	0	76	112	71	84	97	74	108	74	85	100	71	110	76	87	99	88	105	76	85	99
55	Gayatri	257356	45	F	50	152	1	1	22	1	34	1					0	1	1	84	121	95	104	97	49	117	73	88	100	95	119	75	90	100	81	112	79	90	100
56	Shivaray gouda	20754	19	M	52	160	2	1	15	1	8		1				0	0	0	74	105	85	92	97	88	129	86	100	100	69	131	88	102	100	87	122	76	91	100
57	Krishnappa	22105	55	M	64	166	2	2	30	1	8	1					0	1	1	68	119	68	85	98	77	124	76	92	100	79	126	78	94	98	96	117	89	99	98
58	Gouramma Hiremath	304466	24	F	66	170	1	1	20	1	8	1					0	0	0	83	105	76	86	98	68	145	99	114	100	82	147	101	116	100	97	135	78	97	100
59	Gayathri	312988	26	F	49	153	2	1	35	1	36	1					0	0	0	77	141	86	104	98	83	138	94	109	100	69	140	96	111	100	58	129	67	88	100
60	Sudha	27894	50	F	52	157	2	2	30	1	40	1					0	1	1	81	113	75	87	97	77	133	96	108	100	90	135	98	110	100	92	125	64	98	100

GROUP R																																							
										Airway device details							Intraoperative	At Removal	Postoperative	Parameter																			
												Oropharyngeal leak (grade) (%)								Before insertion					Just after insertion					After insertion									
																														2 min					5 min				
Sl No	Name	IPD No	Age	Gender	Weight	Height	ASA(%)	Mallampad Grading (%)	Duration of Surgery (min)	Attempts of insertion	Insertion time	I	II	III	IV	V	Gastric insufflations (%)	Blood staining of device (%)	Sore throat (%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)	H.R. (bpm)	S.B.P. (mmHg)	D.B.P. (mmHg)	M.A.P.(mmHg)	SpO2(%)
1	SIDDARTH PATIL	37752	53	M	68	167	2	2	22	1	8	1					0	0	0	81	97	60	72	97	65	92	54	69	100	69	95	57	70	100	67	95	57	70	99
2	FARIDA BEGUM TORVI	426164	35	F	52	154	2	1	15	1	16	1					1	0	1	117	102	68	79	98	75	112	84	95	100	83	115	87	96	100	86	135	79	98	100
3	RENUKA KUMBAR	433732	27	F	48	147	2	1	24	2	8	1					0	0	0	73	109	82	91	98	94	120	86	100	100	74	123	89	101	100	95	138	101	113	100
4	Puttu Chawan	425671	60	M	69	165	2	1	16	1	19	1					0	1	0	72	118	75	89	99	72	128	84	104	100	93	132	92	105	100	76	142	77	99	100
5	Sumangala Indi	437310	22	F	56	159	2	1	18	1	15	1					0	0	0	91	124	71	89	97	111	133	90	104	100	81	134	91	105	99	74	140		100	99
6	Rajiya Begum	440136	27	F	51	152	2	1	25	1	20		1				1	0	1	70	114	80	92	99	75	120	97	105	99	63	121	98	106	99	46	149	72	98	99
7	Sharada	438048	25	F	57	158	2	1	35	1	9		1				0	0	0	77	124	85	98	100	86	125	65	85	100	109	126	66	86	100	99	108	74	85	100
8	Gowramma	448748	20	F	49	151	2	1	20	1	10	1					0	0	0	83	103	80	88	98	88	108	78	88	100	78	109	79	89	100	82	,125	76	92	100
9	Mahadevvappa	41768	35	M	60	164	2	1	25	1	10	1					0	0	0	74	123	77	92	97	78	126	79	95	100	77	127	80	96	100	81	126	81	96	100
10	Vijayalaxmi Pujari	41093	32	F	58	153	1	2	24	1	11	1					0	0	0	95	109	82	91	97	84	113	75	88	100	108	114	76	89	100	40	121		83	100
11	Jayashree Indi	42062	25	F	54	155	2	1	15	1	8		1				0	0	0	62	123	84	97	98	82	124	86	99	100	88	125	87	100	99	82	135	88	104	99
12	Nimbawwa	7321	25	F	50	150	2	1	16	1	16			1			0	0	0	93	140	88	105	98	85	91	92	92	100	95	92	93	93	100	81	142	95	111	100
13	Poorvi Indi	8336	23	F	59	154	1	1	28	1	11	1					0	0	1	87	120	71	88	99	97	115	81	92	100	112	116	82	93	100	73	128	62	84	100
14	Hanumanthrai	1771	40	M	68	167	2	1	30	1	9	1					0	1	0	92	118	72	87	98	84	120	74	89	100	105	121	75	90	100	77	119	76	90	100
15	Surekha Ikkalaki	27119	25	F	48	154	1	1	25	1	8			1			0	0	0	84	115	68	84	98	94	106	75	85	100	67	107	76	86	100	62	120	85	97	100

16	Bhagya	25731	25	F	53	157	i	1	35	1	14	1					0	0	0	62	116	75	89	99	84	124	79	94	99	67	125	80	95	99	71	125	82	97	99
17	Sudha Basavaraj	3611	23	F	57	159	2	1	25	1	16	1					0	0	0	87	107	76	87	99	80	113	70	84	100	111	114	71	85	100	75	113	88	96	100
18	Savitri Badiger	4935	30	F	51	152	1	1	16	1	8	1					0	0	0	54	101	67	79	98	90	123	72	89	100	113	124	73	90	100	87	117	77	90	100
19	Bilai Krishna Chawan	56028	26	F	54	149	1	1	20	1	12	1					0	0	0	76	122	58	79	98	83	111	66	81	100	66	112	67	82	100	[illegible]	109	72	84	100
20	Suvarna Biradar	64756	24	F	47	150	1	1	35	1	8	1					1	1	0	86	112	79	90	97	86	117	67	84	100	83	118	68	85	100	87	110	81	91	100
21	Shankar Patil	6044	25	M	72	168	2	1	15	1	11	1					0	0	0	108	117	69	85	97	88	138	82	101	100	92	139	83	102	100	70	130	77	95	99
22	Shivaganga math	6010	20	F	50	160	1	1	18	1	15	1					0	0	1	83	111	66	81	97	85	136	97	110	100	77	137	98	111	99	71	149	93	112	99
23	Sarojini Pawar	6493	25	F	55	151	1	1	27	1	10	1					0	0	0	79	118	80	93	98	87	102	80	88	100	81	103	81	89	100	90	128	81	96	100
24	Amruta Savalasang	6859	45	F	58	159	1	1	20	1	12	1					0	0	0	87	110	81	91	99	92	114	70	85	100	85	115	71	86	100	86	113	82	93	100
25	Haseena Attar	78127	19	F	46	155	2	1	30	1	8		1				0	0	0	77	108	81	90	WO	79	121	80	94	100	87	122	81	95	100	84	127	80	96	100
26	Gayatri Akki	7449	24	F	50	161	2	2	22	1	15	1					0	0	0	79	125	84	98	98	78	108	73	85	100	98	109	74	86	100	79	118	59	79	100
27	Laxmi Karadi	9032	27	F	52	153	1	2	19	1	8	1					0	0	1	76	130	73	92	98	84	117	82	93	100	70	118	83	94	100	88	129	53	78	100
28	Annapurna	9388	25	F	56	159	2	1	22	1	10	1					0	0	0	82	114	70	85	98	74	116	72	88	100	78	117	73	87	100	83	116	74	88	100
29	Rukmini bai	9545	23	F	61	157	1	1	23	1	15	1					1	0	0	93	125	78	94	98	83	130	71	91	99	73	131	72	92	99	67	115	89	98	99
30	Sonibai Rathod	116370	20	F	49	150	2	1	28	1	19	1					0	1	0	90	110	78	89	97	82	117	84	95	100	84	118	85	96	100	100	132	60	84	100
31	Tukaram	120160	50	M	69	164	2	2	20	1	15	1					0	0	0	90	111	75	87	97	64	108	81	90	99	105	109	82	90	99	86	128	89	102	99
32	Renuka	119244	21	F	57	151	2	1	15	1	8		1				0	0	0	71	119	67	84	98	78	140	76	97	100	82	141	77	97	100	65	122	85	97	100
33	Abdul Mohammad	12967	55	M	65	160	2	2	30	1	11	1					0	1	0	56	119	81	94	97	100	128	80	96	100	95	129	81	96	99	62	127	79	95	99
34	Uma Talwar	12411	27	F	50	162	1	1	15	1	16	1					0	0	1	73	104	75	85	97	78	133	65	88	100	84	134	66	88	100	89	107	83	91	100
35	Basamma	12465	24	F	45	149	2	1	35	1	20	1					0	0	0	58	121	77	92	97	76	99	76	84	100	75	100	77	84	100	91	122	80	94	100
36	Surekha Kalpa	13349	30	F	51	155	2	1	28	1	10	1					0	0	0	70	120	82	95	98	81	110	83	92	100	79	111	84	92	100	89	130	83	99	100
37	Mahalaxmi	14002	30	F	50	155	2	1	30	1	9	1					0	0	0	77	141	88	96	98	84	122	71	88	100	87	123	72	88	100	79	115	76	89	100
38	Bheemanagouda	12940	35	M	62	153	2	1	35	1	14	1					0	0	1	64	108	77	88	98	91	114	76	88	100	78	115	77	88	100	86	121	74	90	100
39	Tippamma	149120	19	F	45	166	2	1	25	1	12	1					0	0	0	75	115	67	83	99	61	126	76	93	100	81	127	77	93	100	80	121	84	97	100
40	Iramma	160368	20	F	48	147	2	1	18	1	9	1					0	0	0	94	120	71	87	99	91	114	87	96	100	84	115	88	96	100	94	135	77	96	100
41	Yamini Shivaraj	15769	28	F	50	156	1	2	20	1	14	1					1	0	0	66	115	66	88	98	82	106	65	78	100	79	107	66	78	100	89	107	61	77	100
42	Mehaboobsab	19088	42	M	69	155	1	1	15	1	8	1					0	1	0	73	129	78	95	98	78	101	75	84	100	112	102	76	84	100	76	121	78	92	100

43	Gayatri	172809	22	F	52	160	1	2	20	1	8	1					0	0	0	79	114	75	88	98	75	112	81	91	100	74	113	82	91	99	76	128	89	102	99
44	Nandini	1807072	37	F	60	152	2	1	I8	1	13	1					0	0	0	70	119	68	85	98	84	114	88	97	100	109	115	89	97	100	77	137	83	101	99
45	Kamala	192544	25	F	49	159	2	2	35	1	13	1					0	0	0	76	117	69	85	98	81	111	74	86	100	79	112	75	86	100	66	119	79	93	100
46	Renuka Urarad	18508	25	F	60	150	1	2	30	1	20	1					0	0	1	73	_103	77	86	97	71	109	80	90	100	85	110	81	90	100	81	127	83	98	100
47	Sudha	11978	45	F	57	151	1	2	25	1	8	1					0	0	0	70	114	78	90	97	73	110	85	93	100	82	111	86	93	100	76	133	100	111	100
48	Sumangala Patil	217885	23	F	50	156	2	1	20	1	9	1					1	0	0	90	119	89	99	98	73	116	78	91	100	81	117	79	91	100	89	124	67	86	100
49	Gayatri Pattar	21067	25	F	51	149	1	2	30	1	10	1					0	0	0	76	114	73	87	98	53	123	81	95	100	70	124	82	95	100	97	128	92	104	100
50	Meenakshi	235098	22	F	55	150	1	1	25	1	9	1					0	0	0	82	116	86	96	100	79	113	66	82	100	82	114	67	82	100	78	109	79	89	100
51	Shreeram	22885	26	F	64	154	1	2	15	1	13	1					0	0	0	67	130	75	94	97	81	116	79	91	100	88	117	80	91	100	93	126	84	98	99
52	Asha Honakeri	23004	23	F	70	161	1	2	22	1	12		1				0	0	0	92	119	70	86	98	75	144	60	88	100	99	145	61	88	100	91	101	92	95	100
53	Haseena Sawalagi	23676	26	F	50	158	1	1	24	1	10	1					0	0	1 .	71	120	86	97	98	79	128	68	88	100	93	129	69	88	100	82	112	77	88	100
54	Shivvamma	278910	24	F	57	161	1	2	28	1	8	1					0	0	0	87	109	76	87	97	83	100	82	88	100	68	101	83	88	99	87	129	90	103	99
55	Shilpa Patil	26735	26	F	45	160	1	2	15	1	14	1					0	0	0	85	117	74	88	98	81	107	69	82	100	74	108	70	82	99	90	113	92	99	99
56	Shalini	26931	25	F	45	154	1	2	17	1	14	1					0	0	0	94	103	87	93	98	82	117	58	77	100	58	118	59	77	100	66	98	67	77	100
57	Fathima Begam	290638	35	F	50	150	1	1	20	1	12	1					0	0	0	82	115	83	94	97	91	112	76	88	100	97	113	77	88	100	104	122	72	89	100
58	Vandana Gani	28339	27	F	47	149	1	1	30	1	18	1					0	I	0	80	103	79	87	98	76	130	86	101	100	76	131	87	101	100	97	135	59	84	100
59	Bibijan	29203	25	F	51	151	1	2	35	1	9	1					0	0	0	80	135	96	109	98	77	124	76	92	100	94	125	77	92	100	66	121	59	105	99
60	Laxmibai	24573	28	F	65	152	1	1	30	1	8	1					1	0	0	72	109	69	82	97	83	120	93	102	100	82	121	94	102	100	79	144	97	107	100