“COMPARISON OF LARYNGEAL MASK AIRWAY PROSEAL AND LARYNGEAL MASK AIRWAY SUPREME FOR EASE OF INSERTION AND AIRWAY SEALING PRESSURE IN ANAESTHETIZED PARALYZED ADULT PATIENTS UNDERGOING POSITIVE PRESSURE VENTILATION - A RANDOMIZED CLINICAL TRIAL”

REG NO. BA0110005

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. D.

in

ANAESTHESIOLOGY

DEPARTMENT OF ANAESTHESIOLOGY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM, KARNATAKA

APRIL - 2013

"COMPARISON OF LARYNGEAL MASK AIRWAY PROSEAL AND LARYNGEAL MASK AIRWAY SUPREME FOR EASE OF INSERTION AND AIRWAY SEALING PRESSURE IN ANAESTHETIZED PARALYZED ADULT PATIENTS UNDERGOING POSITIVE PRESSURE VENTILATION - A RANDOMIZED CLINICAL TRIAL"

REG NO. BA0110005

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. D.

in

ANAESTHESIOLOGY

**DEPARTMENT OF ANAESTHESIOLOGY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM, KARNATAKA**

APRIL - 2013

KLE UNIVERSITY, BELGAUM, KARNATAKA

ENDORSEMENT

This is to certify that the dissertation entitled **"COMPARISON OF LARYNGEAL MASK AIRWAY PROSEAL AND LARYNGEAL MASK AIRWAY SUPREME FOR EASE OF INSERTION AND AIRWAY SEALING PRESSURE IN ANAESTHETIZED PARALYZED ADULT PATIENTS UNDERGOING POSITIVE PRESSURE VENTILATION - A RANDOMIZED CLINICAL TRIAL"** is a bonafide research work done by **CANDIDATE REG NO. BA0110005**.

Dr. S. N. Suresh **MD,DA**
Professor and Head,
Department of Anaesthesiology,
J. N. Medical College,
Nehru Nagar, Belgaum – 10

Date:
Place: Belgaum

Dr. A. S. Godhi **MS,FICS**
Principal,
J. N. Medical College,
Nehru Nagar, Belgaum – 10

Date:
Place: Belgaum

LIST OF ABBREVIATIONS USED

ASA	– American society of Anaesthesiolosts
BMI	– Body mass index
Cm	– Centimeter
CNS	– Central nervous system
CO_2	– Carbon dioxide
CVS	– Cardiovascular system
ECG	– Electrocardiogram
ETT	– Endotracheal tube
GIT	– Gastrointestinal tract
H_2O	– Water
Hb	– Haemoglobin
ICP	– Intra cuff pressure
Inj.	– Injection
IQR	– Inter quarantile range
IV	– Intravenous
Kgs	– Kilograms
LMA	– Laryngeal mask airway
Mcg	– Micrograms
Mg	– Milligrams
Min	– Minute
Ml	– Millilitre
OGT	– Orogastric tube
OLP	– Oropharyngeal leak pressure
PPV	– Positive pressure ventilation

PR – Pulse rate

PVC – Polyvinyl chloride

RBS – Random blood sugar

RR – Respiratory rate

SPO_2 – Saturation percentage of oxygen

α – Alpha

β – Beta

ABSTRACT

Background and objectives

Newer supraglottic airway devices have been recently introduced, motivated by the need for a single use equivalent to the reusable LMA Proseal. LMA Supreme is a new single use laryngeal mask airway with gastric access providing an easy, reliable airway and good airway seal. The objectives of the present study were to compare LMA Proseal and LMA Supreme for ease of insertion and airway sealing pressure in anaesthetized paralyzed adult patients undergoing positive pressure ventilation.

Methodology:

We conducted a prospective randomized study in 60 ASA grade I and II adult patients posted for elective surgeries under general anaesthesia. The patients were randomly allocated to group LMA Proseal (n=30) or group LMA Supreme (n=30). After anaesthesia induction, the airway devices were (all size 4) were inserted in strict accordance with the manufacturer's recommendations. The ease of insertion was recorded and oropharyngeal leak pressure and intra cuff pressures were determined at 0 to 40 ml cuff volume in 10ml increments.

Results

First attempt and overall success of insertion were similar (LMA Proseal 93.33% and 100%; LMA Supreme 96.66% and 100%). Guided insertion was always successful following failed digital insertion. There was no difference in the mean duration of insertion for both the devices (23.92 ± vs 23.44 ± seconds) ($p<0.05$). The mean oropharyngeal leak pressure was significantly higher for the

LMA Proseal than the LMA Supreme (23.24 vs 19.37 cm of H_2O) ($p<0.05$). The intra cuff pressures were significantly higher for LMA Proseal in comparison to LMA Supreme at all cuff volumes of inflation range ($p<0.05$).

Conclusions

The ease of insertion was similar for the LMA Proseal and LMA Supreme, but oropharyngeal leak pressure and intracuff pressures were higher for the LMA Proseal. The LMA Proseal provides a more effective seal than LMA Supreme for positive pressure ventilation.

Keywords

Airway seal pressure; LMA Proseal; LMA Supreme; positive pressure ventilation;

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF PHOTOGRAPHS

Chapter 1

Introduction

INTRODUCTION

Expertise in airway management is important for every medical specialist and is a lifeline for the anaesthesiologist. Maintaining a patent airway is a vital aspect of providing adequate oxygenation and ventilation.

General anaesthesia has undergone many refinements and advances in the last few decades. The introduction of safe, short-acting induction and maintenance agents with few side-effects, and airway devices such as the laryngeal mask airway, have revolutionized anaesthesia to the point where major complications and morbidity are rare occurrences. Unfortunately, the incidence of some minor complications has not been influenced at all by the wealth of technology.

Respiratory events are the most common anaesthetic related injuries, following dental damage. The three main causes of respiratory related injuries are inadequate ventilation, oesophageal intubation and difficult tracheal intubation. Difficult tracheal intubation accounts for 17% of the respiratory related injuries and results in significant morbidity and mortality. In fact up to 28% of all anaesthesia related deaths are secondary to the inability to mask ventilate or intubate.[1]

Laryngeal mask airway (LMA) is a suitable alternative to the facemask or to the tracheal intubation in a wide variety of clinical situations.[2] LMA fills a niche between facemask and endotracheal tube (ETT) in terms of both anatomical position and degree of invasiveness.

LMA is a key device at several places in the American Society of Anaesthesiologists (ASA) algorithm for difficult airways.[3]

Furthermore, ETTs carry an inherent risk of patient trauma from vocal cord damage to pharyngeal soft tissue injury. Because of ease of insertion and reduced trauma, LMA devices have replaced ETTs in many procedures.[4]

A significant concern to the clinician placing any supraglottic airway is identifying that it is in proper position. Poor placement of the LMA has been blamed for gastric fluid aspiration, neuropraxias and sore throat.[5]

As the airway pressure increases during positive pressure ventilation, gas leaks occur into the oropharynx and, more importantly the oesophagus. Malposition increases the risk of leaks and overpressure (>25 cm of H2O) may lift the LMA tip from its correct position in the hypopharynx, elevate the distal cuff from the larynx and expose the oesophageal inlet. If the leak is sufficiently large or prolonged, gastric distension may occur; ventilation may be inadequate and there will be increased operating room pollution. Gastric distension may lead to impaired respiratory function and increase the risk of regurgitation.[6]

The efficacy of seal depends on the fit between the oval shaped groove surroundings the glottis and the oval shaped cuff of the LMA.[7] The improvement in seal may be an advantage in situations in which higher airway pressures are required for positive pressure ventilation such as in obese patients, the lithotomy-head down position or in patients with restrictive pulmonary pathology. The seal achieved by LMAs provides less protection against pulmonary aspiration than a properly inserted cuffed tracheal tube does.[8]

LMA Proseal is a reusable supraglottic airway device offering gastric access and was introduced into clinical practice in 2000. The LMA Proseal offers higher glottic seal pressures than the LMA Classic[9], facilitating positive pressure ventilation and has been used in obese patients, those with low lung compliance. It has a built-in drain tube that allows expelled gastric contents to bypass the pharynx. This specific feature is designed to decrease the risk of aspiration.[10,11] The drain tube also allows instant clinical diagnosis of device misplacement after insertion and until its removal. The LMA Proseal reduces the likelihood of throat irritation and stimulation, and reduces postoperative nausea and vomiting by as much as 40% compared to an ETT.[12] It includes all the benefits associated with the LMA airway: fewer drugs,[13] less incidence of sore throat in adults, reduced coughing and bucking on emergence and improved haemodynamic stability.[14,15]

Recently a new laryngeal mask airway, LMA Supreme allowing gastric drainage has become available for clinical use. The LMA Supreme is a single-use, latex free laryngeal mask airway, made of medical grade PVC. The firm, elliptical and anatomically shaped airway tube facilitates easy insertion, without placing fingers in the patient's mouth or requiring an introducer tool for insertion. This LMA has demonstrated interesting characterstics including simplicity for novice users to obtain a sealed airway in the obese patients[16] and measured oropharyngeal leak pressures up to 37 cm of H2O[17] without any adverse events or aspiration.[18-20] It enables passive drainage or active management of digestive tract contents independent of ventilation with significantly lower postoperative pharyngolaryngeal morbidity.[21]

Hence this study was designed to compare the clinical efficacy of LMA Proseal and LMA Supreme for ease of insertion and airway sealing pressure in anaesthetized paralyzed adult patients undergoing positive pressure ventilation.

Chapter 2

Objectives

OBJECTIVES

The objectives of the study were to compare LMA Proseal and LMA Supreme for ease of insertion and airway sealing pressure in anesthetized paralyzed adult patients undergoing positive pressure ventilation.

Chapter 3

Review of Literature

REVIEW OF LITERATURE

Airway management for most of the twentieth century has been dominated by the facemask and tracheal tube. However, from an engineering viewpoint, the way these artificial airways are connected to the respiratory tract is less than ideal. When a facemask is used, the gap between the base of the tongue and the glottis is not bypassed. This may cause obstruction during anaesthesia when upper airway muscle tone decreases and gravity approximates the pharyngeal tissues. Tracheal intubation bypasses this problem, but involves positioning a tube within a tube and inflating a sealing balloon in a highly sensitive area where capillary flow is easily interrupted and epithelial damage common. In addition, intubation is usually a direct vision technique which requires the use of a laryngoscope and muscle relaxants with their associated complications.

The LMA was designed in 1981 by Archie Brain, a British anaesthesiologist working at the Royal London hospital, UK, as part of a specific search for an airway that was more practical than the facemask and less invasive than a tracheal tube. The inventor applied principles of bioengineering to the functional anatomy of the pharynx both in terms of anatomical fit and methods of placement.

The first prototype was constructed from the cuff of a Goldman nasal mask for dental anaesthesia stretched over a diagonally cut size 10mm tracheal tube and fixed into position with acrylic glue. This prototype was first used on a human patient undergoing a routine hernia repair at the William Harvey Hospital,

Ashford, Kent, in the summer of 1981. The new device was inserted blindly under halothane anaesthesia; a clear airway was immediately obtained and positive pressure ventilation was possible. As a result of this experience three more prototypes were assembled and a pilot study of 23 patients followed at the London Hospital.

The first publication describing LMA as a possible solution to airway management in the emergency appeared in the Archives of Emergency Medicine in 1984. In 1985 LMA was applied successfully in the management of five patients with anticipated difficult intubation. By October 1987 after an excellent record in 21 adult difficult intubations, LMA was used successfully for the first time in a failed pediatric intubation. Fiberoptic investigation conducted by Dr. Brain suggested the possibility of using the LMA as a guide for tracheal intubation. An awake intubation via the LMA was first reported by McCrinick and Pracilio in 1991. In 1993 the LMA was incorporated into the Practice Guidelines for management of the Difficult Airway by the American Society of Anesthesiologists Task Force on the Management of the Difficult Airway.[22]

The laryngeal mask airway (LMA) is now the most widely used alternative airway device in anaesthesia. It is designed to be inserted blindly into the pharynx and, with the balloon inflated, form a seal around the laryngeal inlet.[23] Whilst primarily used in spontaneously breathing patients undergoing elective anaesthesia, it has also worked well, with few complications, as a ventilatory device in patients who cannot be intubated or whose lungs cannot be ventilated with bag and mask techniques. It is effective even when used by practitioners who have limited experience[24] and has also been useful as a conduit

for endotracheal intubation.

Supraglottic airway devices are developed with increasing frequency following the overwhelming success of the LMA. In contrast to the first generation devices such as the 'classic' LMA and the laryngeal tube, second generation devices usually offer an oesophageal drainage tube and/or an improved oropharyngeal leak pressure during positive pressure ventilation such as the laryngeal mask ProSeal. Recently the disposable versions of these supraglottic airway devices (LMA Unique and LMA Supreme) and the novel I-Gel mask have gained increasing interest. Both the LMA Proseal and the LMA Supreme have been shown to be perfectly suitable for routine anaesthesia and emergency airway management. While the lacking protection against aspiration is still considered a major limitation of the LMA, the value of airway devices with an oesophageal drainage tube in this respect remains undetermined at present.[25]

A study[26] to know the influence of cuff volume on oropharyngeal leak pressure and fibroptic position with the LMA showed that LMA functions better at submaximal cuff volumes and that the optimal volume for the size 4 LMA is 15-20ml. Increasing cuff volume to 25 ml and above does not improve seal pressure or fibreoptic view, commonly results in a deterioration in both and may increase the risk of gastric insufflation. Soft low volume cuff is better able to fit into the variable contours of the periglottic groove than the tense high volume cuff.

A multicenter study[27] comparing the LMA Proseal and LMA Classic in

anaesthetized non paralyzed patients demonstrated that the LMA Classic was easier and quicker to insert at the first attempt than the LMA Proseal. Despite the increased difficulty with insertion, success rates after three attempts for the LMA Proseal were high (98%) and similar to the LMA Classic (100%). The efficacy of seal was 5 cm H_2O higher for the LMA Proseal than the LMA Classic (27 ± 7 vs. 22 ± 6 cm of H_2O). There were no differences in total intraoperative complications, but there was a higher incidence of minor tongue-lip-dental trauma for the LMA Proseal. Although the number of insertion attempts were higher with the LMA Proseal, the incidence of blood detected on removal was similar to the LMA Classic suggesting that the incidence of mucosal trauma might have been similar.

A comparative study[28] of LMA Supreme versus i-gel on 100 paralyzed adult patients with controlled ventilation in Trendelenburg position for laparoscopic surgery demonstrated that there was no difference in the oropharyngeal leak pressure between the LMA Supreme and the i-gel (26.4 ± 5.1 vs 25.0 ± 5.7 cm of H2O respectively). Fourty seven LMA Supremes and fourty eight i-gels were successfully inserted on the first attempt, with similar ease and comparable times to achieve an effective airway successfully. The volume of air needed to achieve a cuff pressure of 60 cm of H2O was 25.2 ± 5.0 ml in the LMA Supreme. After creation of pneumoperitoneum, there was a smaller difference between expired and inspired tidal volumes with the LMA Supreme (21.5 (15.2) ml) than with the i-gel (31.2 (23.5) ml). There was blood staining on removal of two LMA Supremes and one i-gel.

In a randomized, cross over study[29] of LMA Proseal and LMA Supreme

on clinical efficacy in 36 adult female patients, authors demonstrated that ease of insertion of both devices was identical. There were no failures to insert either device. The modified cuff of the LMA Supreme was allowed higher glottis seal pressure (28 cm of H2O) similar to that of the LMA Proseal. Median volume of air for cuff inflation to 60 cm of H2O was 22.4 ml (LMA Proseal) and 21.9 ml (LMA Supreme). The reinforced tip of the LMA Supreme containing the drain tube was not found to have 'folded over' in any patient, as the passage of a gastric tube was easily performed in all cases. Difference in mean airway seal pressure for devices was very small and gastric access was possible at the first attempt with both devices. This study suggested that, the LMA Supreme may also have a role in securing the immediate airway in cardiopulmonary resuscitation and in the 'cannot-intubate, cannot-ventilate' scenario currently recommended for the LMA Classic.

Another study[30] comparing LMA Proseal and ETT in 60 adult patients undergoing laparoscopic surgeries showed that insertion of LMA Proseal was successful in all patients. Insertion time was similar between both devices. There was no statistically significant differences in oxygen saturation or end tidal carbon dioxide between both devices before or during peritoneal insufflation. Median airway pressure at which oropharyngeal leak occurred with LMA Proseal was 35 (24-40) cm of H_2O. There was no case of inadequate ventilation, regurgitation or aspiration recorded. No significant difference in laryngopharyngeal morbidity was noted.

A study[31] of clinical and fiberoptic evaluation of the LMA Supreme in 100 adult female patients demonstrated that insertion of LMA Supreme was

possible in 94% of patients during first attempt and in 5% during the second attempt. Insertion of gastric tube was possible in all patients at the first attempt. The mean duration of insertion was 10.0 ± 4.7 seconds. Laryngeal fit, evaluated by fiberoptic view was rated as optimal in all patients. The mean cuff volume needed to achieve 60 cm of H_2O cuff pressure was 18.4 ± 3.8ml. The mean oropharyngeal leak pressure was 28.1 ± 3.8 cm of H_2O. Eight patients complained of a mild sore throat. No patient reported dysphagia or dysphonia.

A study[32] comparing LMA Proseal and LMA Supreme among 60 adult patients demonstrated that the first insertion attempts and time taken to provide an effective airway were similar for both the devices. OLPs were similar (LMA Proseal: 26.9 ± 6.6 Cm of H_2O; LMA Supreme: 26.1 ± 5.2 Cm of H_2O). ICP increased significantly in the LMA Proseal at the 30 and 60 min during anaesthesia (LMA Proseal: 80.1±12.8, 92.9±14.4 Cm of H_2O; LMA Supreme: 68.3±10.9, 73.7±15.6 Cm of H_2O). OGT placement was successful in all patients in the LMA Supreme, but failed in five patients in the LMA Proseal (p=0.02). Fiberoptically determined anatomic position was better with the LMA Proseal (p=0.03). Study suggested that LMA Supreme had leak pressures similar to the LMA Proseal, and this new airway device proved to be successful during both spontaneous and positive pressure ventilation.

In a randomized trial[33] comparing the size-2 LMA Supreme with the LMA ProSeal in 60 children undergoing surgery, there were no statistically significant differences between the LMA Supreme and LMA ProSeal in median (IQR [range]) insertion time (12 (10–15 [7–18]) s vs 12 (10–13 [8–25]) sec; p=0.90), airway leak pressures (19 (16–21 [12–30]) cmH_2O vs 18 (16–24 [10–

34]) cmH_2O; p=0.55), fibreoptic position of the airway or drain tube, ease of gastric access and complications. Both devices provided effective ventilation requiring minimal airway manipulation. The study reported that, LMA Supreme can be a useful alternative to the LMA ProSeal when single-use supraglottic devices with gastric access capabilities are required.

Chapter 3

Basic Sciences

BASIC SCIENCES

Anatomy

Oral cavity

The oral or mouth cavity is divided into an outer smaller portion, the vestibule and an inner larger part, the oral cavity proper.

Vestibule

The vestibule of the mouth is a narrow space bounded externally by the lips and cheeks, and internally by the teeth and gums.

Oral cavity proper

It is bounded anterolaterally by the teeth, the gums and the alveolar arches of the jaws. The roof is formed by the hard and soft palate. The floor is occupied by the tongue posteriorly, and presents the sublingual region anteriorly, below the tip of the tongue. Posteriorly, the cavity communicates with the pharynx through the oropharyngeal isthmus, which is bounded superiorly by the soft palate, inferiorly by the tongue, and on each side by the palatoglossal arches.

Hard palate

Hard palate is a partition between the nasal and oral cavities. Its anterior two thirds are formed by the palatine processes of the maxillae; and its posterior one third by the horizontal plates of the palatine bones.

It is covered by a thick mucosa bounded tightly to the underlying periosteum.

Soft palate

Soft palate is a movable, muscular fold suspended from the posterior border of the hard palate. It separates the nasopharynx from the oropharynx, and is often looked upon as traffic controller at the crossroads between the food and air passages.

The inferior border of the soft palate is free and bounds the pharyngeal isthmus. From its middle, there hangs a conical projection, called the uvula. From each side of the base of the uvula two curved folds of mucous membrane extend laterally and downwards; anterior palatoglossal arches and posterior palatopharyngeal arches.

Muscles of the soft palate:

1. Tensor palati
2. Levator palati
3. Musculus uvulae
4. Palatoglossus
5. Palatopharyngeus

Tongue

The tongue is a muscular organ situated in the floor of the mouth. It has an oral part that lies in the mouth, and a pharyngeal part that lies in the pharynx.

The oral and pharyngeal parts are separated by a V shaped sulcus, the sulcus terminalis.

The undersurface of the tongue is attached to the floor of the mouth by a fold of mucous membrane, the frenulum.

Muscles of the tongue

A middle fibrous septum divides the tongue into right and left halves. Each half has four intrinsic and four extrinsic muscles.

Intrinsic muscles

1. Superior longitudinal
2. Inferior longitudinal
3. Transverse
4. Vertical

Extrinsic muscles

1. Genioglossus
2. Hyoglossus
3. Styloglossus
4. Palatoglossus

Nerve supply

Vestibule

- Motor - Facial nerve.

- Sensory - Maxillary nerve via alveolar and labial branches.

Hard palate:

- Maxillary nerve via greater palatine and nasopalatine branches.

Soft palate

- Motor - Pharyngeal plexus and mandibular nerve.
- Sensory - Maxillary nerve via palatine branches and glosspharyngeal nerve.
- Taste - Facial nerve via greater petrosal nerve.

Tongue

- Motor - Hypoglossal nerve, pharyngeal plexus.
- Sensory - Mandibular nerve via lingual nerve and glossopharyngeal nerve.
- Taste - Facial nerve via chorda tympani and glossophayrngeal nerve.

Arterial supply

- Lingual, facial and maxillary branches of the external carotid artery.

Venous drainage

- Pterygoid, tonsillar and pharyngeal plexus of veins.

Lymphatic drainage

- Upper deep cervical and retropharyngeal lymph nodes.

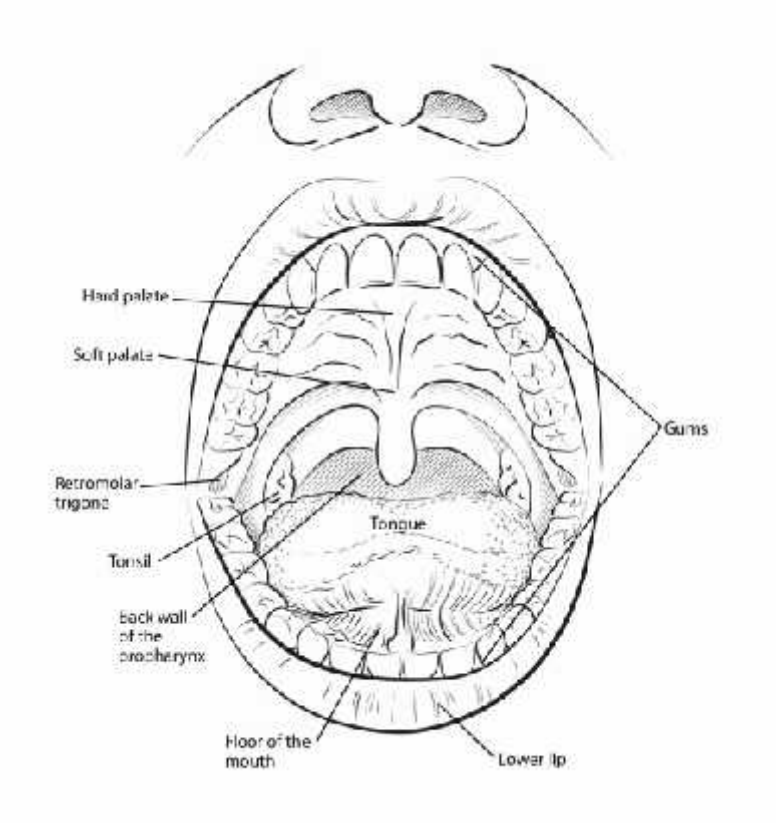


Figure 1. Anatomy of oral cavity

Pharynx

The pharynx is a 12-14 cm long musculo membranous tube shaped like an inverted cone. It extends from the cranial base to the lower border of the cricoid cartilage (the level of the sixth cervical vertebra), where it becomes continuous with the oesophagus.

Parts of the pharynx:

The cavity of the pharynx is divided into;

1. The nasal part, nasopharynx.
2. The oral part, oropharynx.
3. The laryngeal part, laryngopharynx.

Nasopharynx

The nasopharynx lies above the soft palate and behind the posterior nares, which allow free respiratory passage between the nasal cavities and the nasopharynx. On the either side, each lateral wall receives the opening of eustachian tube.

Oropharynx

The oropharynx extends from below the soft palate to the upper border of the epiglottis. It opens into the mouth through the oropharyngeal isthmus, demarcated by the palatoglossal arch and its lateral wall consists of the palato pharyngeal arch and palatine tonsil.

Laryngopharynx

The laryngopharynx is situated behind the entire length of the larynx and extends from the superior border of the epiglottis, where it is delineated from the oropharynx by the lateral glossoepiglottic folds, to the inferior border of the cricoids cartilage, where it becomes continues with the oesophagus.

A small piriform fossa lies on each side of the laryngeal inlet, bounded medially by the aryepiglottic folds and laterally by the thyroid cartilage and thyrohyoid membrane.

Muscles of the pharynx

Beneath the mucosa of pharynx is a fibromuscular sheath, fibrous layer being dense superiorly where muscle is absent. The three constrictors: superior, middle and inferior are so arranged that the inferior overlaps middle which in turn overlaps the superior. The longitudinal muscle coat of pharynx consists of stylopharyngeus, salpingopharyngeus and palatopharyngeus.

Nerve supply

Motor: Glossopharyngeal nerve, cranial part of accessory nerve via pharyngeal plexus.

Sensory: General sensation is carried by the pharyngeal branches of glossopharyngeal nerve and palatine branches of maxillary nerve. The special sensation of taste is carried in the lesser petrosal nerve to the pterygopalatine ganglion, which also supplies secretomotor innervations to the pharyngeal mucosa.

Arterial supply

Ascending pharyngeal, superior thyroid, lingual, facial and maxillary arteries (branches of external carotid artery).

Venous drainage

Pterygoid and pharyngeal plexus of veins.

Lymphatic drainage

Retropharyngeal and upper deep cervical lymph nodes

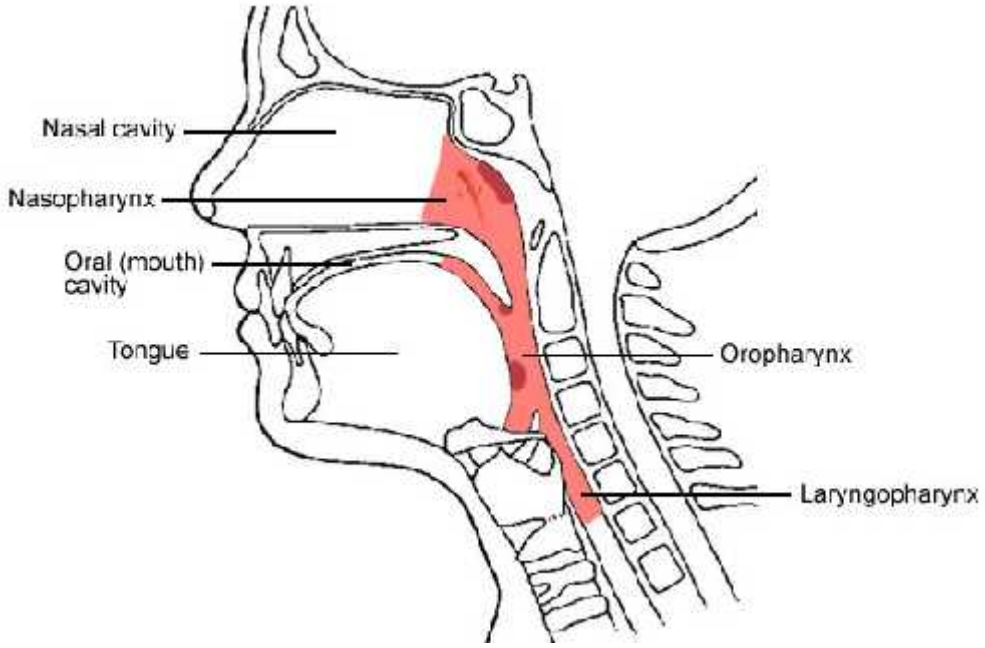


Figure 2. Anatomy of pharynx

Larynx

The larynx is an air passage, a sphincter and an organ of phonation, and extends from the tongue to the trachea. Above it opens into the laryngopharynx and forms its anterior wall; below, it continues into trachea. It is mobile on deglutition. At rest, the larynx lies opposite the third to sixth cervical vertebrae in adult males; it is somewhat higher in children and adult females.

The skeletal framework of the larynx is formed by a series of cartilages interconnected by ligaments and fibrous membranes, and moved by a number of muscles.

Cartilages of larynx

Unpaired cartilages

1. Thyroid
2. Cricoid
3. Epiglottis

Paired cartilages

1. Arytenoids
2. Corniculate
3. Cuneiform

Laryngeal joints (Synovial joints)

1. Cricothyroid joint
2. Cricoarytenoid joint

Laryngeal ligaments and membranes

Extrinsic

1. Thyrohyoid membrane
2. Hyo- and thyroepiglottic ligaments
3. Cricotracheal ligament

Intrinsic

1. Quadrate membrane (Fibroelastic membrane of the larynx)
2. Cricothyroid membrane and Conus elasticus

Cavity of larynx

Two folds of mucous membrane divide the cavity of the larynx into three parts

1. Vestibule of the larynx
2. Ventricle of the larynx
3. Infraglottic part

Intrinsic muscles of larynx

1. Oblique arytenoid and Aryepiglotticus – Sphincter action at the laryngeal inlet
2. Transverse(Inter) arytenoids – adductor of vocal cords.
3. Posterior cricoarytenoid – opens the glottis.
4. Lateral cricoarytenoid – adducts the vocal cords.
5. Cricothyroid – lengthens and affects tension in the vocal cords.
6. Thyroarytenoid and Vocalis – relaxes the vocal cords.
7. Thyroepiglotticus – opens the inlet of the larynx

Extrinsic muscles of larynx

Include the intrahyoid strap muscles, thyrohyoid, sternohyoid and the inferior constrictor of the pharynx.

Nerve supply

Motor: Vagus nerve via recurrent laryngeal nerve to all intrinsic muscles except cricothyroid (supplied by external laryngeal nerve).

Sensory: Mucosal membrane is supplied by internal laryngeal nerve upto the level of vocal cords and recurrent laryngeal nerve below the level of the vocal cords.

Taste fibres from the epiglottis are carried in the vagus nerve.

Arterial supply

1. Superior laryngeal artery and cricothyroid artery (branches of superior thyroid artery)
2. Inferior laryngeal artery (branch of inferior thyroid artery)

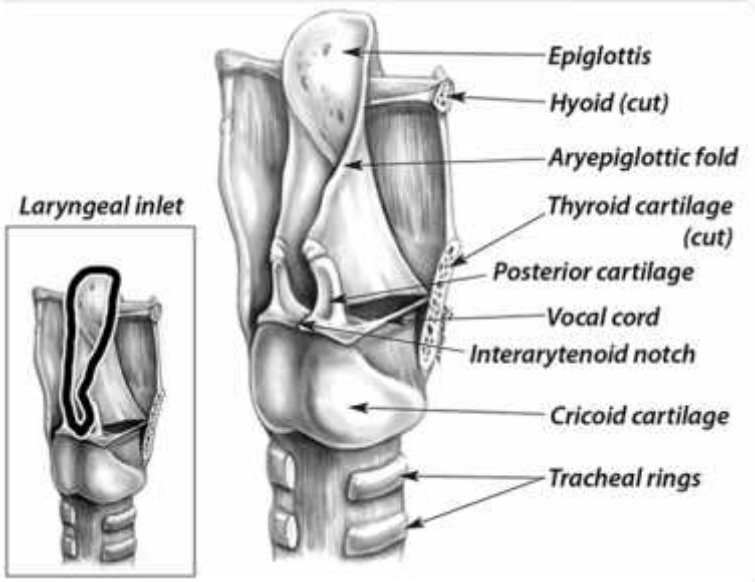


Figure 3. Anatomy of larynx

Venous drainage

Via superior and inferior laryngeal veins to superior and inferior thyroid veins respectively.

Lymphatic drainage

The lymph vessels draining the supra glottis part of the larynx end in the upper deep cervical lumph nodes and below the vocal cords, lymph vessels reach pre and para tracheal lymph nodes and join the lower deep cervical lymph nodes.

LMA Proseal

The LMA Proseal was introduced by Archie Brain in 2000, as a modification of the classic LMA whose design was specifically intended for the provision of positive pressure ventilation in the anaesthetized patient. LMA proseal is an advanced form of LMA airway that may be used for the same indications as the LMA classic, but also has features that provide more patient management options and may expand the procedures where the device can be used.

Characteristics of the LMA Proseal design[26]

- A softer cuff material, deeper mask bowl and special cuff shape allows a higher seal than the LMA classic for a given intra cuff pressure with the adult sizes.

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

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

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

- A strap for the LMA Proseal introducer also accommodates the index finger or thumb for manual insertion.

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

LMA Proseal selection guidelines

LMA size	Patient weight	Maximum inflation volume	Maximum size orogastric tube
11/2	5-10 kgs	7ml	10Fr
2	10-20kgs	10ml	10Fr
21/2	20-30kgs	14ml	14Fr
3	30-50kgs	20ml	16Fr
4	50-70kgs	30ml	16Fr
5	70-100kgs	40ml	18Fr

Insertion methods

LMA Proseal may be inserted using anyone of the three following techniques.

1. Index finger insertion technique.
2. Introducer technique.
3. Thumb insertion technique

Index finger insertion technique

Hold the LMA device like a pen, with the index finger tip placed in the introducer strap. The LMA 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.

Introducer technique

The distal end of the silicon coated metal introducer is placed in the introducer strap and the proximal end in the notch between airway tube and drain tube. Under direct vision, 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.

Thumb insertion technique

This technique is useful if it is difficult to get access to the patient from behind. The LMA airway is held with the thumb in the position occupied by the index finger into the retaining strap. Insertion is similar to that using the index finger. As the thumb nears the mouth, the fingers are stretched forward over the patient’s face. The thumb is advanced to its fullest extent. The pushing action of the thumb against the hard palate also serves to press the head into extension.

Alternative technique for insertion of LMA Proseal

Though no technique has reported significant difference in insertion success between digital and introducer techniques, an alternative method involves placing a gum elastic bougie into the oesophagus using a laryngoscope and rail-roading the LMA drain tube over this. This technique prevents folding of the mask tip and increases correct placement of the LMA Proseal.

Steps to facilitate correct mask position

- After insertion, inflate the cuff to no more than 60 cm H_2O intra cuff pressure.
- Connect to anaesthesia 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.

The ability to provide safe and effective mechanical ventilation depends on the ability of the LMA Proseal to act as an “artificial epiglottis” through separation of the gastrointestinal and respiratory tracts. This depends on:

1. The ability to create an effective seal.

2. Proper positioning of the device.
3. The ability to properly vent air/regurgitant out the drain tube rather than into the respiratory tract.

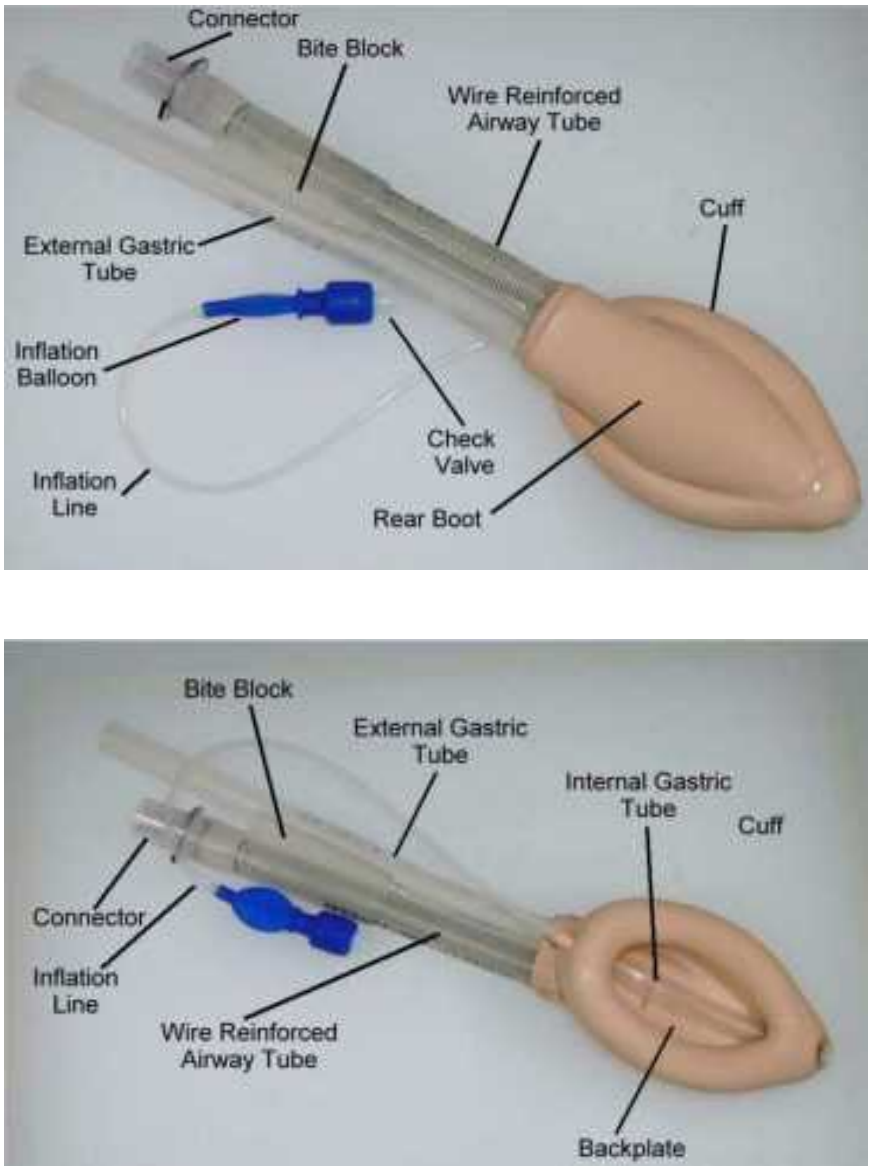


Figure 4. LMA Proseal

LMA Supreme

LMA Supreme is an innovative supraglottic airway that combines the best features of all previous LMA airways in one device. It is intended for use in achieving and maintaining control of the airway during routine anaesthetic procedures and in emergency procedures in which tracheal intubation has failed or in which attendant personnel has limited intubation skills. LMA Supreme may also be used to establish an immediate clear airway during cardiopulmonary resuscitation and also indicated as a 'rescue airway device' in known or unexpected difficult airway situations.

Characteristics of the LMA Supreme design[4]

- It is supplied sterile and ready for use. It is designed as a single use device, unlike the reusable LMA Proseal.

- The anatomically shaped airway tube is elliptical in cross section and is more rigid than the airway tube of the LMA Proseal. This configuration permits easy and reliable insertion without the need for digital or introducer tool technique.

- The inflatable cuff is designed to conform to the contours of the hypopharynx, with its airway lumen facing the laryngeal opening. The new cuff design offers higher seal pressures around the laryngeal opening than the cuff of the LMA Classic during positive pressure ventilation.

- A drain tube that permits venting of the stomach contents and blind insertion of standard gastric tubes. It may be used as a monitor of correct

positioning of the LMA following insertion and then for continuous monitoring of mask displacement during use.

- A built in bite block reduces the potential for airway obstruction or tube damage.

- The design of the cuff bowl includes patented 'fins' and positioning of the drain tube in the bowl prevents epiglottic occlusion of the airway. Aperture bars are therefore not required.

LMA Supreme selection guidelines:

LMA size	Patient size	Maximum inflation Volume	Maximum size orogastric tube
1	Neonates/Infants upto 5kgs	5ml	6F
2	Infants 10-20kgs	12ml	10F
3	Children 30-50kgs	30ml	14F
4	Adults 50-70kgs	45ml	14F
5	Adults 70-100kgs	45ml	14F

Insertion technique

During insertion, stand behind the patient's head, hold the LMA Supreme by the connector end with the hollow side facing away and distal end pointimg downwards. Under direct vision, position the mask tip so that it is flat against the hard palate just inside the mouth immediately posterior to the upper incisiors. Slide the mask tip briefly back and forth on the palate to distribute lubricant

while pressing it against the palate to prevent accidental folding of the tip. Keeping the airway tube close to the chin, rotate the device inwards in one smooth circular movement and advance the airway into the hypopharynx until a definite resistance is felt.

Positive pressure ventilation (PPV)

- Tidal volumes should not exceed 8ml/kg and peak inspiratory pressure should be kept within the maximum airway seal pressure.

- If leak occurs during PPV, this may be due to;

    - Light anaesthesia causing a degree of glottic closure
    - Severe reduction in lung compliance related to the procedure or patient factors, or
    - Displacement or migration of the cuff by head turning or traction, in an inadequately fixed mask.

- Should air 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 tape is still in place and readjust as necessary while pressing the tube downward to relocate the mask tip against the upper oesophageal sphincter.

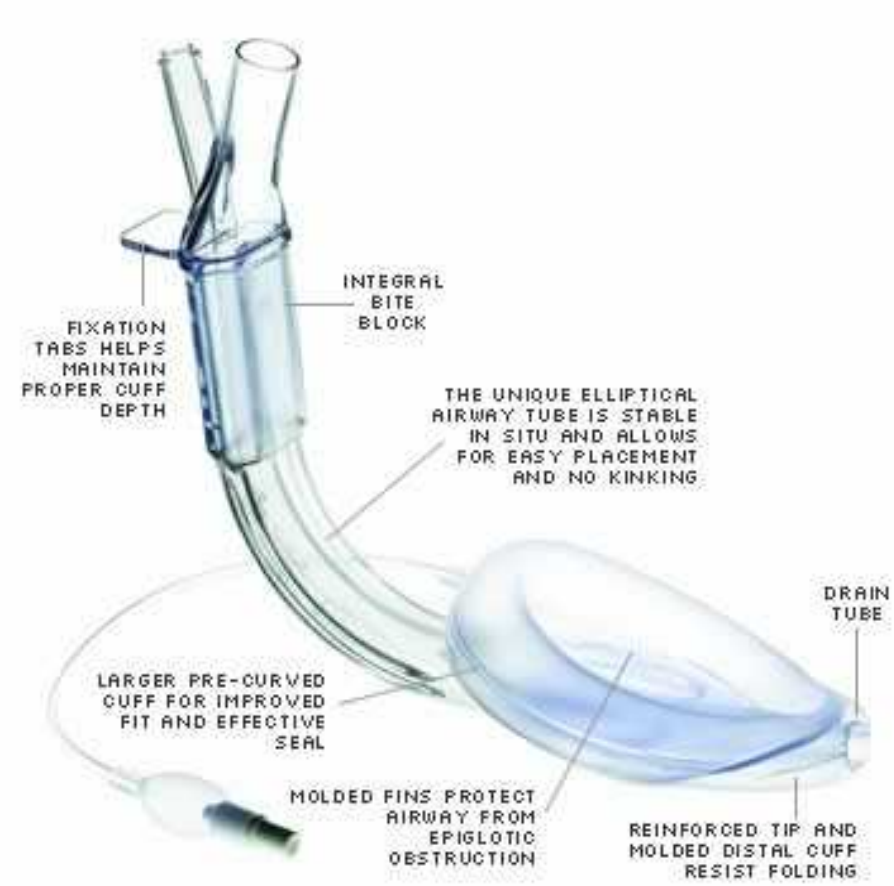


Figure 5. LMA Supreme

Chapter 4

Methodology

METHODOLOGY

This study was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2011 to December 2011.

Study design

The study design was a one year randomized clinical trial.

Study Period

One year from January 2011 to December 2011.

Place

The present study was conducted at Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical College, Belgaum a teaching hospital attached to Jawaharlal Nehru Medical College, Belgaum.

Source of Data

Adult patients undergoing routine elective surgeries under general anaesthesia at KLES Dr. Prabhakar Kore Hospitals and Medical Research Centre, Belgaum.

Sample Size

A total of 60 patients divided into two groups.

Sampling procedure

Sample size was calculated using the formula as below;

$$n = \frac{(Z\alpha + Z\beta)^2 \ 2s^2}{(x_1 - x_2)^2}$$

Where,

Level of significance was taken as 5%

Power of the test was taken as 80%

Hence

$Z\alpha = 1.96$

$Z\beta = 0.84$

With these values, the minimum sample size obtained was 30 in one group. Hence a total of 60 patients equally distributed into two groups namely group LMA Proseal and group LMA Supreme.

Selection criteria

Inclusion

- Patients undergoing elective surgeries under general anaesthesia.
- Patients with age between 18 to 50 years.
- Patients with ASA status I or II.

Exclusion

- Known or predicted difficult airway.

- Any pathology of the neck, upper respiratory tract or upper gastrointestinal tract.
- Body mass index >35 kg/m^2.
- History of obstructive sleep apnea.
- Trendenlenburg's position.
- History of lung diseases.
- Potentially full stomach patients (trauma, pregnancy, morbid obesity, hiatus hernia).

Ethical clearance

Prior to the commencement, the study was approved by the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum.

Informed Consent

All the patients fulfilling selection criteria were explained about the nature of the study and intervention and a written informed consent was obtained from all the patients before enrollment (Annexure I).

Method of collection of data

After the enrollment, demographic data such as age and sex and history was recorded. General physical examination, systemic examination was carried out and the data was recorded on a predesigned and pretested proforma (Annexure II).

Investigations

All the patients were investigated preoperatively and following investigations were done.

- Haemoglobin estimation.
- Routine urine examination.
- Random blood sugar.
- Blood urea and serum creatinine.
- Chest X-ray.
- ECG and echocardiogram if necessary.

The findings of these investigations were recorded on a predesigned and pretested proforma (Annexure II).

Randomization

Patients were randomly allocated into one of the two groups by 'opening a sealed envelope method' that is;

- Group LMA Proseal (n=30)
- Group LMA Supreme (n=30)

Procedure

In the operating room, a standard anaesthesia protocol was followed and routine monitoring was applied with electrocardiograph, non-invasive blood pressure, pulse oximetry (SPO_2) and end tidal CO_2 monitoring. The head and

neck of the patient were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height.

The airway device to be used was prepared for insertion with the cuff completely deflated and shaped, and its dorsal surface lubricated with a clear, water based gel.

An IV access was established. All the patients were preoxygenated with 100% oxygen for three minutes and were premedicated with inj. Glycopyrrolate 0.005mg/kg (IV), inj. Midazolam 0.05mg/kg (IV) and inj. Fentanyl 2 µg/kg (IV).

Anaesthesia was induced with inj. Propofol 2 mg/kg (IV) and neuromuscular blockade was achieved with inj. Vecuronium 0.1 mg/kg (IV). Patient's lungs were ventilated with using a face mask for three to five minutes and then, the airway devices (all size four) were inserted in strict accordance with the manufacturer's recommendations.

Insertion technique

LMA Proseal: The insertion technique for LMA Proseal was identical to the recommended technique for the LMA Classic and included neck flexion, head extension, full deflation of the cuff and the use of the index finger to press the LMA Proseal into, and advance it around the palatopharyngeal curve. A slight lateral approach was used if resistance was felt in the oropharynx.

LMA Supreme: The LMA Supreme was inserted with the cuff deflated, using a single handed rotational technique.

One attempt (using Guided technique) was allowed before insertion considered a failure. For the guided technique, the drain tube of the LMA Proseal/Supreme was primed with a well lubricated gum elastic bougie with its straight end first, leaving the 5 cm bent portion protruding from the proximal end and the maximum length protruding from the distal end. The guided technique involved the following steps.

- Under gentle laryngoscopic guidance, the distal portion of the guide was placed 5 to 10 cm into the oesophagus while the assistant held the LMA and proximal portion.
- The laryngoscope was removed.
- The LMA was inserted using the digital insertion technique while the assistant stabilised the proximal end of the guide so it did not penetrate further into the oesophagus.
- The guide was removed while the LMA was held in position.

All steps were performed with the cuff fully deflated and using a midline approach. Fixation was done in accordance with the manufacturer's instructions.

Failed insertion was defined by any of the following criteria.

- Failed passage into the pharynx.
- Malposition (air leaks).
- Ineffective ventilation (maximum expired tidal volume <6 ml/kg or/and end tidal CO_2 > 60 mm of Hg).

If the device could not achieve a satisfactory airway as defined above, the patient's trachea was intubated conventionally.

The intra cuff pressure was set at 60 cm H_2O or to obtain an effective airway seal for positive pressure ventilation and patient's lungs were ventilated at an inspired tidal volume of 8 ml/kg, at an respiratory rate of 12 breaths/minute and an inspiratory : expiratory ratio of 1:2. Anaesthesia was maintained with 1:1 oxygen-nitrous oxide mixture, isoflurane and inj. Vecuronium 0.025 mg kg^{-1}(IV) boluses.

At the end of procedure, adequate reversal was done with inj. Glycopyrrolate 0.01 mg/kg (IV) and inj. Neostigmine 0.05 mg/kg (IV). After the return of protective airway reflexes, the airway device was removed.

Study variables

- The time between picking up the prepared LMA Proseal or Supreme and successful placement was recorded.
- Number of insertions attempts and overall insertion success were noted.
- The aetiology of failed insertion was documented.
- Oropharyngeal leak pressure and intra cuff pressure were determined at 0 to 40 ml cuff volume in 10 ml increments. Oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 litre/min, and noting the airway pressure in the anaesthetic breathing system(maximum allowed is 40 cm H_2O) at which

audible gas leak occured into the mouth. The intra cuff pressure was measured using cuff pressure gauge.

- The presence/absence of oropharyngeal air leaks (detected by listening over the mouth), gastric air leaks (detected by listening with a stethoscope over the epigastrium), drain tube air leaks (detected by placing lubricant over the proximal end of the drain tube) or an end tidal CO_2 >60 mm of Hg were noted.

- Any episodes of hypoxaemia (SpO_2 <90%) or other adverse events were documented.

- After removal of airway device, it was examined for the presence of visible or occult blood.

Data about insertion time, effective ventilation, hypoxaemic episodes and blood staining were collected by an observer blinded to the airway device used.

Statistical analysis

Data obtained was coded and entered into Microsoft excel spreadsheet. The categorical data was expressed in terms of rates, ratios and percentage and continuous data was expressed as mean ± standard deviation (SD). Student's unpaired 't' test was used to compare quantitative variables in the both groups and the change in the pressures were compared using Student's paired 't' test for each group independently. The categorical data were compared using Chi square test. A probability value (p value) of less than or equal to 0.05 was considered as statistically significant.

Chapter 5

Results

RESULTS

The present study was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2011 to December 2011.

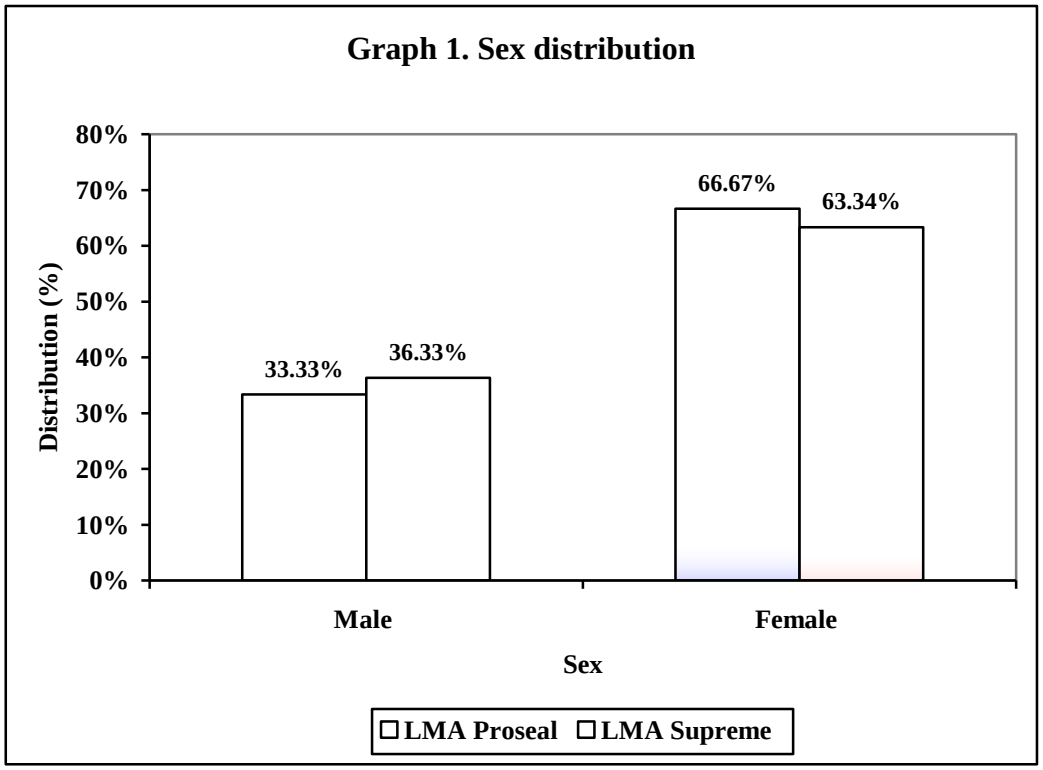
A total of 60 anaesthetized adult patients, undergoing positive pressure ventilation were studied. Patients were randomly allocated into one of the two groups by 'opening a sealed envelope method'.

- Group LMA Proseal (n=30)
- Group LMA Supreme (n=30)

Data obtained was coded and entered into Microsoft excel spreadsheet. The data was analysed and results obtained were tabulated as below.

Table 1. Sex Distribution

Sex	LMA Proseal (n=30)		LMA Supreme (n=30)	
	Number	**Percent**	**Number**	**Percent**
Male	10	33.33	11	36.33
Female	20	66.67	19	63.34
Total	**30**	**100.00**	**30**	**100.00**

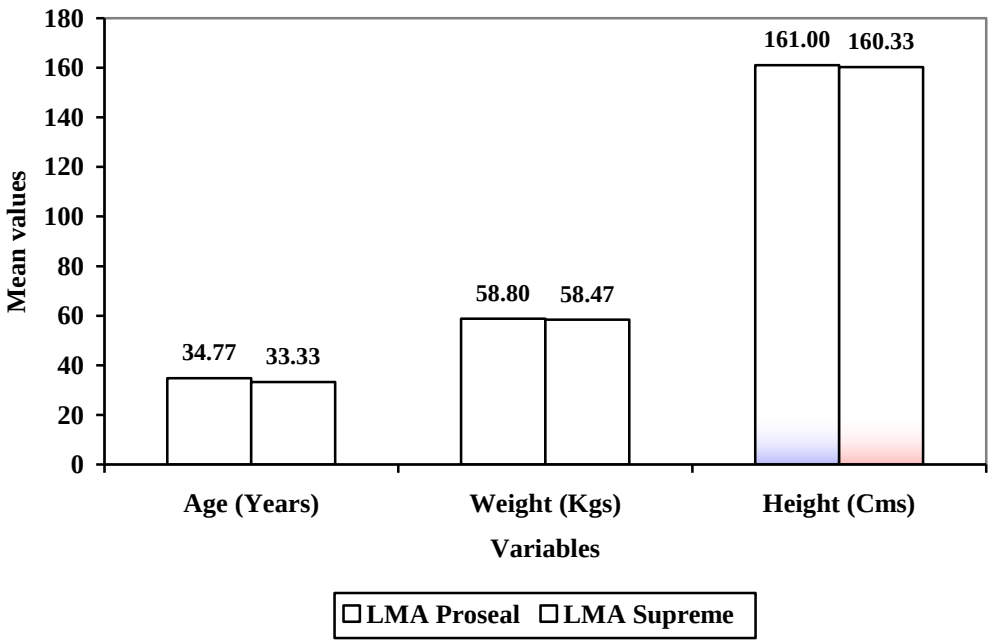


In this study females outnumbered males (LMA Proseal 66.67% vs LMA Supreme 63.64%) with male to female ratio of 1:2 in LMA Proseal and 1:1.72 in LMA Supreme group.

Table 2. Mean age, weight and height

Parameters	LMA Proseal (n=30)		LMA Supreme (n=30)		p' value
	Mean	SD	Mean	SD	
Age (Years)	34.77	7.44	33.33	7.30	0.454
Weight (Kgs)	58.80	4.77	58.47	4.56	0.572
Height (Cms)	161.00	4.74	160.33	4.36	0.783

Graph 2. Mean age, weight and height



The mean age in group LMA proseal was 34.77 ± 7.44 and in group LMA supreme 33.33 ± 7.30 years. However, no statistically significant difference was observed between the two groups suggesting both the groups were comparable with respect to age.

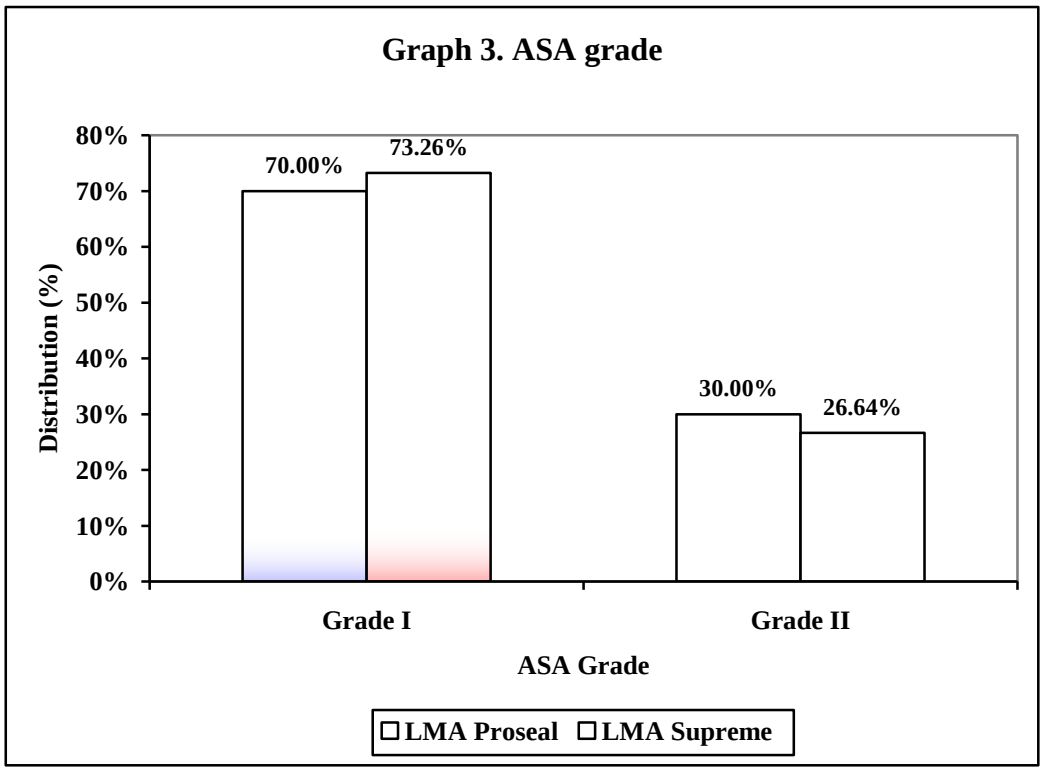
The mean weight in group LMA proseal was 58.80 ± 4.77 Kgs and in group LMA supreme 58.47 ± 4.56 kgs. No statistically significant difference was observed between the two groups suggesting both the groups were comparable with respect to weight.

Similarly the mean height in group LMA proseal was 161.00 ± 4.71 Cms and in group LMA supreme 160.33 ± 4.36 Cms. There was no statistically significant difference between the two groups suggesting both the groups were comparable with respect to height.

Table 3. ASA Grade

ASA Grade	LMA Proseal (n=30)		LMA Supreme (n=30)	
	Number	**Percent**	**Number**	**Percent**
Grade I	21	70.00	22	73.26
Grade II	9	30.00	8	26.64
Total	**30**	**100.00**	**30**	**100.00**

p=0.994

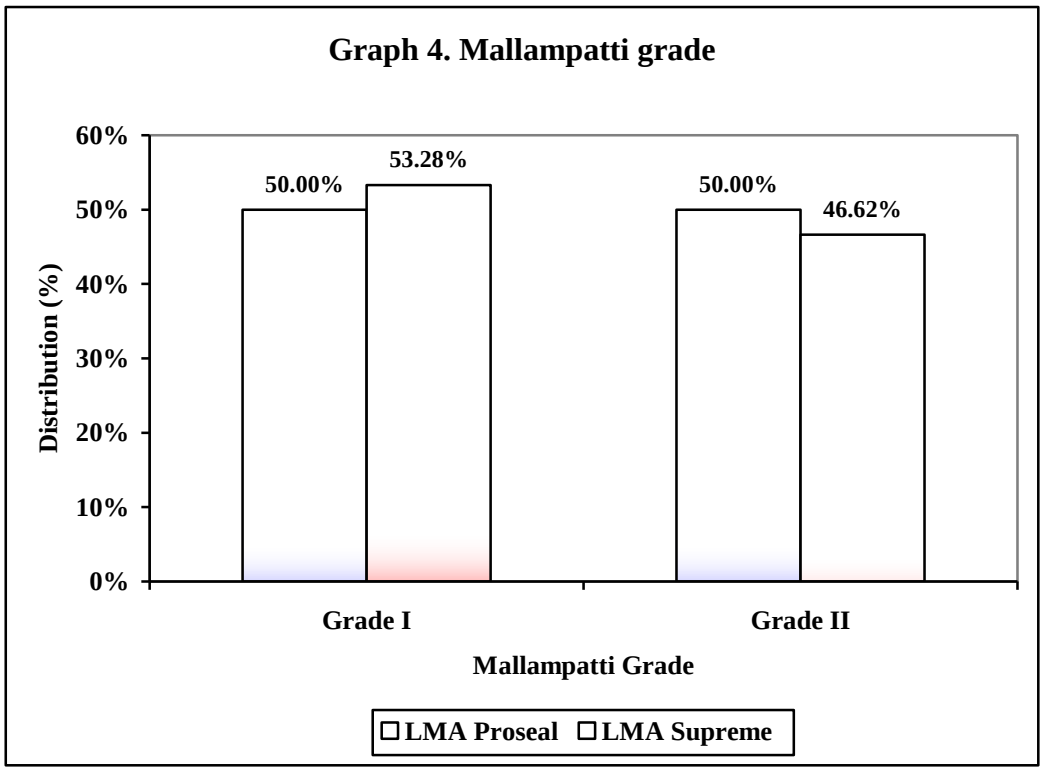


In this study among the patients in LMA proseal group 70% were scheduled for surgery with ASA grade I compared to 73.26% in LMA supreme group.

Table 4. Mallampatti grade

Grade	LMA Proseal (n=30)		LMA Supreme (n=30)	
	Number	**Percent**	**Number**	**Percent**
Grade I	15	50	16	53.28
Grade II	15	50	14	46.62
Total	**30**	**100.00**	**30**	**100.00**

p=0.796

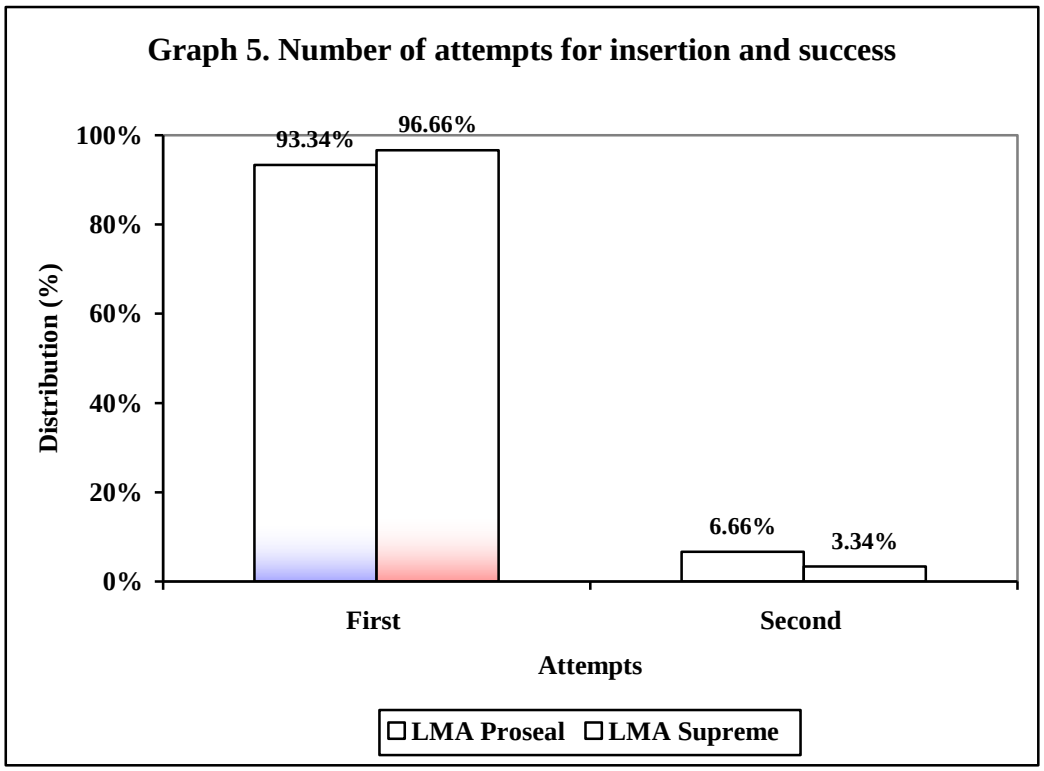


In the present study 50% of patients in LMA Proseal group had Mallampatti grade I in comparison to 53.28% of patients in LMA Supreme group.

Table 5. Number of attempts for insertion and success

Attempts	LMA Proseal (n=30)		LMA Supreme (n=30)	
	Number	**Percent**	**Number**	**Percent**
First	28	93.34	29	96.66
Second	2	6.66	1	3.34
Total	**30**	**100.00**	**30**	**100.00**

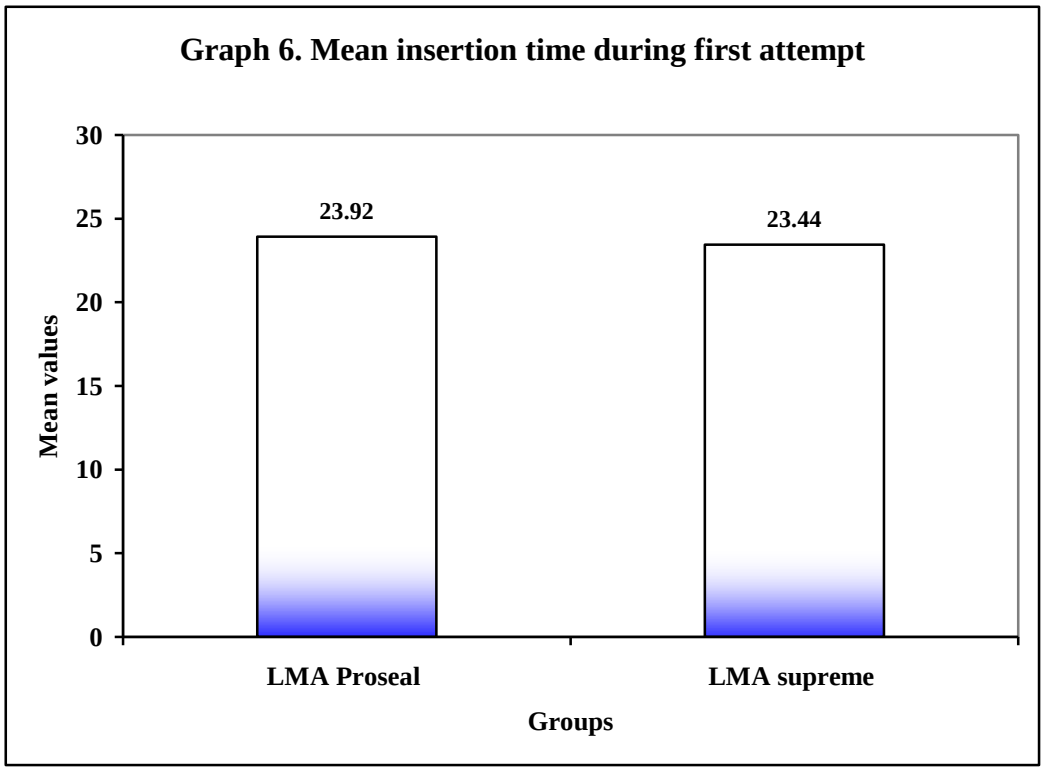
p=0.150



First attempt and overall insertion success for LMA Proseal were 93.34% and 100%, and for LMA Supreme 96.66% and 100% respectively However this difference was not statistically significant.

Table 6. Mean insertion time during first attempt

Insertion time	LMA Proseal (n=30)		LMA Supreme (n=30)		p' value
	Mean	SD	Mean	SD	
Mean	23.92	1.44	23.44	1.72	0.246

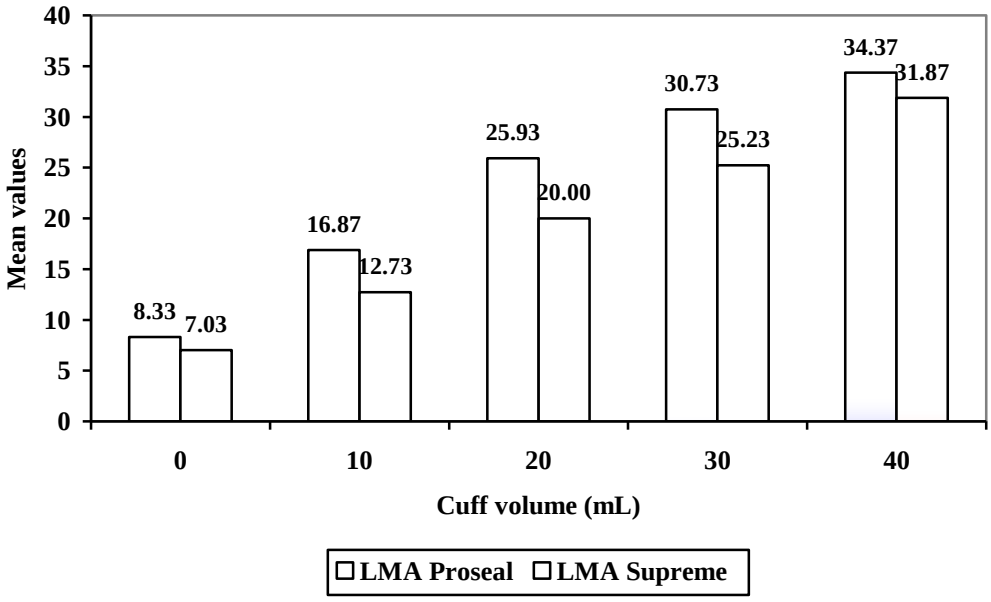


In the present study the mean insertion time was 23.92 ± 1.44 seconds in LMA Proseal group and 23.44 ± 1.74 seconds in LMA Supreme group. This difference was not statistically significant.

Table 7. Oropharyngeal leak pressure for LMA Proseal and Supreme with increasing cuff volume

Cuff volume (mL)	LMA Proseal (n=30)		LMA Supreme (n=30)		p' value
	Mean	SD	Mean	SD	
0	8.33	0.71	7.03	0.85	<0.0001
10	16.87	1.22	12.73	1.89	<0.0001
20	25.93	1.28	20.00	1.84	<0.0001
30	30.73	1.05	25.23	1.07	<0.0001
40	34.37	0.81	31.87	1.28	<0.0001

Graph 7. Oropharyngeal leak pressure for LMA Proseal and Supreme with increasing cuff volume

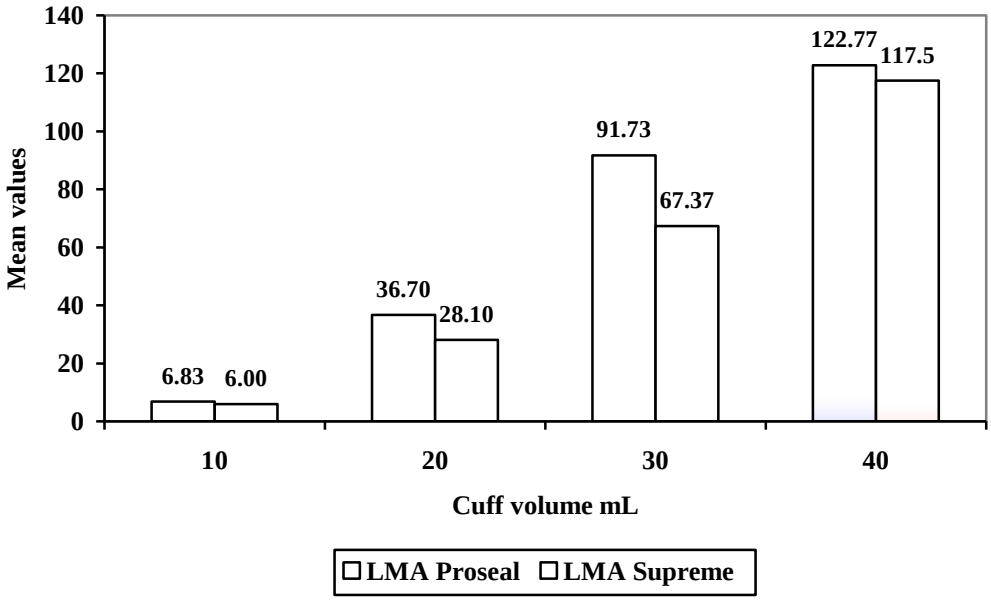


Oropharyngeal leak pressure for LMA Proseal was significantly higher at all the cuff volumes in comparison to LMA Supreme.

Table 8. Intra cuff pressure for LMA Proseal and Supreme with increasing cuff volume

Cuff volume (mL)	LMA Proseal (n=30)		LMA Supreme (n=30)		p' value
	Mean	SD	Mean	SD	
0	-	-	-	-	-
10	6.83	1.09	6.00	0.79	0.0012
20	36.70	2.20	28.10	3.22	<0.0001
30	91.73	3.79	67.37	5.97	<0.0001
40	122.77	5.46	117.50	5.61	0.0005

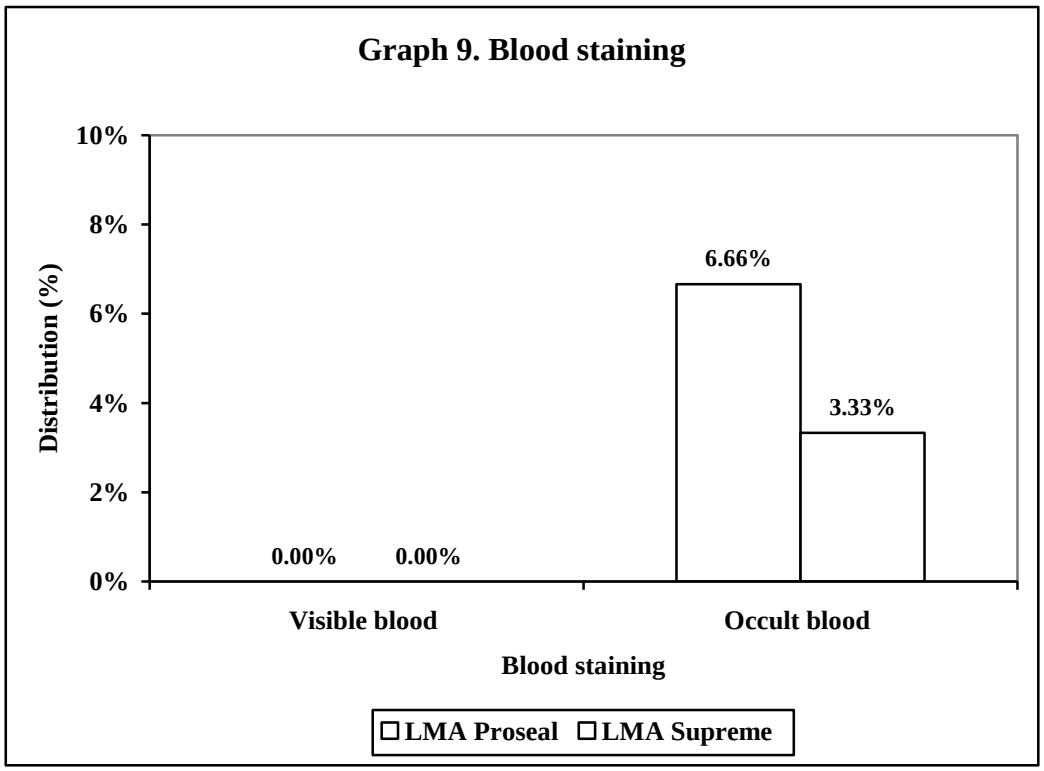
Graph 8. Intra cuff pressure for LMA Proseal and Supreme with increasing cuff volume



The intra cuff pressure for LMA Proseal was significantly higher at all cuff volumes in comparison to LMA Supreme.

Table 9. Blood staining

Blood staining	LMA Proseal (n=30)		LMA Supreme (n=30)	
	Number	**Percent**	**Number**	**Percent**
Visible blood	0	0.00	0	0.00
Occult blood	2	6.66	1	3.33
Total	**0**	**0.00**	**0**	**0.00**



The blood staining (occult blood) was noted in 6.66% of patients in LMA Proseal group compared to 3.33% of patients in LMA Supreme group.

Chapter 6

Discussion

DISCUSSION

The LMA is a novel device that fills the gap in airway management between tracheal intubation and use of the facemask. The LMA is inserted blindly into the pharynx, forming a low pressure seal around the laryngeal inlet and permitting gentle positive pressure ventilation. It allows the administration of inhaled anaesthetics through a minimally stimulating airway.[2]

LMA Proseal is a reusable supraglottic device that allows easy insertion, higher glottic seal pressures and permits the gastric drainage separating respiratory tract from alimentary tract.

LMA Supreme is a new single use laryngeal mask airway with gastric access providing an easy, reliable airway and good airway seal.

This study was undertaken to compare the clinical efficacy of LMA Proseal and LMA Supreme for easy of insertion and airway seal pressures in anaesthetized adult patients undergoing positive pressure ventilation.

A total of 60 patients belonging to ASA status I or II patients between 18-50 years of age who presented for elective surgery under general anaesthesia were enrolled in this study.

In this study females outnumbered males (LMA Proseal 66.67% vs LMA Supreme 63.64%) with male to female ratio of 1:2 in LMA Proseal and 1:1.72 in LMA Supreme group. The mean age in group LMA proseal was 34.77 ± 7.44 and in group LMA supreme 33.33 ± 7.30 years. The mean weight in group LMA proseal was 58.80 ± 4.77 Kgs and in group LMA supreme 58.47 ± 4.56 kgs.

Similarly the mean height in group LMA proseal was 161.00 ± 4.71 Cms and in group LMA supreme 160.33 ± 4.36 Cms suggesting sex, age, weight and height were comparable between both groups.

In the present study 70% of patients in LMA Supreme group were scheduled for surgery with ASA grade I compared to 73.26% of patients in LMA supreme group and 50% of patients in LMA Proseal group had Mallampatti grade I in comparison to 53.28% of patients in LMA Supreme group.

The laryngeal mask airway has a role in the management of the difficult airway both as a substitute airway and as an aid to intubation. The LMA is useful because it can generally be inserted rapidly and accurately with a single attempt, is associated with a low incidence of tissue trauma and is acceptable to patients requiring an awake intubation.[6]

In this study, first attempt and overall success of insertion were similar (LMA Proseal 93.33% and 100%; LMA Supreme 96.66% and 100%). Guided insertion was always successful following failed digital insertion. There was no difference in the mean duration of insertion with the LMA Proseal in comparison to LMA Supreme (23.92 vs 23.44 seconds).

In one study on 99 non-paralyzed adult patients, the safety and efficacy of LMA Supreme were compared with LMA Proseal. The success rate of the first attempt insertion was higher for the LMA Supreme than for the LMA Proseal (98% and 88%, respectively). There was no difference in the median time taken for insertion with the LMA Supreme versus the LMA Proseal (26 and 30 seconds, respectively). There were no complications of aspiration or nerve

injuries. This study concluded that LMA Supreme, a safe, efficacious and easy to use disposable device in elective ambulatory surgeries.[31] Anatomically shaped fixed curve of LMA Supreme facilitates rapid and easy insertion. Newly designed larger cuff for improved anatomical fit conforms rather than deforms the hypopharynx.

Oropharyngeal leak pressure values are commonly performed with the LMA to indicate the degree of airway protection, the feasibility for using positive pressure ventilation, and the likelihood of successful supraglottic airway placement.[34]

In the present study, the mean oropharyngeal leak pressure was significantly higher in the LMA Proseal in comparison to LMA Supreme (23.24 vs 19.37 cm of H_2O) suggesting that the LMA Proseal is a more effective ventilator device. The improved seal is probably unrelated to the higher intra cuff pressure as oropharyngeal leak pressure was 4 cm H_2O higher when the cuff was inflated with 10ml of air and the intra cuff pressures were identical. The oropharyngeal leak pressures were similar to previous studies.[15,35]

In another study on 70 female patients undergoing laparoscopic gynaecological procedures, the oropharyngeal leak pressures were compared between LMA Proseal and LMA Supreme. The mean oropharyngeal leak pressure in the LMA Supreme was significantly lower than in the LMA Proseal (27.9 vs 31.7 cm H_2O). This was consistent with a lower maximum tidal volume achieved with the LMA Supreme (481 ± 76 vs 515 ± 63 ml). This study concluded that there was no difference in the ability of both devices to provide

adequate ventilation and oxygenation during anaesthesia.[36] The LMA Proseal has been designed so that the larger, wedge shaped cuff would plug gaps in the proximal pharynx and the flat dorsal cuff would push the ventral cuff more firmly into the periglottic tissues. The wedge shaped proximal cuff is the more important new design feature with respect to improved seal. This latter concept was supported by the fact that OLP was higher at zero cuff volume when the dorsal cuff was deflated.[37]

Raised intra cuff pressures in LMA are associated with increased incidence of pharyngolaryngeal morbidity such as sore throat. Excessive cuff volumes and pressures have also been found to produce a sub optimal seal and potential LMA malfunction. Cuff under deflation, on the other hand can produce an inadequate seal making PPV and airway protection ineffective. Although cuff pressure monitoring is recommended by the manufacturers, little evidence exists for this in clinical practice.[6]

In the present study, the intra cuff pressures were significantly higher in LMA Proseal in comparison to LMA Supreme at all cuff volumes of inflation range.

In a study using the similar methodology, the intra cuff pressures were compared between LMA Proseal and LMA Supreme at different cuff volumes of inflation. The intra cuff pressure was 16-35 cm H_2O higher for the LMA Proseal when the cuff volume was 20 to 40 mL. There was an increase in oropharyngeal leak pressure with increasing cuff volume from 10 to 30ml for both devices, but no change from 0 to 10 mL and 30 to 40 mL. The higher intra cuff pressures for

the LMA Proseal are probably related to the properties of the cuff rather than increased mucosal pressure: the LMA Proseal is made from silicone and the LMA Supreme is constructed from polyvinyl chloride, which has lower elasticity. It has been shown that mucosal pressures are lower than pharyngeal perfusion pressure over the inflation range for the LMA Proseal.[38]

A preliminary study on 30 female patients describing safety and scope of the LMA Proseal for positive pressure ventilation showed that no patients were judged difficult for insertion of device. At an intra cuff pressure of 60 cm of H_2O, mean seal pressures were twice as high with the LMA Proseal as with the standard LMA Classic (30 vs 15.8 cm H_2O). The mean volume of air injected into the cuff to achieve an intra cuff pressure of 60 cm of H_2O was 25.9 mL. A tidal volume of 8 mL/kg was achieved in all cases. These findings were consistent with the current study results.[11]

A pilot study on 22 adult female and male patients using the size 4 LMA Supreme showed that, insertion was 100% successful at the first attempt and duration of insertion was 28 ± 5 seconds. Oropharyngeal leak pressure averaged 37 cm H_2O with an intra cuff pressure of 60 cm H_2O and increased during anaesthesia. This was probably related to an increase in intra cuff pressure. This finding contrasts with the current study. This may be related to small sample size and differences in gender distribution. There was no blood staining on the device at removal in all cases.[17]

Our study has several limitations. Firstly, our data only apply to the use of the size 4 LMAs among both sexes. However, the use of a size 5 for adult males

and size 4 for adult females would have been more suitable.[39] Judging the correct size of LMA can be difficult since the relationship between gender, weight and upper airway geometry appears inconsistent.[31] Secondly, we did not measure ventilator capability directly; however, it is reasonable to assume that ventilator efficacy will be better for the LMA Proseal, as it has a better seal. Thirdly, although blood staining was similar between devices, we did not determine the frequency of airway morbidity. Although the fixed, curved tube of the LMA Fastrach is associated with higher airway morbidity,[40] perhaps due to high mucosal pressure,[41] the fixed curved tube of the LMA Supreme is flatter and softer and less likely to exert high pressures against the pharyngeal mucosa.

Chapter 7

Conclusion

CONCLUSION

The conclusions drawn from this study are;

- The ease of insertion is similar for the LMA Proseal and LMA Supreme in anaesthetized paralyzed adult patients, but oropharyngeal leak pressure and intracuff pressures are higher for the LMA Proseal.

- The LMA Proseal provides a more effective seal than LMA Supreme for positive pressure ventilation.

Chapter 8

Summary

SUMMARY

In this present study, we compared ease of insertion and airway sealing pressure between LMA Proseal and LMA Supreme in anaesthetized paralyzed adult patients undergoing positive pressure ventilation.

The study was conducted in 60 ASA grade I and II adult patients of both sexes, aged between 18 and 50 years posted for elective surgeries under general anaesthesia. The patients were randomly allocated to group LMA Proseal (n=30) or group LMA Supreme (n=30). The demographic data were comparable in both groups.

Preoperative preparation and premedication were similar in both the groups. Patients were preoxygenated with 100% oxygen for 3 minutes and then, induced with propofol 2mg/kg(IV) and vecuronium 0.1mg/kg (IV). The airway devices were (all size 4) were inserted in strict accordance with the manufacturer's recommendations.

The ease of insertion was recorded and oropharyngeal leak pressure and intra cuff pressures were determined at 0 to 40 ml cuff volume in 10ml increments. The intra cuff pressure was set at 60 cm of H_2O and patient's lungs were ventilated at an inspired tidal volume of 8mL/kg. Anaesthesia was maintained with isoflurane in 1:1 oxygen-nitrous oxide mixture and vecuronium.

At the end of procedure, the airway device was removed and examined for the presence of visible or occult blood.

The ease of insertion was similar for the LMA Proseal and LMA Supreme, but oropharyngeal leak pressure and intracuff pressures were higher for the LMA Proseal. The LMA Proseal provides a more effective seal than LMA Supreme for positive pressure ventilation.

Chapter 9

Bibliography

BIBLIOGRAPHY

1. Gupta S, Sharma R, Jain D. Airway assessment: Predictors of difficult airway. Indian J Anaesth 2005;49(4):257-62.

2. Pennat JH, White PF. The laryngeal mask airway-Its uses in Anesthesiology. Anesthesiology 1993;79:144-63.

3. Miller RD, Eriksson LI, Fleisher LA, Wiener-Kronish JP, Young WL. Miller's Anesthesia. 7th ed., Philadelphia: Churchill Livingstone Elsevier; 2010.

4. LMA Supreme. San diego, CA, USA: LMA North America Inc.; 2006.

5. Barash PG, Cullen BF, Stoelting RK, Cahalan MK, Stock MC. Clinical Anesthesia. 6th ed., Philadephia: Lippincott Williams & Wilkins; 2009.

6. Brimacombe JR, Brain AIJ, Berry AM. The laryngeal mask airway: A review and practical guide. London: W. B. Saunders company Ltd.; 1997.

7. Brimacombe J, Keller C, Mechlem D. A comparison of the disposable vs the reusable laryngeal mask airway in paralyzed adult patients. Anesth Analg 1998;87:921-4.

8. Brimacombe J, Keller C, Fullekrug B, Agro F, Rosenblatt W, Dierdorf SF, et al. A multicenter study comparing the Proseal™ and Classic™ laryngeal mask airway in anesthetized, nonparalyzed patients. Anesthsiology 2002;96:289-95.

9. Lu PP, Brimacombe J, Yang C, Shyr M. Proseal versus classic laryngeal mask airway for positive pressure ventilation during laparoscopic cholecystectomy. Br J Anaesth 2002;88(6):824-7.

10. Mark DA. Protection from aspiration with the LMA Proseal after vomiting: a case report. Can J Anaesth 2003;50:78-80.

11. Brain AIJ, Verghese C, Strube PJ. The LMA 'Proseal'- a laryngeal mask with an oesophageal vent. Br J Anaesth 2000;84(5):650-4.

12. Hohlrieder M, Brimacombe J, Von Goedecke A, Keller C. Postoperative nausea, vomiting, airway morbidity, and analgesic requirements are less for the Proseal laryngeal mask airway than the tracheal tube in females undergoing breast and gynaecological surgery. Br J Anaesth 2007;99(4): 576-80.

13. Hohlrieder M, Brimacombe J, Eschertzhuber S, Ulmer H, Keller C. A study of airway management using the Proseal LMA laryngeal mask airway compared with the tracheal tube on postoperative analgesic requirements following gynaecological laparoscopic surgery. Anaesthesia 2007;62(9):913-8.

14. Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. Can J Anaesth 1995;42:1017-23.

15. Brimacombe J, Keller C, Brimacombe L. A comparison of the Laryngeal mask airway Proseal and the Laryngeal tube airway in paralyzed

anesthetized adult patients undergoing pressure controlled ventilation. Anesth Analg 2002;95:770-6.

16. Abdi W, Dhonneur G, Amathieu R, Abhoum A, Kamoun W, et al. LMA Supreme versus facemask ventilation performed by novices: a comparative study in morbidly obese patients showing difficult ventilation predictors. Obes Surg 2009;19:1624-30.

17. Van Zundert A, Brimacombe J. The LMA Supreme – a pilot study. Anaesthesia 2008;63:209-10.

18. Sharma V, Verghese C, McKenna PJ. Prospective audit on the use of LMA Supreme for airway management of adult patients undergoing elective orthopaedic surgery in prone position. Br J Anaesth 2010;105(2): 228-32.

19. Belena JM, Gracia JL, Ayala JL, Nunez M, Lorenzo JA, et al. The laryngeal mask airway supreme for positive pressure ventilation during laparoscopic cholecystectomy. J Clin Anesth 2011;23(6):456-60.

20. Belena JM, Nunez M, Gracia JL, Perez JL, Yuste J. The laryngeal mask airway supreme: safety and efficacy during gynaecological laparoscopic surgery. South Afr J Anaesth Analg 2012;18(3):143-7.

21. Abdi W, Amathieu R, Adhoum A, Poncelet C, Slavov V, et al. Sparing of larynx during gynaecological laparoscopy: a randomized trial comparing the LMA Supreme and the ETT. Acta Anaesthsio Scand 2010;54(2):141-6.

22. Ferson DZ. LMA uses in difficult airway algorithm. Houstan, Texas: Available from: URL: http://www.mmh.org.tw/taitam/csc/download /LMA_airway.pdf Accessed on: 18.05.2012.

23. Brain AIJ. The laryngeal mask - a new concept in airway management. Br J Anaesth 1983;55:801-4.

24. Verghese C, Brimacombe JR. Survey of laryngeal mask airway usage in 11,910 patients: safety and efficacy for conventional and nonconventional usage. Anesth Analg 1996;82:129-33.

25. Bein B, Francksen H, Steinfath M. Supraglottic airway devices. Anasthesiol Intensivmed Notfallmed Schmerzther. 2011; 46(9): 598-607.

26. Keller C, Puhringer F, Brimacombe R. Influence of cuff volume on oropharyngeal leak pressure and fibreoptic position with the laryngeal mask airway. Br J Anaesth 1998;81:186-7.

27. Brimacombe J, Keller C, Fullekrug B, Agro F, Rosenblatt W, Dierdorf SF, et al. A multicenter study comparing the Proseal and Classic laryngeal mask airway in anesthetized, non-paralyzed patients. Anesthesiology 2002;96:289-95.

28. Teoh WH, Lee KM, Suhitharan T, Yahaya Z, Teo MM, Sia AT. Comparison of the LMA Supreme vs the i-gel in paralysed patients undergoing gynaecological laparoscopic surgery with controlled ventilation. Anaesthesia 2010;65(12):1173-9.

29. Verghese C, Ramaswamy B. LMA-Supreme™-a new single use LMA™ with gastric accesss: a report on its clinical efficacy. Br J Anaesth 2008;101(3):405-10.

30. LMA airway instruction manual. San diego, CA, USA: LMA North America Inc.; 2005.

31. Seet E, Rajeev S, Firoz T, Yousaf F, Wong J, et al. Safety and efficacy of laryngeal mask airway Supreme versus laryngeal mask airway Proseal: a randomized controlled trial. Eur J Anaesthesiol 2010;27(7):602-7.

32. Hosten T, Gurkan Y, Ozdamar D, Tekin M, Toker K, Solak M. A new supraglottic airway device: LMA-supreme, comparison with LMA-Proseal. Acta Anaesthesiol Scand 2009;53(7):852-7.

33. Jagannathan N, Sohn LE, Sawardekar A, Gordon J, Langen KE, Anderson K. A randomised comparison of the LMA Supreme™ and LMA ProSeal™ in children. Anaesthesia 2012;67(6):632-9.

34. Keller C, Brimacombe JR, Keller K, Morris R. Comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. Br J Anaesth 1999;82(2):286-7.

35. Brimacombe J, Keller C, Boehler M, Puehringer F. Positive pressure ventilation with the Proseal versus Classic laryngeal mask airway: a randomized, crossover study of healthy female patients. Anesthesia and Analgesia 2001;93:1351-3.

36. Lee AK, Tey JB, Lim Y, Sia AT. Comparison of the single use LMA Supreme with the reusable Proseal LMA for anaesthesia in gynaecological laparoscopic surgery. Anaesth Intensive Care 2009;37(5):815-9.

37. Keller C, Brimacombe J. Mucosal pressure and oropharyngeal leak pressure with the Proseal versus laryngeal mask airway in anaesthetized paralyzed patients. Br J Anaesth 2000;85(2):262-6.

38. Eschertzhuber S, Brimacombe J, Hohlrieder M, Keller C. The laryngeal mask airway supreme – a single use laryngeal mask airway with an oesophageal vent. A randomised, cross-over study with the laryngeal mask airway proseal in paralysed, anaesthetised patients. Anaesthesia 2009;64:79-83.

39. Brimacombe J, Keller C. Laryngeal mask airway size selection in males and females: ease of insertion, oropharyngeal leak pressure, pharyngeal mucosal pressures and anatomical position. Br J Anaesth 1999;82(5): 703-7.

40. Kihara S, Yaguchi Y, Brimacombe J, Watanabe S, Taguchi N. Routine use of the intubating laryngeal mask airway results in increased upper airway morbidity. Can J Anaesth 2001;48(6):604-8.

41. Keller C, Brimacombe J. Pharyngeal mucosal pressures, airway sealing pressures, and fiberoptic position with the intubating versus the standard laryngeal mask airway. Anesthesiology 1999;90(4):1001-6.

Annexures

Annexure I

ANNEXURE I – CONSENT FORM

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled **"Comparison of Laryngeal Mask Airway Proseal and Laryngeal Mask Airway Supreme for ease of insertion and airway sealing pressure in Anaesthetized Paralyzed adult patients undergoing Positive Pressure Ventilation" – A Randomized Clinical trial** at KLES DR. Prabhakar Kore Hospital and Medical Research Centre, Belgaum conducted by Dr. **** ******, Post Graduate in M.D. Anaesthesiology under the guidance of Dr. **** ******, Professor, Department of Anaesthesiology, J. N. Medical College, Belgaum under KLE university, Belgaum.

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

Your participation in research is voluntary. If you decide to participate, you are free to withdraw at any time.

The purpose of research is to compare laryngeal mask airway proseal and laryngeal mask airway supreme for ease of insertion and airway sealing pressure in anaesthtized paralyzed adult patients undergoing positive pressure ventilation.

Procedure Involved

If you agree to enroll yourself in my study, I will ask your present, past and family history. Then you will be clinically examined in detail and routine investigations like Haemoglobin will be done. After giving General Anesthesia with I.V induction agents and Muscle relaxation with vecuronium, one of the randomized laryngeal mask airway devices is inserted and connected to the mechanical ventilator system for positive pressure ventilation.

Risks and Benefits

The benefits of taking part in this study are that these newer, most advanced airway devices combines the best features of all previous laryngeal mask airways in one device. They can be used as an effective alternative to endotracheal tubes which carry an inherent risk of patient trauma, from vocal cord damage to pharyngeal soft tissue injury. There are no observable risks associated with this study.

Voluntary Participation / Withdrawal

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

Alternatives

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

Privacy and Confidentiality

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except :

1. In emergency to protect your rights and welfare.

2. If required by law.

Authorization to Publish Results

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

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation

In the event of injury related to the study, treatment will be made available through KLES Hospital & Medical Research Centre, Belgaum. There is no compensation or payment for such medical treatment by law. If you are

injured you may contact Dr. ***** *****, at Department of Anaesthesiology, J. N. Medical College, Belgaum or by Ph. No: ***** *****.

Questions

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. ***** ******, Professor, Department of Anaesthesiology, J. N. Medical College, Belgaum Ph: ***** ***** or Dr. ******* *******, Department of Anesthesiology, J. N. Medical College, Belgaum Ph No. **** ****** or ph: ***** *****.

If you have any queries about your rights as a study subject, you may call Principal and Chairman, Institutional Ethical Committee for Human Subjects Research, J. N. Medical College, Belgaum Ph. *** *******.

Consent for participation in research trial

I, _____ voluntarily agree for the participation as a subject of study. By signing this consent form, I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject: _____

Date:

Witness Name : _____

Signature : _____

Date :

Investigators Name : _____

Signature : _____

Date :

Place : _____

Annexures

Annexure II

ANNEXURE II – PROFORMA

TITLE: "COMPARISON OF LARYNGEAL MASK AIRWAY PROSEAL AND LARYNGEAL MASK AIRWAY SUPREME FOR EASE OF INSERTION AND AIRWAY SEALING PRESSURE IN ANAESTHETIZED PARALYZED ADULT PATIENTS UNDERGOING POSITIVE PRESSURE VENTILATION" – A RANDOMIZED CLINICAL TRIAL

Patient's name: ***Age:***

I.P no.: ***Sex:***

Occupation: Address:

Anesthesiologist:

Preoperative diagnosis:

Name of the operation:

PRE-ANAESTHETIC EVALUATION

History in brief

Chief complaints:

Past history:

Personal history:

Drug therapy:

Previous anaesthetic experience:

General physical examination

Height : Weight :

Pallor / Edema / Icterus / Cyanosis / Clubbing / Lymphadenopathy

P.R.: R.R.:

B.P.: Temperature:

Musculoskeletal system examination

Teeth: Jaw movements:

Airway assessment: Spine:

Systemic examination

CVS: RS:

CNS: GIT:

Investigations

Hb%: Urine routine:

RBS: Blood urea:

S. Creatinine: ECG:

Chest X-ray: Echo if necessary:

ASA Grade:

Inclusion criteria

1. ASA grade I and II
2. Age between 18 to 80 years
3. Body weight between 50 to 70 kgs
4. Elective surgeries under general anesthesia in supine position

Exclusion criteria

1. Known or predicted difficult airway
2. Any pathology of neck, upper respiratory tract or upper GIT
3. BMI >35kg/m^2
4. History of obstructive sleep apnea
5. Tredenlenburg's position

6. History of lung diseases
7. Potentially full stomach patients(trauma, pregnancy, morbid obesity, hiatus hernia)

Methods

After obtaining approval of ethical committee, this study is carried out on patients at KLES Dr.Prabhakar Kore hospital and medical research centre, Belgaum.

Patients are allocated in a randomized manner by 'opening a sealed envelope' method into two groups a. LMA Proseal (n=30) and b. LMA Supreme (n=30).

An informed and written consent is obtained from all the patients during pre anesthetic check up one day prior to the surgery.

In the operating room, a standard anesthesia protocol is followed and routine monitoring is applied with electrocardiograph, non-invasive blood pressure, pulse oximetry (SPO_2) and end tidal CO_2 monitoring. The head and neck of the patient are placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height.

The airway device to be used is prepared for insertion with the cuff fully deflated and shaped, and its dorsal surface lubricated with a clear, water based gel.

An intravenous access is established. All the patients are preoxygenated with 100% oxygen for 3 minutes and are premedicated with inj.Glycopyrrolate, 0.005mg kg^{-1}(IV), inj. Midazolam 0.05mg kg^{-1}(IV) and inj.fentanyl 2microg kg^{-1}(IV). Anesthesia is induced with inj. Propofol 2mg kg^{-1}(IV) and neuromuscular

blockade is achieved with inj. Vecuronium 0.1mg kg^{-1}(IV). Patient's lungs are ventilated with using a face mask for 3 to 5 minutes and then, the airway devices (all size 4) are inserted in strict accordance with the manufacturer's recommendations.

The insertion technique for LMA Proseal is identical to the recommended technique for the LMA Classic and included neck flexion, head extension, full deflation of the cuff and the use of the index finger to press the LMA Proseal into, and advance it around the palatopharyngeal curve. A slight lateral approach is used if resistance is felt in the oropharynx. The LMA Supreme is inserted with the cuff deflated, using a single handed rotational technique.

One attempt (using Guided technique) is allowed before insertion considered a failure. For the guided technique, the drain tube of the LMA Proseal/Supreme is primed with a well lubricated gum elastic bougie with its straight end first, leaving the 5cm bent portion protruding from the proximal end and the maximum length protruding from the distal end. The guided technique involved the following steps: 1) under gentle laryngoscopic guidance, the distal portion of the guide is placed 5-10cm into the oesophagus while the assistant held the LMA and proximal portion; 2) the laryngoscope is removed; 3) the LMA is inserted using the digital insertion technique while the assistant stabilised the proximal end of the guide so it do not penetrate further into the oesophagus; and 4) the guide is removed while the LMA is held in position. All steps are performed with the cuff fully deflated and using a midline approach. Fixation is done in accordance with the manufacturer's instructions.

Failed insertion is defined by any of the following criteria.

1. Failed passage into the pharynx
2. Malposition (air leaks) 3.Ineffective ventilation (maximum expired tidal volume <6 ml kg^{-1} or/and end tidal CO_2 >60 mm of Hg). If the device can not achieve a satisfactory airway as defined above, the patient's trachea is intubated conventionally.

The time between picking up the prepared LMA Proseal or Supreme and successful placement is recorded. The aetiology of failed insertion is documented.

Oropharyngeal leak pressure and intra cuff pressure are determined at 0 to 40 ml cuff volume in 10 ml increments. Oropharyngeal leak pressure is determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 litre $min^{-}1$, and noting the airway pressure in the anesthetic breathing system (maximum allowed is 40 cm H_2O) at which audible gas leak occurs into the mouth. The intra cuff pressure is measured using cuff pressure gauge.

The intra cuff pressure is set at 60 cm H_2O or to obtain an effective airway seal for positive pressure ventilation and patient's lungs are ventilated at an inspired tidal volume of 8 ml kg^{-1}, at an respiratory rate of 12 breaths/minute and an inspiratory : expiratory ratio of 1:2. Anesthesia is maintained with 1:1 oxygen-nitrous oxide mixture, isoflurane and inj.Vecuronium 0.02 mg/kg(IV) boluses. The presence/absence of oropharyngeal air leaks (detected by listening over the mouth), gastric air leaks (detected by listening with a stethoscope over the epigastrium), drain tube air leaks (detected by placing lubricant over the proximal end of the drain tube) or an end tidal CO_2 >60 mm of Hg is noted. Any episodes of hypoxaemia (SpO_2 <90%) or other adverse events are documented.

At the end of procedure, adequate reversal is done with inj. Glycopyrrolate 0.01mg kg^{-1}(IV) and inj.Neostigmine 0.05mg kg^{-1}(IV). After the return of protective airway reflexes, the airway device is removed and examined for the presence of visible or occult blood. Data about insertion time, effective ventilation, hypoxaemic episodes and blood staining are collected by an observer blinded to the airway device used.

Observations

Group: LP/LS

Cuff volume(ml)	0	10	20	30	40
Oropharyngeal leak pressure(cm of H_2O)					
Intra cuff pressure(cm of H_2O)					

Insertion success First attempt Second attempt with guide	
Insertion time(seconds) First attempt	
Aetiology of failure Failed passage into pharynx Malposition Ineffective ventilation	
Blood staining Visible blood Occult blood	

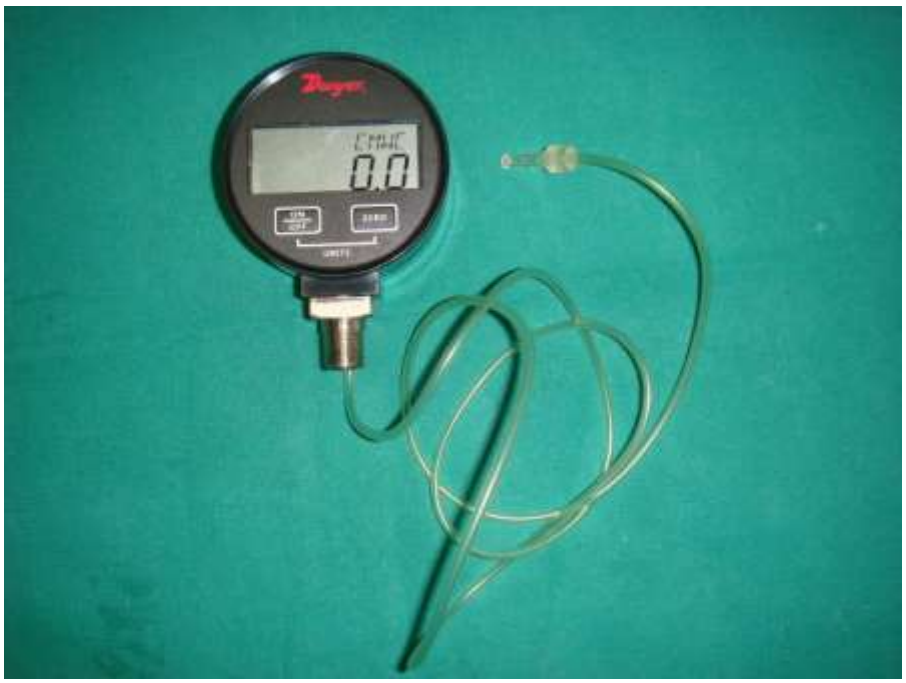
Complications, if any:

Annexures

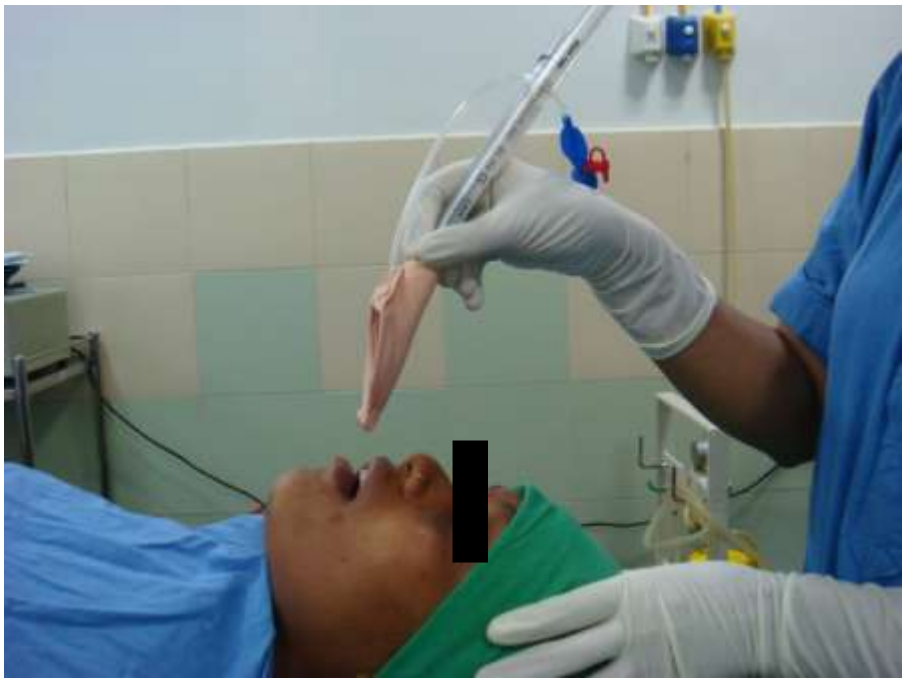
Annexure III

ANNEXURE III – PHOTOGRAPHS

Photograph 1. LMA Supreme, LMA Proseal, Lignocaine 2% gel and inflation syringe



Photograph 2. Cuff pressure manometer



Photograph 3. Insertion of LMA Proseal

Photograph 4. Insertion of LMA Supreme

Photograph 5. Anaesthesia work station(Dragor Fabius plus)

Photograph 6. Measurement of oropharyngeal leak pressure

ANNEXURE IV - MASTER CHART GROUP LMA PROSEAL

Serial Number	In Patient Number	Age (years)	Sex	Height (cms)	Weight (kgs)	ASA grade	Mallampatti grade	Diagnosis	Procedure	Insertion attempt	Insertion time (Sec)	Aetiology of failure	Blood stain	Oropharyngeal leak pressure (cm of H2O) at various cuff volumes (mL)					Intracuff pressure (cm of H2O) at various cuff volumes (mL)				Complications
														0	10	20	30	4 0	10	20	30	40	
1	431906	35	M	168	68	I	2	Cholelithiasis	Cholecystectomy	1	24	Absent	Absent	8	18	26	31	35	8	34	92	123	Nil
2	425843	25	F	155	53	I	1	Wound gaping	Secondary suturing	1	25	Absent	Absent	9	19	26	30	34	7	38	94	112	Nil
3	426442	40	F	160	53	I	1	Inguinal hernia	Mesh repair	1	22	Absent	Absent	9	18	23	29	34	6	34	94	132	Nil
4	429223	28	F	155	58	I	1	Right breast absecess	Incision & drainage	1	24	Absent	Present	7	17	23	28	33	6	38	96	128	Nil
5	436282	31	F	164	62	I	2	Para2, living2	Laparoscopic sterilisation	1	24	Absent	Absent	8	17	25	31	34	5	35	85	126	Nil
6	418905	25	F	161	55	I	1	Fracture right radius	Open reduction & fixation	1	21	Absent	Absent	9	18	24	30	34	6	36	90	126	Nil
7	436356	26	F	158	58	I	1	Para2, living2	Laparoscopic sterilisation	1	28	Absent	Absent	8	17	27	32	35	6	35	92	124	Nil
8	436149	35	F	155	60	II	2	Right breast fibroadenoma	Excision	1	25	Absent	Absent	9	18	25	32	36	5	38	88	122	Nil
9	415216	44	M	163	57	II	1	Fracture right forearm bones	Open reduction & fixation	1	25	Absent	Absent	9	15	26	30	34	6	35	95	126	Nil
10	422856	34	F	152	52	I	1	Wound gaping	Secondary suturing	1	25	Absent	Absent	8	17	26	31	35	8	37	96	118	Nil
11	416611	24	F	160	57	I	1	Primi e 10wks gestation	MTP	1	24	Absent	Absent	9	16	25	32	35	8	36	97	128	Nil
12	431120	28	F	158	54	I	2	Para2, living2	B/L abdominal tubectomy	1	25	Absent	Absent	8	14	26	31	34	9	39	94	129	Nil
13	428581	28	F	157	53	I	2	Wound gaping	Secondary suturing	1	24	Absent	Absent	7	14	26	32	35	8	34	88	119	Nil
14	430469	42	M	165	65	II	2	Ulcer over right leg	Moderate debridement	1	23	Absent	Absent	8	17	28	32	35	7	34	98	131	Nil
15	433280	45	F	160	61	II	2	Ulcer over right hand	Minor debridement	2		Absent	Absent	8	18	27	32	35	7	38	94	126	Nil
16	431055	43	F	157	58	II	2	Uterine polyp	Polypectomy	1	25	Absent	Absent	9	18	26	30	34	8	34	94	127	Nil
17	432110	35	M	167	65	I	1	Abscess over right hand	Debridement	1	24	Absent	Absent	8	18	26	31	35	7	35	87	114	Nil
18	431674	48	M	168	67	II	2	Ulcer over upper abdomen	Debridement	1	22	Absent	Absent	8	17	26	29	33	9	34	89	117	Nil
19	443674	30	F	155	54	I	1	Para2, living2	Laparoscopic sterilisation	1	24	Absent	Present	9	16	25	30	33	7	40	94	125	Nil
20	428194	35	F	165	59	I	2	Lipoma over chest	Excision	1	24	Absent	Absent	7	16	27	31	34	8	36	94	124	Nil
21	430865	27	M	170	65	I	1	Abscess over chest	Incision & drainage	1	23	Absent	Absent	9	18	28	32	36	7	42	97	126	Nil
22	427245	50	M	164	58	II	2	Left leg cellulitis	Moderate debridement	1	21	Absent	Absent	7	16	26	31	33	7	38	88	128	Nil
23	435734	40	F	160	57	I	2	Left breast fibroadenoma	Excision	2		Absent	Absent	9	18	27	31	35	5	38	96	115	Nil
24	441371	28	F	156	53	I	1	Wound gaping	Secondary suturing	1	24	Absent	Absent	8	16	27	30	34	6	36	90	118	Nil
25	441386	36	F	162	61	I	2	Wound gaping	Secondary suturing	1	22	Absent	Absent	9	16	26	31	34	6	37	86	122	Nil
26	433714	35	M	167	64	I	1	O/C/O Pelvic fracture	Implant removal	1	24	Absent	Absent	9	16	28	31	34	7	37	91	121	Nil
27	447622	42	M	162	59	II	2	Fracture left forearm bones	Open reduction & fixation	1	24	Absent	Absent	8	17	26	31	34	6	38	89	112	Nil
28	446453	28	M	167	67	II	1	Right diabetic foot	Debridement	1	24	Absent	Absent	9	16	27	31	35	7	35	86	121	Nil
29	443356	43	F	159	55	I	1	Para2, living2	Laparoscopic sterilisation	1	25	Absent	Absent	8	18	24	31	35	7	39	91	126	Nil
30	447921	33	F	160	56	I	2	Ulcer over abdomen	Debridement	1	25	Absent	Absent	9	17	26	29	34	6	41	87	117	Nil

ANNEXURE IV - MASTER CHART GROUP LMA SUPREME

Serial Number	In Patient Number	Age (years)	Sex	Height (cms)	Weight (kgs)	ASA grade	Mallampatti grade	Diagnosis	Procedure	Insertion attempt	Insertion time (Sec)	Aetiology of failure	Blood stain	Oropharyngeal leak pressure (cm of H2O) at various cuff volumes (mL)					Intracuff pressure (cm of H2O) at various cuff volumes (mL)				Complications
														0	10	20	30	4 0	10	20	30	40	
1	406609	24	F	156	54	I	2	Para 2, Living 2	B/L abdominal tubectomy	1	23	Absent	Absent	7	12	18	25	31	5	28	65	121	Nil
2	432826	36	F	152	52	I	1	Endometrial Carcinoma	Dilatation and currettage	1	21	Absent	Absent	7	14	18	27	33	6	27	64	114	Nil
3	428677	43	M	164	62	I	2	O/C/O right tibial fracture	Dynamisation	1	22	Absent	Absent	6	10	21	25	31	5	32	74	122	Nil
4	437768	28	F	158	54	I	1	Para 2, Living 2	Laparoscopic sterilisation	1	24	Absent	Absent	8	11	23	26	32	5	29	71	118	Nil
5	430939	48	F	155	58	II	2	Abnormal uterine bleeding	Dilatation and currettage	1	25	Absent	Absent	6	12	22	26	32	6	27	69	120	Nil
6	382510	50	M	161	60	II	2	Gangrene of right hand	Debridement	1	23	Absent	Absent	7	10	18	23	30	5	24	65	110	Nil
7	412971	45	F	156	57	II	2	Right leg cellulitis	Moderate debridement	1	27	Absent	Absent	7	11	19	24	33	6	26	62	114	Nil
8	413616	24	F	158	55	I	1	Para 2, Living 2	Laparoscopic sterilisation	1	26	Absent	Absent	6	13	20	24	32	5	34	74	122	Nil
9	417667	26	M	161	59	I	1	O/C/O right tibial fracture	Dynamisation	1	23	Absent	Absent	7	16	23	26	34	6	34	84	124	Nil
10	414959	28	F	159	55	I	1	Wound gaping	Secondary suturing	1	24	Absent	Absent	6	16	24	28	33	7	36	82	113	Nil
11	429790	37	F	160	57	II	1	Para 2, Living 2	B/L abdominal tubectomy	1	22	Absent	Absent	8	14	21	25	30	8	25	70	124	Nil
12	431118	28	F	160	59	I	1	Para 3, Living 3	Laparoscopic sterilisation	1	21	Absent	Absent	7	13	20	25	32	6	25	64	118	Nil
13	413029	30	M	167	67	I	2	O/C/O left femur fracture	Dynamisation	1	24	Absent	Absent	7	18	22	27	34	6	31	70	109	Nil
14	431117	25	F	163	56	I	1	Para 2, Living 2	B/L abdominal tubectomy	1	23	Absent	Absent	7	14	18	25	31	6	24	66	118	Nil
15	437273	29	F	157	52	I	2	Para 2, Living 2	Laparoscopic sterilisation	1	21	Absent	Absent	8	14	19	24	32	6	28	64	116	Nil
16	430168	33	F	161	58	I	1	Fracture right forearm bones	Open reduction & fixation	1	23	Absent	Absent	7	12	18	25	32	7	25	69	116	Nil
17	429244	29	F	160	62	I	2	Wound gaping	Secondary suturing	1	24	Absent	Absent	8	12	18	24	30	7	24	59	122	Nil
18	424200	38	M	167	68	II	1	Phimosis	Circumcision	1	26	Absent	Absent	7	12	20	24	32	6	28	70	120	Nil
19	405985	32	M	162	58	I	2	Osteomyelitis of right femur	Debridement	1	22	Absent	Absent	7	10	18	25	31	7	24	58	126	Nil
20	398094	40	M	165	60	II	2	Right inguinal abscess	Debridement	1	24	Absent	Absent	6	13	21	25	30	6	30	64	109	Nil
21	379524	31	F	158	56	I	1	Ulcer over abdomen	Debridement	2		Absent	Absent	7	12	18	25	32	6	28	64	121	Nil
22	443669	28	F	155	57	I	1	Para 2, Living 2	Laparoscopic sterilisation	1	23	Absent	Absent	8	12	21	25	30	6	29	66	114	Nil
23	443713	32	F	163	59	I	2	Para 2, Living 2	Laparoscopic sterilisation	1	22	Absent	Absent	6	10	18	26	34	5	26	64	112	Nil
24	411418	32	M	167	69	I	2	Cholecystitis	Cholecystectomy	1	23	Absent	Present	8	13	19	25	31	6	26	62	116	Nil
25	430061	26	F	158	55	I	1	Wound gaping	Secondary suturing	1	22	Absent	Absent	9	14	18	25	33	7	28	70	122	Nil
26	435668	40	F	152	52	II	2	Endometrial Carcinoma	Dilatation and currettage	1	25	Absent	Absent	8	13	22	26	32	5	26	65	114	Nil
27	429612	30	M	164	57	I	2	Bilateral varicocele	Excision	1	27	Absent	Absent	6	14	20	24	33	7	28	58	108	Nil
28	403469	45	M	166	64	II	1	Left Galezzi's fracture	Open reduction & fixation	1	24	Absent	Absent	6	11	20	26	31	6	28	68	128	Nil
29	424381	29	F	158	57	I	1	Left breast abscess	Incision & drainage	1	21	Absent	Absent	6	12	21	26	34	5	31	71	109	Nil
30	467211	34	M	167	65	I	1	O/C/O right humerus fracture	Implant removal	1	25	Absent	Absent	8	14	22	26	31	6	32	69	125	Nil

Annexures

Annexure IV

ANNEXURE IV – MASTER CHART

B/L	-	Bilateral
Cms	-	Centimeter
F	-	Female
H2O	-	Water
Kgs	-	Kilograms
M	-	Male
mL	-	Milli Litre
MTP	-	Medical termination of pregnancy
O/C/O	-	Operated case of
Sec	-	Seconds