"ANALYSIS OF THE BASKA MASK VERSUS PROSEAL LARYNGEAL MASK AIRWAY SEALING PRESSURE IN PATIENTS POSTED FOR LAPAROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"

By

REG NO. BA0118003

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This is to certify that the dissertation entitled **"ANALYSIS OF THE BASKA MASK VERSUS PROSEAL LARYNGEAL MASK AIRWAY SEALING PRESSURE IN PATIENTS POSTED FOR LAPAROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"** is a bonafide research work done by **REG NO. BA0118003**.

DR. RAJESH MANE MD,DNB
Professor and Head,
Department of Anaesthesiology,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

Dr. (Mrs) N.S. Mahantshetti MD(paed)
Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

PLAGIARISM CERTIFICATE

JAWAHARLAL NEHRU MEDICAL COLLEGE

(Recognized by Medical Council of India, New Delhi)

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Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA

0831 - 2471350 0831 - 2470759 www.jnmc.edu principal@jnmc.edu

Ref No: MDC/PG/

Date: 07-09-2020

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Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

Reg. No. BA0118003.
Postgraduate Student,
2018-19 Batch,
Department of Anesthesiology,
J. N. Medical College, Belagavi.

LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
ASP	-	Airway sealing pressure
BP	-	Blood Pressure
cLMA	-	Classic Laryngeal Mask Airway
cm	-	Centimetre
CNS	-	Central nervous system
CO_2	-	Carbon dioxide
CVS	-	Cardiovascular system
$EtCO_2$	-	End tidal carbon dioxide
ETT	-	Endotracheal tube
FG	-	French gauge
GIT	-	Gastrointestinal tract
H_2O	-	Water
Hb	-	Haemoglobin
Inj	-	Injection
IPPV	-	Intermittent positive pressure ventilation
IV	-	Intravenous
Kg	-	Kilogram

LMA	-	Laryngeal mask airway
mcg	-	Microgram
mg	-	Milligram
min	-	Minute
ml	-	Millilitre
OGT	-	Orogastric tube
OSP	-	Oropharyngeal sealing pressure
PAE	-	Pre anaesthetic evaluation
PCV	-	Pressure controlled ventilation
PLMA	-	Proseal laryngeal mask airway
PPV	-	Positive pressure ventilation
PR	-	Pulse rate
RR	-	Respiratory rate
SAD	-	Supraglottic airway device
Sec	-	Seconds
SpO_2	-	Saturation percentage of oxygen

ABSTRACT

Introduction: Airway management by anaesthesiologist has come a long way from the invention of endotracheal intubation. Invention of supraglottic airway devices (SAD) provided alternativeairway, without hazards of direct laryngoscopy and intubation. First generation SAD was considered airway tubes, and hence modifications were made to them. PLMA is a second generation SAD which has agastric port along with the airway tube. Baska mask is a novel 3rd generation SAD which has a non inflatable cuff, large sump area to drain gastric contents. We designed this study to compare the clinical efficacy of Baska mask and PLMA for time for insertion, ease of insertion, airway sealing pressure and complications in anaesthetised patients undergoing positive pressure ventilation under general anaesthesia.

Methodology: The present randomized control trial was conducted in 60 ASA-1 and ASA-2, aged between 18-60 years posted for elective laparoscopic surgeries under general anaesthesia in KLES Dr. Prabhakar Kore charitable hospital and medical research centre, Belagavi.Patients were allocated into two equal groups, Group B- Baska mask (n=30) and Group P- PLMA (n=30). All the data Collected were analysed. The demographic data, duration of insertion and airway sealing pressurewere analysed using unpaired‘t’ test.

Results: In our study we observed that, Baska mask took lesser time to insert in comparison to PLMA, the mean duration of insertion was 16.77±2.14 sec in BASKA Mask and 25.40±3.04 sec in PLMA Group. This difference was statistically significant ($p<0.0001$). The Mean airway sealing pressure was 33±2.31 cm of H_2O in BASKA mask group and 27.00±1.84 cm of H_2O in PLMA Group after 5 min of

insertion and 31.33±2.06 cm of H20 in BASKA Mask and 26.90±1.79 cm of H_2O in PLMA Group after 5 min of pneumoperitoneum. The airway sealing pressure was more in BASKA group which was statistically significant both after 5 min insertion and 5 min of pneumoperitoneum. There were no significant mean airway sealing pressures between 5 min after insertion and 5 min after pneumoperitoneum in both the groups. The ease of insertion was more in Baska mask but it was statistically insignificant. The Laryngopharyngeal morbidity score between these groups were statistically insignificant.

Conclusion: To conclude, we observed that Baska mask took lesser time to insert than PLMA in anaesthetized paralysed adult patients. Mean airway sealing pressure was higher in Baska mask than PLMA. The ease of insertion was more in Baska mask but it was statistically insignificant. The LPM score between these groups were statistically insignificant.

CONTENTS

SL. NO.	TOPIC	PAGE NO.
1.	INTRODUCTION	1-3
2.	OBJECTIVES	4
3.	REVIEW OF LITERATURE	5-9
4.	BASIC SCIENCES	10-31
5.	METHODOLOGY	32-39
6.	RESULTS	40-49
7.	DISCUSSION	50-54
8.	CONCLUSION	55
9.	SUMMARY	56-57
10.	BIBLIOGRAPHY	58-62
11.	ANNEXURE I – CONSENT FORM	63-67
12.	ANNEXURE II – PROFORMA	68-71
13.	ANNEXURE III – ETHICAL CLEARENCE CERTIFICATE	72
14.	ANNEXURE IV – PHOTOGRAPHS	73-76
15	ANNEXURE V- MASTER CHART	77
16	ANNEXURE VI- KEY TO MASTER CHART	78-79

LIST OF TABLES

TABLE NO.	DESCRIPTION	PAGE NO.
1	PLMA selection guidelines	24
2	Baska mask selection guidelines	30
3	LPM score	38
4	Mean age	41
5	Gender distribution	42
6	Mean weight	43
7	ASA grade distribution	44
8	MPG grade distribution	45
9	Mean insertion time	46
10	Mean Airway sealing pressure after 5 min of insertion and 5 min of pneumoperitoneum	47
11	Ease of insertion	48
12	Laryngopharyngeal morbidity score	49

LIST OF GRAPHS

GRAPH NO.	DESCRIPTION	PAGE NO.
1	Age distribution(years)	41
2	Gender distribution	42
3	Mean weight	43
4	Distribution of ASA	44
5	Mallampati grade	45
6	Mean insertion time (sec)	46
7	Mean ASP (cm of H_2O)	47
8	Ease of insertion	48
9	LMP Scores	49

LIST OF FIGURES

FIGURE NO.	DESCRIPTION	PAGE NO.
1	Anatomy of oral cavity	10
2	Anatomy of pharynx	14
3	Anatomy of larynx	17
4	Proseal Laryngeal Mask Airway	25
5	Baska mask	30

LIST OF PHOTOGRAPHS

FIGURE NO.	DESCRIPTION	PAGE NO.
1	**Bska mask size 3 and 4 – Anterior view**	73
2	**Baska mask –Lateral**	73
3	**Proseal LMA size 3 and 4**	74
4	**PLMA metal introducer**	74
5	**PLMA mounted on metal introducer**	75
6	**Baska mask insitu**	75
7	**PLMA insitu**	76
8	**Anaesthesia Workstation**	76

INTRODUCTION

The most important part in providing functional respiration is to secure a patent airway. The primary goal of Anaesthesiologist is to maintain a patent airway. In addition to this, providing adequate oxygenation and ventilation is an important consideration in both emergency and elective situations.

Over the years securing an airway has improved drastically from the time of introduction of endotracheal tube by MacEwan in 1880 till present day, where use of sophisticated devices has helped us in securing a definitive airway.[1] However, laryngoscopy and tracheal intubation triggers adverse response such as increase in the level of plasma catecholamines, hypertension, tachycardia, arrhythmia, myocardial ischemia and an increase in intraocular and intracranial pressures.[2,3] Apart from the above-mentioned adverse effects, laryngoscopy and endotracheal intubation requires skill, continuous training and practice.

Dental damage remains to be the most common anaesthesia related injury, followed by respiratory associated events. Respiratory tract related injuries are mainly caused by ventilating inadequately, intubating into the oesophagus and difficult intubation. A study demonstrated that respiratory tract related injuries due to difficult intubation correspond to 17% and cause significant morbidity and mortality. Inability to ventilate or intubate results in almost 28% of deaths related to anaesthesia.[4]

Supraglottic Airway Devices (SADs) were considered to be an alternative airway device as a potential lifesaving tool which has now been integrated into American Society of Anaesthesiologists (ASA) guidelines for most of the difficult airway management algorithms.[5]Considering the invasiveness degree and the

anatomical position, the SAD fills the gap between the face mask and the endotracheal tube.[6]

First Supraglottic Airway Device (SAD) or Laryngeal Mask Airway (LMA) was described in 1981 by Dr. Archie Brain. Since the time of its discovery, though initially criticized, later was accepted worldwide by 1988.[3]

During their usage, certain drawbacks were encountered which included gastric aspiration, imperfect sealing of airway, airway obstruction at glottic and subglottic levels. Imperfect sealing of airway can be identified by either fibre optic scope or by measuring airway sealing pressure (ASP) which helps us to know the pressure level beyond which patent airway cannot be maintained.[7,8]

All the newer SADs provided superior efficacy regarding ease of insertion and prevention of aspiration. In addition to these, SADs have certain other advantages when compared to endotracheal intubation namely avoiding the use of rigid laryngoscopes, avoiding the stressor response associated with intubation.[8]

The classic LMA (cLMA) is not a very popular device due to risk of aspiration of gastric contents and inadequate ventilation during positive pressure ventilation (PPV).[8,9] Further few modifications were made in cLMA for easier and effective usage. These modifications led to invention of newer supraglottic airways namely LMA Supreme, Proseal LMA, LMA Fastrach, SLIPA, i-gel etc.

Proseal Laryngeal Mask Airway (PLMA), a second generation SAD offering gastric access, which is re-usable, was introduced in 2000. The PLMA facilitates PPV as it offers higher glottic seal pressures than the cLMA. It has a built in drain tube that allows passage of orogastric tube for draining the gastric contents and preventing

aspiration. The drain tube also allows instant clinical diagnosis of device misplacement if we were not able to not pass an orogastric tube. “The PLMA decreases the chances of throat irritation and stimulation, which in turn reduces postoperative nausea and vomiting by as much as 40% compared to an ETT”.[10,11]

The BASKA mask is a new SAD device. It has new modifications more importantly its non-inflatable cuff that is designed appropriately considering the anatomy of the airway providing us with lower risk of nerve damage that are commonly associated with inflation of the cuff. During IPPV as the pressure increases with PPV the cuff gets inflated itself. This improves the seal and aids during ventilation. It has a large sump with two drains to which suction can be attached to aspirate the gastric contents.[12]

The gold standard 2nd gen. SAD that is used for surgical procedures is PLMA, till date. There are very few studies evaluating the benefits of the BASKA mask over Proseal LMA. So, a further study regarding usage of these devices had to be done. Hence, we compared BASKA Mask and Proseal LMA regarding ASP, time of insertion, ease of insertion, post-operative complications and Laryngopharyngeal morbidity(LPM) score in adult patients undergoing laparoscopic surgeries under general anaesthesia.

OBJECTIVES

Primary Objective: Comparison of airway sealing pressure of BASKA and PROSEAL LMA

Secondary Objectives: Comparison of

- Insertion time
- Ease of insertion
- LMP Score

REVIEW OF LITERATURE

Endotracheal intubation is considered gold standard for establishment of a definite airway for positive pressure ventilation.[5,13]Tracheal intubation or ventilation with face mask was the only option available for airway management in the 20th century. During induction, as the upper airway muscle tone decreases and as the tongue falls back on to the pharyngeal tissues due to gravity, it causes obstruction of trachea while ventilating with the face mask. Tracheal intubation bypasses all these problems but has its own disadvantages as mentioned earlier.[3,14]

To overcome these problems, in 1981, LMA was designed by Dr.Archie Brain.[3,15] The prototype of LMA was first made using Goldman paediatric dental mask's cuff. A 10mm portex clear plastic tube was taken and its endotracheal end was diagonally cut. The cut cuff of the dental mask was then stretched and fixed to the portex tube using acrylic glue.[15]This was first used on a human patient undergoing a routine hernia repair where the device was inserted blindly under halothane and positive pressure ventilation was possible. The first results of its use were published in British journal of Anaesthesia in August 1983.[3,4,15]

First independent assessment of the LMA was made by Brodrick*et al,*[16] in 1989, who obtained a clinically satisfactory and unobstructed airway in 98/100 patients. They described the LMA as the missing link between the face mask and tracheal tube. Their excellent features were described in this study: excellent airway patency, no manual support of jaw required which allowed to free anaesthesiologist hands for monitoring and documenting and good for transfer of the patient to post anaesthesia care unit and recovery. By 1993, the LMA was widely accepted and was included in the ASA algorithm for unanticipated difficult airway.[3]

Invention of LMA, led to their extensive usage in patients requiring controlled ventilation. First generation devices such as cLMA, flexible LMA and LMA-unique are simply 'airway tubes'. During their usage, they encountered certain drawbacks like gastric insufflations and gastric content aspiration. Hence changes were made to increase the efficiency of LMA. This lead to invention of newer SAD, LMA supreme and I-gel airwaywhich have inbuilt orogastric tube port which drains gastric contents and protects patient from aspiration of gastric contents.[8]

The PLMA is a second generation LMA which was introduced in the year 2000. PLMA is a reusable SAD which was modified to separate respiratory tract from gastrointestinal system.

A study conducted by Ganzouri*et al,*[17] compared PLMA and endotracheal tube regarding insertion, hemodynamic changes and emergence characteristics. Results of this study revealed that ease of PLMA insertion was rated excellent in 98% of patients. It was accomplished in 7±14 sec. Nineteen per cent of patients required reinsertion due to unsatisfactory initial positioning.

Significant hemodynamic differences were observed between the groups in response to the airway device insertion. Maximum MAP and HR were significantly increased in ETT group when compared to PLMA group, during insertion and removal. During emergence, PLMA patients had significantly lower incidence of coughing. Both PLMA and ETT patients had similar incidence of sore throat 24hrs postoperatively.

A multicentre study was done by Brimacombe*et al,*[18]compared the PLMA with LMA classic(cLMA) in anaesthetised non paralysed patients, it was found that

in cLMA the insertion time was shorter than PLMA. The ASP was higher in PLMA v/s cLMA (27±7v/s 22±6 cm of H_2O).

In a randomized cross over study done to compare the Proseal LMA and classic LMA in anaesthetized paralysed patientsconducted by Brimacombe*et al*,[19]the placement of PLMA at the first attempt was higher (60 of 60 v/s 52 of 60; p = 0.003) and the time to secure cLMA was shorter.ASP was significantly higher in PLMA group (8-11 cm of H2O), at all cuff volumes (p <0.00001), but vocal cord visibility was similar (cLMA- 59/60). "When the devices were introduced with introducer, first time success rates were comparatively higher (59of 60 v/s 53 of 60; p=0.03) and the insertion time was shorter with PLMA (15 ±13sec v/s 23 ± 18 sec; p = 0.008)".

A study done by Brimacombe*et al*,[20] compared PLMA and laryngeal tube airway(LTA) in paralysed anaesthetized adult patients undergoing pressure controlled ventilation (PCV). In this study, it was seen that first attempt success rates were similar in both the groups with PLMA 1st attempt success rate being 85% and LTA's 1st attempt success rate being 87%. The success rate was found to be higher for PLMA after 3 attempts (100% v/s 92%, p = 0.02). Time for insertion was similar in both the groups."Oropharyngeal leak pressure was higher for PLMA at 50% maximal recommended cuff volume (33±7 v/s 31±8 cm of H_2O). Tidal volumes (614±173 v/s 456±207ml, p < 0.001) were significantly larger and $EtCO_2$ (33±9 v/s 40±11mm Hg, p<0.0001) significantly lower for PLMA." The study concluded that the PLMA is superior over the LTA.

Evans *et al,* [21] studied PLMA in 300 cases and concluded that the PLMA is a reliable airway management device which provides an effective glottis seal in bothparalysed and non-paralysed patients.Results of this study revealed successful

insertion rate of 98% (294/300) of which 91% were graded as easy (274). They did not find any statistically significant difference for insertion with introducer or finger insertion method. Mean airway seal pressure was 29cm of H_2O with 20% patients having sealing pressures greater than 40 cm H_2O (59/294). Success rate of orogastric tube placement was 98.6% (290/294). Haemodynamic stability was observed during insertion of the device, with a small reduction in HR 5 minutes after insertion and significant decrease in MAP at 1 and 5 minutes after insertion. Twenty three percent of patients had sore throat immediately after surgery and 16% had sore throat after 24 hours. 90% of the patients with sore throat described it to be of mild grade.

The BASKA mask was designed by Australian anaesthetistKanag and Meenakshi BASKA. It is made up of silicone having a non- inflatable cuff. It gets into the form of supraglottic airway thereby potentially reducing the risk of oropharyngeal injury or nerve damage induced by cuff over inflation. “The cuff is continuous with central channel of the device and as the pressure increases with PPV the cuff gets inflated by itself which improves the seal, reducing leak and makes ventilation more efficient”[12]

Chaudhary UK et al,*[22]*conducted the “Comparison of the BASKA mask versus I-gel in patients undergoing laparoscopic surgeries”. “The mean OLP in BASKA mask v/s I-gel at insertion (29.54 ± 1.41 cm of H_2O v/s. 23.16 ± 3.07 cm of H_2O, p = 0.02) and after 30 min of insertion was (33.54 ± 1.16 cm of H_2O vs. 25.97 ± 2.25 cm of H_2O, $p<0.001$)”. The mean OLP was higher in BASKA mask.

SO Ronchoi*et al,[23]*conducted study between “BASKA mask and I-gel in patients undergoing Laparoscopic cholecystectomy”. “The mean ASP was more in the

Baska Mask group than in the i-gel group (29.6 ± 6.8 cmH_2O and 26.7 ± 4.5 cmH_2O, respectively (p = 0.014)".

Alexiev V *et al,*[24] conducted a comparative study of BASKA mask with LMA in 150 female patients in a RCT. They found that "median seal pressure was significantly more with BASKA mask (34-40 cm H_2O) compared with LMA (18-22 cm H_2O) thereby indicating a better seal with BASKA mask".

Thus taking into consideration of data available in literature with respect to the supraglottic devices, BASKA mask and Proseal LMA, which provided different conclusions, we undertook this study to evaluate their clinical efficacy with regards to the ASP in laparoscopic surgeries before pneumoperitoneum, 5 minutes after creation of pneumoperitoneum, duration of insertion, ease of insertion and post op laryngopharyngeal morbidity score in anaesthetized paralysed adult patients undergoing positive pressure ventilation.

BASIC SCIENCE

Anatomy[25,26,27]

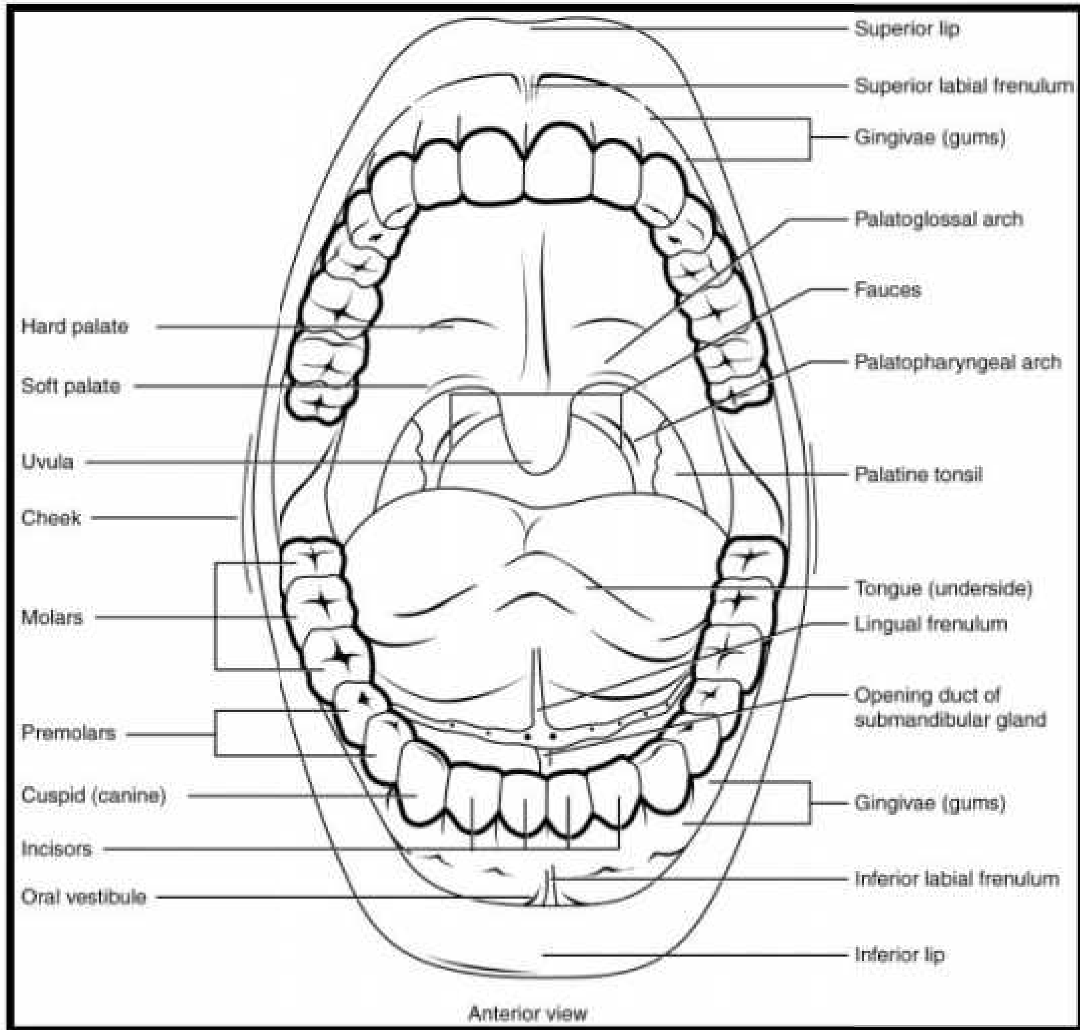


Figure 1: Anatomy of oral cavity

Oral cavity:

It has two parts,

- Vestibule,
- Oral cavity proper.

Vestibule:

- It is a narrow space.
- Boundaries:
  - External: lips and cheek
  - Internal: the teeth and gums.

Oral cavity proper:

- Boundaries include the teeth, gums and the jaw's alveolar arches.
- Roof: Hard and Soft palate.
- Floor:
  - Posterior: Tongue.
  - Anterior: Sublingual region (below the tongue's tip).
- Posterior:

  Oro-pharyngeal isthmus (pharyngeal communication): It is bounded by soft palate superiorly, tongue inferiorly and palato-glossal arches on the sides.

Hard palate:

- It is a partition between the nasal and oral cavities.
- Anterior 2/3rd: the maxillae (palatine process).
- Posterior 1/3rd: palatine bones (horizontal plates).
- It is bounded to the periosteum tightly by thick mucosa.

Soft palate:

Soft palate is a muscular fold that is mobile. It is suspended from the hard palate (posterior border). Nasopharynx and oropharynx are separated by the soft palate. It controls the traffic between the air and food pathways.

Muscles of the palate:

- Palato-pharyngeus,
- Musculus uvulae,
- Tensor palate,
- Palato-glossus,
- Levator palate.

Tongue:

- It is a muscular organ.
- It has two parts that are separated by sulcus terminalis
    - oral
    - Pharyngeal.
- Attachment of the tongue's inferior surface to the mouth is by frenulum.
- Muscles of the tongue:
    - Tongue is divided into left and right halves by a fibrous septum in the middle.
    - Each half consists of 4 intrinsic and 4 extrinsic muscles.

Intrinsic muscles	Extrinsic muscles
Superior longitudinal	Genioglossus
Inferior longitudinal	Hyoglossus
Transverse	Styloglossus
Vertical	Palatoglossus

- Nerve supply:
  - Motor: Hypoglossal nerve, pharyngeal plexus
  - Sensory: Mandibular nerve via lingual nerve and glossopharyngeal nerve
  - Taste: Facial nerve via chorda tympani and glossopharyngeal nerve
- Arterial supply:

  External carotid artery's branches: The maxillary, facial and lingual arteries.
- Venous drainage:
  - Pterygoid plexus,
  - Tonsillar plexus and
  - Pharyngeal plexus.
- Lymphatic drainage:
  - Upper deep cervical lymph nodes.
  - Retropharyngeal lymph nodes.

Pharynx:

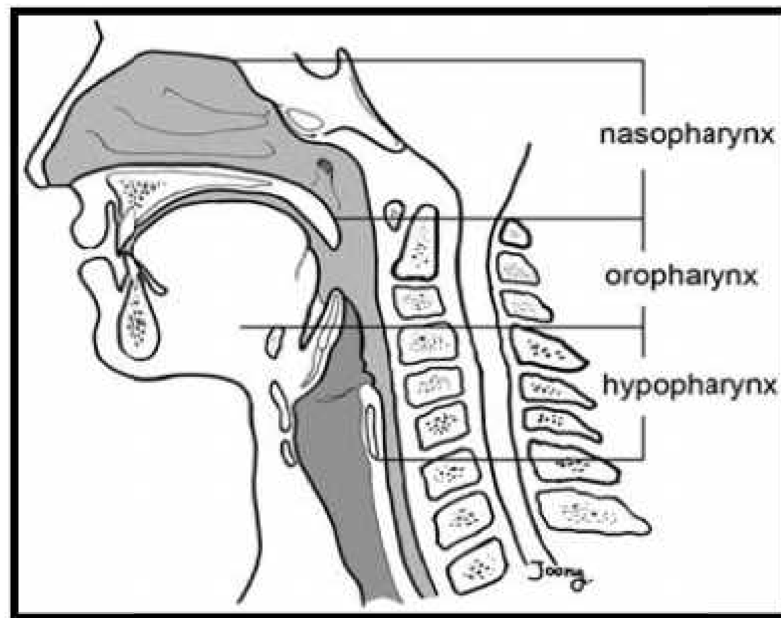


Figure 2: Anatomy of pharynx

- The pharynx is a 12-14 cm long musculo-membranous tube.
- Inverted cone in shape.
- Extension:
    - Superiorly: Base of cranium.
    - Inferiorly: Cricoid cartilage's lower border.

Parts of pharynx:

- It includes naso-, oro- and laryngo-pharynx.

Nasopharynx:

- Extension:
    - Superior: Base of the skull.
    - Inferior: Soft palate's superior surface.
    - It allows free passage for respiration.
    - On each side the eustachian tube opens.

Oropharynx:

- The extension of oropharynx is from uvula to hyoid bone.
- The palatoglossal arch (that passes through the oropharyngealisthumus) delineates the mouth and the oropharynx.
- Lateral wall: Palatopharyngeal arch and palatine tonsil

Laryngopharynx:

- It forms the posterior part of the pharynx in its entire length.
- Extension: superior – epiglottis (superior border), inferior – cricoid cartilage.
- Borders:
  - Superior: Lateral glosso-epiglottic folds - Delineates oro-pharynx and laryngo-pharynx
  - Inferior: continuous with oesophagus.
- On either side of the inlet of larynx lies the pyriform fossa. Its boundaries include:
  - Medial: Aryepiglottic fold.
  - Lateral: Thyroid cartilage and thyrohyoid membrane.

Muscles of the pharynx:

- Constrictors:
  - Superior,
  - Middle
  - Inferior.
- Longitudinal muscle coat:

- The Palato-pharyngeus muscle.
- The Stylopharyngeus muscle, and
- The Salphingo-pharyngeus muscle.

Nerve supply of pharynx:

- Motor: Glossopharyngeal nerve, cranial part of accessory nerve.
- Sensory: General sensation is carried by the pharyngeal branches of glossopharyngeal nerve and palatine branches of maxillary nerve.
- Taste: The lesser petrosal nerve to the pterygopalatine ganglion (also has secretomotor innervations to the pharyngeal mucosa).

Arterial supply:

The arterial supply is provided by the lingual, facial and maxillary arteries. Ascending pharyngeal as well as the superior thyroid artery also provides arterial supply.

Venous drainage:

Venous drainage is by both the pterygoid and the pharyngeal plexus.

Lymphatic drainage:

- Retropharyngeal lymph nodes
- Upper deep cervical lymph nodes.

Larynx:

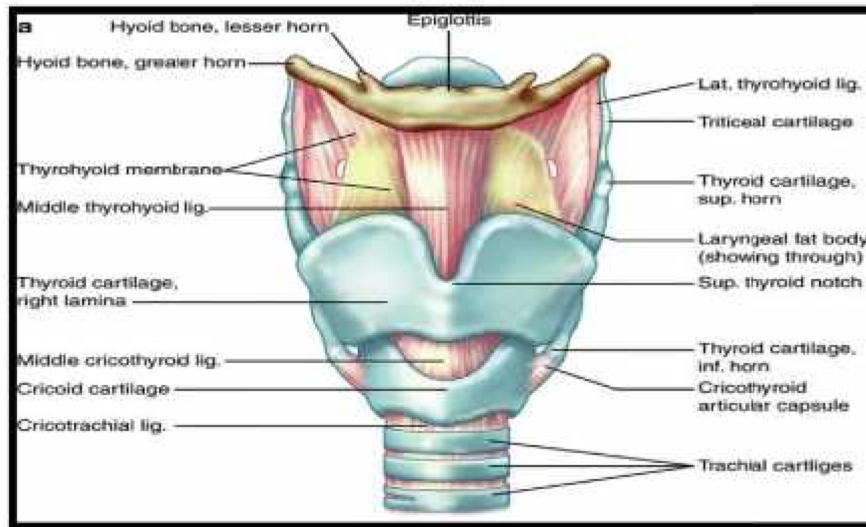


Figure 3: Anatomy of larynx

- The larynx is an air passage, a sphincter and an organ of phonation.
- Extension of larynx is from the tongue to the trachea.
- Superior: It forms the anterior wall of laryngo-pharynx.
- Inferior: Continues as trachea.
- Larynx moves on deglutition.
- It is present opposite to 3rd-6th cervical vertebrae in adult males and situated at higher level in children and adult females.

The laryngeal framework is formed by a set of cartilages connected to ligaments and fibrous membranes, and moved with help of numerous muscles.

Cartilages

Paired cartilages:

1. Arytenoid Cartilage
2. Corniculate Cartilage
3. Cuneiform Cartilage

Unpaired cartilages:

1. Epiglottis
2. Thyroid Cartilage
3. Cricoid Cartilage

Laryngeal joints

1. Cricothyroid joint
2. Cricoarytenoid joint

Laryngeal ligaments and membranes:

Extrinsic ligaments

1. Thyrohyoid membrane
2. Thyro and hyoepiglottic ligaments
3. Cricotracheal ligament

Intrinsic ligaments

1. Quadrate membrane
2. Cricothyroid membrane and conuselasticus.

Cavity of larynx

The larynx is divided into:

- Vestibule of larynx,
- Ventricle of the larynx and
- Infra-glottic part by the two mucous membrane folds.

Muscles of larynx

Intrinsic muscles of larynx

1. Oblique arytenoids and aryepiglotticus-sphincter action at the laryngeal inlet
2. Transverse arytenoids-Adductor of vocal cords
3. Posterior cricoarytenoid- Abductor of glottis
4. Lateral cricoarytenoid-Adducts the vocal cords
5. Cricothyroid - Elongates and tenses the vocal cords
6. Thyroarytenoid and vocalis-Relaxes the vocal cords
7. Thyroepiglotticus –Opens the inlet of the larynx.

Extrinsic muscles of larynx

1. Suprahyoid muscles:
   a. Stylohyoid.
   b. Digastric
   c. Mylohyoid
   d. Geniohyoid
2. Infrahyoid muscles:
   a. Sternohyoid
   b. Omohyoid
   c. Sternothyoid
   d. Thyrohyoid

Nerve supply of larynx:

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

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

Arterial supply:

- The larynx is supplied by the Superior and inferior laryngeal artery.
- Cricothyroid artery also provides arterial supply to the larynx.

Venous drainage:

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

Lymphatic drainage

The supraglottic part of the larynx is drained by lymph vessels into the upper deep cervical lymph nodes and the infraglottic part of larynx; lymph vessels reach pre and para tracheal lymph nodes and join the lower deep cervical lymph nodes

Applied anatomy:[28,29,30]

Supra-glottic devices come into contact with the mouth and pharynx (except nasopharynx).

Mouth:

Hard palate makes up anterior 2/3rd of roof of oral cavity and soft palate forms the posterior 1/3rd. Supraglottic airway device needs optimum opening of the mouth. Upon entry of food into oral cavity, it is diverted into oropharynx by the shape of hard palate whereas the soft palate protects food from entering the nasopharynx. If

the angle formed by hard palate and the posterior oropharyngeal wall is below 90 degrees, it might be difficult to place the SAD.

Oropharynx:

SAD passes through the oropharynx to enter the laryngopharynx. The oral cavity continues as oropharynx posteriorly running from the end of soft palate till the superior border of epiglottis. Prevertebral fascia and second and third cervical vertebra make up the posterior wall of oropharynx. The palatoglossal and palatopharyngeal folds make up the lateral wall of oropharynx. The lateral wall houses the paired tonsillar fossae inside which palatine tonsils are present. Palatine tonsils when inflamed or swollen might hinder the placement of SAD in the oropharynx. Base of the tongue is related to the tonsillarfauces in its lateral aspect.

Neurovascular considerations:

Excessive inflation of the laryngeal mask cuff or malposition of the SAD can cause compression of the blood vessels and nervous tissue around the oropharynx.

Cuff related complications commonly affect,

- Glossopharyngeal nerve: between superior constrictor and middle constrictor,
- Recurrent laryngeal nerve: lies deep to inferior constrictors.
- Lingual nerve: inferior to the superior constrictor's inferior border.

Physiological implications:

Cardiovascular system:

Insertion of the SAD when compared to ETT insertion is associated with,

- smaller rise in blood pressure and
- smaller rise in heart rate.

Respiratory system: Airway complications such as laryngospasm, bronchospasm, trauma and sore throat are less frequent with SAD than with the endotracheal intubation

Intracranial pressure: Use of SAD as a conduit to endotracheal intubation in patients has a minor effect on the ICP during insertion.

Gastrointestinal system:

The swallowing reflex:

When the SAD is inserted during lighter planes of induction of anaesthesia various defensive reflexes such as gagging, coughing, swallowing, retching and hypersalivation occurs which on deepening the plane of anaesthesia can be suppressed. The tip of the SAD contacting the glottis results in coughing which may also result as a consequence of irritation due to increased secretions due to opening of the glottis.

When the blind technique is used for insertion of the SAD, swallowing as a physiological mechanism and the natural curve of the airway aids in a successful attempt when a finger is used for insertion.

Oesophagus:

Upper GI tract reflexes are also involved during the process of inserting the LMA. The presence of chemoreceptors and mechanoreceptors stimulates a primary deglutition peristaltic wave. When these receptors are stimulated inappropriately, uncoordinated waves of primary and secondary peristalsis is produced leading to relaxed lower oesophageal sphincter.

Pharyngeal mucosa:

The inflated cuff causing compression of the pharyngeal mucosa results in tissue trauma. No major pharyngeal trauma has been associated with supraglottic airway insertion and airway complications are less as compared to the endotracheal intubation. A very rare complication is risk of ischemia of the pharyngeal mucosa produced by the pressure of the mask over it. This can be avoided by keeping cuff pressure values under 60 cm of H_2O, which is perfusion pressure of the capillaries of pharynx.

The Proseal laryngeal mask airway (PLMA):[13,31]

- Dr. Archie brain designed PLMA based on the cLMA in 2000.
- It was specifically designed for positive pressure ventilation.

Both PLMA and cLMA comprises of cuff, bowl and airway tube. The PLMA's airway tube is strengthened with diameter equal to flexible LMA (fLMA).

Modifications compared to the cLMA are:

1. Deep and large bowl
2. Cuff extends posteriorly
3. Airway tube and draining tube run parallel to each other and exit at the tip of the mask.

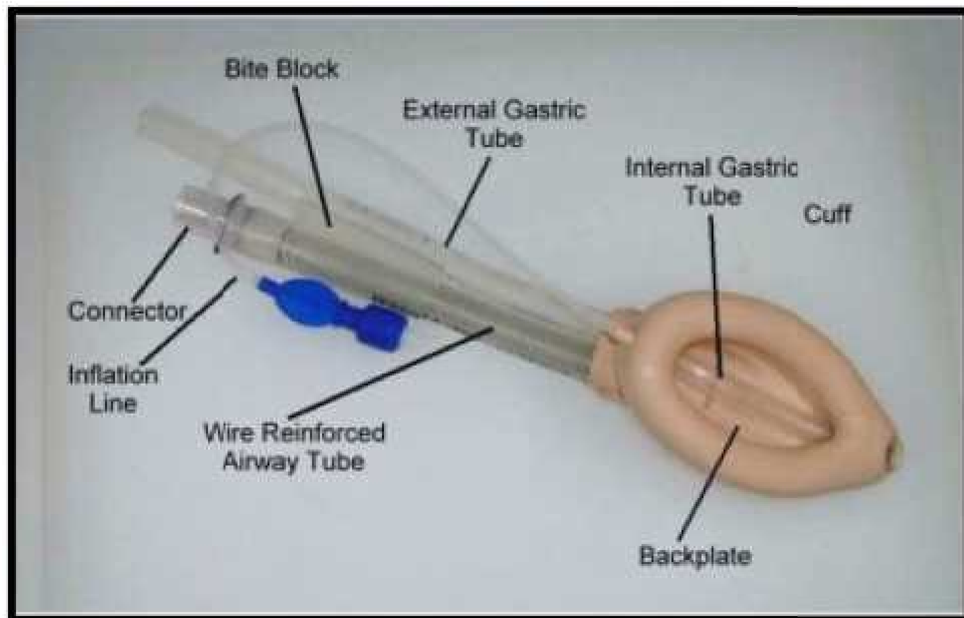
4. Bite block is made of silicone.
5. For insertion, the finger or introducer is aided by presence of anterior pocket.

PLMA's Design:

- In comparison to classic LMA, the PLMA has a softer cuff, mask bowl is deeper and a special cuff shape
- This allows the PLMA to provide a higher sealing pressure when compared to a given cuff pressure in a classic LMA (adult sizes).
- It allows venting the stomach by having a drain tube that is in continuation with the upper oesophageal sphincter through which a standard gastric tube can be inserted.
- Having two tubes provide it with more stability and anchorage.
- Tube damage and airway obstruction is prevented by the bite block which is built in.
- The drain tubes position prevents the epiglottis from causing airway obstruction.

Table 1- PLMA selection guidelines

PLMA Size	Weight in kg	Maximum inflation volume (ml)	Orogastric tube (Fr)
1	<5	4	8
1.5	5-10	7	10
2	10-20	10	10
2.5	20-30	14	14
3	30-50	20	16
4	50-70	30	16
5	70-100	40	18



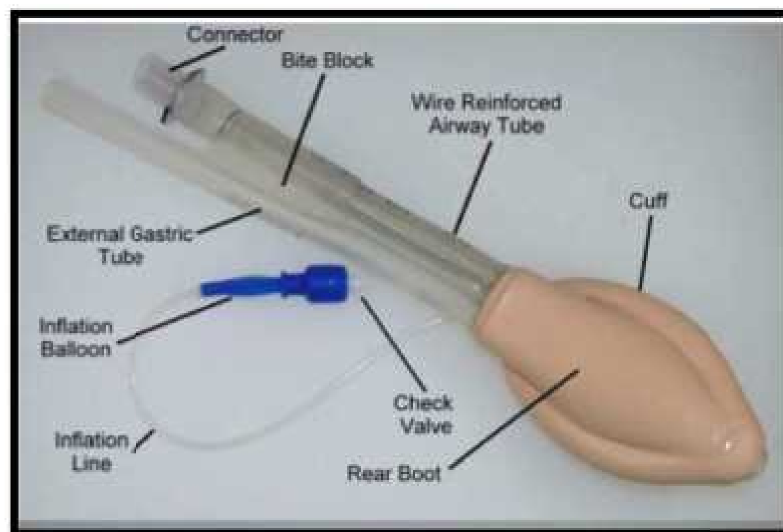


Figure 4:PLMA

Pre insertion technique

- Wear gloves
- Using the cuff deflator, the cuff has to be deflated completely (forms a flattened wedge shape) before inserting the PLMA.

- In order to prevent the blockage of the airway opening, water based jelly that is used for lubrication should be applied only on the posterior aspect of the cuff.

Insertion methods:

1. Index finger insertion technique
2. Introducer technique

Index finger technique

- The PLMA to be held like a pen.
- The index finger tip placed in the introducer strap.
- Till a resistance is felt, the LMA is advanced while pressing over the hard palate.
- In order to maintain a sniffing position,
    - The advancing finger is pushed in the direction of the occiput.
    - Other hand should exert counter pressure.
- Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube.
- This prevents the PLMA from being pulled out of place when finger is removed.

Introducer technique

This technique is commonly used for size 1 to 2.5 PLMA. It can also be used for adult sizes. The distal end of the silicone coated metal introducer is placed in the introducer strap. The proximal end is placed in the notch between airway tube and drain tube. Under direct vision, the bowl is placed into mouth, guided against the hard

palate and advanced in a smooth arc with handle until resistance is encountered. The introducer is then removed, taking care to avoid dental damage.

Steps to facilitate correct mask position

- Upon inserting the LMA, the cuff is inflated to intracuff pressure of less than 60 cm of H_2O.
- Just half of the maximum volume is required in order to achieve adequate intracuff seal pressure.
- The anaesthesia circuit is connected to the LMA and leakage from the drain tube and airway tube is checked.
- Correct placement can also be confirmed by square wave capnography, bilateral chest rise, equal air entry on both sides of chest.
- If necessary, patency of the drain tube can be checked by passing the orogastric tube till the end of mask tip.

The PLMA should act as an artificial epiglottis (By the separation of gastrointestinal and respiratory tract) to ensure safe and effective mechanical ventilation.

This ability depends on:

1. Creating an effective seal.
2. Proper positioning of the device.
3. Prevent gastric contents entering into respiratory tract.

Indications:

- For securing airway during routine and emergency anaesthetic procedures in fasted patients.
- Used in emergency airway securement in the event of difficult airway (anticipated/unanticipated) and during cardiopulmonary resuscitation.

Contraindications

PLMA should not be used in substitute of an ETT in the following elective or difficult airway patients on a non-emergency pathway:

- Inadequate NBM status.
- Morbid obesity.
- Women > 14 weeks pregnant.
- Thoracic/abdominal injury.
- Patients with delayed gastric emptying.
- Patients with respiratory pathology.

BASKA mask[12]

It is a 3rd generation supraglottic airway device introduced by Kanag and Meena BASKA.

Features:

- Cuff:
  - Cuff balloon has a thin membrane.
  - Cuff balloon is non inflatable and can recoil on its own.
  - There is neither pilot tube nor pilot balloon.

  - During IPPV the cuff pressure depends only on the max. inspiratory pressure and the pressure varies during the ventilator cycle.
  - Because of its soft nature there is lower risk of nerve damage or any other trauma.
- Sump Area:
  - Clears the gastric fluid.
  - There is an inbuilt cushion device that provides cricoid pressure internally.
  - This cricoid pressure is responsible for maintaining communication between the upper end of oesophagus and the sump area. This allows effective suctioning in the sump area.
- Airway Tube:
  - Presence of bite block – prevents airway obstruction.
  - Resistant to kinking.
- Shape and Design**:**
  - It is made in a "single injection" moulding.
  - It has no joints except for the 22mm connector on the top end
  - Its ease of insertion is contributed by its shape and differential flexibility.
  - It can be inserted in a neutral position avoiding the need for head or neck extension.
  - No need for extension of head or neck for insertion.
  - The presence of oral tab aids in easy and fast insertion.
  - Using fingers for positioning and inserting the LMA is not needed.

- Presence of two ports allows us to suction in one while allowing the other to act as an access to free airflow.

Baka mask selection guidelines:

Table 2: Baska mask selection guidelines

Size	Weight(kg)	Colour coded connectors
3	30-50	Green
4	50-70	Yellow
5	70-100	Red
6	>100	Blue

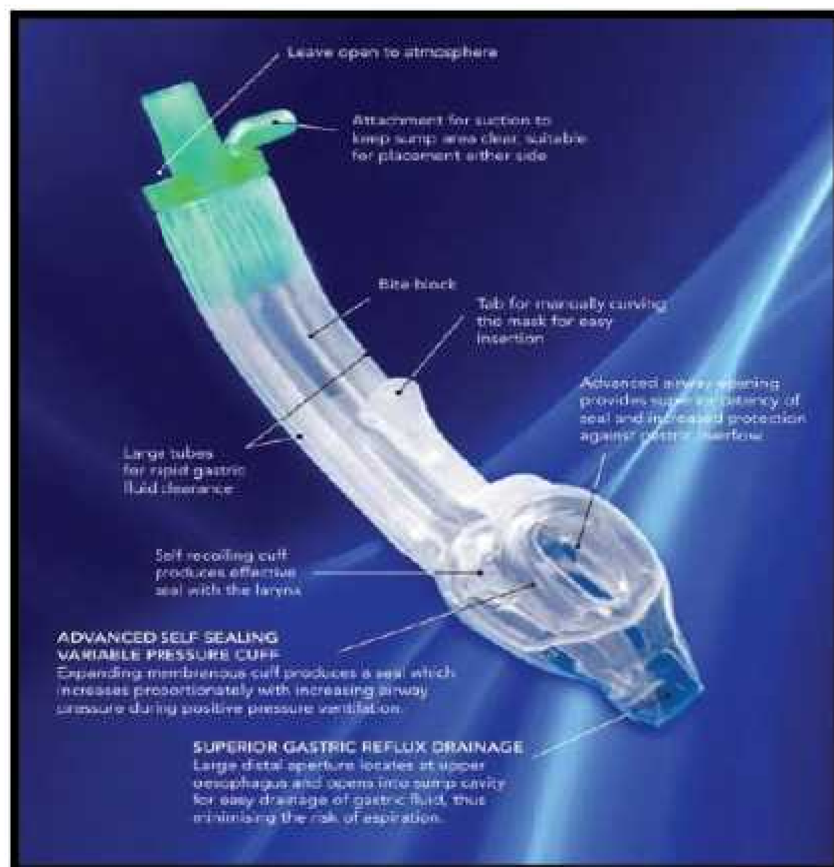


Figure 5: Baska mask

- **Insertion technique:**
    - Lubricate the BASKA mask with water-based jelly on its posterior surface.
    - The patient should be in neutral position and adequately anesthetised.
    - The proximal part should be compressed between thumb and two fingers and it should be advanced against hard palate.
    - The oral tab should be pulled if there is any difficulty to pass the device, it helps to negotiate the palate pharyngeal curve
    - The device should be advanced till resistance is felt
- **Steps for facilitating ventilation and correct placement:**
    - After insertion the anaesthesia circuit should be connected.
    - Check for leaks from airway tube and drain tube.
    - There should be bilateral equal air entry and chest rise,
    - Square wave capnography should be present.

METHODOLOGY

STUDY DESIGN: Randomised Controlled trial.

STUDY PERIOD: One year, from January 2019 to December 2019.

PLACE: The study was conducted at “Department of Anaesthesiology, KLE’S Dr.PrabhakarKore Hospital and Medical Research Centre,KAHER, Belagavi”.

SOURCE OF DATA: Adult patients undergoing routine elective laparoscopic surgeries under general anaesthesia at KLES Academy of Higher Education and Research, Belagavi - 10.

SAMPLE SIZE:A total of 60 patients divided into two groups.

SAMPLING PROCEDURE: Sample size was calculated using the results of previous similar studies and substituting them in the formula as below:

$$n = \frac{(z_{\alpha} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

Where,

Level of significance was taken as 5% (error = 0.05)

Power of the test was taken as 80% (error = 0.84)

Hence,

Z = 1.96

Z = 0.84

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

Group B – BASKA mask

Group P – Proseal LMA

- Selection Criteria: Adults undergoing Laparoscopic surgeries under general anaesthesia aged 18-60 years.
- Surgeries lasting up to 120 min or less.
- ASA physical status I and II.
- Mallampati grade I and II.

Exclusion Criteria:

- Significant lung diseases.
- Neck and upper respiratory tract pathology.
- Potential difficult intubation.
- High risk of aspiration (gastro-oesophageal reflux or full stomach).
- Pregnant women.
- BMI >30.

Ethical Clearance:

The approval by the institutional Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi, was taken before starting the study.

Informed Consent:

All the patients who fulfilled the selection criteria were explained about the nature of the study and intervention being done. A written informed consent was obtained from all patients before enrolment in their vernacular language.

Method of Collection of Data:

After the enrolment in the study, patients demographic data such as age, sex, and history were recorded. General physical examination and systemic examinations were carried out. Data was recorded on a predesigned and pretested proforma.

Investigations:

All the patients were subjected to following investigations:

- Complete blood count
- Routine urine examination
- Fating blood sugar
- Blood urea and serum creatinine
- Chest X-ray
- ECG

The findings of these investigations were recorded on a predesigned and pretested proforma.

Randomization:

Patients were randomly allocated by opening a computer generated ‘sealed envelope’ method into two groups :

Group B – BASKA mask (n = 30)

Group P – Proseal LMA (n = 30)

Procedure:

A thorough Pre anaesthetic evaluation (PAE) was done previous day of the surgery. Patient was enrolled into the study after considering inclusion and exclusion criteria, consent for anaesthesia and participation in the study was taken. On the day of surgery after confirming nil by mouth for 6 hours, intravenous line was secured.

In the operating room, a standard anaesthesia protocol was followed. Routine monitoring devices were applied – Electrocardiography(ECG), non- invasive blood pressure(NIBP), pulse oximetry (SpO_2). The patients were placed in sniffing position with occiput rested on a pillow (7 cm of height).

The airway device to be used was prepared for insertion with the cuff completely deflated (in case of PLMA) and its dorsal surface lubricated with the clear water-based gel.

All the patients were initially pre-medicated with intravenous inj.Glycopyrrolate, inj. midazolam and inj. fentanyl citrate of doses 0.005mg/kg, 0.05mg/kg and 2mcg/kg respectively. Pre-oxygenation with 100% oxygen for 3 minutes was done.

Anaesthesia was induced with intravenous inj.Propofol of dose 2mg/kg and neuromuscular blockade was attained with inj.Atracurium of dose 0.5mg/kg. The airway devices of appropriate size were inserted in strict accordance with the Manufacturers recommendation.

Insertion Technique:

BASKA mask: The proximal part of cuff is compressed between thumb and other two fingers, and then it is passed along the curve of hard palate. The oral tab was pulled to increase the device curvature to negotiate the palato-pharyngeal curve. It was passed till the resistance is felt.

Proseal LMA: The cuff of PLMA was completely deflated and the dorsum of the cuff was lubricated with water based jelly. The device was then mounted onto a metal introducer with the tip of the introducer resting in the introducer strap. PLMA is inserted in the oral cavity with the dominant hand of the anaesthesiologist. It is then advanced around the palato – pharyngeal curve using a single hand technique until a resistance is felt. Then the metal introducer is removed keeping LMA in place.

Successful placement of the device was assessed by square wave capnography, adequate chest expansion, absence of audible leak and lack of gastric insufflation.

Failed insertion was defined by any of the following criteria:

- Failed passage into the pharynx.
- Malposition.
- Ineffective ventilation (maximum expired tidal volume <6ml/kg or and the end tidal co2 >60 cm of H_2O.
- More than three attempts.

  If the device could not achieve a satisfactory airway as defined above, endotracheal intubation was done to establish a patent airway.

For PLMA, the intra cuff pressure was set at 60cm of H_2O to obtain an effective airway seal for positive pressure ventilation. Patients were ventilated at an inspired tidal volume of 6- 8 ml/kg, respiratory rate of 12-14 breaths/minute and an inspiratory: expiratory ratio of 1:2. Anaesthesia was maintained with 1:1 oxygen-nitrous oxide mixture, isoflurane (0.6-1%) and inj. Atracurium 0.15 mg/kg (IV) boluses. Intraoperative analgesia was taken care by inj. Paracetamol 10mg/kg IV.

Once the procedure is done, the neuromuscular blockade was reversed with intravenous inj.Glycopyrrolate of dose 0.001mg/kg and inj. Neostigmine of dose 0.05mg/kg. After the return of protective airway reflexes, regain of consciousness, the airway device was removed and ventilated with facemask for 5 min.

Study variables:

The ease of insertion was defined as:

- 1-Very easy : absolutely no resistance to LMA
- 2-Easy : no resistance to insertion in the single manoeuvre.
- 3-Difficult : resistances to insertion.
- 4-Very difficult :more than one manoeuvre was required for the correct placement of the device.

If an effective airway could not be achieved, the device was removed and failure of insertion was recorded and endotracheal intubation was done.

The duration of insertion was defined as the time taken from the prepared BASKA mask or PLMA touching the incisors of the teeth to the successful placement of the device confirmed by square wave capnography, bilateral equal air entry and bilateral chest rise.

ASP was determined by placing patient in manual mode with APL valve closed with fresh gas flow of 6L/min (Datex/Drager anaesthesia delivery system). The pressure at which audible leak occurred at the throat by keeping stethoscope taken as ASP.

The presence/absence of oropharyngeal air leaks (detected by audible leak over the mouth), gastric air leaks (detected by auscultating over the epigastrium) were noted.

Any episodes of laryngospasm and bronchospasm, intra-operatively were documented. Postoperatively, incidence of LPM Score was recorded at the 4th hour.

Table 3:LPM Score

SCORE	0	1	2	3
Sorethroat	none	Minimal	Moderate	Severe: never an SAD again
Dysphagia	none	Minimal	Moderate	severe: cannot eat
Hoarseness	none	Minimal	Moderate	Severe: cannot speak

Statistical analysis

Data obtained was coded and entered into Microsoft excel spread sheet. The categorical data was expressed in terms of rates, ratios and percentage and continuous data was expressed as mean ±standard deviation (SD). The demographic data, duration of insertion and ASP were analysed using unpaired‘t’ test. The ease of insertion was analysed using fisher exact test. A probability value (p value) of less than or equal to 0.05 was considered as statistically significant.

RESULTS

A total of 60 anaesthetized, paralysed adult patients, undergoing positive pressure ventilation for elective laparoscopic surgeries were studied. Patients were randomly allocated into one of the two groups by a computer-generated sealed envelope

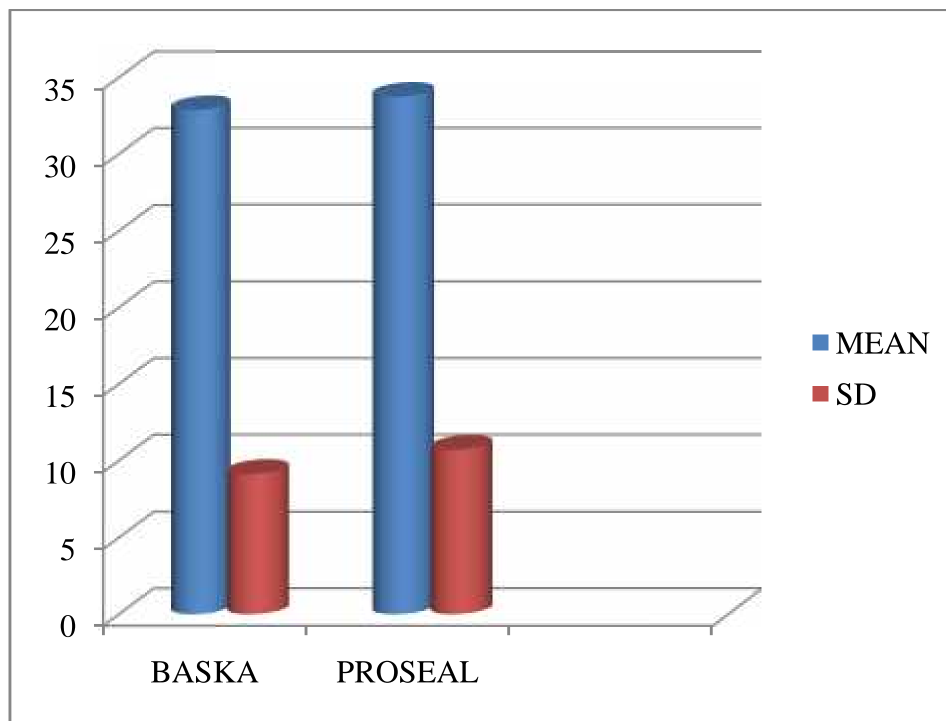
- Group B – BASKA mask (n=30)
- Group P –PLMA (n=30)

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

Table 4: Age distribution (years)

GROUP	Mean	S.D	MINIMUM	MAXIMUM	P-VALUE
BASKA	32.87	9.13	19	54	0.7372
PROSEAL	33..73	10.71	19	58	

Graph 1: Age distribution(years)

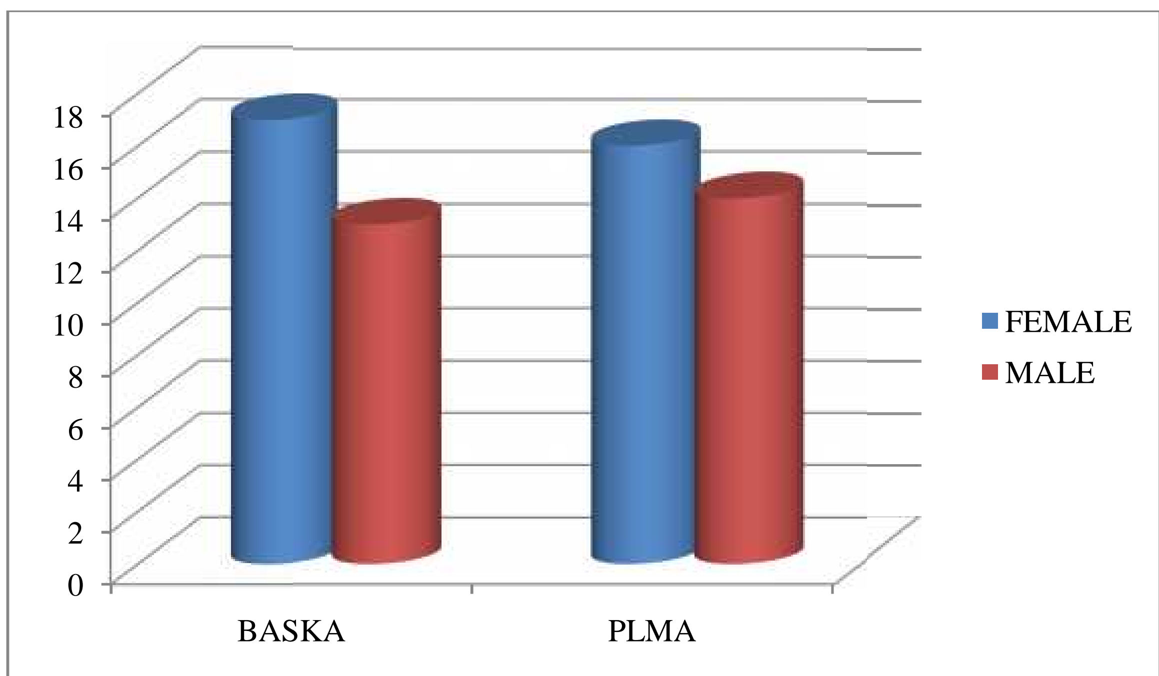


The mean age was 32.87±9.13 years in BASKA and 33.73±10.71 years in PLMA. There was no statistically significant difference between both the groups.

Table 5: Gender distribution

GROUP	BASKA MASK		PROSEAL MASK		P-VALUE
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE	
FEMALE	17	56.67	16	53.33	0.795
MALE	13	43.33	14	46.67	
TOTAL	30	100.00	30	100.00	

Graph 2: Gender distribution

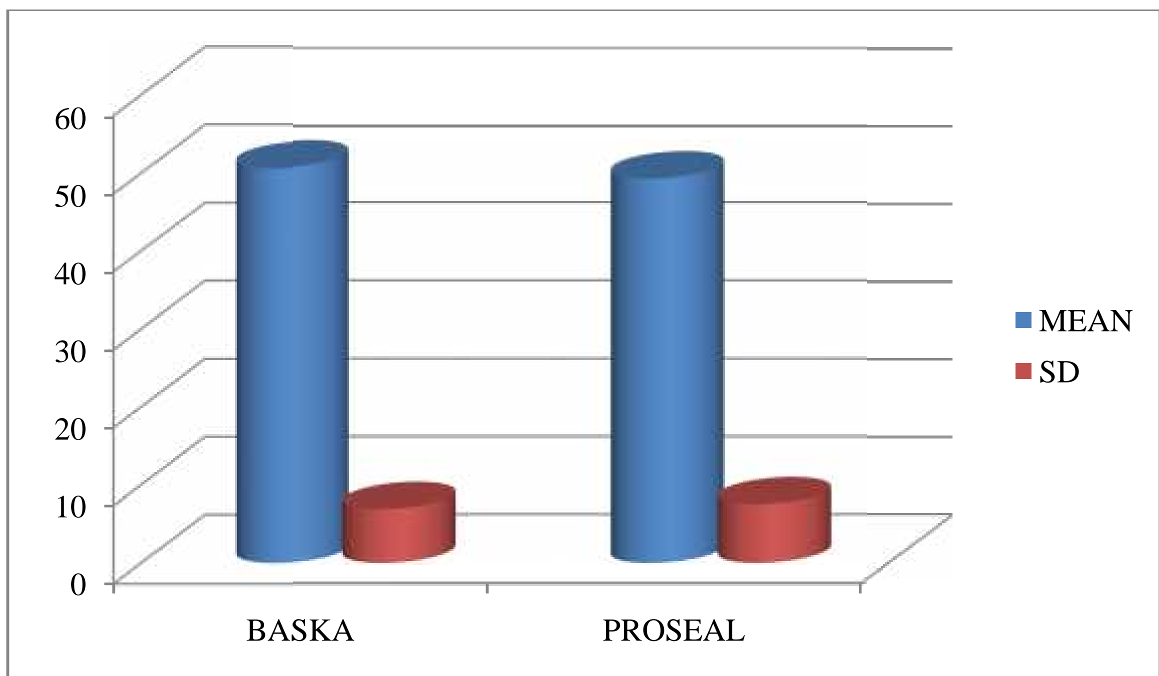


In our study, there were 17 female, 13 male patients in BASKA Group and 16 female, 14 male patients in PLMA Group, sex distribution did not account to statistical significance.

Table 6: Mean Weight(Kg)

Groups	N	Mean (kg)	SD	P-VALUE
BASKA	30	50.60	6.87	0.443
PROSEAL	30	49.17	7.49	

Graph 3: Mean Weight (Kg)

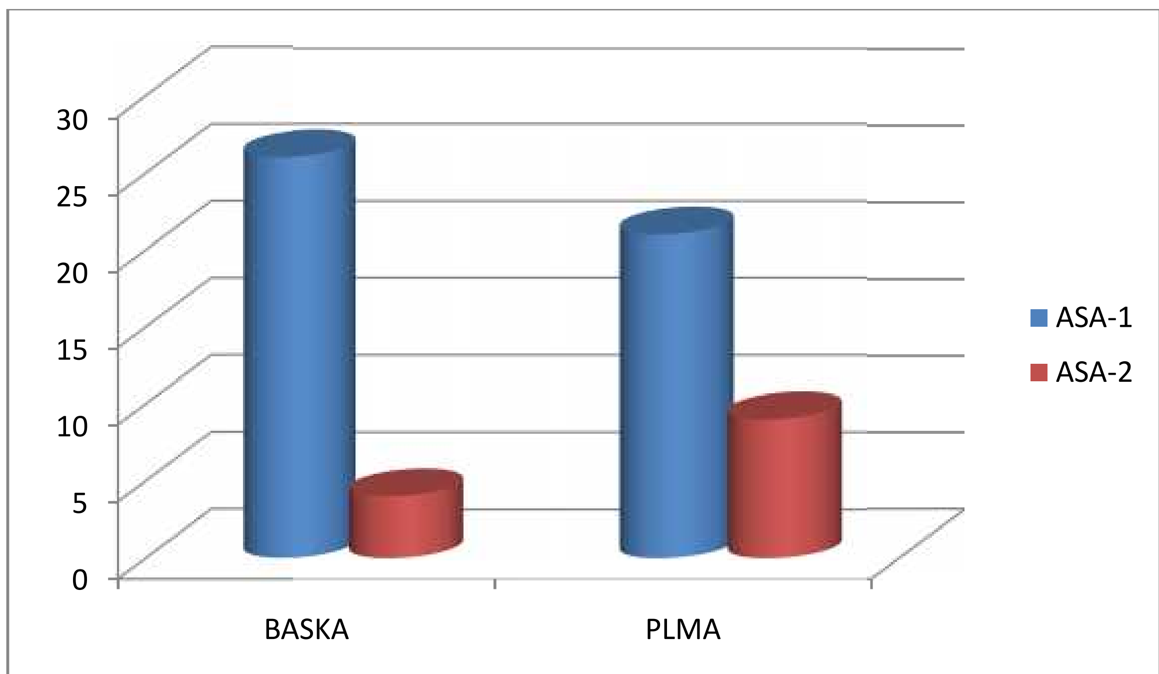


The mean weight in BASKA Mask group was 50.60 ± 6.87kg and in PLMA Group 49.17±7.49 kg, which was not statistically significant(p=0.443). Both groups were comparable with respect to weight.

Table 7:Distribution of ASA

ASA grade	BASKA	%	PLMA	%	P-VALUE
Grade 1	26	86.87	21	70.00	.1171
Grade 2	4	13.33	9	30.00	
Total	30	100.00	30	100.00	

Graph 4: Distribution of ASA

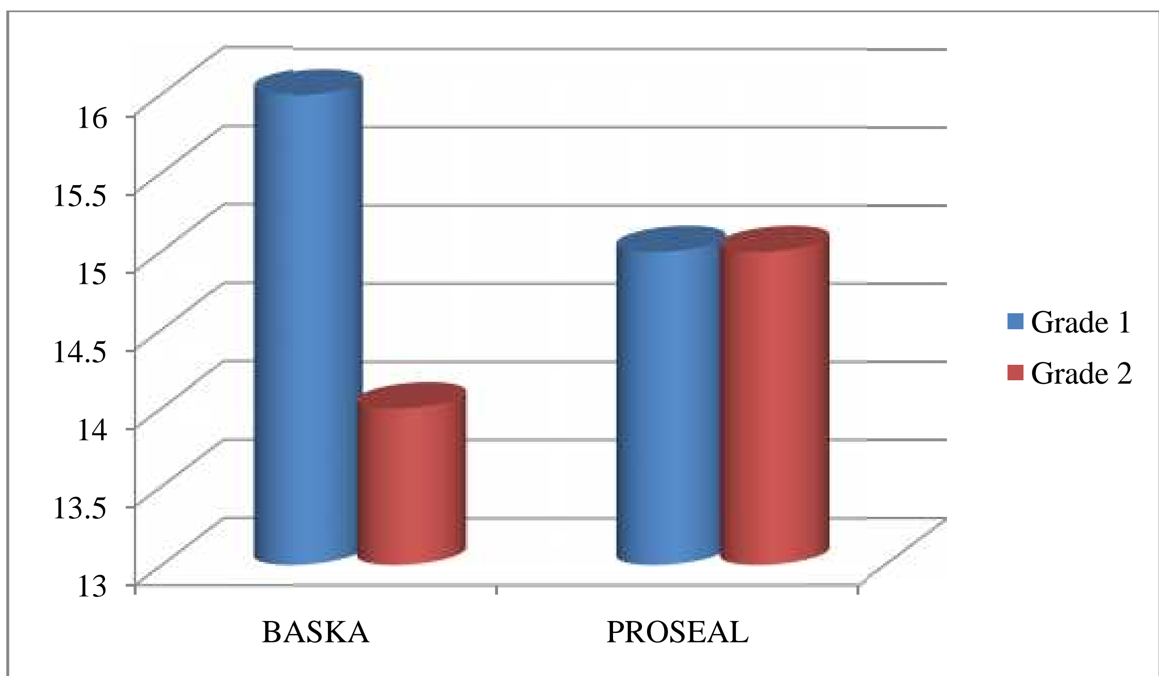


In this study, among the patients who were scheduled for surgery, 86.67% in BASKA Group belonged to ASA grade 1 compared to 70% in PLMA Group. ASA grade 2 of BASKA mask 13.33% and 30% of PLMA.There is no statistical significance between two groups.

Table 8:Mallampati grade

MPG Grade	BASKA (n =30)	%	PROSEAL(n = 30)	%	P-VALUE
Grade 1	16	53.28	15	50.00	0.796
Grade 2	14	46.62	15	50.00	
Total	30	100.00	30	100.00	

Graph 5: Mallampati grade

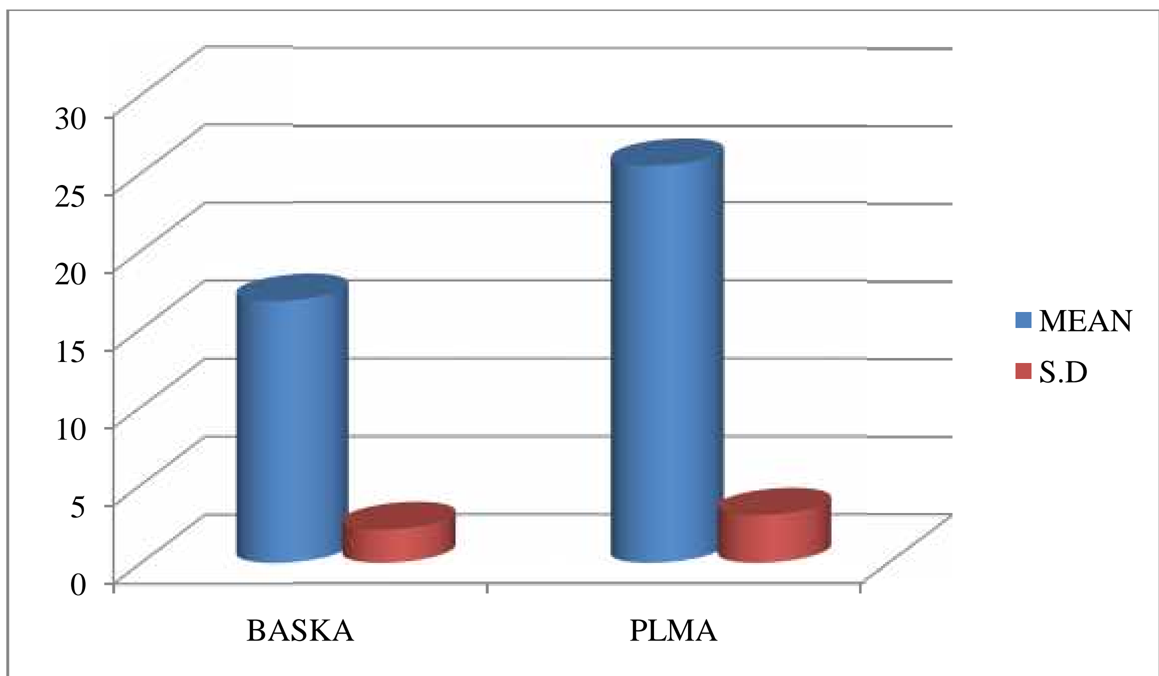


In the present study, 53.28% of patients in BASKA Group had Mallampati grade 1 in comparison to 50% of patients in PLMA group. MPG grade 2 46.62% BASKA group and 50% in PLMA group.Both groups were comparable with respect to MPG Grading (p=0.796)

Table 8: Mean insertion time (sec)

GROUP	MEAN	S.D	MIN	MAX	P-VALUE
BASKA	16.77	2.14	14	21	<0.0001
PLMA	25.40	3.04	20	31	

Graph 6: Mean insertion time (sec)

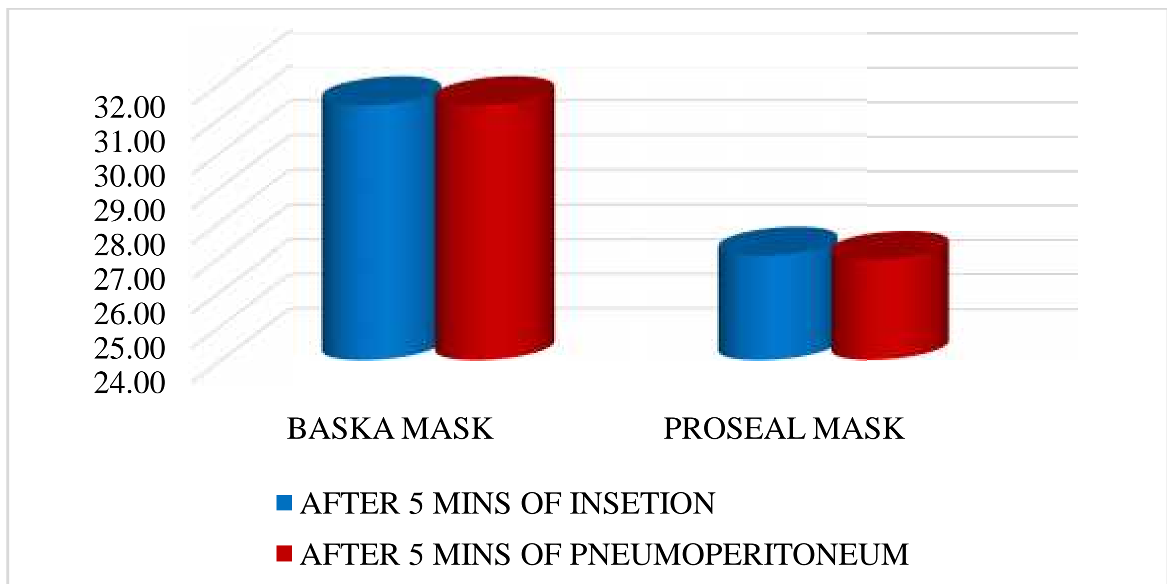


In our study, the mean duration of insertion was 16.77±2.14 sec in BASKA Mask and 25.40±3.04 sec in PLMA Group. This difference was statistically significant ($p<0.0001$)

Table 10:Mean ASP (cm of H_2O)

	BASKA MASK				PLMA				
ASP	MEAN	S.D	MIN	MAX	MEAN	S.D	MIN	MAX	P-VALUE
AFTER 5 MIN OF INSERTION	31.33	2.31	28	35	27.00	1.84	24	30	<0.0001
AFTER 5 MIN OF PNEUMOPERITONEM	31.33	2.06	26	35	26.90	1.79	24	30	<0.0001

Graph 7: Mean ASP (cm of H_2O)

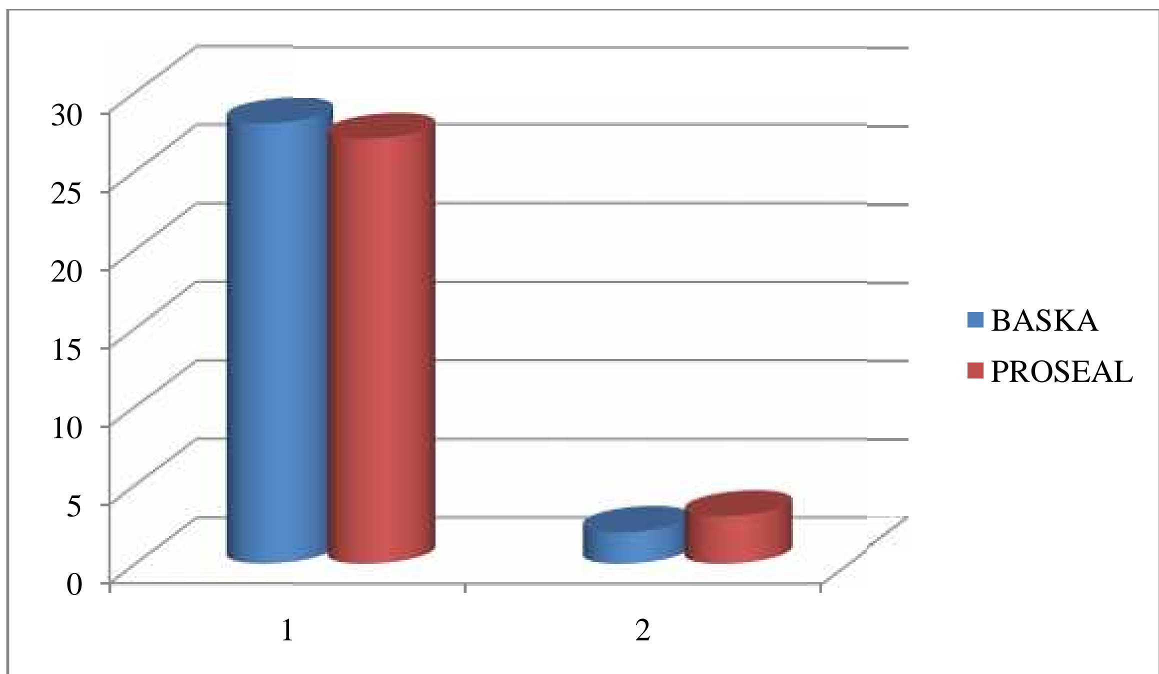


The mean ASP was 33±2.31 cm of H_2O in BASKA mask group and 27.00±1.84 cm of H_2O in PLMA Group after 5 min of insertion and 31.33±2.06 cm of H_2O in BASKA mask and 26.90±1.79 cm of H_2O in PLMA Group after 5 min of pneumoperitoneum. The ASP was more in BASKA mask group which was statistically significant both after 5 min insertion and 5 min of pneumoperitoneum. There were no significant mean ASPs between 5 min after insertion and 5 min after pneumoperitoneum in both the groups.

Table 11:Ease of insertion

EASE OF INSERTION	BASKA MASK		PROSEAL MASK		P-VALUE
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE	
1(very easy)	28	93.33	27	90.00	0.6404
2(easy)	2	6.67	3	10.00	
TOTAL	30	100.00	30	100.00	

Graph 8: Ease of insertion

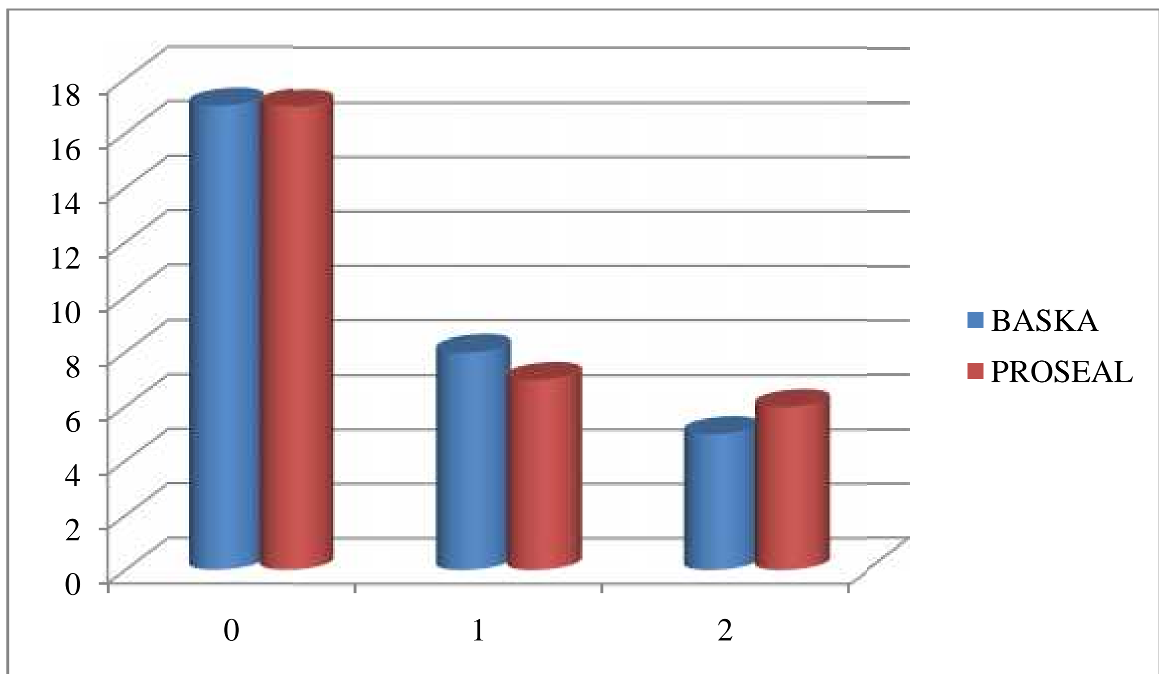


In our study insertion was very easy in 28 patients of BASKA mask Group and 27 patients of PLMA Group. Easyin 2 patients of BASKA Group and 3 patients of PLMA Group. This difference was statistically insignificant.

Table 12:LMP Scores

LMP SCORES	BASKA MASK		PROSEAL MASK		p-value
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE	
0	17	56.67	17	56.67	0.1576
1	8	26.67	7	23.33	
2	5	16.67	6	20.00	
TOTAL	30	100.00	30	100.00	

Graph 9: LMP Scores



In the recovery area patients were assessed for LPM score,

- 17 patients had score of 0 in both BASKA Group and PLMA Group.
- 8 patients of BASKA Group and 7 patients of PLMA Group had score of 1
- 5 patients of BASKA Group and 6 patients of PLMA Group had a score of 2.
- The difference between the two groups was statistically insignificant.

DISCUSSION

From the 19th century, endotracheal intubation was considered as the only way of establishing a definitive airway. But invention of supraglottic airway devices (SAD) has proven to effectively replace endotracheal tube in securing a definitive airway. SAD has various advantages like easy insertion, minimal hemodynamic changes, hands free maintenance, and lesser airway morbidity with relatively secure airway.[32,33] It is also better tolerated in lighter planes of anaesthesia. Because of the above mentioned advantages, SADs have been used ideally as an alternative to tracheal intubation as it has more advantages than endotracheal tube. Current guidelines on cardiopulmonary resuscitation recommend SADs as an alternative to tracheal intubation.[34,35,36]

PLMA is a reusable SAD that allows easy insertion, higher glottis seal pressures, and separation of respiratory tract from gastrointestinal tract via the gastric port which permits gastric drainage

In this study we compare BASKA Mask and PLMA for ease of insertion, time taken for insertion, ASP at insertion, 5 min after pneumoperitoneum and PLM scoring in anaesthetised, paralysed patients on positive pressure ventilation undergoing laparoscopic surgeries.

We enrolled a total of 60 ASA 1 and 2 patients aged 18-60 years, posted for elective laparoscopic surgeries under general anaesthesia. They were randomly divided into two groups of 30 each by computer generated sealed envelope method.

Among the patients enrolled in the study, there were 13 male, 17 female patients in BASKA group and 14 male, 16 female patients in PLMA group. The mean

weight was 49.17±7.49 kg in BASKA mask group and 50.60±6.87 kg in PLMA group. The mean age was 32.87±9.13 in BASKA mask group and 33.73±10.71in PLMA group. Both groups were comparable with respect to sex distribution, weight and age.

In our study, 86.67% of patients in BASKA mask group were ASA grade 1 and in comparison to 70% of patients in PLMA group. 53.28% of patients in BASKA mask group were MPG 1 in comparison to 50% in PLMA group. Both groups were comparable with respect to MPG and ASA grading.

When comparing the ease of insertion, it was observed that insertion was very easy in 28 patients of BASKA mask group and 27 patients of PLMA group; easy in 2 patients of BASKA mask group and 3 patients of PLMA group. The difference was statistically insignificant.

Time taken for insertion of SAD in our study was observed to be 16.9±2.14 sec in BASKA mask group and 25.40±3.04 sec in PLMA group. This difference is statistically significant ($p<0.0001$).

The observations of our study were similar to a study by Balwinderjit Singh *et al,*[37] comparing BASKA mask versus PLMA for general anaesthesia, where time taken for insertion was lower in BASKA group compared to PLMA group(14.25±3.82 sec and 22.01±2.64 sec) respectively.

In a study done by Ebenezer *et al,*[38] the mean insertion time for BASKA mask is 13.3 sec while for PLMA it was 19.7sec.

In a study conducted by Sharifa Ali Sabeeh Al-Rawahi *et al,*[39] comparing BASKA mask versus PLMA group for general anaesthesia The mean insertion time

was significantly shorter in the BASKA mask group as compared to the PLMA group (16.43±4.54 vs. 21.45±6.13) (p =0.001).

In a study conducted by Ranjith Kumar Kachakayala1 *et al,*[40] the time (in seconds) required for insertion of BASKA mask group was significantly less in duration compared to PLMA (20.9 vs. 16) ($p<0.0001$).

The time for insertion of Baska mask was shorter compared to PLMA which was similar to our study in the above four studies.

The lesser time taken for insertion for BASKA mask was attributed to any difficulty in negotiating oropharyngeal curve which was overcome by pulling the tab of BASKA mask and being a non inflatable cuff there was no need to inflate the cuff which reduces the time consumption.

The mean ASP after 5 min of insertion was 31.33±2.31 cm of H_2O in BASKA Group and 27±1.84 cm of H_2O in PLMA Group. The mean ASP measured after 5 min of pneumoperitoneum was 31.33±2.06 cm of H_2O in BASKA Group and 26.90±1.79 cm of H_2O in PLMA Group. The mean airway pressure is significantly higher in BASKA mask Group compared to PLMA group after 5 min of insertion and 5 min of pneumoperitoneum.

In a study conducted by Sharifa Ali Sabeeh Al-Rawahi *et al,*[39] comparing BASKA mask versus PLMA for general anaesthesia, the mean ASP was 29±8.51cm of H_2O for BASKA group and 24.50±6.19cm of H_2O. These results were similar to that found in our study.

In an another study conducted by Balwinderjit singh *et al,*[37] the mean ASP was 30.25±3.34 cm of H_2O in BASKA Group and 22.01 ±2.64cm of H_2O in PLMA Group in patients posted for general anaesthesia.

In the study conducted by Alexiev V, Salim A *et al,*[41] on 30 female patients, states that the mean airway leak pressure of BASKA mask was 35.7cm H_2O indicating a better seal which is comparable to our study.

In the study done byTom van Zundert *et al,*[12] on 50 patients, ASP was above 30 cm H_2O in all patients. The maximum ASP was 40 cm H_2O. Even in our study ASP of BASKA mask was around 30cm of H_2O in all patients.

The mean ASP is better in BASKA mask compared to PLMA. This may be attributed to thermolability of the membranous mask which makes it more adaptable to the shape of laryngeal outlet over time, hence a better seal.

In our study, insertion was very easy in 93.33% patients of BASKA mask and 90.00% patients of PLMA Group. Easy insertion was found in 6.67%patients in BASKA group and 10.00% patients in PLMA Group.

In the study conducted by Alexiev V, Salim A *et al,*[41]it was found that BASKA mask insertion was relatively easy with a mean VAS insertion difficulty score of 0.9 (1.6) out of 10.

In the study conducted by Rehab Abdel Raof Abdel Aziz,[42] "ease of insertion was comparable in patients of both groups. An easy insertion (score 1) and effective airway was achieved on the first attempt without performing adjustment manoeuvres in 76.67% of BASKA mask group versus 73.3% of I-gel".

In the study conducted by Alexiev V *et al,*[24] compared BASKA mask with single use classic LMA in 150 females. They concluded that BASKA mask was difficult to insert without any additional manoeuvres in 99% of patient whereas cLMA insertion success rate in 96% of patients.

In the study conducted by Tom van Zundert *et al,*[12] concluded that "compared to other SADs, BASKA mask cuff can easily be decreased in size by compressing the proximal, firmer part of the mask between thumb and fingers making insertion easier".

In our study 8 patients of BASKA mask Group and 7 patients of PLMA Group had LPM score of 1, 5 patients of BASKA mask Group and 6 patients of PLMA Group had a LPM score of 2. The difference between the two groups is statistically insignificant.

Study conducted by Sharifa Ali Sabeeh Al-Rawahi *et al,*[39] also concluded that there is no significant difference between BASKA mask group and PLMA Group of LPM scores.

Limitations

Sizes of the SAD used were either size 3 or 4. Therefore the results may not be applicable to other sizes.

Patients enrolled in our study had normal airways, thus no conclusion can be made regarding patients with difficult airways.

Use of SAD were done on ASA-1 and 2, hence cannot be projected on ASA-3 and 4 patients.

CONCLUSION

In our comparative study of BASKA mask and PLMA, we compared BASKA Mask (size 3 and 4) and PLMA (size3 and 4) and it was concluded that:

- BASKA mask insertion time was significantly lower than that of PLMA.
- The mean ASP was significantly higher in BASKA mask compared to PLMA both after 5 min of insertion and 5 min of pneumoperitoneum.
- The ease of insertion comparison between the BASKA mask and PLMA was found to have no statistical significance.
- The LPM score between BASKA mask and PLMA didn't show significant difference.

SUMMARY

Our present study was aimed to compare the BASKA mask and PLMA with regard to time duration for insertion, mean ASP after 5 min of insertion, 5 min after pneumoperitoneum, ease of insertion and LPM scoring.

The study was conducted with 60 ASA 1 and 2 adult patients of both sex, aged between 18 and 60 years posted for elective laparoscopic surgeries under general anaesthesia in the "Department of Anaesthesiology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre,KAHER, Belagavi -10, during the period of January 2019 to December 2019. After obtaining the approval from the hospital ethical committee, the patients were randomly allocated to group B: BASKA(n=30) and group P: PLMA(n=30). The demographic data were comparable in both groups.

All the patients were premedicated with inj. Glycopyrrolate 0.005mg/kg (IV), inj. Midazolam 0.05mg/kg (IV) and inj. Fentanyl 2mcg/kg (IV). Patients were pre-oxygenated with 100% oxygen for 3 minutes.

Anaesthesia was induced with inj. Propofol 2mg/kg (IV) and neuromuscular blockade was achieved with inj. Atracurium 0.5mg/kg (IV). Patients were ventilated using face mask for 3 min and then the airway device of appropriate size was inserted in strict accordance with the Manufacturers recommendation.

In our study, the mean duration of insertion was 16.77±2.14 sec in BASKA mask and 25.40±3.04 sec in PLMA Group. This difference was statistically significant ($p<0.0001$).

In our study insertion was very easy in 28 patients of BASKA mask and 27 patients of PLMA Group. Easy insertion was found with 2 patients in BASKA mask Group and 3 patients in PLMA Group. This difference was statistically insignificant.

BASKA mask provided a better seal than PLMA for positive pressure ventilation. The mean ASP was 33±2.31cm of H_2O in BASKA mask group and 27.00±1.84 cm of H_2O in PLMA Group after 5 min of insertion and 31.33±2.06 cm of H_2O in BASKA mask and 26.90±1.79 cm of H_2O in PLMA Group after 5 min of pneumoperitoneum. The ASP was more in BASKA mask group which was statistically significant both after 5 min insertion and 5 min of pneumoperitoneum.

Intraoperatively, no complications were encountered in either group. The LPM score was 1in eight patients of BASKA mask and seven patients of PLMA. The LPM score was 2 in five patients of BASKA mask group and six patients of PLMA group, the difference between the two group is statistically insignificant.

To summarise our study, BASKA mask took lesser time to insert and mean ASP was higher after 5 min of insertion and 5 min of pneumoperitoneum in BASKA mask. There were no statistically difference between BASKA mask and PLMA for ease of insertion and LPM scores.

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. ______________________________, we are requesting you to enroll yourself in **"ANALYSIS OF THE BASKA MASK VERSUS PROSEAL LARYNGEAL MASK AIRWAY SEALING PRESSURE IN PATIENTS POSTED FOR LAPAROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA - A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL".** Conducted by **Dr. ___________**, Post Graduate in M.D. Anaesthesiology under the guidance of **Dr. __________________MD, DA**, Associate Professor, Department of Anaesthesiology, J.N. Medical College, Belagavi – 10, under KLE Academy of Higher Education & Research, Belagavi.

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

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

The purpose of the research is to evaluate efficacy of two different supraglottic airway devices regarding airway sealing pressure, time of insertion, ease of insertion and LPM score.

Procedure Involved:

If you agree to enroll yourself in my study, you will be premedicated with inj. Metoclopramide 10mg, inj. Ranitidine 50mg intravenously 15 min before surgery. Inj. Glycopyrrolate 0.005mg/kg, inj.Midazolam0.05mg/kg, inj. Fentanyl 1mcg/kg, are administered intravenously. Following pre-oxygenation for 3minutes, anaesthesia will be induced with inj. propofol titrated to loss of verbal contact with the patient, loss of eyelash reflex and relaxation of jaw. If coughing, gagging or body movement occurs during insertion of device, inj. propofol 1mg/kg will be added to achieve an adequate level of anaesthesia. For the safety reason of patients before the insertion of any of the devices after loss of verbal contact, the anaesthetist will check that hand-ventilation with a face mask is possible. Once the patient becomes apnoeic and LMA insertion depth is achieved on the basis of clinical judgment, (i.e. jaw relaxation), the deflated Proseal LMA or Baskamask of appropriate size based on weight will be inserted. The patients will be assigned to their groups using Secret envelope method, i.e. Proseal LMA or BASKA group.

Benefits and Risks

These airway devices have become very popular because of their ability to maintain an airway without intubating into trachea and can be used in patients who are undergoing short surgical elective procedures. There is incidence of postoperative sore throat and blood staining on the Baska mask and proseal LMA.

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 Dr. PrabhakarKore Hospital and Medical Research Centre, Belagavi - 10.

Alternatives

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

Confidentiality

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

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

Authorization to Publish Results:

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

Financial Incentives for participation

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

Compensation

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

Queries/ Contact details

If you have any queries about your right as a study subject, you may callDr. ROOPA M BELLAD, Professor, Department of Paediatrics and Chairman of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No.9448113403 or Extension-4052 at J. N. Medical College, Belagavi.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

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

Subject Name : ____

Signature or the Left Thumb Print:__________________

Date: _____________

Witness Name : ____________________________

Signature: ______________ Date:

Investigators Name: ________________________

Signature: ______________

Date: ________ Place:_______

ANNEXURE II – PROFORMA

"ANALYSIS OF THE BASKA MASK VERSUS PROSEAL LARYNGEAL MASK AIRWAY SEALING PRESSURE IN PATIENTS POSTED FOR LAPAROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA - A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL''.

Patient Name: IP No.:

Age: Gender:

Date of Operation: Occupation:

Address: Anaesthesiologist:

Preanesthetic Evaluation:

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

General physical examination

Pallor / Icterus / Clubbing / Cyanosis / Lymphadenopathy / Edema

Pulse Rate: BP:

Respiratory Rate: Temperature:

Systemic Examination

RS: CNS:

CVS: Abdomen:

Airway examination:

Jaw movements: Teeth:

Airway assessment: Spine:

Investigations

Hb: Total Leucocyte Count:

Platelet count: Serum Urea:

Serum Creatinine: RBS:

ECG: Chest X-Ray:

Urine R/M: Others:

ASA GRADE: I II III IV V E

Diagnosis:

Proposed Surgery:

Preoperative baseline values:

Pulse: BP:

Monitors attached:

Pulse oximetry: NIBP:

ECG:

Group of study belongs to:

BASKA MASK GROUP:

PROSEAL MASK GROUP:

Study Parameters:

The airway sealing pressure of both BASKA mask and Proseal LMA is the outcome of study and is recorded on the basis of audible leak occurring when APL valve is closed and fresh gas flow of 6L/min.

Hemodynamic parameters such as, heart rate, systolic and diastolic blood pressure as well as SpO_2 will be recorded before and during Baska mask and proseal LMA insertion.

Definition of variables:

- Insertion time: The time interval from SAD touching the teeth to the first recorded near rectangular capnogram curve.
- Airway seal pressure: The airway pressure at which leak is heard over throat by keeping stethoscope is noted as the airway seal pressure.
- The end point of each insertion is taken when there is bilateral chest movement, a square wave on a capnograph and $SpO_2 > 95\%$.

- Failed insertion of the LMA is defined as the inability to position the device within 60 seconds or more than 2 attempts.

- Hypoxemia is $SpO_2 < 90\%$

- LPM score: Sum of sore throat,dysphagia,hoarseness score

Inclusion Criteria:

- The subjects are adult laparoscopic surgical candidates aged 18-60 years.
- Laparoscopic surgeries lasting 120 min or less.
- ASA physical status I and II.
- Mallampati grade I and II.
- Both male and female patients will be included.

Exclusion Criteria:

- Presence of any significant acute or chronic lung disease.
- Pathology of the neck or upper respiratory tract.
- Potential difficult intubation.
- Increased risk of aspiration
- Pregnant women.
- BMI >30.

ANNEXURE III – ETHICAL CLEARANCE LETTER

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 24 **Date: 24/11/2018**

To,

PG student in Anaesthesiology,
J.N.Medical College,
BELAGAVI.

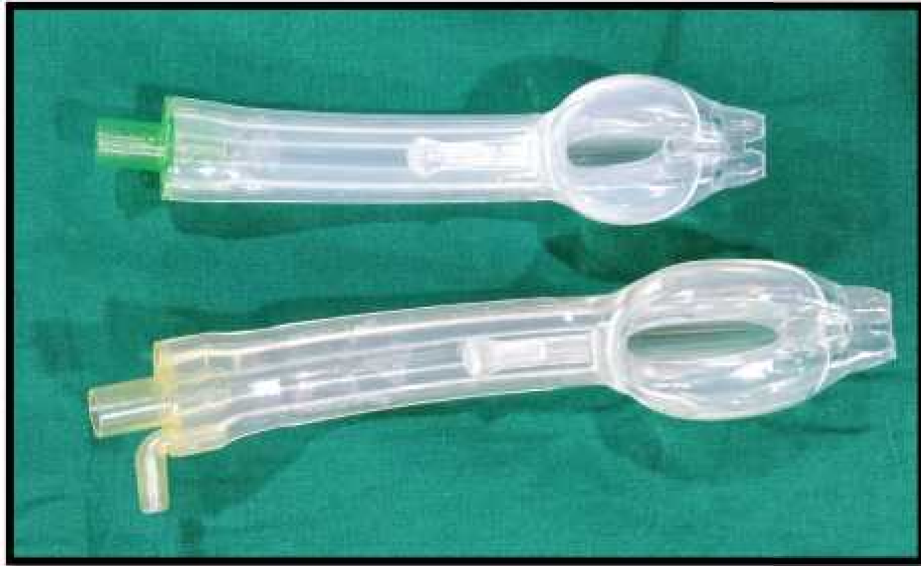
Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ANALYSIS OF THE BASKA MASK VERSUS PROSEAL LARYNGEAL MASK AIRWAY SEALING PRESSURE IN PATIENTS POSTED FOR LAPROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA – A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

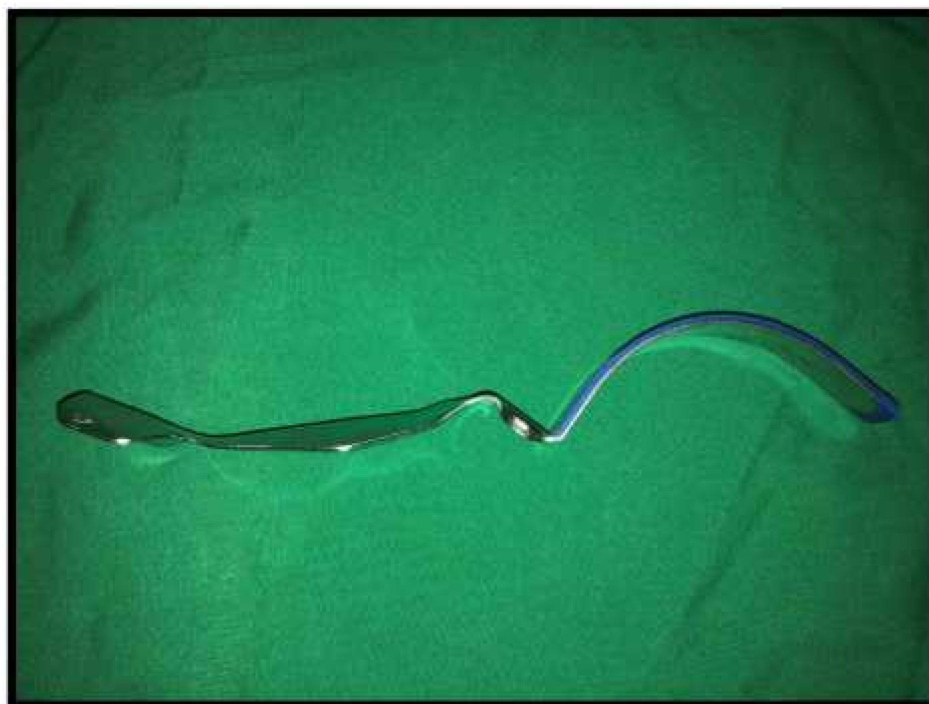
ANNEXURE – IV-PHOTOGRAPHS



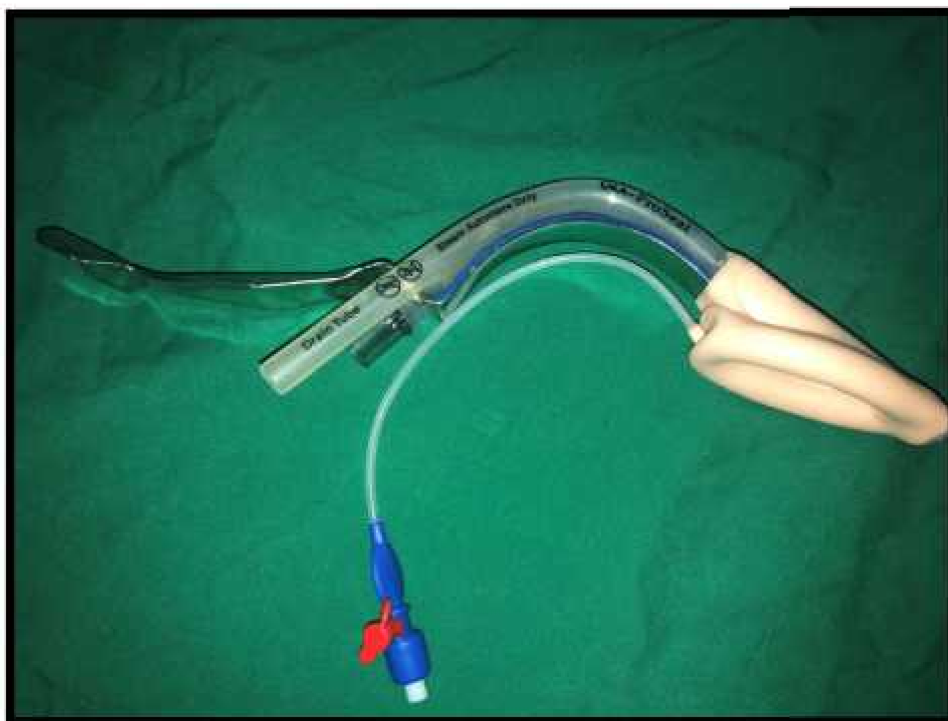
Photograph 1: Baska mask size 3 and 4-anterior view

Photograph 2: Baska mask-Lateral view

Photograph 3: Proseal LMA size 3 and 4



Photograph 4: Metal introducer of PLMA



Photograph 5: PLMA mounted on metal introducer

Photograph 6:Baska mask insitu

Photograph 7:PLMA insitu

Photograph 8:Anaesthesia Workstation

ANNEXURE – V - KEY TO MASTERCHART

ASA	**-**	**American society of Anaesthesiologist**
Cm	**-**	**Centimeter**
F	**-**	**Female**
H_2O	**-**	**Water**
Kg	**-**	**Kilogram**
M	**-**	**Male**
MPG	**-**	**Mallampati Grade**

ANNEXURE – VI
BASKA MASK

Sl. No	Randomization no	IP no	ASA	Age(yrs)	Sex	WEIGHT (Kg)	MPG	Airway sealing pressure		Insertion time	Number of attempts	LMP score (0-4)	Ease of insertion (0-4)
								after 5 mins of insertion	after 5 mins of pneumoperitoneum				
1	1	901633	1	45	M	56	I	28	29	14	1	1	1
2	2	900664	1	22	M	60	I	30	32	16	1	0	1
3	4	906975	2	50	F	45	I	30	30	18	1	2	1
4	7	913690	1	40	M	62	I	30	28	15	1	0	1
5	9	918864	1	35	F	55	I	32	30	16	1	1	1
6	10	937786	1	26	M	60	II	35	35	14	1	0	1
7	14	934390	1	32	F	48	I	28	30	18	1	0	1
8	15	960655	1	30	F	50	I	29	30	14	1	0	1
9	17	961274	1	34	F	60	II	30	32	17	1	2	1
10	19	960134	2	38	F	45	II	34	34	20	2	1	1
11	21	960244	1	30	F	40	I	33	32	14	1	2	1
12	22	960432	1	25	F	44	II	29	30	18	1	0	1
13	24	977581	1	24	M	45	II	35	34	16	1	1	1
14	25	977214	2	54	M	60	I	29	30	18	1	0	1
15	26	977461	1	19	F	55	I	32	33	20	2	0	2
16	28	977489	1	32	M	40	II	29	30	16	1	1	1
17	30	977619	1	25	F	45	II	34	32	14	1	0	1
18	31	974971	1	22	F	55	I	33	34	19	1	1	1
19	32	975589	1	25	M	52	I	30	32	18	1	0	1
20	37	975772	1	44	F	44	I	32	30	21	2	0	1
21	38	976098	1	43	M	58	II	29	30	20	1	0	2
22	39	976041	1	30	F	40	I	28	26	18	1	1	1
23	41	977014	1	26	M	57	II	34	32	14	1	2	1
24	42	977227	1	21	F	52	II	33	33	16	1	0	1
25	43	961148	1	34	F	45	II	35	34	16	1	0	1
26	45	967008	1	30	M	56	II	29	30	18	1	0	1
27	48	983039	1	42	F	43	I	32	32	17	1	1	1
28	49	966965	2	45	M	50	II	32	30	14	1	0	1
29	52	970123	1	28	M	46	I	34	34	15	1	0	1
30	55	972350	1	35	F	50	II	32	32	19	1	2	1

PROSEAL

Sl. No	Randomization no	IP no	ASA	Age(yrs)	Sex	WEIGHT (Kg)	MPG	Airway sealing pressure		Insertion time in seconds	LMP score(0-4)	Ease of insertion (0-4)
								after 5 mins of insertion	after 5 mins of pneumoperi toneum			
1	3	895516	1	33	M	60	I	29	28	20	0	1
2	5	895315	2	58	F	45	II	30	29	22	2	1
3	6	893543	1	39	M	42	I	24	25	25	2	1
4	8	896386	1	19	F	44	II	26	25	26	1	1
5	11	899812	1	19	F	65	I	28	27	28	0	1
6	12	897279	1	20	F	50	II	24	25	29	0	1
7	13	918882	1	23	m	55	I	26	25	30	1	2
8	16	961507	1	30	F	65	II	28	29	24	0	1
9	18	959867	1	28	M	44	I	30	30	24	0	1
10	20	961702	1	42	M	52	II	26	25	25	0	1
11	23	982632	1	19	F	45	I	27	28	29	1	2
12	27	960312	1	40	M	46	II	28	29	28	2	1
13	29	960324	1	30	M	39	I	28	28	24	0	1
14	33	900827	2	45	M	42	II	27	27	26	0	1
15	34	966533	2	45	F	48	I	30	29	25	0	1
16	35	981790	2	45	M	54	I	27	28	21	0	1
17	36	971891	1	32	F	46	II	28	28	23	1	1
18	40	972523	2	43	M	49	I	26	25	27	1	1
19	44	972865	1	30	F	55	I	28	27	28	2	1
20	46	973264	1	25	F	43	II	29	29	24	0	1
21	47	974589	1	30	M	42	I	26	26	25	0	1
22	50	974680	2	45	F	44	II	27	27	26	1	1
23	51	975856	1	24	F	45	I	27	27	21	1	1
24	53	976878	1	20	F	65	II	26	26	23	0	1
25	54	977571	2	50	M	54	I	30	30	25	0	1
26	56	978654	1	30	F	55	II	26	26	20	2	1
27	57	978582	2	48	M	50	I	25	25	29	0	1
28	58	979164	1	27	F	49	II	24	24	30	0	2
29	59	979236	1	31	F	38	II	24	24	24	1	1
30	60	979456	2	42	M	44	II	26	26	31	0	1