"A COMPARATIVE STUDY OF BASKA MASK AND PROSEAL LARYNGEAL MASK FOR GENERAL ANAESTHESIA WITH INTERMITTENT POSITIVE PRESSURE VENTILATION"

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MAY 2019

DECLARATION BY THE CANDIDATE

I, **Dr. S. GARPAGALAKSHMI,** solemnly declare that the dissertation, titled **"A COMPARATIVE STUDY OF BASKA MASK AND PROSEAL LARYNGEAL MASK FOR GENERAL ANAESTHESIA WITH INTERMITTENT POSITIVE PRESSURE VENTILATION"**, is a bonafide work done by me during the period of APRIL 2018 TO SEPTEMBER 2018 at Government Stanley Medical College and Hospital, Chennai under the expert supervision of **Dr. SEVAGAMOORTHY, M.D.,** Professor, Department Of Anaesthesiology, Government Stanley Medical College, Chennai.

This thesis is submitted to The Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of the rules and regulations for the M.D. degree examinations in Anaesthesiology to be held in May 2019.

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This is to certify that the dissertation titled **"A COMPARATIVE STUDY OF BASKA MASK AND PROSEAL LARYNGEAL MASK FOR GENERAL ANAESTHESIA WITH INTERMITTENT POSITIVE PRESSURE VENTILATION"** is a genuine work done by **Dr. S.GARPAGALAKSHMI** for the partial fulfilment of the requirements for M.D.(Anaesthesiology) Examination of The Tamilnadu Dr.M.G.R. Medical University to be held in May 2019, under my supervision and guidance.

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ABBREVIATION	EXPANSION
ASA-PS	AMERICAN SOCIETY OF ANESTHESIOLOGIST PHYSICAL STATUS
BM	BASKA MASK
BMI	BODY MASS INDEX
LMA	LARYNGEAL MASK AIRWAY
LPM	LARYNGOPHARYNGEAL MORBIDITY
MMS	MODIFIED MALLAMPATTI SCORING
OLP	OROPHARYNGEAL LEAK PRESSURE
PLMA	PROSEAL LARYNGEAL MASK AIRWAY
PPV	POSITIVE PRESSURE VENTILATION
SAD	SUPRAGLOTTIC AIRWAY DEVICE

CHAPTER 1

INTRODUCTION:

Dr. Archie Brain's 'Laryngeal Mask Airway', a supraglottic device introduced in 1981[1] made a revolution in the management of airway, replacing the most commonly used endotracheal tubes for general anaesthesia by negating the need for laryngoscopy and sometimes muscle relaxants. Since then many other Supraglottic airway devices have been developed and added to the supraglottic airway device family.

Supraglottic airway devices (SAD) are an alternate to facemasks and endotracheal tubes and are designed to provide ventilation, oxygenation and administration of anaesthetic gases to a patient admitted for a surgical procedure under general anaesthesia or during a respiratory arrest. Previously, SADs were mainly used for maintenance of a patent airway during elective procedures under general anaesthesia but, during years following the introduction of the prototypical classic LMA, these devices have also found other areas of utilization, like as conduits for tracheal intubation in difficult airway [2] or as airway adjuncts in cardiac arrest in prehospital setting[3]. Compared to endotracheal intubation, the use of SAD's is associated with stable haemodynamics [4], intracranial pressure[5] and intraocular pressure[6-8]. A potential risk of SAD use is incomplete airway sealing, which may cause gastric insufflation at pressures above 20cmH_2O

by opening the oesophageal sphincter. The newer SAD's are designed to decrease the risk of aspiration and to increase the oropharyngeal leak pressure (OLP), improving the airway seal at higher airway pressures during intermittent positive pressure ventilation without significant gastric inflation.

Proseal LMA is a second generation reusable supraglottic airway device with an airway lumen and a drain tube. The drain tube helps in decompression of stomach and drainage of regurgitant material. The median airway seal with a Proseal LMA is above 30cm H_2O[9]. The PLMA was 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 peri-glottic tissues. There is evidence towards the cuff of Proseal LMA exerting higher pressure on the laryngopharyngeal mucosa causing nerve injury, impeding venous and lymphatic return.

BASKA MASK is the latest addition to the supraglottic airway devices, with a cuffless dynamic self inflating membranous bowl and a dual drainage tube system for effective drainage of gastric contents providing option for continuous suctioning of gastric contents. As there is no inflated cuff in the Baska mask, neither does it cause tissue or nerve damage nor does it require intracuff pressure monitoring. The newer Baska mask has many novel features which improves safety when used during controlled ventilation or in spontaneously breathing patients[10-11].

Ease of insertion, airway sealing pressure, ability to protect against gastric regurgitation, ease of intubation through the device, patient comfort and cost need to be considered while choosing a Supraglottic airway device.

To the best of our knowledge, there is only one study comparing Proseal LMA with Baska mask, hence we conducted this study to generate more evidence on the safety and efficacy of the newer Baska mask compared to Proseal LMA. In this study conducted in the Department of Anaesthesiology and Critical care, Government Stanley Medical College and Hospital, we have compared the Proseal LMA with its proven efficacy in reducing aspiration and withstanding higher sealing pressure with the newer Baska mask in terms of Airway sealing pressure, ease of insertion, perioperative complications and postoperative laryngopharyngeal morbidity.

Chapter 2

AIM OF THE STUDY

To compare the sealing pressure of the Bask mask with Proseal laryngeal mask in adult patients undergoing elective surgeries under general anaesthesia with intermittent positive pressure ventilation.

PRIMARY OBJECTIVES

To determine the Airway sealing pressure at 5mins, 30mins post placement and at the end of surgery.

SECONDARY OBJECTIVES

To determine the Insertion time, number of attempts, ease of insertion, Post-operative laryngopharyngeal morbidity of the supraglottic airway device in the study population.

Chapter 3

INTRODUCTION TO SUPRAGLOTTIC AIRWAY DEVICES

Airway management devices that are placed above the glottis and allow gases to enter and exit the airway are referred to as "Supraglottic airway devices". They provide a bridge between facemask and tracheal tube in terms of anatomical position and degree of invasiveness[12]. Most supraglottic airway devices (SADs) are designed for use during routine anaesthesia, but there are other roles such as airway rescue after failed tracheal intubation, use as a conduit to facilitate tracheal intubation and use by primary responders at cardiac arrest or other out-of-hospital emergencies. Supraglottic airway devices (SAD) play an important role in the management of patients with difficult airways. Therefore, the use of the LMA is now included in many difficult airway guidelines. The American Society of Anaesthesiologists includes the LMA as a ventilatory device at two points in the algorithm: first in the anaesthetised patient whose trachea cannot be intubated (anaesthetised non-emergency limb); and second in the anaesthetised patient whose trachea cannot be intubated and whose lungs cannot be conventionally ventilated (anaesthetised emergency limb).

HISTORY OF SUPRAGLOTTIC DEVICES:

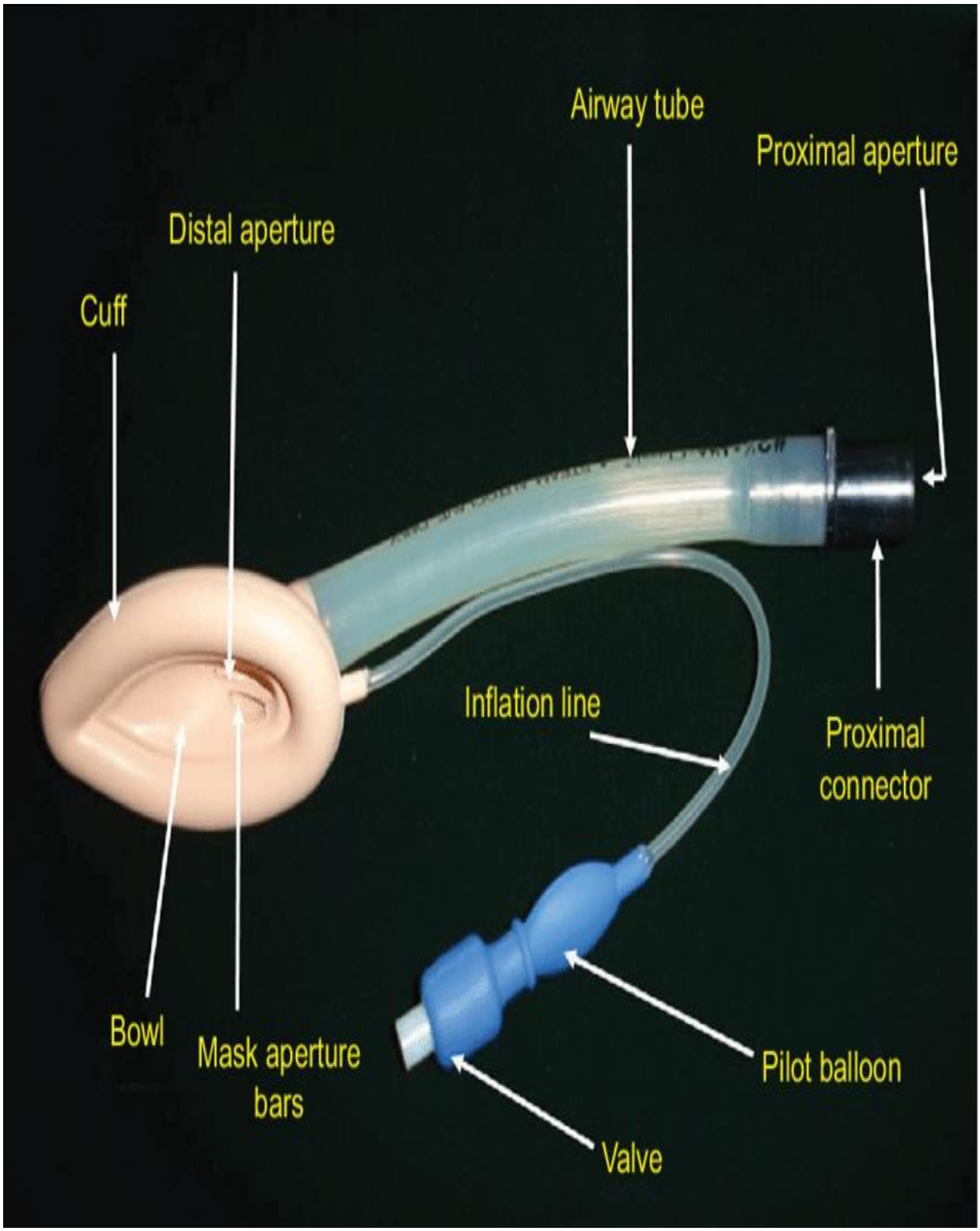
In the early 20th century, endotracheal intubation was a very complex procedure, with a high failure rate[13]. Awake intubation was quite difficult due to gag reflex and laryngospasm was very common, often resulting in mortality.

Trying to find a solution for these problems, Leech introduced the Pharyngeal Bulb Gasway in 1937[14]. Instead of entering into the trachea, this device would be stuck in the pharynx by means of an anatomically-shaped, hollow rubber bulb, becoming the first supraglottic airway device (SAD). Despite the advantages of Leech's airway compared to the face mask (FM) or the ET at the time, it was never very popular.

The use of curare as muscle relaxant by Griffith and the refinement of the laryngoscope by Macintosh led to the widespread adoption of tracheal intubation as the gold standard for airway management in general anaesthesia.

In 1981, Archie Brain designed the first laryngeal mask airway, which was called LMA classic, at the Royal London Hospital. The classic LMA was first sold in the United Kingdom in 1988, and then the United States in 1992 by LMA North America[1].

Fig 1: Classic LMA



CHAPTER 4

ADVANTAGES AND DISADVANTAGES OF SAD[12]

ADVANTAGES:

- Ease of insertion
- Smooth emergence
- It is tolerated at lighter planes of anesthesia with a lower risk of bronchospasm, laryngospasm and sore throat.
- Avoiding the complications of intubation and face mask
- **ADVANTAGES OVER THE ENDOTRACHEAL TUBE:**

1. The ease of insertion is greater and has a faster learning curve.

2. Laryngoscopy and muscle relaxants are not always needed.

3. Haemodynamic changes are less when compared with the endotracheal tube.

4. Time for insertion is less.

5. Incidence of sore throat is less.

6. Less manipulations of airway compared with endotracheal tube in a reactive airway.

- **ADVANTAGES OVER FACEMASK:**

1.Hands free technique.

2. Work of breathing (WOB) is less with the LMA.

3. Airtight seal with an LMA.

4. Better airway protection against regurgitation when compared with the facemask.

5. Children with a difficult mask fit do well with an LMA. Oropharyngeal airway obstruction is avoided.

6. Less operating room pollution as waste gases can be scavenged.

DISADVANTAGES:

- **Relative contraindications** to use of the LMA include situations associated with increased risk of aspiration (full stomach, previous gastric surgery, gastroesophageal reflex, diabetic gastroparesis, >14 weeks pregnant, dementia, trauma, opiate medications, increased intestinal pressure) unless other techniques for securing the airway have failed.
- **Patient with glottic and supraglottic obstruction**. Supraglottic pathologies make the proper positioning of SAD difficult.
- **Requirement of paralysis or obtunded airway reflexes**: It can't be inserted unless the jaw and pharynx are fully relaxed.
- **Less reliable airway:** Does not secure a definitive airway.
- **Unreliable drug administration:** Drug administration through LMA during resuscitation is not as reliable as a tracheal tube.

CHAPTER 5

USES OF SUPRAGLOTTIC AIRWAY DEVICES[12]:

- **Difficult face mask technique:** In difficult airway scenarios like Edentulous patients, facial injuries, facial contour not suiting face masks, facial burns without upper airway burns.
- **Difficult or failed intubations:** In cannot intubate situations or in can't intubate can't ventilate situations, supraglottic airway device may be lifesaving by maintaining adequate ventilation or to facilitate passage of tracheal tube. In anticipated difficult airway like Pierre Robin or Treacher Collin syndrome, poor neck mobility, pressure of cervical collar, supraglottic airway device can be used as primary airway device and to facilitate intubation.
- **Resuscitation:** Classic LMA and Fastrach LMA have been successfully used for cardiac arrest in adults and in neonates. It is also used in out of hospital situations like air transit.
- **Ophthalmic surgery:** Intraocular pressure is lower after inserting a LMA than a tracheal tube and also during emergence.
- **Tracheal procedure:** Compression of the trachea by a mediastinal mass can cause problems similar to tracheal stenosis. Mediastinoscopy and thoracotomy have been performed with LMA and spontaneous ventilation.

- Supraglottic devices can be used for procedures like Tracheal tube exchange, Transesophageal echocardiography and Endoscopic procedures[12].
- **Paediatric patients:** Supraglottic airway devices (SADs) have been used increasingly in pediatric anesthesia. It is used as an alternative to tracheal tube in children with URI. The ProSeal laryngeal mask airway (PLMA) has been considered a reliable SAD in children with its superior ability for airway sealing even under high pressure. It is used in situations like Subglottic stenosis, anaesthesia for radiotherapy, MRI examinations and in those requiring multiple anaesthesia over a short time. SAD has also been used in anticipated difficult airway like Treacher Collins syndrome, Pierre Robin syndrome, Beckweith Weidmann syndrome, Goldenhar syndrome and Mucopolysaccaridosis. Even though SAD is widely used, larger epiglottis makes airway obstruction with SAD more likely in children.
- **Supplementary regional block:** When surgery outlasts regional block or when only a partial block is present, supplementation with general anaesthesia using SAD is desirable as it requires lighter plane than tracheal tube.

CHAPTER 6

CLASSIFICATION OF SUPRAGLOTTIC AIRWAY DEVICES:

Brimacombe, was the first to propose the classification in 2004[15], based on three criteria: whether the device has a cuff; if it is introduced through nose or mouth; and the anatomic location of the tip when correctly placed. Shortcoming of this classification is that most of the devices used belong to the same group in this classification - cuffed, introduced through the mouth with the tip at the proximal end of the oesophagus.

Miller classified SAD based on the sealing mechanism[16], placing all SADs in 3 groups: cuffed perilaryngeal sealers; cuffed pharyngeal sealers; and pre-shaped cuffless devices. Each of these groups had subgroups and then each device could be further categorized as reusable or single-use.

Hernandez classified SAD[17] based on the presence or absence of a cuff and the number of cuffs as a means to develop a nomenclature. He divided all SADs into four groups, those with a single periglottic cuff, those with a single pharyngeal cuff, those with two cuffs regardless of their location of sealing, and those with no cuff.

In 2011, Cook proposed a new classification[18], dividing all SADs into 1st or 2nd generation devices. A first generation SAD has just a simple airway tube, with no specific design features for aspiration safety. Second generation SAD have a gastric drain tube, improved pharyngeal seal and a bite block.

Miller felt Cook's classification to be simple and proposed in 2014[19] another classification, based on the sealing mechanism (three generations) and on the anatomic location of sealing (base-of-tongue or peri-laryngeal)

Fig 2: Miller's classification of SAD

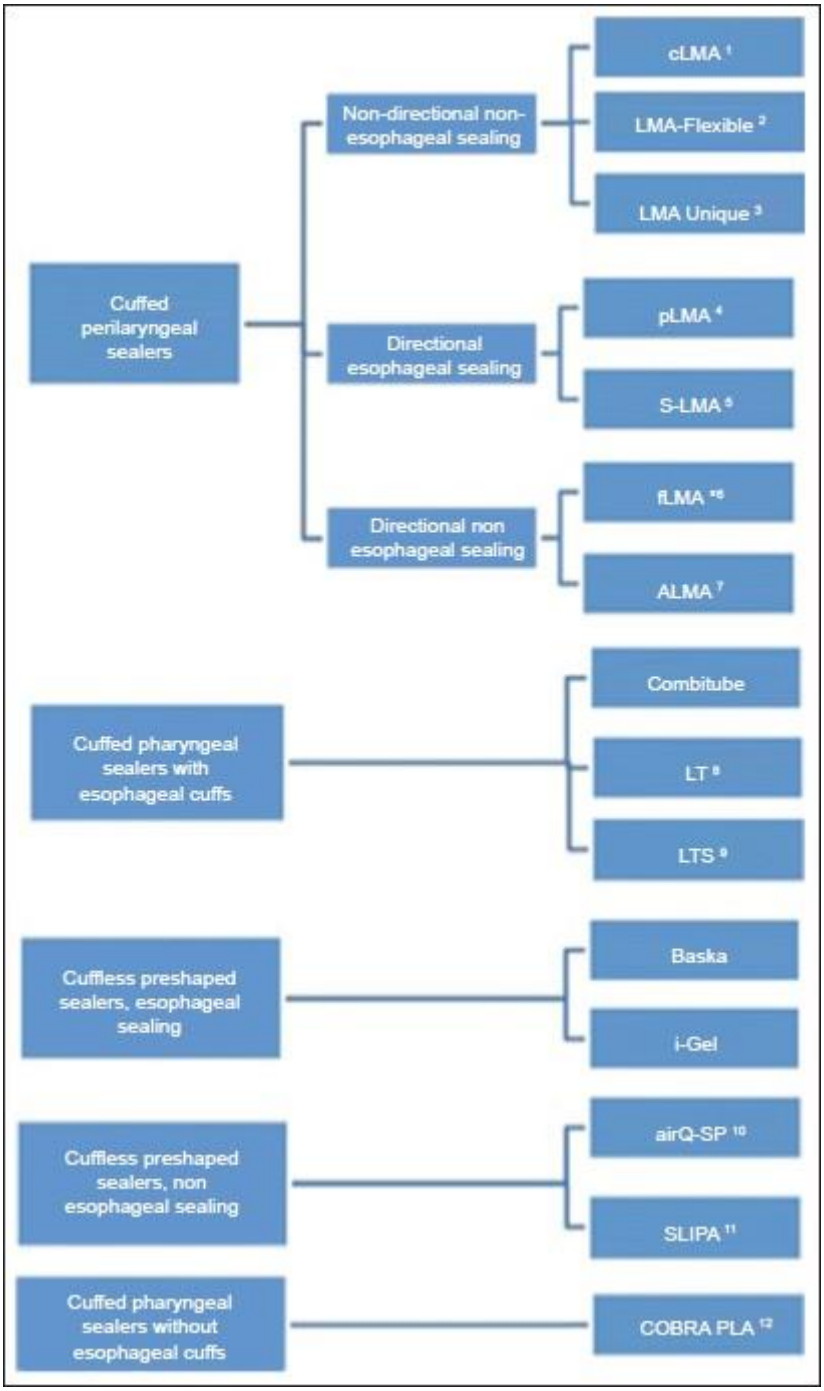


Fig 3: Cook's classification of SAD

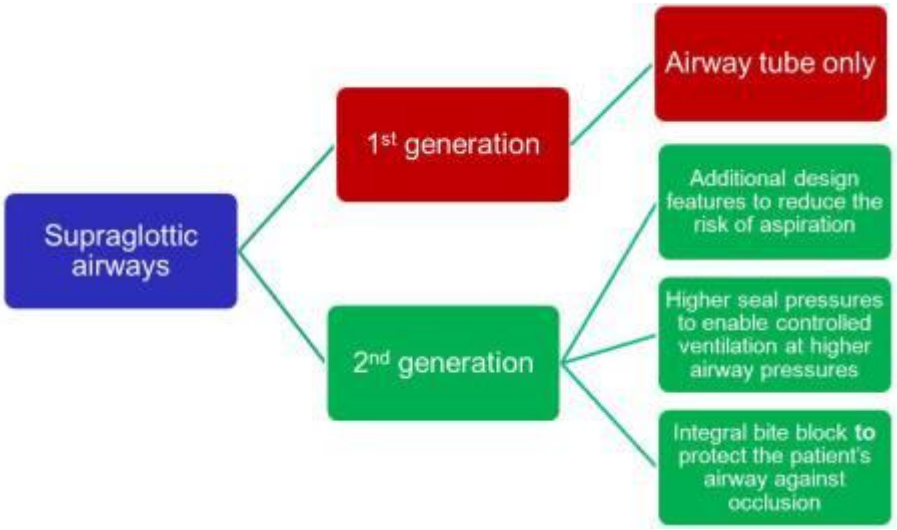


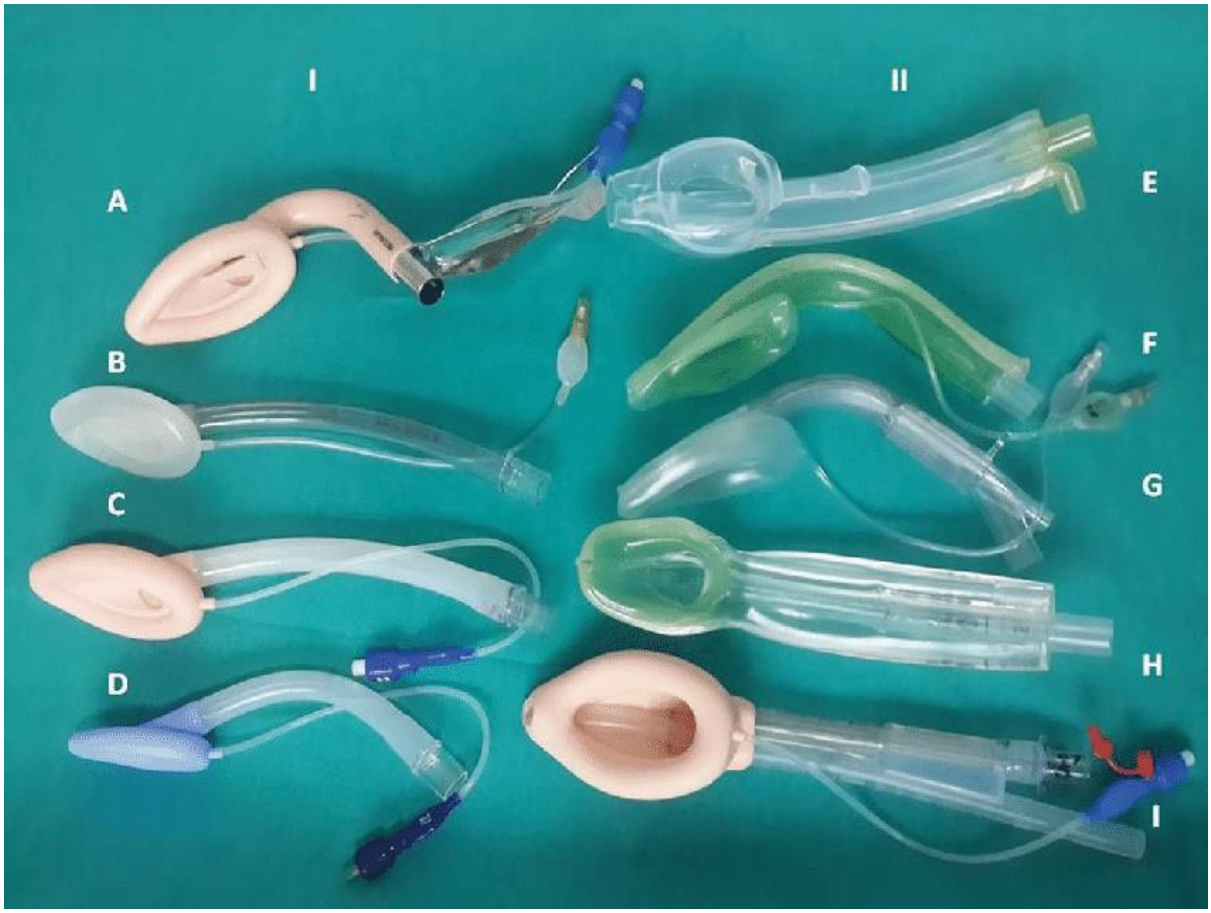
Table 1: Miller's new classification of supraglottic airway devices[19]

Sealing Mechanism	Location of Sealing	
	Peri-laryngeal	Base-of-tongue
1st generation-inflatable cuff	cLMA, PLMA (§)	Combitube (§)
2nd generation-pre-shaped	i-gel (§, #)	SLIPA (§)
3rd generation-self-energizing	Baska mask (§, #)	-

Table 2: Commonly available SAD features[20]

SAD	Location of sealing	Sealing mechanism	Aspiration protection	Single-use	Conduit for intubation
cLMA	Perilaryngeal	Inflatable cuff	No specific feature	No	No
LMA Unique	Perilaryngeal	Inflatable cuff	No specific feature	Yes	No
LMA Flexible	Perilaryngeal	Inflatable cuff	No specific feature	Yes	No
Intubating LMA	Perilaryngeal	Inflatable cuff	No specific feature	Yes	Yes
LMA ProSeal	Perilaryngeal	Inflatable cuff	Drainage channel	No	No
LMA Supreme	Perilaryngeal	Inflatable cuff	Drainage channel	Yes	No
Combitube	Base-of-tongue	Inflatable cuff	Drainage channel + Esophageal cuff	Yes	No
King LT	Base-of-tongue	Inflatable cuff	Esophageal cuff	Yes	No
King LTS-II	Base-of-tongue	Inflatable cuff	Drainage channel + Esophageal cuff	Yes	No
CobraPLA	Perilaryngeal	Inflatable cuff	No specific feature	Yes	Yes
SLIPA	Base-of-tongue	Pre-shaped	Storage chamber	Yes	No
i-Gel	Perilaryngeal	Pre-shaped	Drainage channel	Yes	Yes
Baska Mask	Perilaryngeal	Self-energizing	Drainage channel	Yes	No
3gLM	Perilaryngeal	Self-energizing	Drainage channel	Yes	No

Fig 4: DIFFERENT SAD (I)



(I) Supralottic devices with airway tube only: (A) intubating laryngeal mask airway (B) LMA Unique, (C) classic LMA and (D) disposable laryngeal mask

(II) Supraglottic devices with both airway and drain tube: (E) Baska mask, (F) Ambu AuraGain , (G) LMA Supreme, (H) i-gel (I) ProSeal laryngeal mask airway.

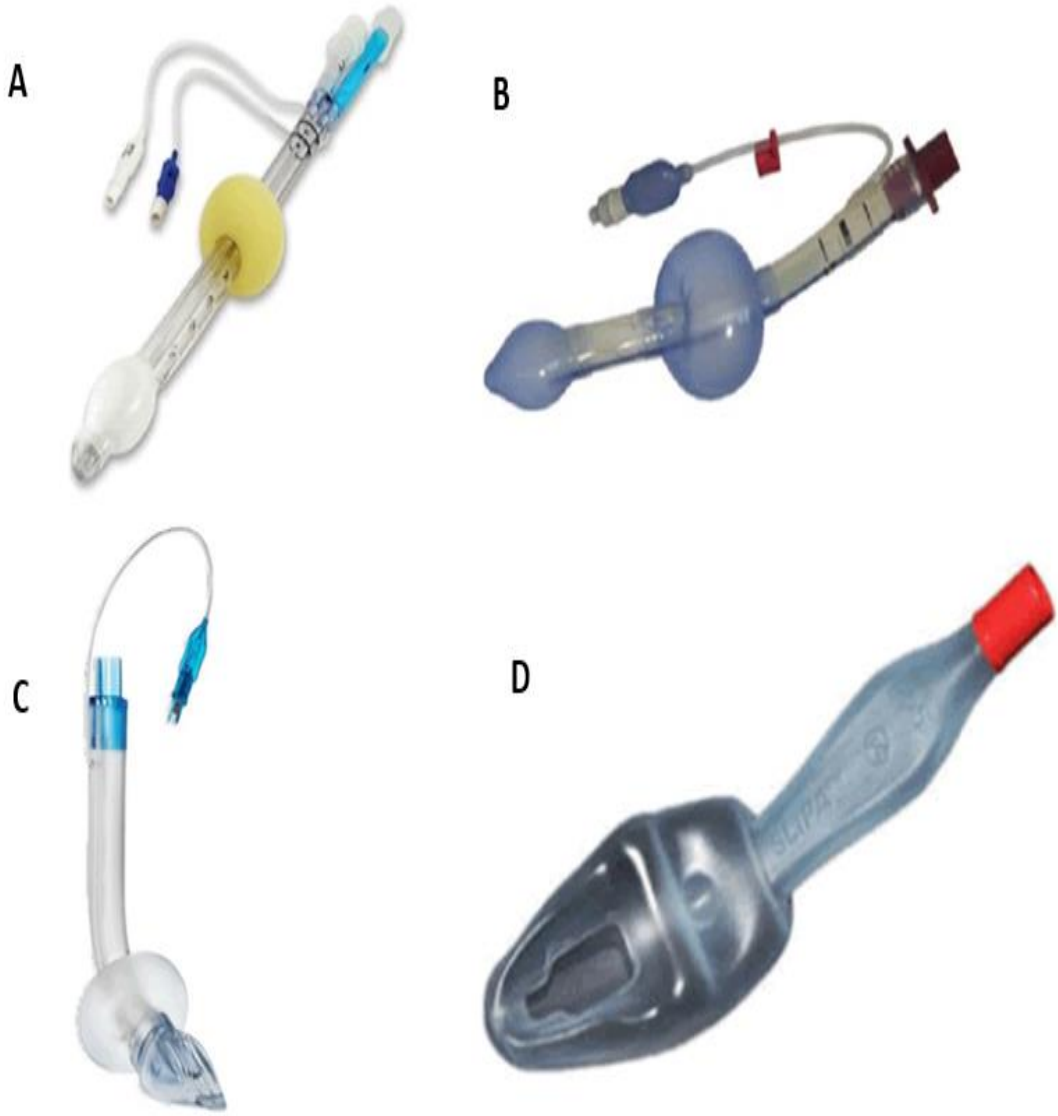


Fig 5: DIFFERENT SAD (II) A. COMBITUBE, B. KING LT, C. COBRA PERILARYNGEAL AIRWAY , D.SLIPA

Oropharyngeal leak pressure:

OLP is also referred to as airway sealing pressure or airway leak pressure[21]. OLP is the anaesthesia circuit pressure at which there is leak around the airway. OLP indicates airway protection, successful SGA placement and PPV[22,23]. Higher the oropharyngeal leak pressure, greater is the seal between the artificial airway and patients's airway. Oropharyngeal leak pressure (OLP) is measured by closing the expiratory valve of the anesthetic circle system at a fixed gas flow rate and noting the equilibrium airway pressure. It is used to quantify the efficacy of airway sealing in SAD devices[22]. Several methods are used to quantify OLP, including audible noise detection, oral capnography, stethoscopic noise and manometric stability. Factors that may affect OLP include the use of neuromuscular blockers, intra-abdominal pressure during surgery and intracuff pressure of the SAD device[24,25,26] .

CHARACTERISTICS OF AN IDEAL SUPRAGLOTTIC DEVICE:

In 2004, Don Miller suggested that the "Core" Desirable Features of a Supraglottic Airway were[27]:

• Non-invasive (supraglottic) airway conduit.

• Easy insertion, even by a nonspecialist.

• Good first-time insertion success rate.

• Stable airway once positioned, i.e. reliable hands-free airway.

• Sufficient sealing quality to apply PPV.

• Minimal risk of aspiration.

• Minimal risk of cross-infection.

• Minimal risk of serious side-effects.

CHAPTER 7

PROSEAL LMA:

The proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in 2000. Proseal LMA is a reusable second generation LMA which is a modification of classic LMA with a gastric drain tube to improve controlled ventilation, airway protection and diagnosis of misplacement[28,29,30,31].

PARTS OF A PROSEAL LMA:

It has a larger and deeper bowl with no grills, wire reinforced shorter airway tube, second tube placed lateral to airway tube ending at the tip of the mask, a dorsal cuff which improves the airway seal, integral bite block, an anterior pocket for seating an introducer or finger during insertion. Gastric drain tube separates airway from alimentary track channelling the regurgitated gastric fluid, providing opportunity to pass Ryle's tube through the gastric drain tube, avoidance of gastric insufflation during positive pressure ventilation. Effective mask seal achieved partly by deeper bowl and partly by smaller posterior cuff[12].

Fig 6: Proseal LMA

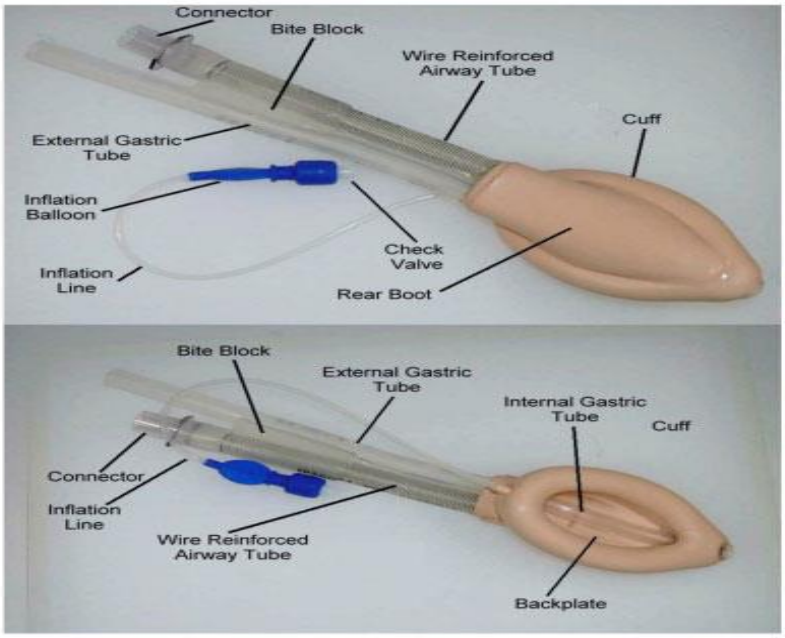


Table 3: Proseal LMA sizes

LMA Size	*Patient Size (kg)*	*Maximum Cuff Inflation Volume (mL)*	*Maximum Gastric Tube Size (French)*	*Maximum Fiberoptic Scope Size (mm)*	*Length of Drain Tube (cm)*	*Largest Tracheal Tube (ID in mm)*
1.5	5 to 10	7	10	—	18.2	4.0 uncuffed
2	10 to 20	10	10	—	19.0	4.0 uncuffed
2.5	20 to 30	14	14	—	23.0	4.5 uncuffed
3	30 to 50	20	16	—	26.5	5.0 uncuffed
4	50 to 70	30	16	4	27.5	5.0 uncuffed
5	70 to 100	40	18	5	28.5	6.0 cuffed

ID, internal diameter.

INSERTION TECHNIQUES OF PROSEAL LMA[12]:

i. **Standard technique:**

The patient's head is placed in sniffing position (head extended and neck flexed). This position is maintained during insertion by the non-inserting hand to stabilize the occiput. The Proseal LMA is held like a pen with the index finger placed at the junction of the cuff and the two tubes. The tip of the cuff is placed against the inner surface of the upper incisor with the aperture facing forwards. The mask is pressed against the hard palate by using the index finger. A change in direction can be sensed as the mask tip encounters the posterior pharyngeal wall, now the index finger is gradually withdrawn and the tube is grasped with other hand and then pressed down with a single swift movement till a definite resistance is felt.

ii. **Introducer technique:**

A metal introducer is attached to the concave side of the device. As the Proseal LMA is inserted the introducer is kept close to the chin, it is swung inwards in a smooth circular manner and it is advanced until a resistance is felt. The non-dominant hand is used to stabilize the airway tube as the introducer is removed out of the mouth.

iii. **Bougie-guided technique:**

A bougie is placed upside down into the oesophagus and the PLMA is railroaded into place via the drain tube (suction catheters or orogastric tubes are alternatives).

Fig 7: Standard insertion technique

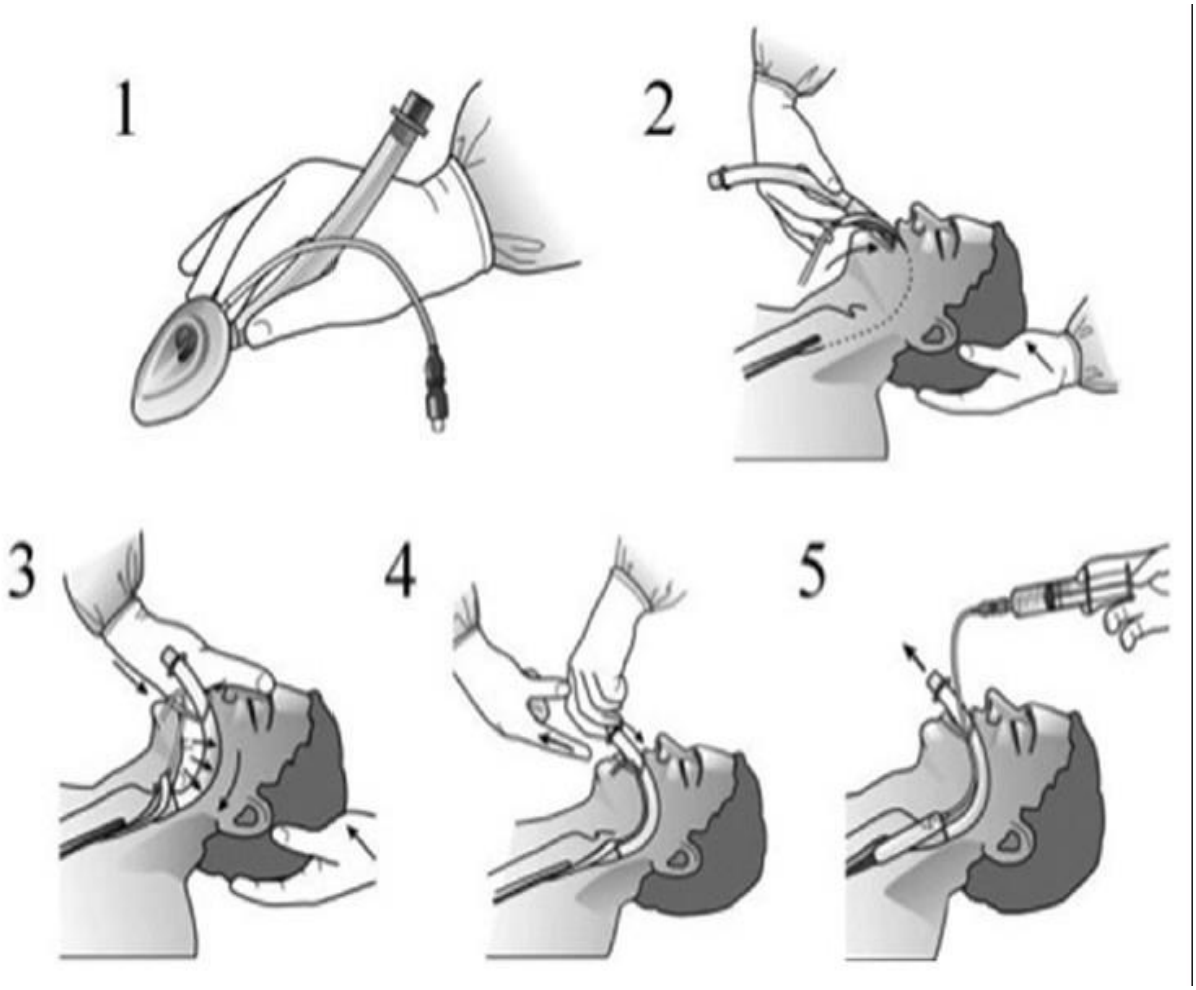
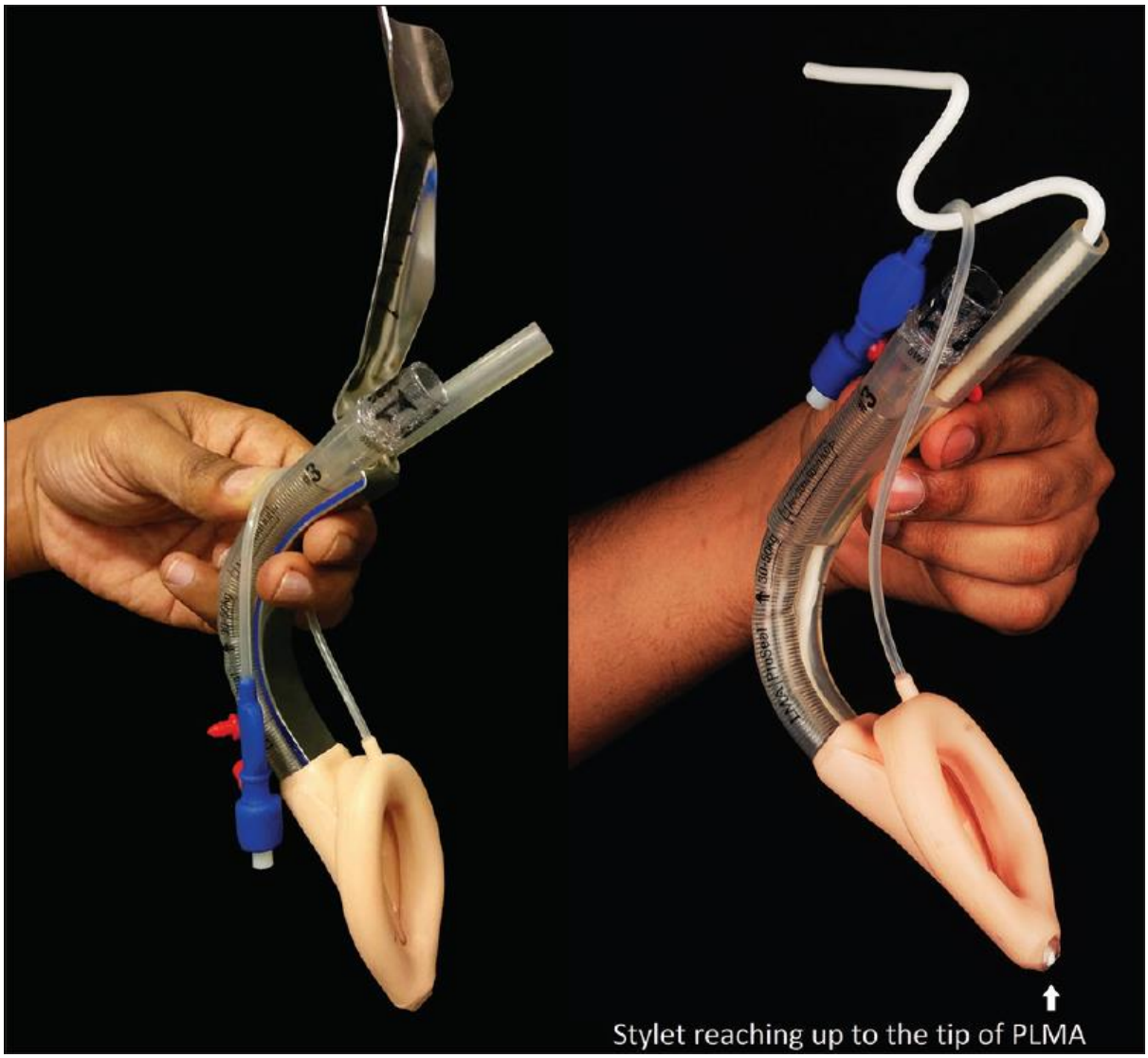


Fig 8: Introducer and stylet guided Proseal LMA insertion



ASSESSMENT OF PROPER PLACEMENT:

Once inserted assessment of proper placement is confirmed by delivering adequate tidal volume with reasonable peak inspiratory pressure, leak pressure above 20cm of H2O with controlled ventilation and greater than 10 cm of H2O with spontaneous ventilation, gel displacement test, easy passage of orogastric tube, a normal square capnography and by fibreoptic confirmation. X-ray or MRI can also be used to confirm the position[32].

Causes of airway obstruction:

- Incorrect mask position
- Downfolded epiglottis
- Closed glottic sphincter
- Over inflated cuff

Difficulties encountered with Proseal LMA:

- ✓ Less suitable as an intubating device because of narrow airway tube.
- ✓ It takes comparatively longer time to insert than classic LMA in adults.
- ✓ Requires greater depth of anaesthesia for insertion
- ✓ Malposition's are more common with Proseal LMA
- ✓ Has a shorter life span than classic LMA.

CHAPTER 8

Baska mask :

The Baska Mask, an Australian designed and manufactured device which is available in four sizes: #3, 4, 5 and 6 for patients ranging between 30 to >100 kg is made entirely from medical grade silicone, except for the 15 mm connector that fits into the proximal ends of the main (ventilation/breathing) airway tube and clearance tubes with an interchangeable (left or right) swivel suction elbow, attached to either of the suction ports[33, 34]. It is available in both disposable single use and reusable forms.

It has a cuff-less membranous bowl which inflates and deflates with each positive pressure inspiration and expiration respectively, an inbuilt "tab" that permits to increase its angulation for easy negotiation of the oropharyngeal curve during placement, a dual drainage system for pharyngeal contents; and a bite block. The membranous cuff of the Baska Mask appears bulkier than the equivalent inflatable cuff on cuffed laryngeal masks. The mask can easily be decreased in size during insertion by compressing the proximal, firmer (though still easily compressible) part of the mask below the airway tube, between the thumb and two fingers.

It is checked by occluding the airway opening of the proximal connector end with one thumb, placing the other thumb over the airway opening of the mask to seal and applying pressure for 5 s using a reservoir-bag squeeze to confirm the absence of leak in the device.

Insertion Technique: The entire body of the mask was lubricated with a water-based lignocaine gel. The entire mask needs to be lubricated before insertion into the mouth, otherwise the bulk of the mask "cuff" may produce resistance as it traverses the hypopharynx. With the head in neutral position, Baska mask is pushed past the front teeth towards the hard palate, avoiding the tongue. If necessary, when the mask is fully within the mouth, the tab, a unique feature of the Baska Mask, is used to help negotiate the palato-pharyngeal curve and advanced until a definite resistance is felt[34].

Fig 9: Disposable Silicone Baska mask

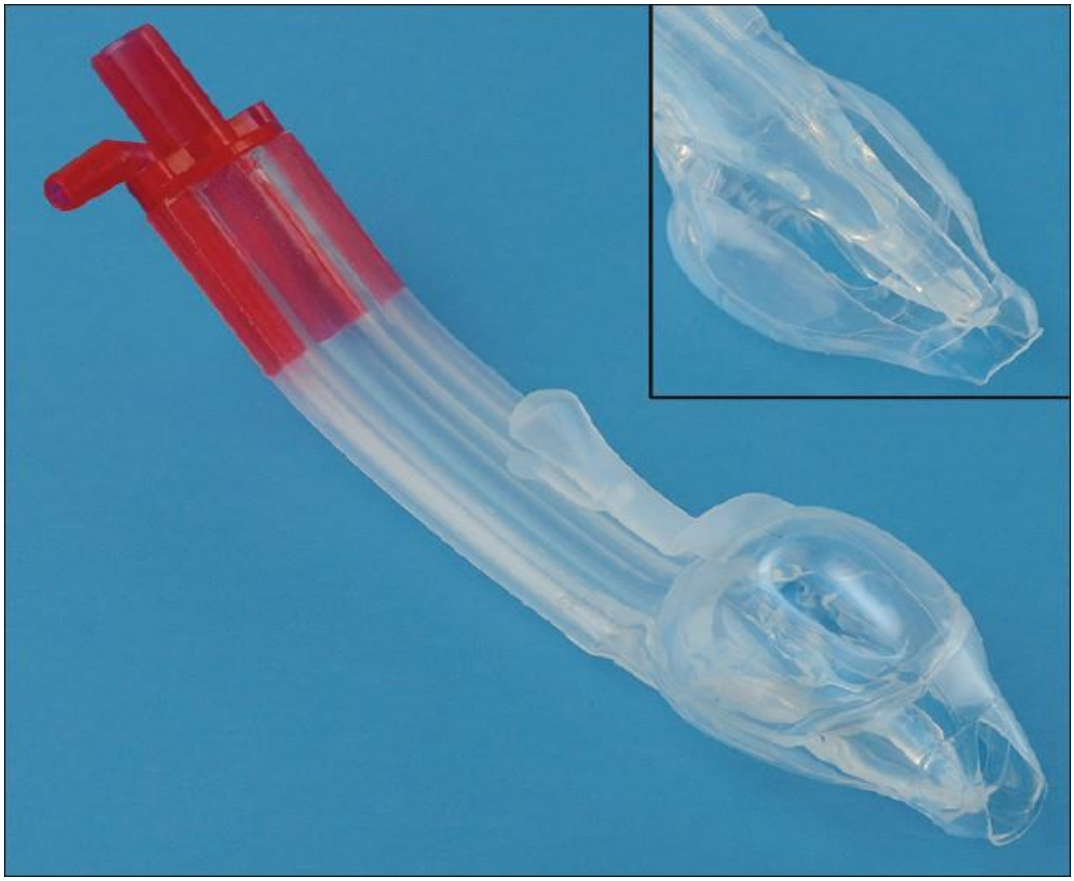
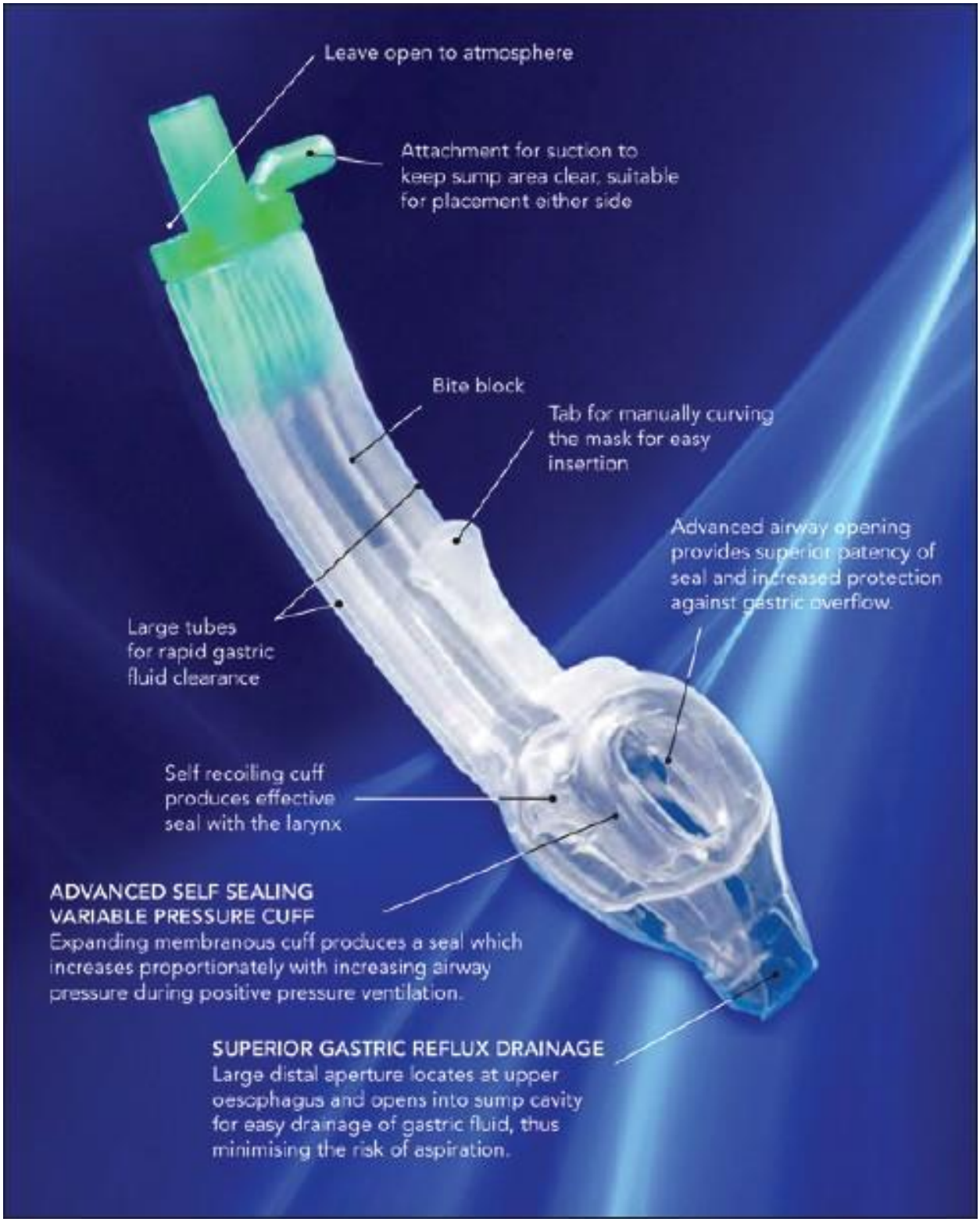


Fig 10: Special features of BASKA mask



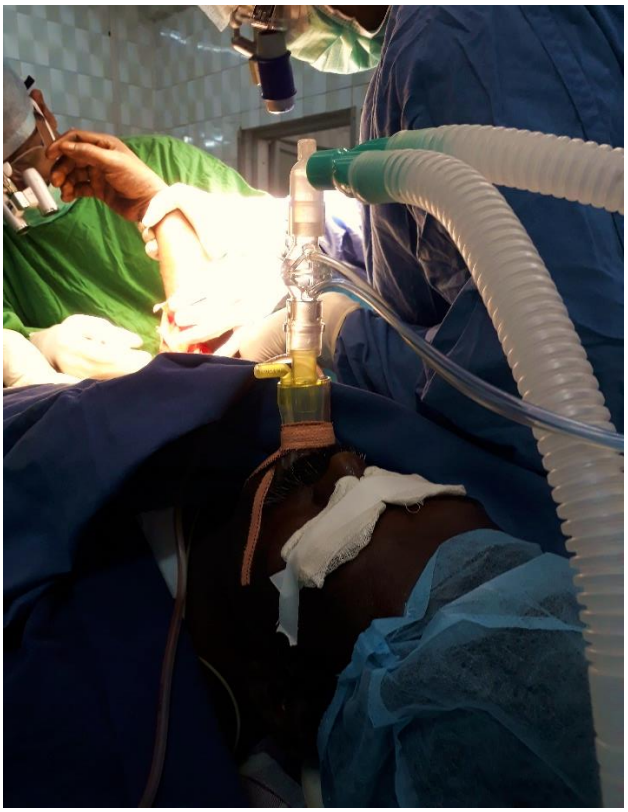


Fig 11: Size 3 Baska Mask Insertion **Fig 12: Size 4 Baska Mask Insertion**

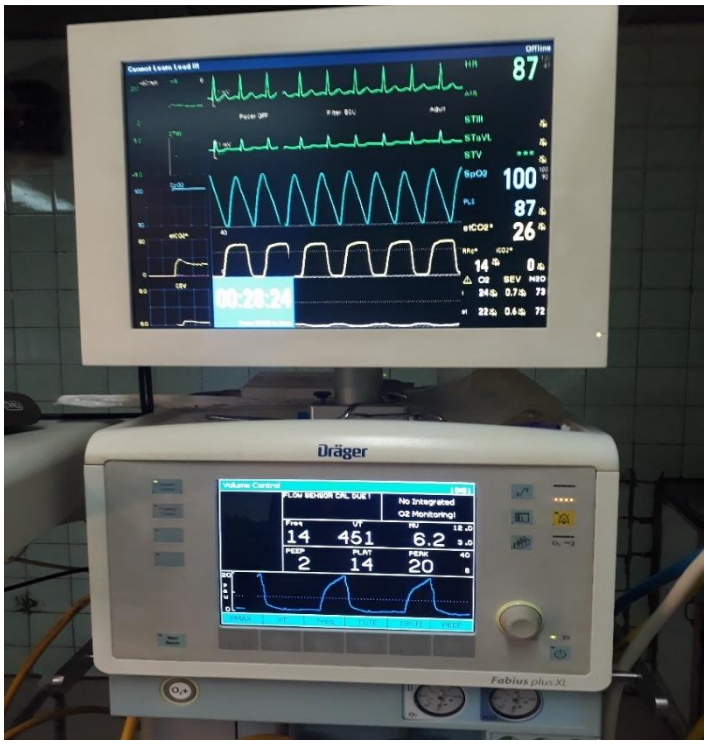


Fig 13: MONITORS

Table 4: Special Characteristics Of Baska Mask[34]

Cuff
No inflatable self-recoiling thin membranous cuff balloon
No pilot balloon/pilot tube
Pressure limited to maximum inspiratory pressure during IPPV; fluctuates with ventilator cycle
Soft – lower propensity for nerve damage or other trauma
Sump Area
Efficacy of clearance of gastric fluids.
Internal cricoid pressure provided by the inbuilt cushion device maintains communication between the sump area and the upper end of esophagus. Allowing efficient suction of fluid from the sump area via the two tubes built into the stem of the device alongside the airway.
Airway Tube
Efficacy of bite block.
Kink resistance.
Two tubes in the stem alongside the airway tube in the mask will function as additional airways to allow air entry and maintain oxygenation in the event of the mask being bitten while still in the mouth with the main airway opening blocked by the tongue.
Shape and Design
Made using a single injection molding process without any joints except for a 22mm connector inserted at top end.
Influence of shape and differential flexibility on ease of insertion.
No need for extension of head or neck for insertion.
Insertion in neutral position.
No need for the use of fingers for insertion and/or positioning.
Tab to make intubation easier and faster
Suction elbow integral on one port with second port acting as free airflow access point
Australian designed and manufactured mask

CHAPTER 9:

REVIEW OF LITERATURE

1. **BOSLEY NJ et al**[35] studied 98 patients belonging to ASA-PS-I – III undergoing elective surgical procedures, randomised to have either the LMA Proseal or Igel for spontaneous and controlled ventilation during routine anaesthesia. Aim of the study was to determine if there was a clinically significant difference in the performance characteristics of two second generation SAD. The primary outcome was first attempt insertion success and time of insertion. Secondary outcomes were ease of insertion, manipulations to establish patent airway, fiber optic view of larynx, complications during anaesthesia, emergence, recovery and anaesthetic assess of device performance. They found that the first time insertion rate was higher in LMA proseal group, number of insertion attempts did not differ between two groups. Ease of insertion, time to establish a patent airway, number of manipulations and anatomical positioning of the device and ventilated performance ,total number of complications were similar between the two groups. The leak pressure was significantly higher in the LMA Proseal group (28cmH2O) than I-Gel (22cmH2O). It was concluded that LMA Proseal and I-gel have comparable performance characteristics during routine general anaesthesia in non-paralysed patients. The LMA

proseal has a higher airway seal that is statistically significant and clinically important.

2. **ZUNDERT TV, GATT S. et al**[34] evaluated the performance of BASKA mask in 50 adult patients belonging to ASA-PS-I-III undergoing surgery under general anaesthesia. Patients were induced using Inj. Fentanyl 1mcg/kg, Inj. Propofol 2.5 mg/kg. Anaesthesia was maintained with sevoflurane 1.5%-2% in oxygen 40% in air. The first attempt success rate was 88% and overall insertion success rate was considered "easy " to "very easy" in 92% cases. At fiber optic evaluation of anatomical position , vocal cord could not be seen in 12% of patients. An oropharyngeal leak pressure of >30 cm H 2 O was obtained with all Baska masks, whereas three quarters of the patients (76%) had a maximum leak pressure of 40 cm H_2O, confirming a good airway seal, which is typical for the second-generation SAD (e.g. LMA-ProSeal, LMA-Supreme, I-gel) and much higher than the first-generation LMA-Classic-type laryngeal masks. Fiberoptic evaluation of the anatomic position of the Baska Mask in situ [revealed that, in half of the patients studied (54%), a perfect or near-perfect position of the vocal cords could be obtained.

3. **ALEXIEV, V et al**[36] conducted an observational study of BASKA mask on 30 female patients of ASA-PS-I-III aged 18yrs or older undergoing non-urgent surgery lasting for less than 2 hours, it was concluded that the overall success rate for device insertion was 96.7%, first insertion success rate was 76.7%. The mean airway leak pressure was 35.7 cm of water. The incidence of throat pain, dysphagia, dysphonia was low.

4. **AL-RAWAHI SAS et al**[37], studied 52 ASA PS I and II, non-obese (BMI<30) adult patients ranging from18-45 yrs of age, belonging to either sex undergoing a variety of elective surgical procedures in the supine position with SAD placement of ≤ 2 hours duration for a three month period. Patients were then randomized into two groups; PLM Group (n=22) and BM Group (n=30) according to the use of SAD. Patients. All patients were premedicated with oral 0.1 mg/kg midazolam about an hour prior to induction of anesthesia. Anesthesia was induced in the supine position with the patient's head in neutral position using propofol 2–2.5 mg/kg, fentanyl 1.0-1.5 µg/kg, and cisatracurium 0.1 mg/kg. Anesthesia was maintained with sevoflurane 1.0% to 2.0% in a mixture of 60% nitrous oxide and oxygen. PLM or BM # 3, 4 or 5 (according to the manufacturers' recommendations) was digitally placed by an anesthesiologist with at least 15 BM placements previously. They noted that the number of attempts needed to place the device correctly, were similar in both of the groups. It

was observed that it took a mean of 16.48 sec to place the BM which is identical to that observed by van Zundert and Gatt. They found that BM placement time was significantly shorter as compared to PLM. However they concluded that the short placement time of the BM by 5 sec as compared to PLM may not be of much clinical significance.

5. **V TRIVEDI et al**[38] studied 60 adult patients of ASA grade-I and II posted for routine surgeries under general anaesthesia, divided equally into two groups group-I and group-II. In group-I, the airway was secured with a PROSEAL LMA (PLMA) while in group-II it was secured with I-GEL. Number of attempts of insertion and mean duration of insertion in both groups were noted. In group-I the mean duration of insertion was 11.73 (±3.084) sec while in group-II it was 9.63 (±2.23) sec. Changes in mean pulse rate in both groups were comparable, statistically not significant. Changes in mean arterial pressure (MAP) was significant intraoperatively, higher in Proseal group. It was concluded that I -gel airway is a better alternative user friendly device than PLMA in patients with high risk and having predicting difficult airway because of ease of insertion and maintenance of haemodynamic stability.

6. **GAURAV CHAUHAN et al**[39], did a randomized controlled study in 80 patients [Group I - I-gel insertion (n = 40) and Group P - LMA Proseal

insertion (n =40)] of ASA grades I/II, of either sex in the age group 18-65 years. Both groups were compared with respect to ease of insertion, insertion attempts, fiberoptic assessment, airway sealing pressure, ease of gastric tube placement, and other complications. Mean insertion time for the I-gel (11.12 ± 1.814 sec) was significantly lower than that of the PLMA (15.13 ± 2.91 sec). I-gel was easier to insert with a better anatomic fit. Mean airway sealing pressure in the PLMA group (29.55 ± 3.53 cm H_2O) was significantly higher than in the I-gel group (26.73 ± 2.52 cm H_2O; P = 0.001). Ease of gastric tube insertion was significantly higher in the I-gel group (P = 0.001). Incidence of blood staining of the device, sore throat and dysphagia were observed more in PLMA group. No other complications were observed in either of the groups.

7. **WOO JAE JEON et al**[40], studied 30 adult patients randomly allocated to two groups (the PLMA or I-gel group). Insertion time and number of attempts were recorded. Time to insertion was similar (26.4 ± 1.4 and 26.4 ± 0.8 for PLMA and I-gel, respectively). After successful insertion, airway leak pressure was measured. Oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/ min and noting the airway pressure (maximum allowed was 40 cm H2O) at which equilibrium was reached. Leak pressure did not vary significantly either between or within groups after CO2 insufflation. Leak volume was

the difference between the inspired versus the expired tidal volume. The leak fraction was calculated as the leak volume divided by inspired tidal volume. In addition, differences between leak volume and leak fraction between groups were not significant. It was concluded that the I-gel was a reasonable alternative to the PLMA for controlled ventilation during laparoscopic gynaecologic surgery.

8. **R. E. GALGON et al**[41], conducted a study on 100 subjects (ASA-PS 1–3) presenting for elective, outpatient surgery, randomly assigned to air-QR and ProSeal devices. The primary study endpoint was airway seal pressure. Mean (SD) airway seal pressures for the air-QR and ProSeal were 30 cmH2O and 30 cmH2O, respectively. Postoperative sore throat was more common with the air-QR (46% vs 38%, p = 0.03) as was pain on swallowing (30% vs 5%, p = 0.01). It was concluded that, the air-QR performs well as a primary airway during the maintenance of general anaesthesia with an airway seal pressure similar to that of the ProSeal, but with a higher incidence of postoperative oropharyngolaryngeal complaints.

9. **SHARMA M et al**[42], randomly allocated 120 patients to four groups, according to composition of gases used to inflate the PLMA cuff to achieve 40 cmH2O cuff pressure, air (Group A), 50% O2:air(Group OA), 50% O2:N2O (Group ON) and 100% O2 (Group O). After induction of general

anaesthesia, Ventimask tubing was attached to fresh gas outlet of Drager anaesthesia work station for desired composition of gas for different groups (air [Group A], O2:air [50% O2] [Group OA], O2:N2O [50% O2] [Group ON] or 100% O2 [Group O]) according to the group. The other end of the tubing was attached to 50 ml syringe via three-way assembly. The fresh gas flow was set at desired concentration and gas mixture at 5 L flow. Once desired gas is filled in the syringe, three-way was put in off position towards syringe and disconnected from the tubing. After PLMA insertion , cuff was inflated by the specified syringe to obtain a cuff pressure of 40 cmH2O with the help of aneroid cuff pressure manometer, attached to the pilot balloon. Cuff pressure, cuff volume and ventilator parameters were monitored intraoperatively. At cuff pressure of 40 cmH2O, oropharyngeal leak pressure (OLP) was checked by closing adjustable pressure limiting valve at fixed gas flow of 3 L/min. The airway pressure at which leak was heard (by stethoscope) was noted. Pharyngolaryngeal parameters were assessed at 1, 2 and 24 h postoperatively. There was statistically significant increase in the gas volume in the PLMA cuff in the Group A, Group OA and O. There was insignificant decrease in the gas volume in Group ON. The incidence of sore throat, dysphagia, and dysphonia were not statistically significant at any point of time till 24 h in between the groups. Sore throat did not have a statistically significant correlation with cuff pressure . Sore throat had statistical significant correlation with duration of anaesthesia ,

with more than one attempt of LMA insertion , blood on LMA , oral suctioning. None of the predictors showed correlation with dysphagia and dysphonia.

10. **G. SHANMUGAVELU et al**[43] , studied 60 patients of either sex scheduled for short duration laparoscopic surgeries (<2 hrs). The study conducted on ASA I and II patients with a BMI of <30kg/m2. Patients were induced with fentanyl 2µg/ kg, propofol 2-2.5mg/kg and neuromuscular paralysis facilitated with atracurium 0.5mg/kg. Anaesthesia was maintained with oxygen, air (fio2 40%) with isoflurane1.5-2%. Oropharyngeal seal pressure was measured after five minutes of placement. FGF 5L/min was used after closing the APL valve at 70cm h2o, recording the pressure at which pressure is plateaued. Presence of sore throat, dysphagia and dysphonia were examined 2hrs and 24hrs post operatively. The insertion time was shorter for I-gel (12.3±3.8secs) than Baska mask (20.1±8.1secs). Oropharyngeal leak pressure was significantly higher for Baska mask (24-32cmh20). Oropharyngeal airway morbidity was not significantly different between two groups.

11. **ISHWARSINGH et al**[44] studied comparison of clinical performance of I-gel with LMA proseal in elective surgeries. 60 ASA I,II adult patients were randomly assigned into 2 groups. Group I(n=30) for I-gel and group

P(n=30) for LMA proseal. The success rate of first attempt of insertion and ease of gastric tube placement was more with group I. Blood staining of device and tongue, lip and dental trauma was more with group P. There was no evidence of bronchospasm, laryngospasm, regurgitation, aspiration or hoarseness in either group.

12. **SUN KYUNG PARK et al**[45] Conducted a systematic review and meta analysis to identify randomized clinical trials that compared the LMA-Proseal with the i-gel during general anesthesia. Twelve randomized clinical trials met the eligibility criteria. It was found that, there were no significant differences in insertion success rate at the first attempt, ease of insertion, oropharyngeal leak pressure (OLP), quality of fiberoptic view and success rate of gastric tube insertion between the i-gel and the LMA-Proseal, respectively. The I-gel had a shorter insertion time than the LMA-Proseal and a lower incidence of blood staining on the device, sore throat and dysphagia. It was concluded that both devices were comparable in ease of insertion and both had sufficient OLP to provide a reliable airway. The i-gel was found to have fewer complications (blood staining, sore throat, dysphagia) than the LMA-P and offers certain advantages over the LMA-Proseal in adults under general anesthesia.

13. **HYE WON SHIN et al**[46] conducted a meta-analysis and systematic review on Comparison of oropharyngeal leak pressure and clinical performance of LMA ProSeal and I-gel in adults and concluded that that LMA ProSeal provides superior airway sealing (higher OLP) compared to I-gel, while I-gel offers rapid insertion time, and lower incidences of blood on the device after removal and sore throat compared to LMA ProSeal in anesthetized adult patients.

CHAPTER 10:

MATERIALS AND METHODS

This was a prospective randomized study done on patients undergoing elective surgeries in the Department of Anaesthesiology, Stanley Medical College, Chennai.

After obtaining the approval of the Institutional Ethical Committee, a randomized, prospective study was conducted on 70 patients over a period of six months.

SAMPLE SIZE:

In a study conducted by Sharifa Ali Sabeeh Al-Rawahi et al[31] the mean airway sealing pressure was 29.98±8.51 in Baska mask group (n= 30) and 24.50±6.19 in Pro-seal group (n=22). To detect similar difference in means with 80% power, a sample size of 70 (35 in each group) was calculated with nMaster software Version 2.0 by applying the following formula.

Formula

$$n = \frac{2s_p{}^2\left[Z_{1-\alpha/2} + Z_{1-\beta}\right]^2}{\mu_d^2}$$

$$s_p^2 = \frac{s_1^2 + s_2^2}{2}$$

Where,

s_1^2 : Standard deviation in the first group

s_2^2 : Standard deviation in the second group

μ_d^2 : Mean difference between the samples

α : Significance level

1- β : Power

Randomization was done by allocating the patients to either the Proseal group (PLM) or Baska group (BM) by computer generated random numbers. Each group had 35 patients. The patients who met the inclusion and exclusion criteria were only included in the study.

To find the association of significance in categorical data the Chi-Square test was used. In all the statistical tools the probability value of 0.05 was considered as significant level.

PRE-ANESTHETIC EVALUATION:

Pre anesthetic assessment was done by recording a detailed history and performing a complete physical examination including airway examination. Complete blood count, Renal function tests, Random blood sugar, electrocardiograph and chest X ray were done. Patients were explained about the procedure in detail and written informed consent was obtained for the same.

SELECTION OF CASES:

INCLUSION CRITERIA:

All consented adult patients aged between 18 – 65 yrs belonging to ASA physical status I - II undergoing elective surgical procedures requiring general anaesthesia with Intermittent positive pressure ventilation of less than 2 hours duration.

EXCLUSION CRITERIA:

- Anticipated difficult airway
- Mouth opening of <2.5 cm
- Increased risk of aspiration (Pregnancy, BMI > 30, GERD, hiatus hernia)
- Patients with increased airway resistance and decreased lung compliance (obstructive and restrictive lung diseases)
- Requiring surgery in the non-supine position
- Patient refusal

EQUIPMENTS:

1. Anaesthesia work station
2. Oxygen source
3. Suction apparatus
4. Intravenous cannula
5. 10 ml syringe
6. Sterile gloves
7. Supraglottic airway device (Baska mask, Proseal LMA)
8. Water soluble lubricant (lignocaine) gel
9. Plasters

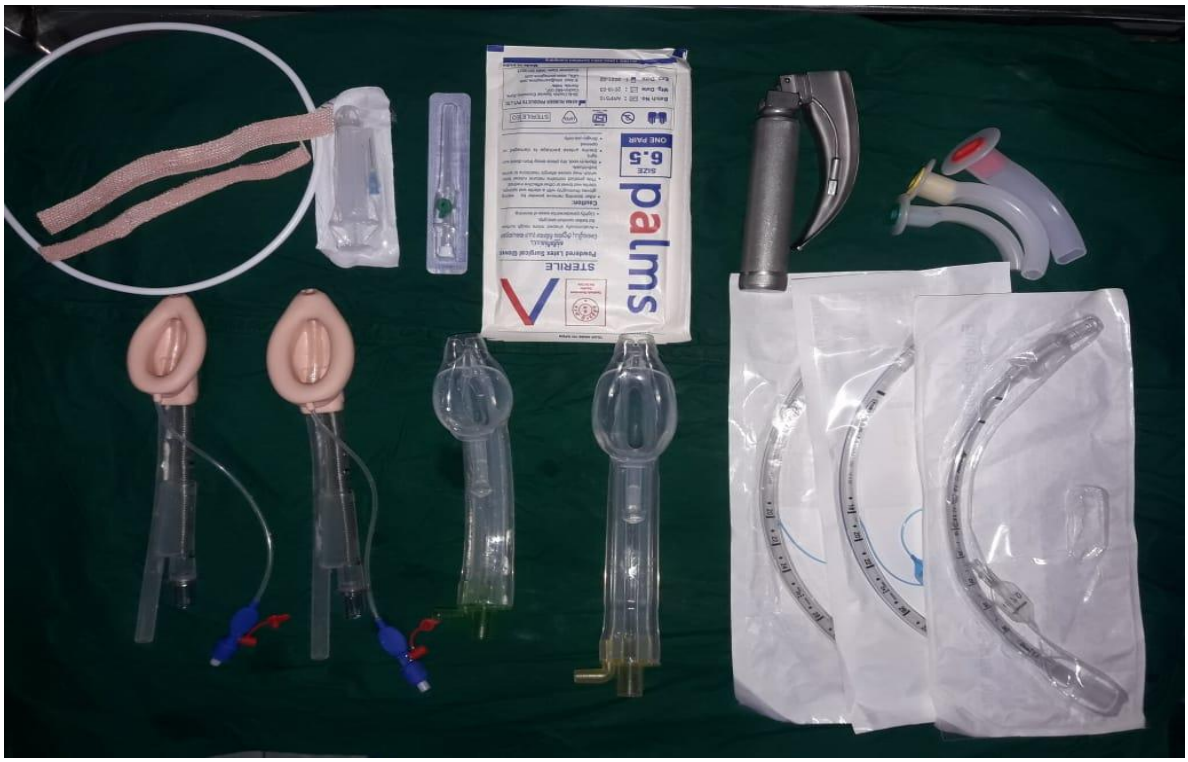


Fig 14: Equipments

GROUPS

- **GROUP PLM**

General anaesthesia maintained with Proseal LMA.

- **GROUP BM**

General anaesthesia maintained with Baska mask.

MONITORING

1.Heart rate

2.Continuous ECG

3.Peripheral oxygen saturation

4.Noninvasive blood pressure

5.ETCO2

METHODOLOGY :

After institutional Ethics Committee approval and informed written consent, 70 ASA I-II patients were selected for the study based on the inclusion and exclusion criteria. Patients were randomised into two groups i.e. group PLM & group BM using computerised random number.

On arrival of the patient in the operating room standard anaesthesia monitors like pulse oximeter, non invasive BP and ECG were connected and baseline values (values taken just before the start of the procedure) of HR, BP,

SPO2 were recorded. Peripheral IV access obtained with 18G IV cannula. Patients were premedicated with Inj.Glycopyrrolate 0.2mg IV, Inj.Midazolam 1mg IV.

Anesthesia induced using Inj.Fentanyl 2micg/kg, Propofol 2 mg/kg and relaxation obtained with Inj.Atracurium 0.5mg/kg IV,with the patient in the supine position with the patient's head in neutral position.

The supraglottic airway device inserted as per the group allotment and anaesthesia was maintained with sevoflurane 1-2% in a 66% nitrous in oxygen mixture.

GROUP BM:

- ✓ Baska mask Size three (30 to 50 kg), size four (50 to 70 kg) selected as per manufacturers recommendations.
- ✓ The integrity and function of the Baska Mask checked.
- ✓ With patients head in neutral position, the Baska mask is pushed past the front teeth towards the hard palate, avoiding the tongue. If necessary, when the mask is fully within the mouth, the tab, a unique feature of the Baska Mask, is used to help negotiate the palato-pharyngeal curve.
- ✓ Correct placement of device confirmed by observing the amplitude of end-tidal carbon dioxide waveforms (square waveform pattern) and the presence of bilateral chest movements and SpO2 of >95%.

GROUP PLM:

- ✓ Manufacturers guidelines followed for sizing (size 3 for 30-50kg, size 4 for 50-70kg)
- ✓ Patients head placed in sniffing position and a firm pillow placed under the patients occiput.
- ✓ Standard Insertion (digital method) technique followed for PLMA insertion.
- ✓ Cuff inflated with 20ml of air for size 3 LMA and 30ml of air for size 4 LMA.
- ✓ Correct placement was confirmed similar to group BM.

If device placement fails, manipulations including jaw thrust, chin lift, head extension or flexion, in/out movements done. Maximum of 2 reattempts done for failed placement which was later switched over to endotracheal intubation. Haemodynamic monitoring was done and any untoward haemodynamic changes were noted.

Definitions of parameters measured:

1. **AIRWAY SEALING PRESSURE OR OROPHARYNGEAL LEAK PRESSURE:** APL valve closed to 40cm of H2O and a constant fresh gas flow of 6L/min is kept and continuous pressure applied over reservoir bag. The pressure at which there is no further increase in airway pressure is taken as the oropharyngeal leak pressure. Airway pressure was not allowed to rise above 40 cmH2O.
2. **INSERTION TIME:** Time from taking SAD in hand to obtaining first rectangular capnogram.
3. **ATTEMPT:** SAD removed and reinserted.
4. **LPM (LARYNGOPHARYNGEAL MORBIDITY) score** = sum of sore throat, dysphagia and hoarseness

Scores	0	1	2	3
Sore throat	none	minimal	moderate	Severe; never an SAD again
Dysphagia	none	minimal	moderate	Severe; cannot eat
Hoarseness	none	minimal	moderate	Severe; cannot speak

Table 5: LPM SCORE

5. **EASE OF INSERTION GRADING:**

- Easy: single pass without manipulations or significant resistance
- Slight difficulty: single pass with upto 2 manipulations or 1 complication
- Difficult : ≥ 2 attempts or >2 manipulations or > 1 complication
- Impossible: Three failures

Manipulations: jaw thrust, chin lift, head extension or flexion, in/out movements.

Complications during insertion: Soft tissue damage, dental damage, bleeding, hypoxia SpO2<92%, failure to establish/maintain airway, regurgitation, aspiration, laryngospasm, gagging, coughing, stridor, gross movement, others.

6. **INTRAOPERATIVE COMPLICATIONS:**

- Dislodgement
- Regurgitation
- Hypoxia
- Laryngospasm

7. **COMPLICATIONS DURING EMERGENCE:**

- Regurgitation
- Dislodgement
- Laryngospasm
- Hypoxia
- Vomiting
- Nausea
- Staining of supraglottic device with blood/secretions
- Others

CHAPTER 11

OBSERVATIONS AND RESULTS:

Findings:

A Prospective randomized control study for six months of seventy patients using Baska mask (n=35, 50%) and Proseal Laryngeal Mask (n=35, 50%) revealed the following results.

Age distribution:

The following table shows the mean age distribution between the two study groups. Analysis of age distribution between both the groups showed the mean age of 33.09 (S.D=12.862) in BM group and 37.37 (S.D=14.25) in PLM group.

AGE		
	BM	**PLM**
Mean	33.09	37.37
S.D	12.862	14.25
p-value	>0.05	

Table 6: Mean age distribution

The following figure shows the mean age distribution between two groups.

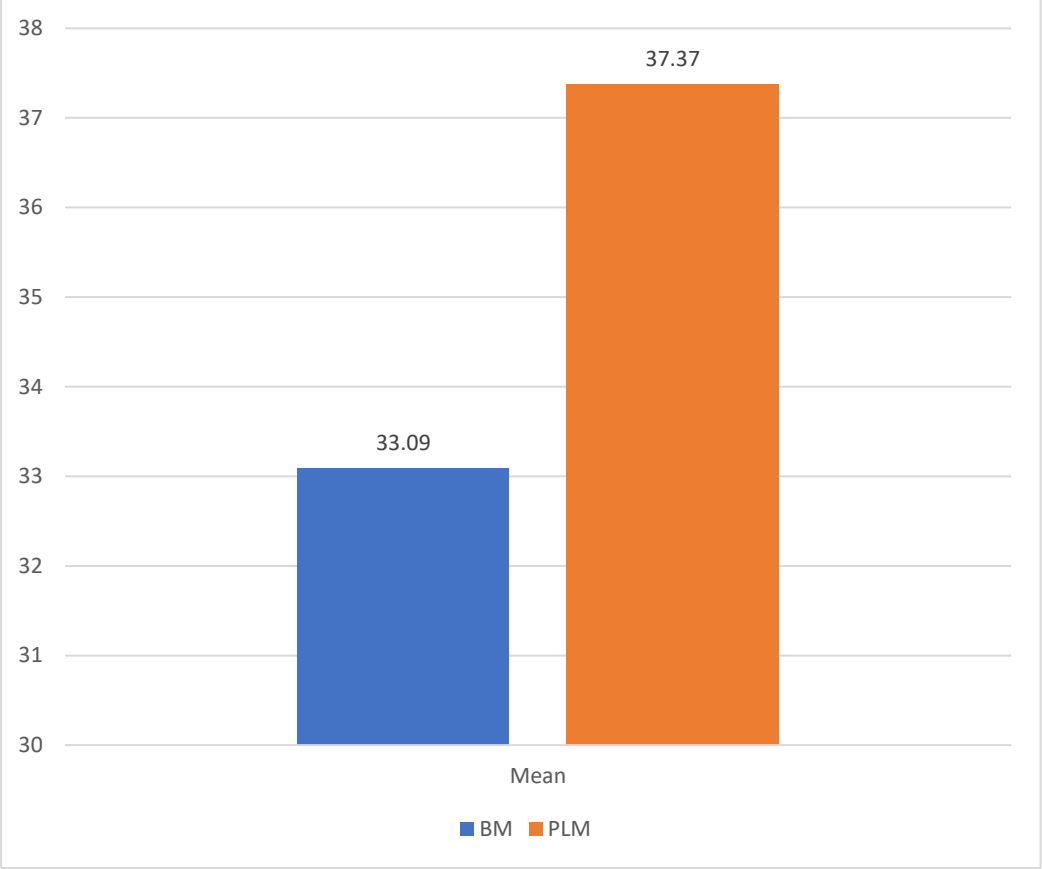


Figure 15: Mean Age distribution

BMI distribution

The following table shows the mean BMI distribution between the two study groups. Analysis of BMI distribution between both the groups showed the mean BMI of 22.14 (S.D=3.083) in BM group and 22.73 (S.D=2.94) in PLM group.

BMI		
	BM	PLM
Mean	22.14	22.73
S.D	3.083	2.94
p-value	>0.05	

Table 7: Mean BMI Distribution

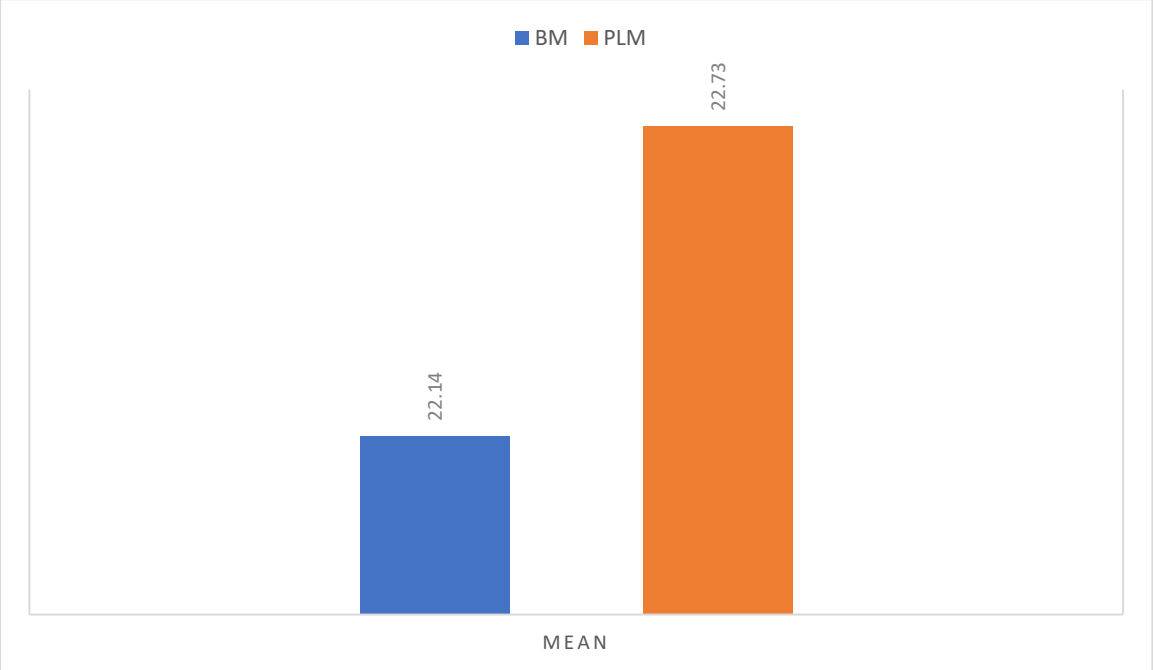


Figure 16: Mean BMI distribution

Gender distribution between the two groups

The following figure shows the gender distribution between two groups. There were more number of females in our study. There were 24 (68.6%) females in BM groups while there were 21(60%) females in PLM group.

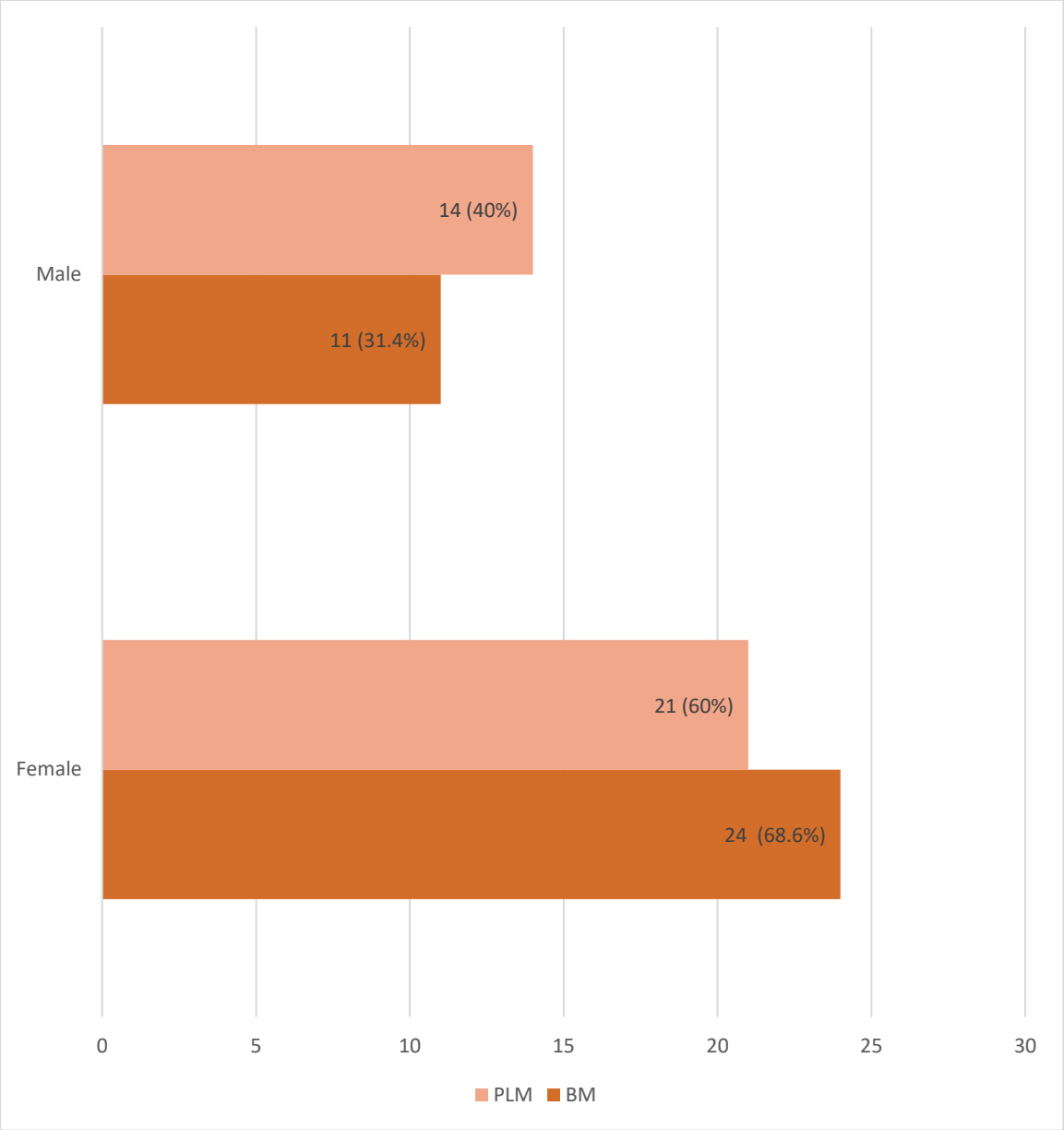


Figure 17: Gender distribution between two groups

Modified Mallampatti Score between two groups

Modified Mallampatti Score between both the groups is seen in the following table. Majority of them had MPC II (BM=51.4%; PLM=60%). The chi-square test for Modified Mallampatti score between both the groups shows a value of 1.764 which is not statistically significant.

		GROUP		Total	Pearson Chi-Square	p-value
		BM	PLM			
MPC	I	17 (48.6%)	13 (37.1%)	30	1.764[a]	>0.05
	II	18 (51.4%)	21 (60%)	39		
	III	0	1 (2.9%)	1		
Total		35	35	70		

Table 8: Modified Mallampatti Score between two groups

Following figure shows the MPC distribution between both the groups.

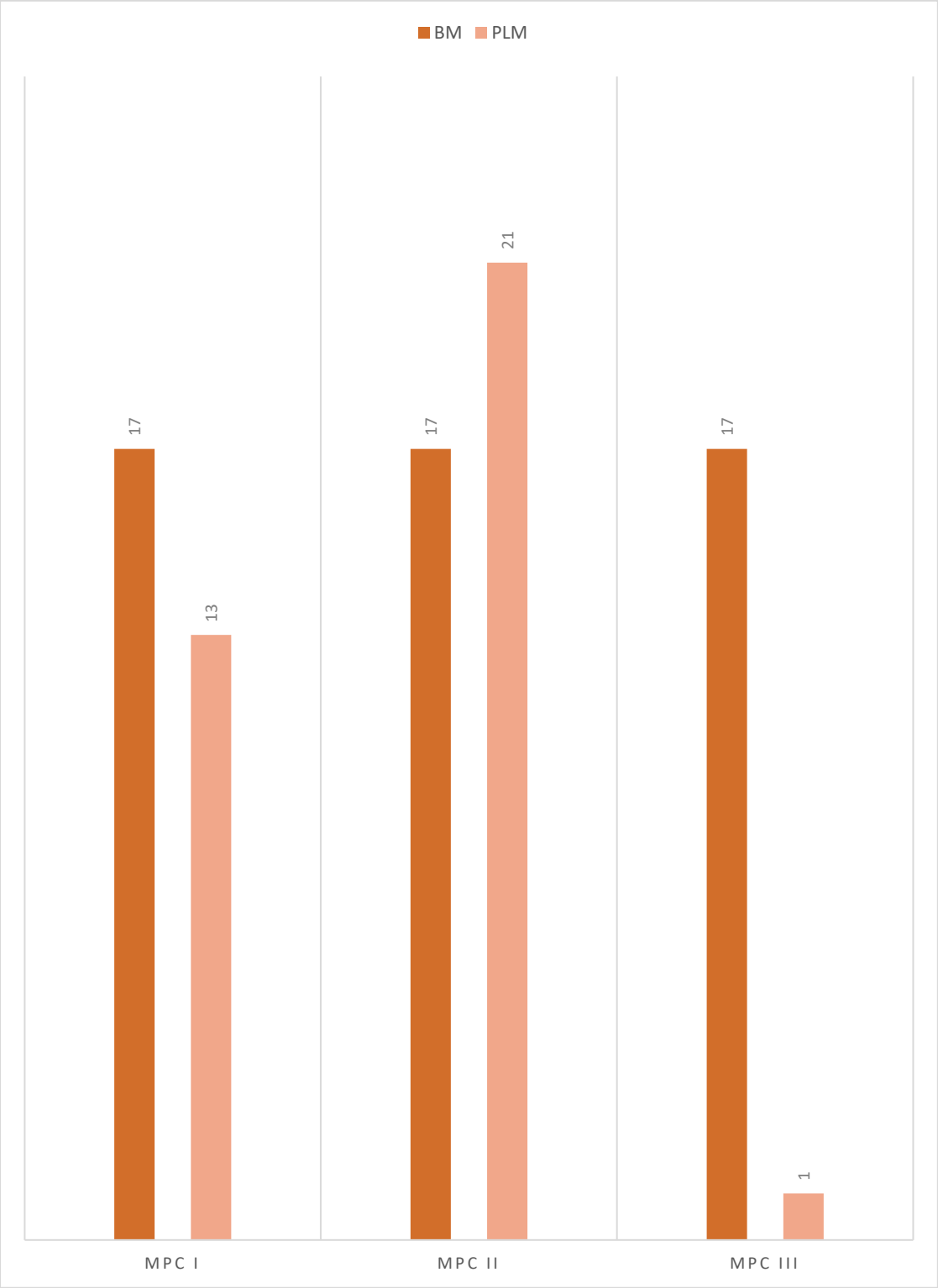


Figure 18: Modified Mallampatti score between two groups

ASA-PS between two groups

Table 9 shows the distribution of number of patients according to ASA-PS classification. Majority of them were in ASA PS I (BM=65.7%; PLM=60%). Chi-square test shows a value of 0.245 which is not statistically significant (p>0.05).

		GROUP		Total	Pearson Chi-Square	p-value
		BM	PLM			
ASA-PS	I	23 (65.7%)	21 (60%)	44	0.245	>0.05
	II	12 (34.3%)	14 (40%)	26		
Total		35	35	70		

Table 9: ASA-PS between two groups

The following figure shows the ASA physical status distribution between both the study groups.

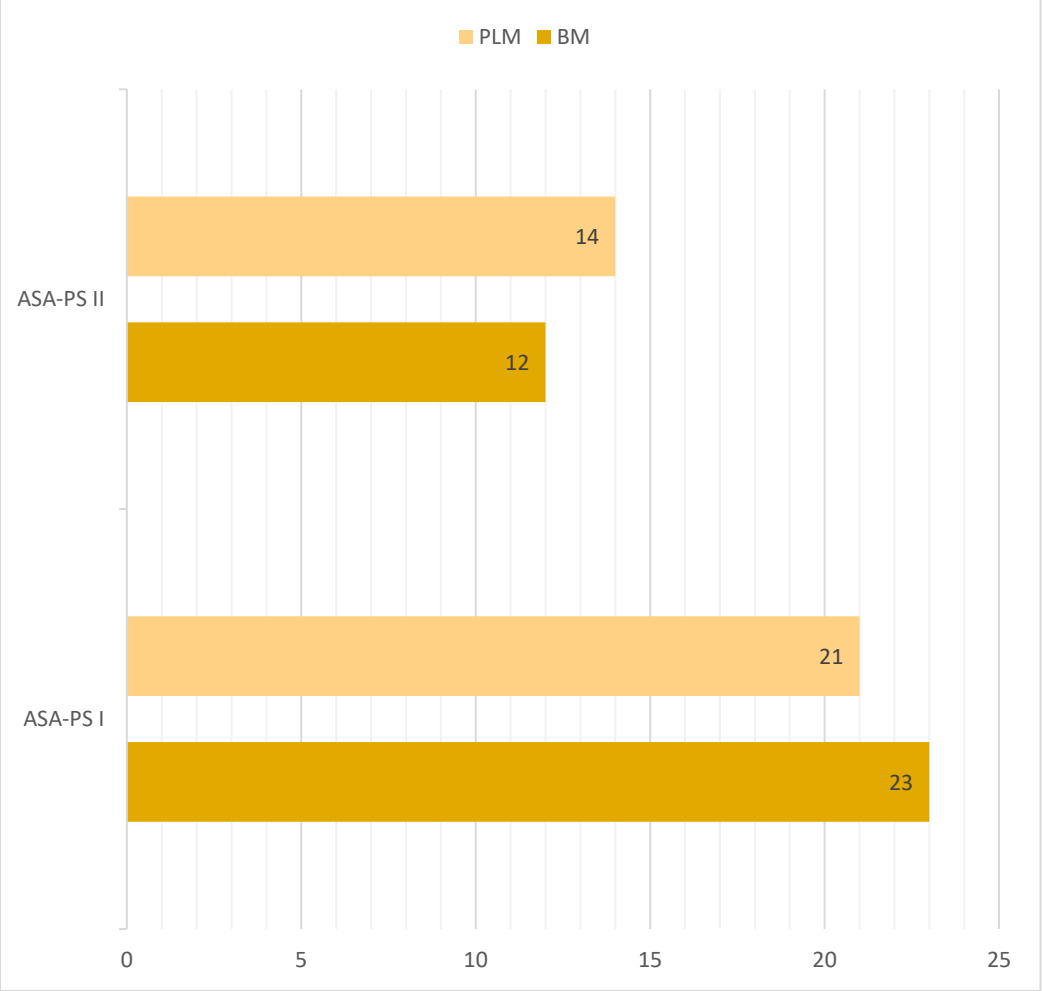


Figure 19: ASA-PS between two groups

Size of SAD

The following table shows the distribution of study sample based on the size of SAD inserted. Maximum number of size 3 SAD were inserted in BM (57.1%, n=20). Equal number of size 4 supraglottic device was found in both the groups. Chi-square tests were 1.429 which is not statistically significant ($p<0.05$).

		GROUP		Total	Pearson Chi-Square	p-value
		BM	PLM			
SIZE OF SAD	3	20 (57.1%)	15 (42.9%)	35	1.429[a]	>0.05
	4	15 (42.9%)	20 (57.1)	35		
Total		35	35	70		

Table 10: Size of SAD

The following figure shows the size of SAD used in both the two groups.

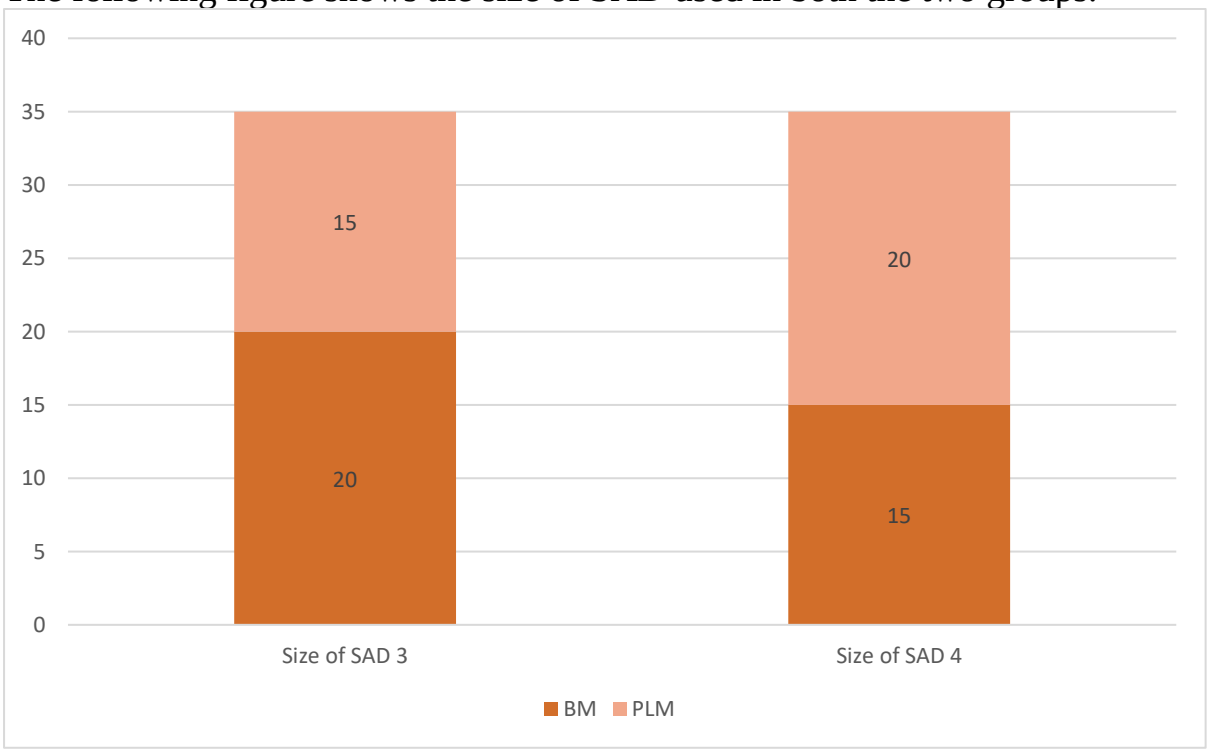


Figure 20 : Size of SAD

Number of attempts

The following tables shows the distribution of sample size based on the number of attempts required to place the supraglottic airway device. BM group had more number of single attempt insertions (n=32, 91.4%) compared to PLM group (n=29, 82.9%). Chi-square tests shows a value of 1.148 with p>0.05 which is not statistically significant.

		GROUP		Total p-value	Pearson Chi-Square	p-value
		BM	PLM			
NO.OF ATTEMPTS	1	32 (91.4%)	29 (82.9%)	61	1.15	>0.05
	2	3 (8.6%)	6 (17.1%)	9		
Total		35	35	70		

Table 11: Number of attempts

The following figure shows the number of attempts between both the groups.

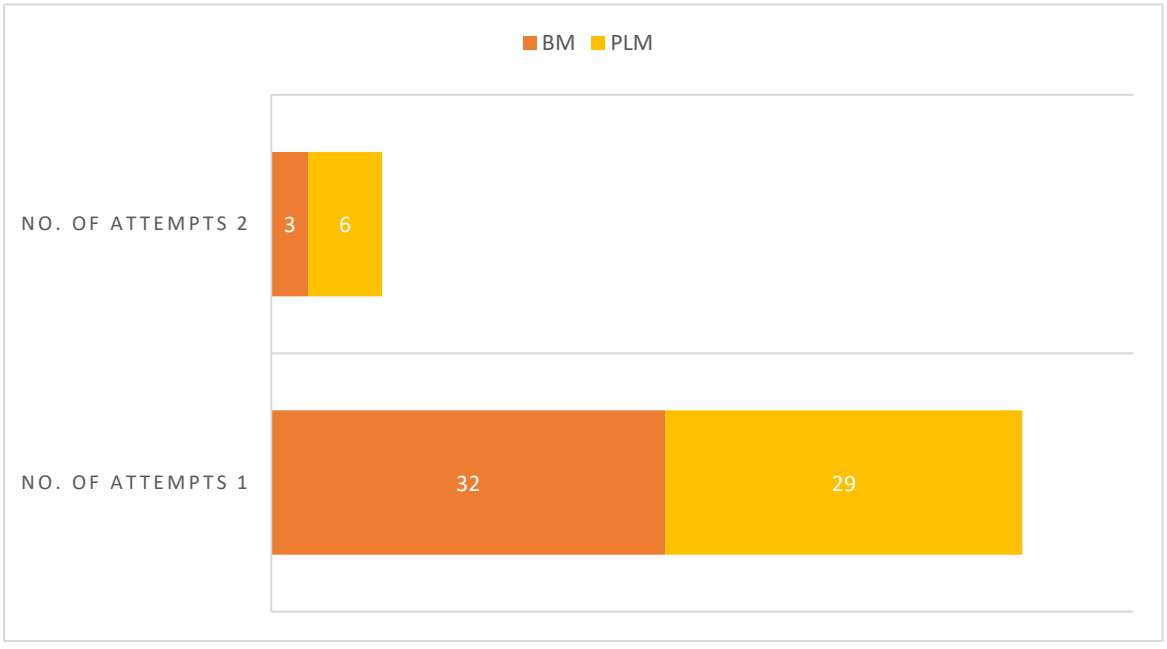


Figure 21: Number of attempts

Ease of insertion grading

The following table shows the ease of insertion grading between both the study groups. Majority of the cases were easy to insert (BM=85.7%; PLM=65.7%). Difficulty and slight difficulty was higher among PLM group (11.4% and 22.9% respectively). Chi-square test shows a value of 3.864 which is statistically significant.

		GROUP		Total	Pearson Chi-Square	p-value
		BM	PLM			
EASE OF INSERTION GRADING	EASY	30 (85.7%)	23 (65.7%)	53	3.85	<0.05
	SLIGHT DIFFICULTY	3 (8.6%)	8 (22.9%)	11		
	DIFFICULT	2 (5.7%)	4 (11.4%)	6		
Total		35	35	70		

Table 12: Ease of insertion grading

The following figure shows the distribution of study population based on the Ease of insertion grading of SAD.

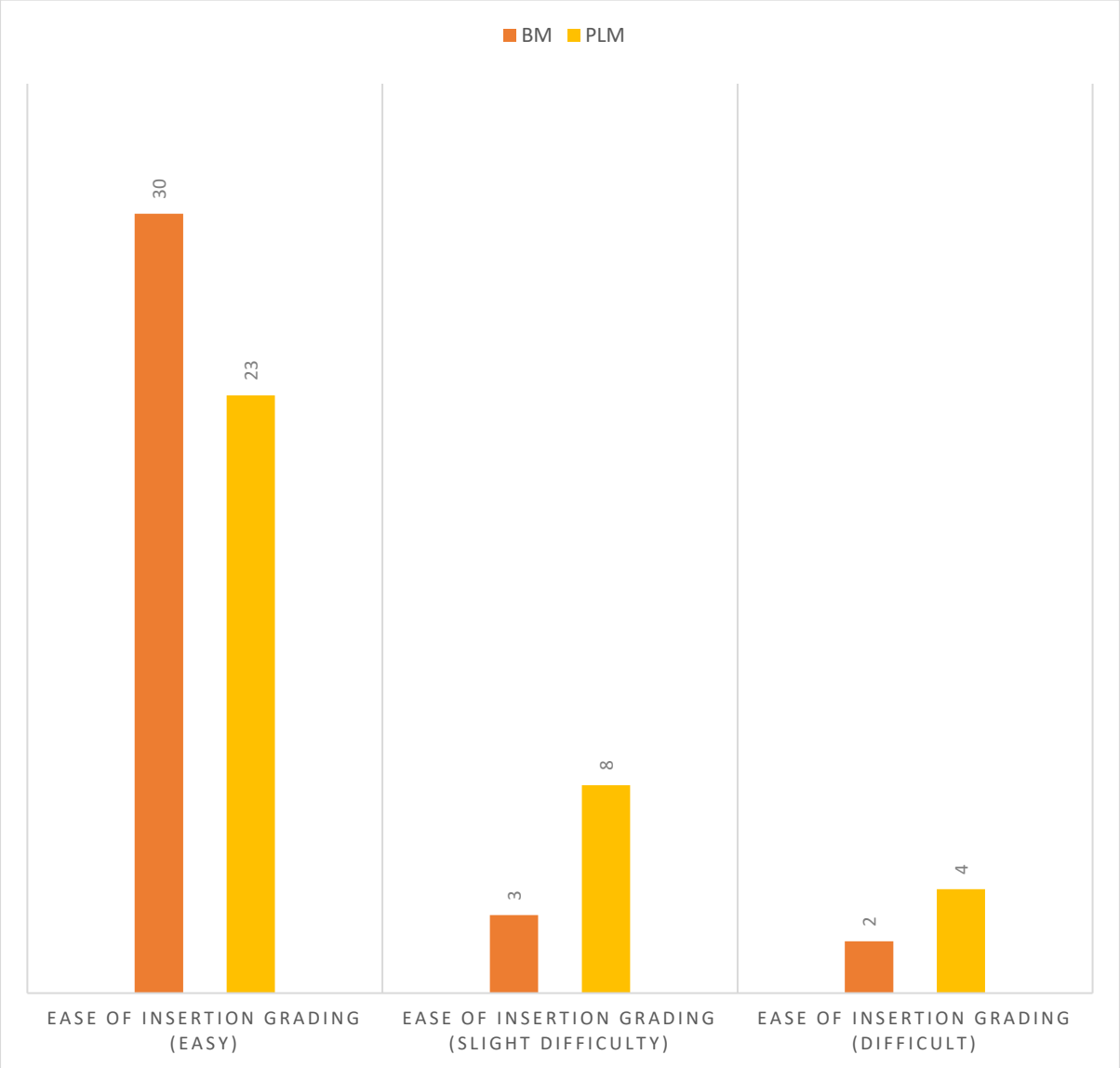


Figure 22: Ease of insertion grading

Number of manipulations

Table 13 shows the number of manipulations required to place the SAD between two groups along with chi-square tests. The number of manipulations were higher among PLM (n=12) compared to BM (n=5). Number of single and double manipulations were higher in PLM compared to BM. Chi-square test revealed a score of 3.925 (p>0.05) which is not statistically significant.

		GROUP		Total p-value	Pearson Chi-Square	p-value
		BM	PLM			
NO. OF MANIPULATIONS	1	3 (8.6%)	6 (17.1%)	9	3.93	>0.05
	2	2 (5.7%)	6 (17.1%)	8		
	NIL	30	23	53		
Total		35	35	70		

Table 13: Number of Manipulations

The following figure shows the distribution of study participants based on the number of manipulations required to insert SAD.

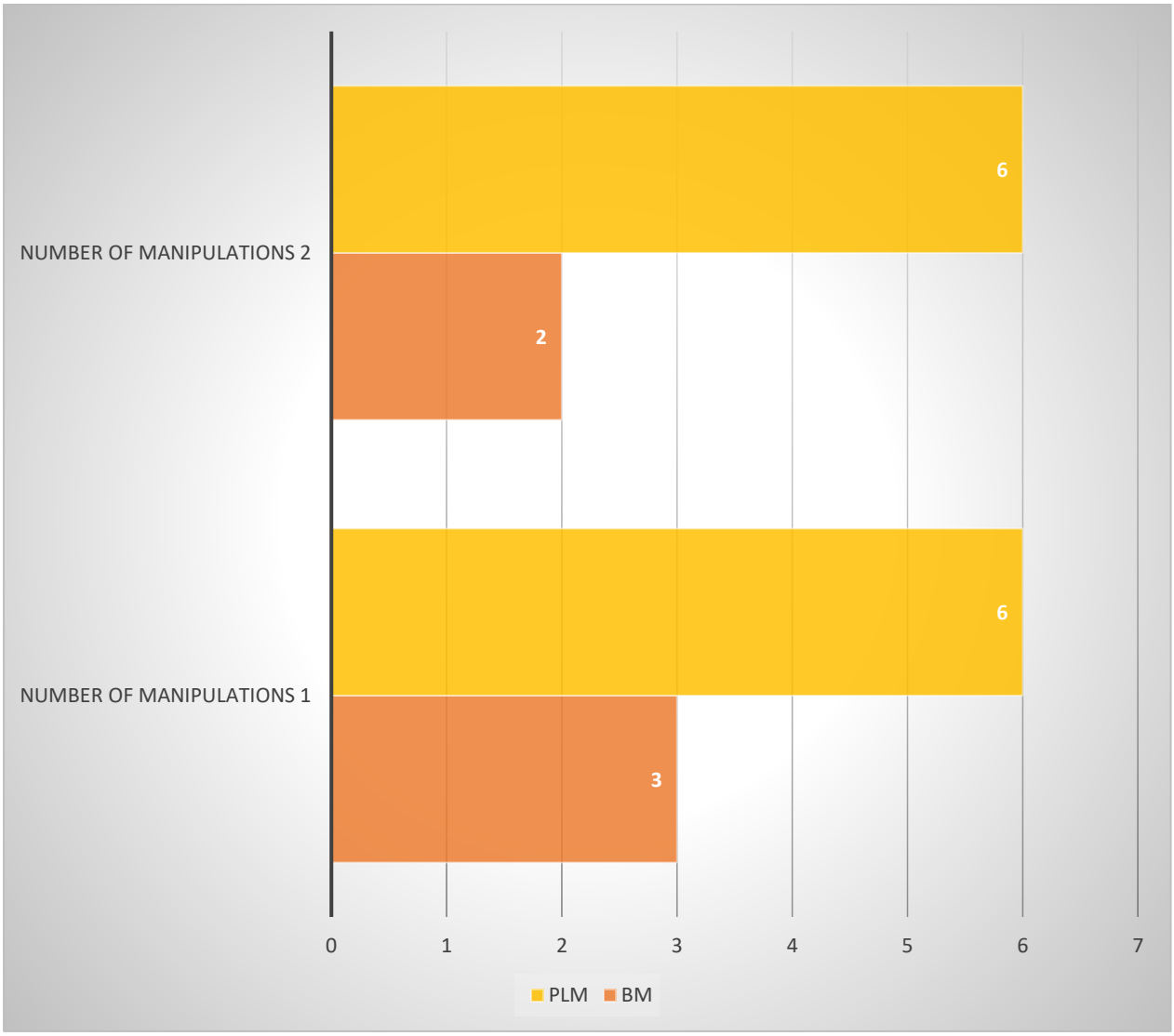


Figure 23: Number of manipulations

Complications and untoward hemodynamic changes

There were no complications during insertion of SAD in both the groups. There were no intraoperative complications including any untoward hemodynamic changes in both the groups.

Complications during emergence

The following table shows the complications during emergence between both the groups. Blood staining of SAD was more among BM (20%), Nausea was found more in PLM (17.1%), vomiting was more among PLM (17.1%) while secretions staining SAD was equal in both the groups. Chi-square test for different complications during emergency revealed a score of 7.13 (p>0.05) which is not statistically significant.

COMPLICATIONS DURING EMERGENCY	GROUP		Total	Chi-Square	p-value
	BM	PLM			
NO	18 (51.4%)	19 (54.3%)	37	7.13	>0.05
BLOOD STAINING OF SAD	7 (20%)	1 (2.9%)	8		
NAUSEA	3 (8.6%)	6 (17.1%)	9		
SECRETIONS STAININGSAD	3 (8.6%)	3 (8.6%)	6		
VOMITING	4 (11.4%)	6 (17.1%)	10		
Total	35	35	70		

Table 14: Complications during emergence

Laryngopharyngeal morbidity score

The following table shows the Laryngopharyngeal morbidity score distribution among the study population. PLM group has a maximum score of 2 in 57.1% of the cases while BM group has 51.4% in the same score. BM group has more number of Laryngopharyngeal morbidity score of 1 compared to PLM group. Chi-square tests shows a value of 7.272 with $p<0.05$ which is statistically significant.

LPM SCORE	GROUP		Total	Chi-square	p-value
	BM	PLM			
1	16 (45.7%)	8 (22.9%)	24	7.27	<0.05
2	18 (51.4%)	20 (57.1%)	38		
3	1 (2.9%)	7 (20%)	8		
Total	35	35	70		

Table 15: Comparison of Laryngopharyngeal Morbidity Score

Insertion time

The mean insertion time is higher for PLM with mean = 36.69 (S.D=8.341) against BM with mean = 33.37 (S.D=10.781). The means significantly differ between the two groups with $p<0.005$.

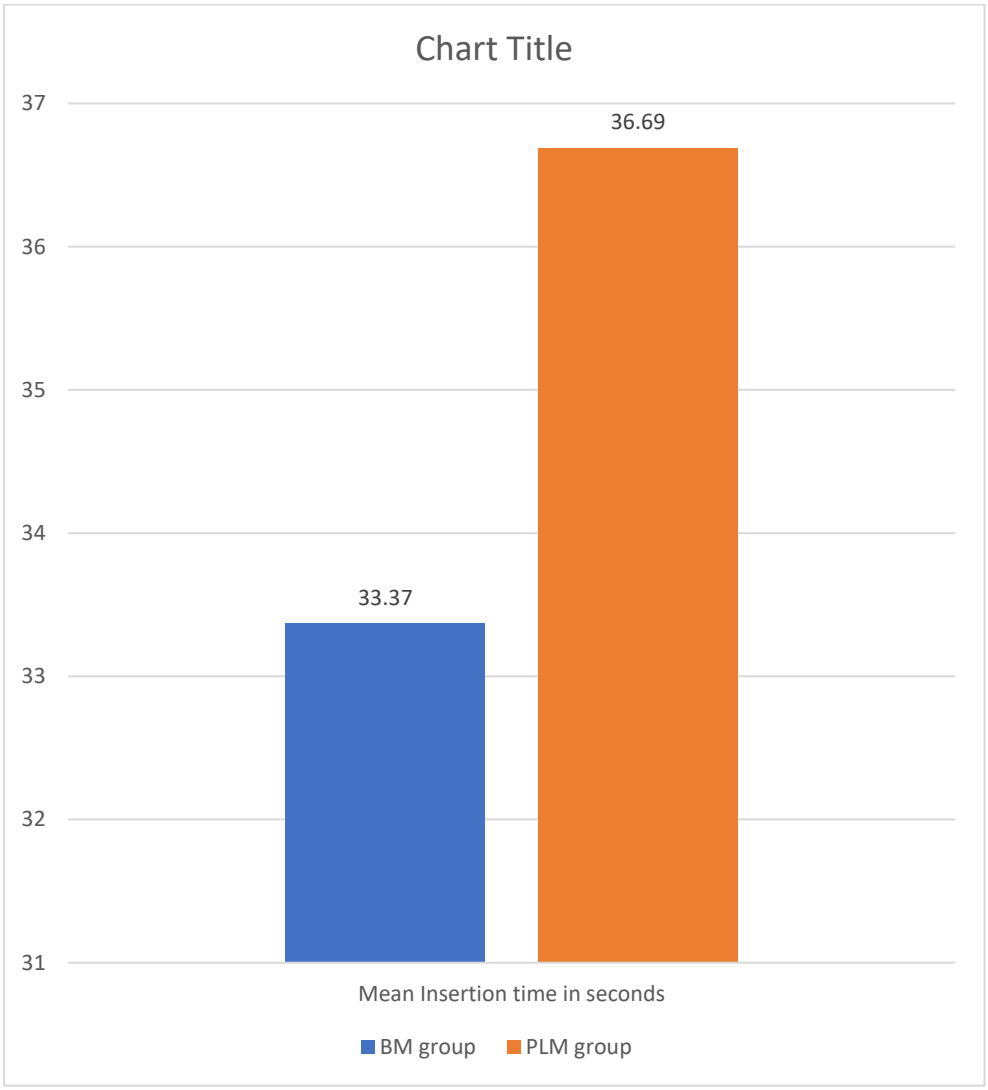


Figure 24: Mean insertion time in seconds

Duration in oropharynx

The following table shows the duration of supraglottic airway device in oropharynx for the two groups. The mean duration in oropharynx is considerably higher for PLM (mean=70.34, S.D=27.69) compared to BM (mean=61.23, S.D=27.55). The p-value is not statistically significant between both the groups.

Duration in Oropharynx		
	BM	PLM
Mean	70.34	61.23
S.D	27.69	27.55
p-value	>0.05	

Table 16: Mean duration in Oropharynx in minutes

The following figure show the mean duration of SAD in oropharynx in the two groups.

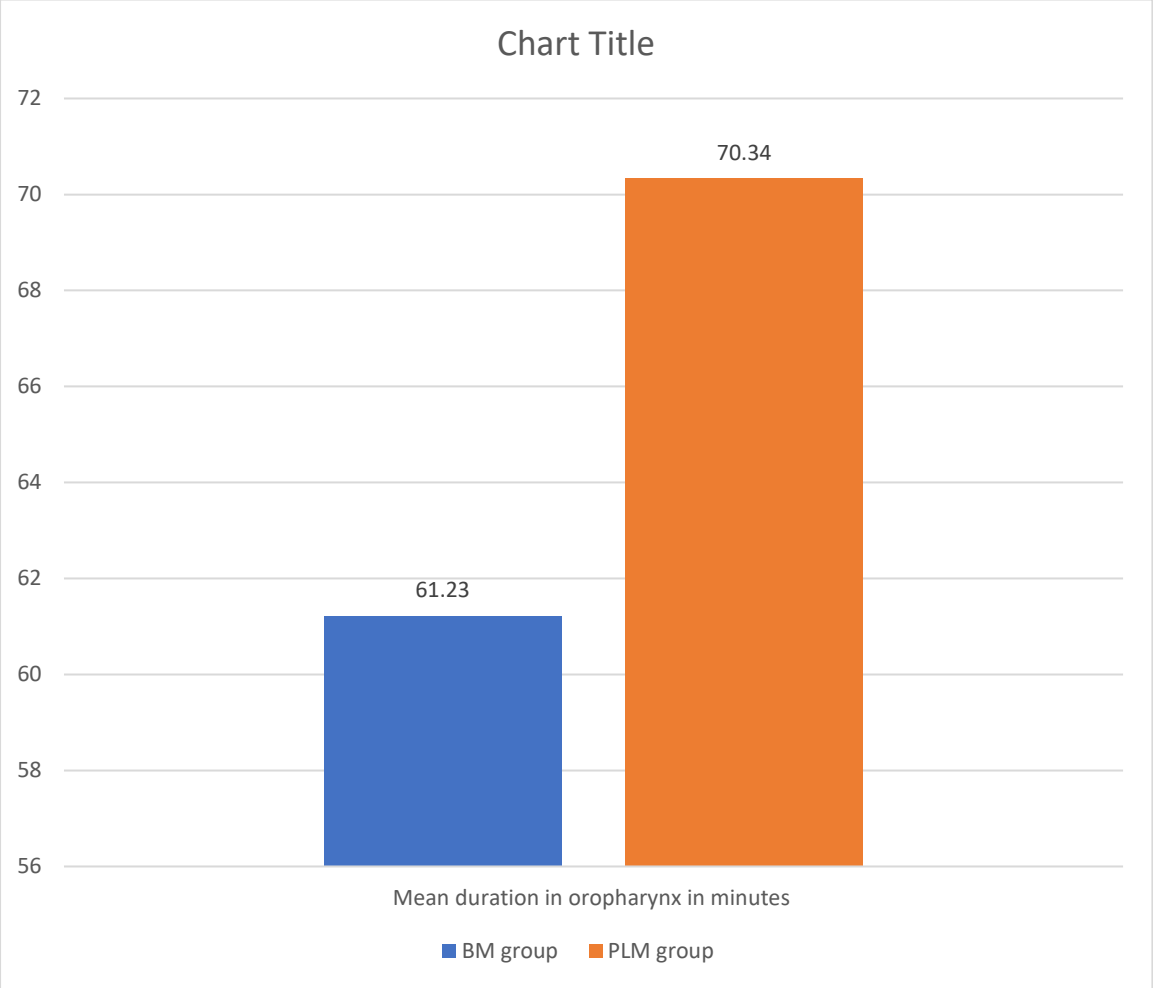


Figure 25: Mean duration in oropharynx in minutes

Airway sealing pressure

The following figures show the distribution of airway sealing pressure in the two groups. The mean airway sealing pressure was higher in BM compared to PLM at 5 minutes, 30 minutes and at the end of the surgery.

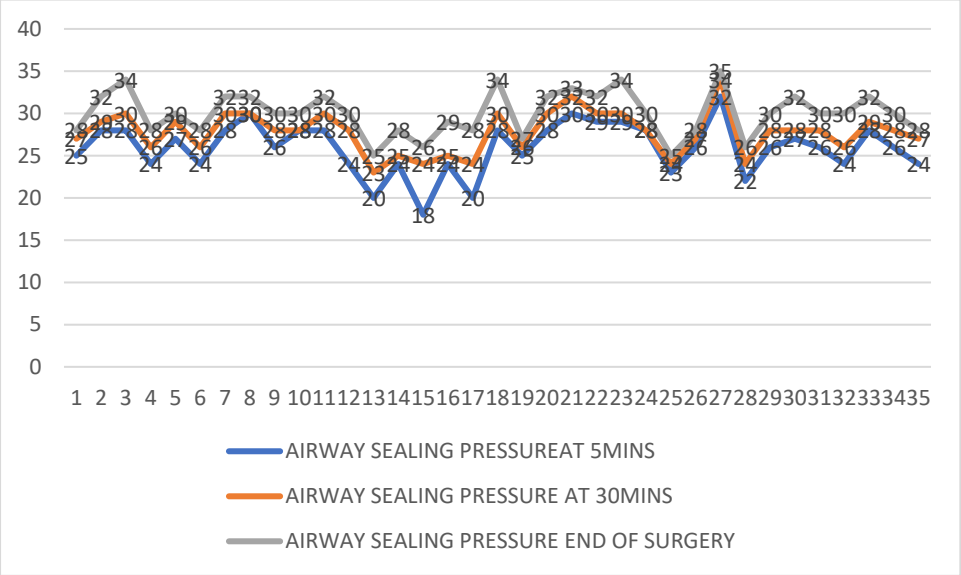


Figure 26: Airway sealing pressure for BM

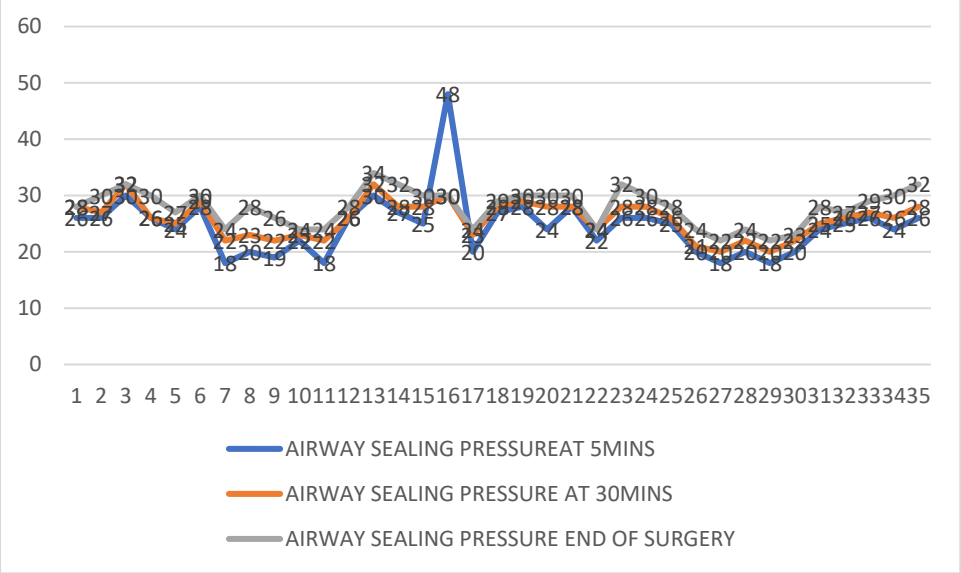


Figure 27: Airway sealing pressure for PLM

Multivariate analysis

The following tables show the multivariate analysis of airway sealing pressure between two groups. They vary significantly between groups with $p<0.05$.

	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.
	AIRWAY SEALING PRESSURE AT 5MINS	36.013	1	36.013	6.318	.003
	AIRWAY SEALING PRESSURE AT 30MINS	68.014[a]	1	68.014	8.217	.006
	AIRWAY SEALING PRESSURE END OF SURGERY	80.357[b]	1	80.357	9.257	.003

Table 17: Multivariate analysis of airway sealing pressure

	Dependent Variable	GROUP BM	GROUP PLM
	MEAN AIRWAY SEALING PRESSURE AT 5MINS	25.914	21.257
	MEAN AIRWAY SEALING PRESSURE AT 30MINS	27.742	25.177
	MEAN AIRWAY SEALING PRESSURE END OF SURGERY	30	26.984

Table 18: Mean airway sealing pressure

CHAPTER 12

DISCUSSION:

Supraglottic airway management devices comprise a family of medical devices that facilitate oxygenation and ventilation without endotracheal intubation. Second-generation SGAs including LMA ProSeal and i-gel were introduced in 2000 and 2007, respectively. They provide better airway sealing characteristics than classic LMA, have an additional drainage tube for stomach decompression to reduce the risk of pulmonary aspiration, and are designed for use with spontaneous or positive pressure ventilation (PPV). Baska mask is a newer third generation supraglottic airway device according to new Miller's classification of SAD in 2014[19], with additional safety features, requiring comparative studies with the existing second generation devices to evaluate its safety and efficacy.

In our study we compared the gold standard second generation supraglottic device, Proseal LMA with the newer BASKA mask in patients undergoing General anaesthesia with intermittent positive pressure ventilation. This study was conducted to compare the airway sealing pressure of the BASKA mask and Proseal LMA and to find out the ease of insertion, time taken for insertion of SAD, number of manipulations required and perioperative complications between BASKA mask and Proseal LMA.

70 patients were studied, 35 in each group. Analyzing the demographic profile there were more females (64.29%) in our study with 68.6% females in BM group and 60% females in PLM group. Comparing the two groups more females were there in PLM group. In a Cohort study conducted by Saito et al[47] on difficult ventilation via a supraglottic airway device they demonstrated an independent increase in the risk of difficult ventilation via a SAD for male patients. This is related to the greater incidence of increased upper airway resistance in men compared with women, leading to upper airway narrowing, obstruction and obstructive sleep apnea. This is in contrary to our study where 4 out of 6 difficult supraglottic device insertions was found in females. This we conclude may be due to selection of supraglottic airway device based on actual weight rather than ideal weight.

There was no significant difference in the two groups with regards to mean age (BM Group=33.09, PLM Group= 37.37). Abramson et al[48] demonstrated age-related changes in the airway, in that the upper airway becomes more elliptical, less uniform and less compact as confirmed with three-dimensional computed tomography. These anatomical changes explain the increased risk of difficult mask ventilation with age which is also a plausible explanation for difficult ventilation via a SAD. In a retrospective review conducted by Saito et al[47] on 14,480 south east Asian population it was concluded that age > 45 years is an independent risk factor for difficult ventilation via a supraglottic device.

This is against the finding in our study, where the mean age for patients with difficult SAD placement was 37.17.

There was no significant difference in the two groups with regards to mean BMI (BM Group=22.14, PLM Group= 22.73). In South-East Asians, the body mass index is significantly lower than that of the Western population[49].

ASA physical status and Modified Mallampatti scores were similar between both the groups. In BM group 65.7% of study population belonged to ASA-PS I and 34.3% belonged to ASA-PS II. In PLM group 60% of the study population belonged to ASA-PSI and 40% ASA-PS II. 48.6% of patients in BM group had MMS-I while 51.4% had MMS-II on airway examination. There were no patients with MMS-III in BM group. In PLM group 37.1% of patients had MMS-I, 60% had MMS-II and 2.9% had MMS-III grade.

In our study, 57.1% of patients underwent surgery with size 3 BM inserted, whereas 42.9% received size 4 BM. In PLM group 42.9% patients received size 3 PLM and 57.1% received size 4 PLM. There was no statistical significance in terms of size of SAD inserted between both the groups.

We found that most of our patients in BM group (91.4%, n=32 out of 35) had SAD inserted in single attempt while only 82.9% (29 out of 35 patients) had successful single attempt SAD insertion in PLM group. More than 1 attempt for insertion was seen in 8.6% (n=3 out of 35) of patients in BM group and 17.1% (n=6out of 35) of patients in PLM group. However there was no statistical

significance between both the groups with respect to the number of attempts required for supraglottic device insertion. This is in similarity to a study conducted by Al-Rawahi SAS et al[37].

Patients in PLM group had higher number of manipulations of SAD (34.2% with single manipulation in 6 out of 35 patients and double manipulations in 6 out of 35 patients) whereas in BM group only 14.3% of patients required manipulations while inserting SAD (single manipulations in 3 out of 35 and double manipulations in 2 out of 35 patients). However there was no statistical significance in terms of number of manipulations between both the groups which is in accordance with the study conducted by Al-Rawahi SAS et al[37].

There were no complications while inserting the SAD in both the groups. In our study there were no intraoperative complications in both the groups and no untoward hemodynamic changes occurred in either of the groups.

The mean insertion time of SAD was significantly higher ($p<0.005$) for PLM group with a mean value of 36.69 secs compared to a mean of 33.37 secs in BM group in our study. This is in accordance with the study conducted by Al-Rawahi SAS et al[37], in which the time taken for BM placement (16.43 ± 4.54secs) was significantly shorter as compared to PLM (21.45 ± 6.13 secs).

In our study it was found that 85.7% of patients (n=30 out of 35) in BM group had easy insertion of SAD while only 65.7% (n=23) patients had easy insertion in PLM group. The incidence of slight difficult insertion (22.9%, n=8

out of 35) and difficult insertion (11.4%, n=4 out of 35) were higher in PLM group compared to BM group where slight difficult insertion was found in 8.6% (n=3 out of 35) patients and difficult insertion was found in 5.7% (n=2 out of 35) of patients. There is a statistical difference between both the groups in terms of ease of insertion grading.

The primary outcome of mean airway sealing pressure was significantly higher with a p-value < 0.05 in BM group compared to PLM group at 5 minutes, 30 minutes and at the end of the surgery which is similar to the study conducted by Zundert Tv, Gatt S[34].

In our study the mean duration of SAD in the oropharynx was higher for PLM group (mean=70.34mins) compared to BM group (mean=61.23mins). However the p-value was not statistically significant between both the groups.

In our study there was an increased rate of blood staining of the Baska mask following removal (20% of patients, n=7) while only 2.9% (n=1) of patients in PLM group had blood staining of SAD following removal. This was similar to a study by Alexiev, V et al[36] where there was increased blood staining of Baska mask after removal. Complications like nausea and vomiting were more in PLM group. 17.1% of patients in PLM group and 8.6% of patients in BM group had nausea following removal of SAD. Vomiting was seen in 17.1% (n=6 out of 35) of patients in PLM and 11.4% (n=4out of 35) of patients in BM group. Secretions staining of the SAD was equal in both the groups (8.6%, n=3 in each group).

51.4%(n=18) of the patients in the BM group and 54.3% (19) of patients in PLM group did not have any complications during emergence. There is no statistical difference in complication rates between both the groups.

The laryngopharyngeal morbidity score which includes sore throat, dysphagia and hoarseness was significantly higher among PLM group which could be because of the inflated cuff in the oropharynx which can absorb anesthetic gases leading to increased mucosal pressure. Soliveres et al[50]. compared two second generation supraglottic devices and found that the use of LMA-Proseal produces more sore throat as compared to the I-gel which they attributed to the soft seal non inflatable mask of I-gel. Similarly Baska mask with a non-inflatable cuff produced less postoperative Laryngopharyngeal morbidity in our study.

CHAPTER 13

SUMMARY:

The following observations were made in our study.

1. Baska mask provides superior airway sealing (higher OLP) compared to Proseal LMA.
2. The insertion time was significantly lower for Baska mask and Baska mask was easy to insert.
3. Insertion characteristics like number of attempts, number of manipulations were similar between both the groups.
4. Incidences of blood staining of the device after removal was higher in Baska mask compared to LMA ProSeal.
5. The postoperative Laryngopharyngeal morbidity scores were higher in PLM group in anesthetized adult patients.

CONCLUSION:

In our study we conclude that Baska mask can be used as an alternative for second generation Proseal LMA because of its safety profile in terms of higher sealing pressure, shorter insertion time, greater ease of insertion with lesser emergence complications and postoperative laryngopharyngeal morbidity compared to Proseal LMA.

CHAPTER 14

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CHAPTER 15
ANNEXURES

ETHICAL COMMITTEE APPROVAL LETTER

GOVERNMENT STANLEY MEDICAL COLLEGE & HOSPITAL,CHENNAI -01
INSTITUTIONAL ETHICS COMMITTEE

TITLE OF THE WORK : A COMPARATIVE STUDYOF BASKA MASK AND PROSEAL LARYNGEAL MASK FOR GENERAL ANAESTHESIA WITH IPPV.

PRINCIPAL INVESTIGATOR : DR. S. GARPAGALAKSHMI
DESIGNATION : PG IN MD ANAESTHESIOLOGY
DEPARTMENT : DEPARTMENT OF ANAESTHESIOLOGY, GOVT. STANLEY MEDICAL COLLEGE.

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 13.04.2018 at the Council Hall, Stanley Medical College, Chennai-1 at 10am.

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY,
IEC, SMC, CHENNAI

PROFORMA:

- NAME: Age: sex: Height: Weight: BMI:
- Occupation: Address:
- Hospital no:
- Consent form:
- MPC:
- ASA-PS:
- DIAGNOSIS:
- PROCEDURE:
- SURGERY DATE:
- DRUGS USED:
- BASKA MASK / PROSEAL LMA:
- Size of SAD:
- Baseline HR: NIBP: SpO2:

- **INSERTION:**
- SAD insertion time: secs
- Attempts to place SAD correctly:
- Ease of insertion: Easy/ slight difficulty/ difficult/ impossible.
- Complication duration insertion:
- Total manipulations:
- Airway sealing pressure:

  5mins: cm of H2O 30mins: End of surgery:
- **MAINTENANCE:**
- Duration of SAD in oropharynx: mins
- Intraoperative complications: yes/no
- Intraoperative vitals: HR: BP: SPO2:
- Untoward haemodynamic changes if any:
- **EMERGENCE:**
- Complications during emergence: yes/no
- **POSTOPERATIVE PERIOD:** LPM score:

MASTER CHART:

SL.NO	NAME	AGE	SEX	HEIGHT	WEIGHT	BMI	DATE OF SURGERY	IP.NO	DIAGNOSIS	PROCEDURE	MPC	ASA-PS	GROUP	SIZE OF SAD
1	JAYALAKSHMI	30	F	154CM	56KG		16/04/2018	1825937	BILATERAL STAGHORN CALCULUS WITH RIGHT UPPER	B/L URSL WITH DJ STENTING	II	II	BM	4
2	KALAUTHEEN	55	M	160	60		16/04/2018	1825943	LEFT UPPER URETERIC CALCULUS	LEFT URSL WITH DJ STENTING	I	II	BM	4
3	KARTHIKA	22	F	153	50		19/04/2018	1826285	LEFT LOWER URETERIC CALCULUS	LEFT URSL AND DJ STENTING	I	I	BM	3
4	SARAVANAN	47	M	158	58		19/04/2018	63371/73	GUTB	DJ STENT EXCHANGE	I	I	PLM	4
5	GAJALAKSHMI	39	F	157	48		20/04/2018	3092	FIBROID UTERUS	B/L URSL WITH DJ STENTING	II	II	BM	3
6	AMBIKA	42	F	154	45		20/04/2018	1826123	LEFT VUJ CALCULUS	LEFT URSL AND DJ STENTING	I	II	BM	3
7	AMUDHA	39	F	158	50		23/04/2018	1827604	RIGHT LOWER URETERIC CALCULUS	RIGHT URSL AND DJ STENTING	II	I	PLM	3
8	SHAHUL HAMEE	51	M	154	58		23/04/2018	1826869	RIGHT UPPER URETERIC CALCULUS	RIGHT URSL AND DJ STENTING	II	II	BM	4
9	DHAMODHARA	35	M	155	60		23/04/2018	1827190	LEFT UPPER URETERIC CALCULUS	LEFT URSL AND DJ STENTING	I	II	BM	4
10	MOHAN	27	M	166	64		24/04/2018	1827197	RIGHT RENAL CALCULUS	RIGHT URSL AND DJ STENTING	I	I	BM	4
11	FATHIMA	52	F	154	56		25/04/2018	1827397	LEFT RETAINED STENT WITH VESICAL CALCULUS	VESICOLITHOPAXY WITH DJ STENT REMOV	II	II	BM	3
12	KARUNISHA	57	F	150	48		25/06/2018	1826812	LEFT UPPER URETERIC CALCULUS	LEFT URSL AND DJ STENTING	II	I	BM	3
13	RAGU KUMAR	44	M	165	65		26/04/2018	1827378	POST HYPOSPADIAS REPAIR URETHROCUTANEOUS FI	DIAGNOSTIC CYSTOSCOPY	II	I	PLM	4
14	GOPI	26	M	160	60		26/04/2018	1827194	RIGHT VUJ CALCULUS	RIGHT URSL AND DJ STENTING	I	I	BM	4
15	SABARISH	23	M	164	62		26/04/2018	1810978	BILATERAL URETERIC CALCULUS	B/L URSL WITH DJ STENTING	II	I	PLM	4
16	RAJENDREN	52	M	160	70		27/04/2018	1828220	CYSTITIS	DIAGNOSTIC CYSTOSCOPY	II	II	PLM	4
17	NAGARAJAN	59	M	158	60		30/04/2018	1826734	RIGHT LOWER URETERIC CALCULUS	RIGHT URSL AND DJ STENTING	II	II	PLM	4
18	PRAVEENA	18	F	150	45		16/04/2018	1822979	LEFT FIROADENOMA	EXCISION BIOPSY	II	I	BM	3
19	GOKILA	29	F	154	50		16/04/2018	1824286	LEFT AXILLARY LIPOMA	EXCISION BIOPSY	I	I	PLM	3
20	POOVITHA	18	F	152	48		17/04/2018	1825168	RIGHT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
21	SARAN KUMAR	25	M	160	60		18/04/2018	1832108	LEFT INGUINAL HERNIA	OPEN HERNIOPLASTY	II	II	BM	4
22	MURUGAN	54	M	158	65		18/04/2018	1830563	LEFT INGUINAL HERNIA	OPEN HERNIOPLASTY	II	II	PLM	4
23	BALAKRISHNAN	18	M	156	40		19/04/2018	1821286	RIGHT AXILLARY LYMPHADENOPATHY	EXCISION BIOPSY	I	I	BM	3
24	BABY	23	F	159	45		19/04/2018	1833149	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
25	RAJESHWARI	19	F	153	42		20/04/2018	1832109	RIGHT FIBROADENOMA	EXCISION BIOPSY	II	I	PLM	3
26	VAJRAVEL	57	M	162	64		20/04/2018	1830591	INCISIONAL HERNIA	MESH REPAIR	II	II	PLM	4
27	HEMALATHA	18	F	156	50		02/05/2018	1829780	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
28	NAGAJOTHI	33	F	162	65		02/05/2018	1829447	LEFT FIBROADENOMA	EXCISION BIOPSY	III	I	PLM	4
29	MALLIGA	47	F	158	56		04/05/2018	1828648	PARAUMBILICAL HERNIA	MESH REPAIR	II	I	BM	4
30	MONIKA	18	F	150	42		08/05/2018	1831558	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	PLM	3
31	MARY	18	F	155	48		11/05/2018	1831528	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	PLM	3
32	SUMATHY	43	F	160	62		12/05/2018	1827580	RECURRENT INCISIONAL HERNIA	MESH REPAIR	II	II	BM	4
33	NAVEENKUMAR	27	M	165	70		16/05/2018	1826136	BILATERAL GYNAECOMASTIA	WEBSTERS PROCEDURE	II	I	BM	4
34	SOUNDARYA	18	F	158	38		18/05/2018	1828371	RIGHT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
35	KASTHURI	52	F	156	58		18/06/2018	1837352	INCISIONAL HERNIA	MESH REPAIR	II	II	PLM	3
36	SATHYARATHI	30	F	152	45		19/06/2018	1838810	HIDRADENITIS SUPPURATIVA	WIDE LOCAL EXCISION	I	I	PLM	3
37	AISHAGANI	32	F	154	50		20/06/2018	1832505	POST TOILET MASTECTOMY RAW AREA	SSG WITH SECONDARY SUTURING	II	II	PLM	3
38	RAVANA	23	F	154	40		21/06/2018	1837458	POST ILEOSTOMY STATUS	ILEOSTOMY TAKE DOWN	II	II	PLM	3
39	INDUMATHI	25	F	157	60		25/06/2018	1837437	INCISIONAL HERNIA	MESH REPAIR	II	I	PLM	4
40	MEGATHA	55	F	158	62		28/06/2018	1839692	POST ILEOSTOMY STATUS	ILEOSTOMY TAKE DOWN	II	II	PLM	4
41	ELUMALAI	60	M	160	50		01/07/2018	1839539	AXILLARY LYMPHOMA	EXCISION BIOPSY	II	II	PLM	3
42	VIJAYA	58	F	154	65		03/07/2018	1842044	EPIGASTRIC HERNIA	MESH REPAIR	II	II	PLM	4
43	NANDHA KUMA	47	M	166	70		04/07/2018	1842161	UMBILICAL HERNIA	MESH REPAIR	II	I	BM	4
44	VANATHAIYAN	52	M	156	60		05/07/2018	1837655	RIGHT GYNAECOMASTIA	EXCISION BIOPSY	II	I	BM	4
45	VELANKANNI	25	F	150	45		06/07/2018	1842468	LEFT FIBROADENOMA	EXCISION BIOPSY	II	I	PLM	3
46	JAYABALAN	59	M	158	63		09/07/2018	1843410	UMBILICAL HERNIA WITH LEFT INGUINAL HERNIA	MESH REPAIR/HERNIOPLASTY	II	II	PLM	4
47	NASRIN	35	F	154	50		11/07/2018	1842332	LEFT BREAST FIBROADENOMA	EXCISION BIOPSY	II	I	BM	3
48	SRIDHAR	24	M	158	66		11/07/2018	1842331	LEFT GYNAECOMASTIA	WEBSTERS PROCEDURE	I	I	PLM	4
49	PARIMALA	28	F	154	48		12/07/2018	1846918	LEFT BREAST FIBROADENOMA	EXCISION BIOPSY	I	I	PLM	3
50	JAYA	30	F	153	62		21/07/2018	1845729	PARAUMBILICAL HERNIA	ANATOMICAL MESH REPAIR	II	II	PLM	4
51	PARVEEN	18	F	150	45		21/07/2018	1847690	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	PLM	3
52	RAMAKRISHNAN	40	M	160	68		22/07/2018	1847234	EPIGASTRIC HERNIA	MESH REPAIR	II	II	PLM	4
53	SANGEETHA	23	F	154	50		23/07/2018	1849072	HIDRADENITIS SUPPURATIVA	EXCISION BIOPSY	II	I	PLM	3
54	MALIYA	19	F	148	40		24/07/2018	1844193	RIGHT FIBROADENOMA BREAST	EXCISION BIOPSY	I	I	PLM	3
55	AARTHI	18	F	150	45		25/07/2018	1852593	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
56	SELVI	47	F	152	56		26/07/2018	1854830	RIGHT FIBROADENOMA	EXCISION BIOPSY	I	I	PLM	4
57	KATHIRVEL	45	M	158	64		27/07/2018	1858741	UMBILICAL HERNIA	MESH REPAIR	I	I	PLM	4
58	AMUDHA	40	F	154	50		28/07/2018	1855330	LEFT LUMP FIBROCYSTIC DISEASE	EXCISION BIOPSY	I	I	BM	3
59	SHANMUGAM	50	M	162	68		13/08/2018	1852182	BILATERAL INGUINAL HERNIA	STOPPAS PROCEDURE	II	II	BM	4
60	RAJA	48	M	165	60		14/08/2018	1854588	AXILLARY LIPOMA	EXCISION BIOPSY	II	II	PLM	4
61	NAGAMMAL	28	F	162	55		18/08/2018	1852522	BILATERAL FIBROADENOMA	EXCISION BIOPSY	II	I	BM	4
62	ANNAKILI	45	F	150	50		18/08/2018	1858158	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
63	JAYANDA	38	F	158	60		21/08/2018	1858029	BILATERAL FIBROADENOMA	EXCISION BIOPSY	I	I	PLM	4
64	NIVETHA	20	F	152	46		27/08/2018	1860112	RIGHT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
65	SHAMABANU	18	F	157	40		03/09/2018	1803421	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
66	SATHISH	37	M	165	64		05/09/2018	1824748	RIGHT INGUINAL HERNIA	RIGHT HERNIOPLASTY	I	I	PLM	4
67	VAITHEGI	18	F	155	55		06/09/2018	1856701	LEFT FIBROADENOMA	EXCISION BIOPSY	I	I	BM	3
68	KOWSALYA	34	F	154	58		07/09/2018	1852521	LEFT FIBROADENOMA	EXCISION BIOPSY	II	I	BM	4
69	GOMATHY	32	F	158	66		20/09/2018	1857822	RIGHT FIBROADENOMA	EXCISION BIOPSY	II	II	BM	3
70	SAHIRA BANU	30	F	150	66		20/09/2018	1860745	SCAR ENDOMETRIOSIS	WIDE LOCAL EXCISION	II	II	BM	3

SL.NO	BASELINE HR	BASELINE NIBP	BASELINE SPO2	AIRWAY SEALING PR	AIRWAY SEALING P	AIRWAY SEALING P	INSERTION TIME	NO.OF ATTEMPTS	EASE OF INSERTION GRADING
1	87/MIN	116/80MMHg	98%	25CMH2O	27	28	45secs	1	EASY
2	78	128/84	98	28	29	32	40	1	EASY
3	72	110/68	99	28	30	34	42	1	EASY
4	70	114/76	98	26	28	28	38	1	EASY
5	99	110/60	98	24	26	28	36	1	EASY
6	90	126/76	99	27	29	30	35	1	EASY
7	82	120/78	99	26	27	30	36	1	EASY
8	76	128/70	97	24	26	28	30	1	EASY
9	88	130/86	98	28	30	32	30	1	EASY
10	84	120/88	98	30	30	32	32	1	EASY
11	80	124/76	98	26	28	30	45	2	DIFFICULT
12	85	130/90	98	28	28	30	30	1	EASY
13	76	110/80	98	30	32	32	34	1	EASY
14	80	116/80	97	28	30	32	30	1	EASY
15	68	122/74	98	26	26	30	38	2	DIFFICULT
16	75	130/84	97	24	25	27	35	1	EASY
17	64	124/80	97	28	29	30	36	2	DIFFICULT
18	92	110/70	99%	24	28	30	40	1	EASY
19	78	100/70	98	18	22	24	60	1	SLIGHT DIFFICULTY
20	96	120/74	98	20	23	25	45	1	EASY
21	70	126/80	98	24	25	28	30	1	EASY
22	68	130/80	98	20	23	28	50	2	EASY
23	90	110/74	99	18	24	26	30	1	EASY
24	88	114/76	99	24	25	29	20	1	EASY
25	80	112/70	99	19	22	26	45	2	DIFFICULT
26	72	130/90	97	22	23	24	52	1	EASY
27	100	110/70	98	20	24	28	30	1	EASY
28	75	128/84	98	18	22	24	50	1	SLIGHT DIFFICULTY
29	84	120/88	98	28	30	34	28	1	EASY
30	110	130/80	99	26	26	28	38	1	EASY
31	94	116/74	99	30	32	34	20	1	EASY
32	90	118/88	99	25	26	27	24	1	EASY
33	98	126/90	99	28	30	32	25	1	EASY
34	88	110/68	99	30	32	33	28	1	EASY
35	86	114/70	98	27	28	32	38	2	DIFFICULT
36	84	120/70	98	25	28	30	40	1	EASY
37	76	100/60	98	48	30	30	32	2	SLIGHT DIFFICULTY
38	66	104/70	98	20	23	24	26	1	EASY
39	96	130/84	98	27	28	29	30	1	EASY
40	90	108/68	99	28	29	30	32	1	EASY
41	78	130/90	97	24	28	30	20	1	EASY
42	72	124/80	98	28	28	30	34	1	SLIGHT DIFFICULTY
43	70	130/80	98	29	30	32	25	1	EASY
44	76	126/78	99	29	30	34	20	1	EASY
45	86	118/72	98	22	24	24	38	1	EASY
46	76	128/68	98	26	28	32	35	1	SLIGHT DIFFICULTY
47	74	110/72	99	28	28	30	25	1	EASY
48	80	126/72	99	26	28	30	35	1	EASY
49	70	106/66	99	25	26	28	30	1	EASY
50	72	126/86	98	20	21	24	35	1	EASY
51	70	120/72	99	18	20	22	30	1	EASY
52	84	130/80	98	20	22	24	38	1	SLIGHT DIFFICULTY
53	83	128/70	99	18	20	22	30	1	EASY
54	110	110/68	99	20	22	23	32	1	EASY
55	104	114/60	99	23	24	25	28	1	SLIGHT DIFFICULTY
56	100	118/70	98	24	25	28	35	1	EASY
57	92	120/72	99	25	26	27	34	1	EASY
58	96	124/70	98	26	27	28	30	1	EASY
59	80	130/92	99	32	34	35	40	1	SLIGHT DIFFICULTY
60	72	128/80	98	26	27	29	50	1	EASY
61	84	112/74	99	22	24	26	30	1	EASY
62	68	104/70	98	26	28	30	25	1	EASY
63	73	108/70	99	24	26	30	38	1	SLIGHT DIFFICULTY
64	94	124/76	99	27	28	32	28	1	EASY
65	90	108/70	99	26	28	30	25	1	EASY
66	74	118/76	99	26	28	32	40	1	SLIGHT DIFFICULTY
67	86	120/68	99	24	26	30	45	2	DIFFICULT
68	80	122/76	98	28	29	32	22	1	EASY
69	92	137/94	98	26	28	30	60	2	SLIGHT DIFFICULTY
70	90	124/80	98	24	27	28	70	1	EASY

SL.NO	NO.OF MANIPULATIONS	DURATION IN OR	COMPLICATION	INTRAOPERATIVE	UNTOWARD HEMOD\	COMPLICATIONS DURING E	LPM SCORE
1	NIL	60MINS	NO	NO	NO	NAUSEA	2
2	NIL	35	NO	NO	NO	BLOOD STAINING OF SAD	1
3	NIL	40	NO	NO	NO	NO	2
4	NIL	35	NO	NO	NO	NO	1
5	NIL	35	NO	NO	NO	NO	2
6	NIL	35	NO	NO	NO	NO	1
7	NIL	40	NO	NO	NO	NO	1
8	NIL	50	NO	NO	NO	BLOOD STAINING OF SAD	2
9	NIL	60	NO	NO	NO	NAUSEA	2
10	NIL	45	NO	NO	NO	NO	1
11	2	100	NO	NO	NO	BLOOD STAINING OF SAD	2
12	NIL	60	NO	NO	NO	NO	1
13	NIL	45	NO	NO	NO	NO	1
14	NIL	45	NO	NO	NO	NAUSEA	1
15	2	115	NO	NO	NO	NAUSEA	2
16	NIL	35	NO	NO	NO	NAUSEA	1
17	2	40	NO	NO	NO	NO	2
18	NIL	60	NO	NO	NO	NO	1
19	1	90	NO	NO	NO	NAUSEA	3
20	NIL	45	NO	NO	NO	BLOOD STAINING OF SAD	2
21	NIL	100	NO	NO	NO	SECRETIONS STAINING SAD	2
22	NIL	90	NO	NO	NO	NO	2
23	NIL	60	NO	NO	NO	NO	1
24	NIL	40	NO	NO	NO	BLOOD STAINING OF SAD	1
25	2	50	NO	NO	NO	VOMITING	3
26	NIL	62	NO	NO	NO	NO	2
27	NIL	45	NO	NO	NO	NO	2
28	1	60	NO	NO	NO	VOMITING	3
29	NIL	110	NO	NO	NO	NO	2
30	NIL	70	NO	NO	NO	SECRETIONS STAINING OF S	2
31	NIL	50	NO	NO	NO	BLOOD STAINING OF SAD	2
32	NIL	118	NO	NO	NO	NO	2
33	NIL	112	NO	NO	NO	BLOOD STAINING OF SAD	2
34	NIL	93	NO	NO	NO	NO	1
35	2	110	NO	NO	NO	VOMITING	3
36	NIL	75	NO	NO	NO	NO	2
37	1	60	NO	NO	NO	SECRETIONS STAINING OF S	1
38	NIL	120	NO	NO	NO	NO	3
39	NIL	110	NO	NO	NO	NAUSEA	2
40	NIL	90	NO	NO	NO	SECRETIONS STAINING OF S	2
41	NIL	50	NO	NO	NO	NAUSEA	2
42	1	100	NO	NO	NO	NO	2
43	NIL	75	NO	NO	NO	NO	1
44	NIL	50	NO	NO	NO	NO	1
45	NIL	30	NO	NO	NO	NO	1
46	2	115	NO	NO	NO	NO	3
47	NIL	40	NO	NO	NO	BLOOD STAINING OF SAD	1
48	NIL	65	NO	NO	NO	NAUSEA	2
49	NIL	35	NO	NO	NO	NO	1
50	NIL	85	NO	NO	NO	NO	2
51	NIL	40	NO	NO	NO	NO	1
52	1	80	NO	NO	NO	NO	2
53	NIL	95	NO	NO	NO	NO	2
54	NIL	55	NO	NO	NO	NO	2
55	1	45	NO	NO	NO	NO	1
56	NIL	40	NO	NO	NO	NO	2
57	NIL	70	NO	NO	NO	VOMITING	2
58	NIL	60	NO	NO	NO	VOMITING	2
59	1	120	NO	NO	NO	NO	2
60	NIL	55	NO	NO	NO	VOMITING	2
61	NIL	75	NO	NO	NO	VOMITING	2
62	NIL	40	NO	NO	NO	NO	1
63	1	100	NO	NO	NO	VOMITING	2
64	NIL	30	NO	NO	NO	SECRETIONS STAINING OF S	1
65	NIL	45	NO	NO	NO	NO	1
66	2	100	NO	NO	NO	NO	3
67	2	60	NO	NO	NO	NO	2
68	NIL	50	NO	NO	NO	SECRETIONS STAINING OF S	2
69	1	90	NO	NO	NO	VOMITING	3
70	NIL	15	NO	NO	NO	VOMITING	2

ANTI PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled A study on "**A COMPARATIVE STUDY OF BASKA MASK AND PROSEAL LARYINGEAL MASK FOR GENERAL ANAESTHESIA WITH INTERMITTENT POSITIVE PRESSURE VENTILATION"** of the candidate **Dr. GARPAGALAKSHMI. S** with registration Number **201620051** for the award of **M.D ANAESTHESIOLOGY** in the branch of **X.** I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **1%** percentage of plagiarism in the dissertation.

Guide & Supervisor sign with Seal.

PLAGIARISM CERTIFICATE:

CERTIFICATE – II

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சுய ஒப்புதல் படிவம்

ஆராய்ச்சி நிலையம் : மயக்க மருந்து துறை (பிரிவு)
ஸ்டான்லி மருத்துவ கல்லூரி

தலைப்பு : பொது மயக்க மருந்தின் போது பஸ்கா மற்றும் ப்ரோசீல் எல்.எம்.ஏ.வின் ஒப்பீட்டு ஆய்வு

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் எண் :

மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது எனது நோய் பற்றிய சந்தேகங்களை கேட்கவும் அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பு அளிக்கப்பட்டது. இந்த நோயை குணப்படுத்தும் சிகிச்சைகள் ..... விளக்கப்பட்டது. இந்த ஆய்வின் நோக்கம் மற்றும் அதன் நிறை, குறைகள் மற்றும் தேவையான காலவரையரை அனைத்தும் விளக்கப்பட்டது. இந்த சிகிச்சை முறைகளை பயன்படுத்த சுய நினைவுடன் சம்மதிக்கிறேன். இந்த பரிசோதனையின் விளைவுகளை ஆய்வில் பயன்படுத்த தன்னிச்சையாக சம்மதிக்கிறேன். எக்காரணத்தினாலும் எந்த கட்டத்திலும் எந்த சட்ட சிக்களுக்கும் உட்படாமல் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் பரிசோதனையின் முடிவுகளையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்தி கொள்ளவும் அதை பிரசுரிக்க தேவைப்பட்டால் என்னையும் எனக்கு நடக்கும் பரிசோதனையையும் புகைப்படம் எடுக்கவும் நான் முழுமனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்

நாள் : கட்டைவிரல் ஒப்பம்
இடம் :

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்
ஆய்வாளரின் பெயர்
இடம் :

சாட்சி 1 :	சாட்சி 2 :
கையொப்பம் :	கையொப்பம் :
பெயர் :	பெயர் :
முகவரி :	முகவரி :

தகவல் தாள்

இந்த ஆராய்ச்சியை பற்றிய முக்கியமான தகவல்களை தெரிந்து கொண்டு இதில் பங்கேற்க உங்கள் சம்மதத்தை தெரிவிக்குமாறு நாங்கள் விடுத்த வேண்டுகேளை ஏற்றுக் கொண்டமைக்கு நன்றி, இந்த ஆராய்ச்சி, சம்மந்தமான தகவல்கள் இதில் பங்கு பெறுவதினால் உங்களுக்கு ஏற்படக்கூடிய அசௌகரியங்கள் பாதிப்புகள் மற்றும் நன்மைகள் அனைத்தும் இப்படிவத்தில் கொடுக்கப்பட்டிருக்கின்றன இதை நீங்களாகவே படித்து தெரிந்து கொள்ளலாம் அல்லது நீங்கள் விருப்பப்பட்டால், நாங்கள் இதை உங்களுக்கு படித்துக்காட்டி புரியும்படி சொல்வதற்கு தயாராக இருக்கிறோம். உங்களுக்கு ஏதேனும் புரியவில்லை என்றாலும் அல்லது கூடுதல் தகவல்கள் ஏதேனும் தேவை என்றாலும் நாங்கள் உங்களுக்கு உதவ தயாராக இருக்கிறோம்.

1. இந்த ஆய்வின் நோக்கம் என்ன?
   இந்த ஆய்வின் நோக்கம் அறுவை சிகிச்சையின் போது பஸ்கா மற்றும் ப்ரோசீல் எல்.எம்.ஏ. எது சிறந்தது என்பதை கண்டறிவது.

2. இந்த மருத்துவ சோதையில் யார் பங்கேற்க முடியும்?
   இதில் முன்பதிவு செய்து, முழு மயக்கத்துடன் அறுவை சிகிச்சை செய்ய வயது 18-65 வரை உள்ளவர்கள் பங்கேற்கலாம்.

3. இந்த ஆய்வில் யார் பங்கேற்கக் கூடாது?
   கர்பிணி பெண்கள், உடல் பருமன் உள்ளவர்கள், புரைக்கேரும் ஆபத்து உள்ளவர்கள்

4. இந்த மருத்துவ சோதனை நடைமுறை என்ன?
   இந்த சோதனையை ஏற்றுகொண்ட நோயாளிகளை தோராயமாக இருபிரிவுகளாக பிரித்து ஆய்வு மேற்கொள்ளப்படும்.
   குரூப் PLM - ப்ரோசீல் எல்.எம்.ஏ. வைத்து முழு மயக்கம் கொடுக்கப்படும்.
   குரூப் BM - பாஸ்கா எல்.எம்.ஏ. வைத்து முழு மயக்கம் கொடுக்கப்படும்.

5. இந்த செய்முறையின் நன்மைகள் என்ன?
   இந்த அறுவை சிகிச்சை முடிந்தபின் தொண்டை வலி, விழுங்குவதில் சிரமம், குரல் மாற்றம் போன்ற பக்கவிளைவுகள் குறைவாக இருக்கும் என்பதையும் யாருக்கெல்லாம் புரோசீல் மற்றும் பஸ்கா எல்.எம்.ஏ. உபயோகில்கலாம் என்பதையும் கண்டறிய முடியும்.

6. இந்த செயல்முறையின் பின் விளைவுகள் என்ன?
   இந்த சோதனையின் வெற்றி நோயாளியின் உடல் நிலை பொருத்துள்ளது.

7. இந்த மருத்துவ சோதனையில் சேருவது கட்டாயமா?
இல்லை இந்த மருத்துவ சோதனையில் சேருவது உங்கள் விருப்பம், நீங்கள் எந்த நேரத்திலும் இந்த மருத்துவ சோதனையை விட்டுச் செல்ல முடியும்.

8. என்னைப் பற்றிய தகவல் இரகசியமாக இருக்குமா?
ஆம். உங்கள் பெயர் மற்றும் தனிப்பட்ட விவரங்கள் இரகசியமாக இருக்கும்.

9. இந்த ஆராய்ச்சியின் முடிவுகள் எனக்கு தெதரிவிக்கப்படுமா?
நீங்கள் விரும்பினால், எங்களிடம் பெற்றும் கொள்ளலாம்.