
“COMPARISON OF PROSEAL LARYNGEAL MASK
AIRWAY AND I-GEL SUPRAGLOTTIC AIRWAY
FOR EASE OF INSERTION AND AIRWAY SEALING
PRESSURE IN ADULT PATIENTS UNDER
GENERAL ANAESTHESIA – A ONE YEAR
RANDOMIZED CLINICAL TRIAL”

By

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Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. D.
in
ANAESTHESIOLOGY

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

APRIL-2015

**KLE UNIVERSITY, BELGAUM,
KARNATAKA**

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This is to certify that the dissertation entitled
**“COMPARISON OF PROSEAL LARYNGEAL MASK
AIRWAY AND I-GEL SUPRAGLOTTIC AIRWAY FOR EASE
OF INSERTION AND AIRWAY SEALING PRESSURE IN
ADULT PATIENTS UNDER GENERAL ANAESTHESIA – A
ONE YEAR RANDOMIZED CLINICAL TRIAL”** is a bonafide
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LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
BP	-	Blood Pressure
cLMA	-	Classic Laryngeal Mask Airway
cm	-	Centimeter
CNS	-	Central nervous system
CO ₂	-	Carbon dioxide
CVS	-	Cardiovascular system
etCO ₂	-	End tidal carbon dioxide
ETT	-	Endotracheal tube
FG	-	French guage
GIT	-	Gastrointestinal tract
H ₂ O	-	Water
Hb	-	Haemoglobin
i-gel	-	Intersurgical
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
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 anaesthesiologists is no longer confined to endotracheal intubation. The use of supraglottic airway devices has added a whole new dimension to airway management. The proseal laryngeal mask airway (PLMA) has been a boon to anaesthesiologists ever since it came into clinical practice. The i-gel is a recent novel supraglottic airway device designed to fit the pharyngeal, laryngeal and perilaryngeal structures without use of an inflatable cuff. Hence, we designed this study to compare the clinical efficacy of PLMA (size 4) and i-gel (size 4) for ease of insertion, airway sealing pressure, duration of insertion and complications in anaesthetized, paralysed adult patients undergoing positive pressure ventilation.

Methodology: The present randomized clinical trial was conducted in 60 ASA I and II patients aged between 18-50 years, weighing 50 to 70 Kgs posted for elective surgeries under general anaesthesia in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. Patients were allocated into two equal groups, Group A. i-gel (n=30) and Group B. PLMA (n=30). All the data collected were analysed. The demographic data, duration of insertion and airway sealing pressure were analysed using unpaired 't' test. Sex and complications were compared using chi square test. Ease of insertion was analysed using fisher exact test.

Results: In our study, the i-gel was easier to insert in comparison to PLMA. Difficult insertion was seen in 2 patients in i-gel group (6.67%) and 8 patients in PLMA group (26.7%). However the difference was not statistically significant. (p=0.08). The mean duration of insertion was 20.73 ± 2.12 sec in i-gel

group and 27.37 ± 2.44 sec in PLMA group which was statistically significant ($p < 0.001$). The PLMA provided a more effective seal than i-gel for positive pressure ventilation. The mean airway sealing pressure was 29.83 ± 1.39 in PLMA group and 25.07 ± 1.44 in i-gel group which was statistically significant ($p < 0.001$). Visible blood on the device was noted in 6 patients in the PLMA group and 1 patient in i-gel group which was statistically insignificant. No bronchospasm and laryngospasm were noted in patients of either group.

Conclusion: The i gel was easier to insert than PLMA in anaesthetized paralysed adult patients, but airway sealing pressure was higher for the PLMA. The PLMA provided a more effective seal than i gel for positive pressure ventilation. The PLMA was associated with higher incidences of visible blood on the device and both devices had no incidences of laryngospasm and bronchospasm.

Keywords: Proseal Laryngeal Mask Airway, i-gel supraglottic airway, Airway sealing pressure, positive pressure ventilation.

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Chapter 1

Introduction



INTRODUCTION

The primary goal of the anaesthesiologist is to maintain a patent airway and provide adequate oxygenation and ventilation. The most vital element in providing functional respiration is the airway.

Management of the airway has come a long way since the development of endotracheal intubation by Macewen in 1880 to the present day usage of sophisticated devices.^{1,2} When a face mask is being used, the gap between the base of the tongue and the glottis is not bypassed, which may cause obstruction during anaesthesia. The tracheal intubation bypasses this problem and is the gold standard method for maintaining a patent airway during anaesthesia. However, this maneuver requires skill and continuous training and practice and usually requires direct laryngoscopy, which may cause laryngopharyngeal lesions. Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension.^{3,4}

Respiratory events are the most common anaesthetic related injuries, following dental damage. The three main causes of respiratory related injuries are inadequate ventilation, oesophageal intubation and difficult tracheal intubation. Difficult tracheal intubation accounts for 17% of the respiratory related injuries and results in significant morbidity and mortality. In fact up to 28% of all anaesthesia related deaths are secondary to the inability to mask ventilate or intubate.⁵

Thus the Laryngeal Mask Airway(LMA)fills a niche in between the face mask and endotracheal tube in terms of both anatomical position and degree of invasiveness.⁶

The LMA has been well established for more than a decade and is often used for management of unanticipated difficult intubation. It is a key device at several places in the American Society of Anaesthesiologists (ASA) guidelines algorithm for difficult airway.⁷

Furthermore, endotracheal tubes (ETT) carry an inherent risk of patient trauma from vocal cord damage and pharyngeal soft tissue injury. Because of ease of insertion and reduced trauma, LMA devices have replaced ETTs in many procedures.

The Classic LMA(cLMA) is not a very popular device for positive pressure ventilation for fear of gastric distension, aspiration of gastric contents and inadequate ventilation.^{8,9}

Proseal Laryngeal Mask Airway(PLMA) is a reusable supraglottic airway device offering gastric access and was introduced into clinical practice in 2000. The PLMA offers higher glottic seal pressures than the cLMA, facilitating positive pressure ventilation and has been used in obese patients and those with low lung compliance. It has a built-in drain tube that allows expelled gastric contents to bypass the pharynx. This specific feature is designed to decrease the risk of aspiration. The drain tube also allows instant clinical diagnosis of device misplacement after insertion and until its removal. The PLMA reduces the likelihood of throat irritation and stimulation, and reduces postoperative nausea

and vomiting by as much as 40% compared to an ETT.^{10,11} However, it has the potential to cause tissue distortion and venous compression by virtue of its inflatable cuff.

The i-gel supraglottic airway device (Intersurgical Ltd., Wokingham, Berkshire, UK) was developed in 2007 and is a single use supraglottic airway device. It is made up of a thermoplastic elastomer (SEBS -styrene ethylene butadiene styrene) with a soft durometer (hardness), which has a gel-like feel.¹² It was designed to create a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures while avoiding compression and trauma. The shape, softness and contour accurately mirror the perilaryngeal anatomy to create a perfect fit. Compression and displacement trauma are significantly reduced and it has cheaper manufacturing costs due to the simplicity of design.¹³ Growing concern over the ability to clean reusable devices effectively led to the increase in the use of single-use devices.^{14,15}

Hence, we compared the clinical performance of the PLMA and i-gel with respect to ease of insertion, airway sealing pressure, duration of insertion and complications in anesthetized and paralysed adult patients on controlled ventilation, undergoing elective surgical procedures.

Chapter 2

Objectives



AIMS AND OBJECTIVES

The aims and objectives of the study were to compare the supraglottic airway devices, PLMA(size 4) and i-gel (size 4)for :

1. Ease of insertion
2. Airway sealing pressure
3. Duration of insertion
4. Post operative complications(visible blood on device, bronchospasm and laryngospasm)

in adult patients under general anaesthesia.

Chapter 3

Review of Literature



REVIEW OF LITERATURE

Airway management for most of the 20th century has been dominated by the face mask and tracheal tube. However, from an engineering viewpoint, the way these artificial airways are connected to the respiratory tract is less than ideal. When a face mask is used, the gap between the base of the tongue and glottis is not bypassed. This may cause obstruction during anaesthesia when upper airway muscle tone decreases and gravity approximates the pharyngeal tissues. Tracheal intubation bypasses all these problems but has its own disadvantages as mentioned above.^{3,16}

To circumvent these problems the LMA was conceived and designed in 1981 by Dr. Archie Brain at the Royal London hospital.³ He applied principles of bioengineering to the functional anatomy of the pharynx both in terms of anatomical fit and methods of placement.

The first prototype was constructed from the cuff of a goldman nasal mask for dental anaesthesia and fixed into position with acrylic glue. This prototype 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 the British Journal of Anaesthesia in August 1983.^{3,4}

As a result of this experience three more prototypes were assembled and a pilot study of 23 patients followed at the London Hospital. The first publication describing LMA as a possible solution to airway management in the emergency appeared in the Archives of Emergency Medicine in 1984. In 1985, LMA was

applied successfully in the management of five patients with anticipated difficult intubation. By October 1987, after an excellent record in 21 adult difficult intubations, LMA was used successfully for the first time in a failed pediatric intubation.

In 1989, the first independent assessment of the LMA was made by Brodrick et al,¹⁷ who obtained a clear and unobstructed airway in 98/100 patients. They described the LMA as the missing link between the face mask and tracheal tube and confirmed that the device had three excellent features: excellent airway patency, no manual support of jaw required and good for transfer to the post anaesthesia care unit. In 1993, the LMA was included in the ASA algorithm for difficult airway.³

Ever since its invention, the LMA has undergone various modifications to suit different airway situations. First generation devices such as cLMA, flexible LMA and LMA-Unique are simply 'airway tubes' whereas, second generation devices such as LMA Proseal, LMA Supreme and i-gel airway incorporates specific design features to improve safety by protecting against regurgitation and aspiration.

The Proseal Laryngeal Mask Airway (PLMA) was introduced in 2000 and is a new laryngeal mask device with a modified cuff to improve seal and a drainage tube to provide a channel for regurgitated fluid and gastric tube placement.¹⁸

A study done by Ganzouri et al,¹⁹ Proseal Laryngeal Mask Airway Versus Endotracheal Tube: Ease of Insertion, Hemodynamic Responses and Emergence

Characteristics, showed that ease of PLMA insertion was rated excellent in 98% of patients and was accomplished in 7 ± 14 sec. Unsatisfactory initial positioning required reinsertion in 19% of patients. There were significant hemodynamic differences between the groups in response to the airway device insertion. After insertion, maximum MAP and HR were significantly increased from preinsertion values with the ETT and were increased compared to PLMA at this time. Immediately prior to removal, MAP and HR were also increased with ETT from preinduction and preinsertion values and compared to PLMA just prior to removal. During emergence, PLMA patients had significantly lower incidence of coughing (15% vs. 86%, $p<0.01$). At 24 hours postoperatively both PLMA and ETT patients had similar incidence of sore throat (48% vs. 41%, respectively).

A multicenter study done by Brimacombe et al,²⁰ compared the LMA Proseal and LMA Classic in anaesthetized non paralyzed patients, demonstrated that the LMA Classic was easier and quicker to insert at the first attempt than the LMA Proseal. Despite the increased difficulty with insertion, success rates after three attempts for the LMA Proseal were high (98%) and similar to the LMA Classic (100%). The efficacy of seal was 5cm H₂O higher for the LMA Proseal than the LMA Classic (27 ± 7 vs. 22 ± 6 cm of H₂O). There were no differences in total intraoperative complications, but there was a higher incidence of minor tongue-lip-dental trauma for the LMA Proseal. Although the number of insertion attempts were higher with the LMA Proseal, the incidence of blood detected on removal was similar to the LMA Classic suggesting that the incidence of mucosal trauma might have been similar.

In a randomised cross over study²¹ done to compare the PLMA and classic LMA in anaesthetised paralysed patients, it was observed that first-time success rates were higher (60 of 60 vs. 52 of 60; $P = 0.003$) and the effective airway time was shorter for the LMA. There were no failed uses of either device within three attempts. Airway sealing pressure was 8-11 cm H₂O higher for the PLMA at all cuff volumes ($P < 0.00001$) and was higher in females for both devices. Fiberoptic position was better with the LMA at all cuff volumes ($P < 0.00001$), but vocal cord visibility was similar (LMA, 59 of 60; PLMA, 56 of 60). First-time success rates were higher (59 of 60 vs 53/60; $P = 0.03$) and the effective airway time shorter (15 +/- 13 s vs 23 +/- 18 s; $P = 0.008$) with the introducer.

Another study²² done to compare Laryngeal Mask Airway Proseal and the Laryngeal Tube Airway(LTA) in Paralyzed Anesthetized Adult Patients Undergoing Pressure-Controlled Ventilation, it was seen that first attempt success rates at achieving an effective airway were similar (PLMA: 85%; LTA: 87%), but after 3 attempts, success was more frequent for the PLMA(100% versus 92%, $P = 0.02$). Effective airway time was similar. Oropharyngeal leak pressure was larger for PLMA at 50% maximal recommended cuff volume (29 ± 7 versus 21 ± 6 cm H₂O, $P < 0.0001$), but was similar at the maximal recommended cuff volume (33 ± 7 versus 31 ± 8 cm H₂O). Tidal volumes (614 ± 173 versus 456 ± 207 mL, $P < 0.0001$) were larger and ETCO₂ (33 ± 9 versus 40 ± 11 mm Hg, $P = 0.0001$) lower for the PLMA. The number of airway interventions was significantly less frequent for the PLMA. The study concluded that The PLMA offers advantages over the LTA in most technical aspects of airway management in paralyzed patients undergoing pressure-controlled ventilation.

Evans et al,²³ studied the PLMA in 300 cases and concluded that the PLMA is a reliable airway management device that can give an effective glottic seal in paralysed and non-paralysed patients. Insertion was successful in 294 patients (98%) and graded as easy in 274 patients (91%). They found no difference in ease of insertion or success rate with either the introducer or the finger insertion method, or in paralysed or non-paralysed patients. Mean airway seal pressure was 29 cm H₂O, and 59 patients (20%) had seal pressures greater than 40 cm H₂O. No gastric insufflation was detected. Gastric tube placement was successful in 290 of 294 patients (98.6%). There was no cardiovascular response to insertion, with a small reduction in heart rate 5 min after insertion and significant decreases in mean arterial pressure at 1 and 5 min after insertion. Sore throat was noted in 23% patients after operation and in 16% of patients after 24 h, with 90% of the sore throats described as mild.

The i-gel (Intersurgical Ltd., Workingham, Berkshire, UK) is a recent novel supraglottic airway device brought into market in 2007, designed to fit the peripharyngeal and hypopharyngeal structure without use of an inflatable cuff. It is made of a thermoplastic elastomer with a soft cuff which provides a seal in patients with a wide range of anatomical variations.²⁴ It is a single use supraglottic airway device which was introduced in the market in January 2007 and was invented by Dr. Mohammed Aslam Nasir.²⁵

Richez et al,²⁶ carried out one of the earliest studies to evaluate the i-gel. They found that insertion success rate was 97%. Insertion was easy and was performed at the first attempt in every patient. i-gel was easily and rapidly inserted, providing a reliable airway in over 90% of cases.

In a study done by Uppal V et al,²⁷ i-gel was compared with cuffed tracheal tube for gas leaks during pressure-controlled ventilation. They concluded that there was no statistically significant difference between the leak fractions of the i-gel and the tracheal tube at 15 and 20 cm H₂O PCV. Hence, i-gel can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures

A comparative study²⁸, between LMA Supreme and i-gel on 100 paralyzed adult patients with controlled ventilation in Trendelenburg position for laparoscopic surgery showed that there was no difference in the oropharyngeal leak pressure between the LMA Supreme and the i-gel (26.4 ± 5.1 vs 25.0 ± 5.7 cm of H₂O respectively). Forty seven LMA Supremes and forty eight i-gels were successfully inserted in the first attempt, with similar ease and comparable times to achieve an effective airway successfully. The volume of air needed to achieve a cuff pressure of 60 cm of H₂O was 25.2 ± 5.0 ml in the LMA Supreme. After creation of pneumoperitoneum, there was a smaller difference between expired and inspired tidal volumes with the LMA Supreme (21.5 (15.2) ml) than with the i-gel (31.2 (23.5) ml). Blood staining was seen on removal of two LMA Supremes and one i-gel.

A study²⁹, which evaluated the size 4 i-gel airway in 100 non-paralyzed patients, found that first insertion attempt was successful in 86% of patients, the second attempt in 11% of patients and the third attempt in 3% of patients.

Similar results were also obtained in study done by Acott,³⁰ where the use of i-gel was assessed as an airway device during general anesthesia. They

reported that a single insertion attempt was required in the majority of patients and all the insertion times recorded were less than 10 seconds.

Schmidbauer et al,³¹ compared the oesophageal seal of the novel supralaryngeal airway device i-gel with the laryngeal mask airways Classic and Proseal using a cadaver model, and observed that during the slow increase of pressure, the PLMA withstood an oesophageal pressure up to a median of 58 cm H₂O, while the cLMA was able to block the oesophagus up to a median of 37 cm H₂O, and i-gel already lost its seal at 13 cm H₂O. One minute after maximum pressure was applied, the PLMA withstood an oesophageal pressure of 59 cm H₂O, the cLMA of 46 cm H₂O, and i-gel airway of 21 cm H₂O. A fast release of oesophageal fluid was accomplished through the oesophageal lumen of both the PLMA and i-gel.

In a randomised, non-crossover study,³² the hypothesis that the ease of insertion using a duodenal tube guided insertion technique and the oropharyngeal leak pressure differ between the LMA Proseal and the i-gel in non-paralysed, anaesthetised female subjects was tested and the results were as follows. One hundred and fifty-two females aged 19–70 years were studied. Insertion success rate, insertion time and oropharyngeal leak pressure were measured. First attempt and overall insertion success were similar (LMA Proseal, 75/76 (99%) and 76/76 (100%); i-gel 73/75 (97%) and 75 (100%), respectively). Mean (SD) insertion times were similar (LMA Proseal, 40 (16) s; i-gel 43 (21) s). Mean oropharyngeal leak pressure was 7 cm H₂O higher with the LMA Proseal ($p < 0.0001$). Insertion of the LMA Proseal and i-gel was similarly easy using a duodenal tube guided technique, but the LMA Proseal forms a more effective seal for ventilation.

Shin et al,³³ compared supraglottic airway i-gel with Proseal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. They found that the airway leak pressures of the i-gel group (27.1 ± 6.4 cmH₂O) and PLMA group (29.8 ± 5.7 cmH₂O) were significantly higher than that of the cLMA group (24.7 ± 6.2 cmH₂O). The success rates for first attempt of insertion were similar among the three groups ($P = 0.670$). There were no differences in the incidence of adverse events except for the larger incidence of sore throat in the cLMA group.

In one of the foremost studies comparing PLMA, i-gel and LMA supreme by Zundert and Brimacombe,³⁴ in 150 consecutive patients, it was reported that there were no differences in oxygen saturation, end-tidal CO₂ or hemodynamic data among groups. The LMA-Supreme was easier ($P < 0.05$) and quicker ($P < 0.01$) to insert than the LMA-Proseal and i-gel. The first attempt success rates were 80% (i-gel), 84% (LMA-Proseal) and 100% (LMA-Supreme). Oropharyngeal leak pressures were similar among groups during apnoea (1 min) and spontaneous ventilation (at 30 and 60 min). A small, but statistically insignificant, increase in intradevice OLP was seen when comparing apnoea with spontaneous breathing at 30 and 60 minutes. There was a similar, but small increase in intracuff pressure for the LMA-Supreme and LMA Proseal. There were no differences in secondary variables (blood staining, airway trauma or airway morbidity) among the groups.

In a study done,³⁵ comparing postoperative throat and neck complaints after the use of the i-gel versus the traditional Laryngeal Mask, they concluded that the group of patients where the i-gel was used presented lower incidence of

sore throat (11% vs 27%) and cervical pain (3% vs 9%) and lower values of pressure on the airway tract compared with the group in which the conventional laryngeal mask was used. On the other hand, there was no difference in the presence of dysphonia, trauma or number of attempts used to insert the mask. The i-gel laryngeal mask demonstrated to be safe, with low incidence of morbidity to the administrated general anesthesia.

Thus, taking into consideration the data available in literature with respect to the supraglottic airway devices, PLMA and i-gel, we undertook this study to evaluate their clinical efficacy with regard to ease of insertion, duration of insertion, airway sealing pressure and complications in anaesthetized paralysed adult patients undergoing positive pressure ventilation.

Chapter 4

Basic Sciences



BASIC SCIENCES

Anatomy^{36,37,38}

Oral cavity

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

Vestibule

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

Oral cavity proper

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

Hard palate

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

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

Soft palate

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

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

Muscles of the soft palate:

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

Tongue

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

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

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

Muscles of the tongue

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

Intrinsic muscles

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

Extrinsic muscles

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

Nerve supply

Vestibule

- Motor - Facial nerve.
- Sensory - Maxillary nerve via alveolar and labial branches.

Hard palate:

- Maxillary nerve via greater palatine and nasopalatine branches.

Soft palate

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

Tongue

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

Arterial supply

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

Venous drainage

- Pterygoid, tonsillar and pharyngeal plexus of veins.

Lymphatic drainage

- Upper deep cervical and retropharyngeal lymph nodes.

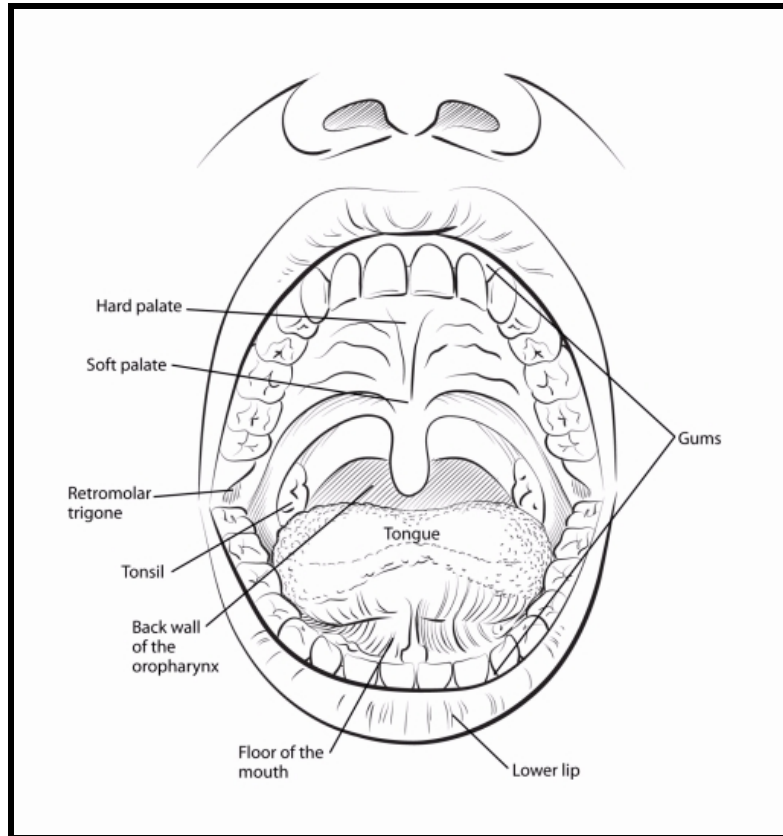


Figure 1. Anatomy of oral cavity

Pharynx

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

Parts of the pharynx:

The cavity of the pharynx is divided into;

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

Nasopharynx

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

Oropharynx

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

Laryngopharynx

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

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

Muscles of the pharynx

Beneath the mucosa of pharynx is a fibromuscular sheath, fibrous layer being dense superiorly where muscle is absent. The three constrictors: superior,

middle and inferior are so arranged that the inferior overlaps middle which in turn overlaps the superior. The longitudinal muscle coat of pharynx consists of stylopharyngeus, salpingopharyngeus and palatopharyngeus.

Nerve supply

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

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

Arterial supply

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

Venous drainage

Pterygoid and pharyngeal plexus of veins.

Lymphatic drainage

Retropharyngeal and upper deep cervical lymph nodes

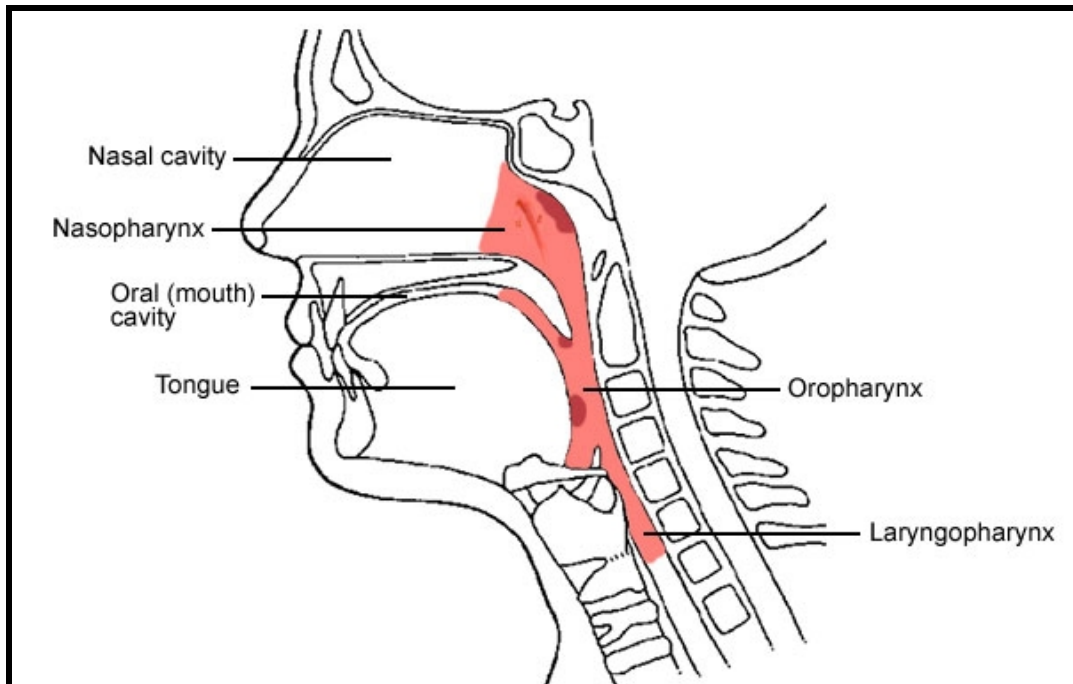


Figure 2. Anatomy of pharynx

Larynx

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

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

Cartilages of larynx

Unpaired cartilages

1. Thyroid

2. Cricoid
3. Epiglottis

Paired cartilages

1. Arytenoids
2. Corniculate
3. Cuneiform

Laryngeal joints (Synovial joints)

1. Cricothyroid joint
2. Cricoarytenoid joint

Laryngeal ligaments and membranes

Extrinsic

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

Intrinsic

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

Cavity of larynx

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

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

Intrinsic muscles of larynx

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

Extrinsic muscles of larynx

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

Nerve supply

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

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

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

Arterial supply

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

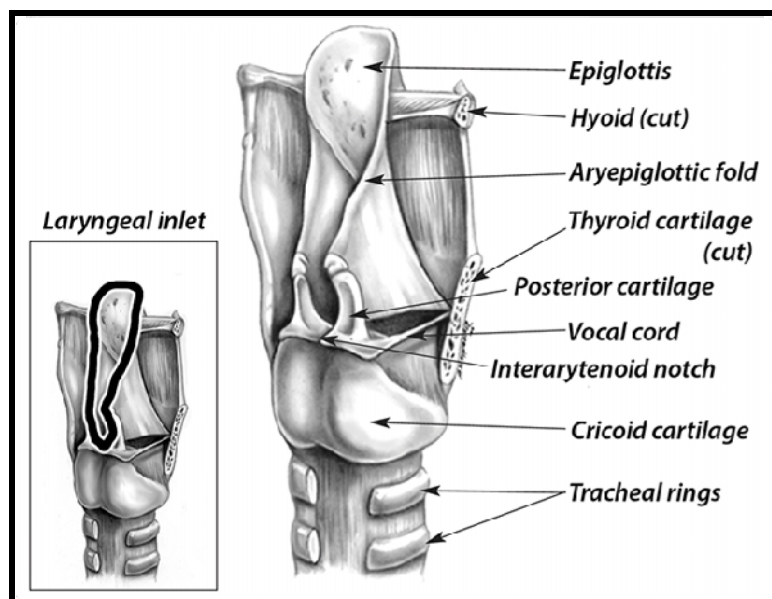


Figure 3. Anatomy of larynx

Venous drainage

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

Lymphatic drainage

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

APPLIED ANATOMY:^{39,40,41} Anatomical structures relevant to supraglottic devices include mouth, oropharynx, laryngopharynx and hypopharynx²¹.

MOUTH: The roof of the mouth is formed by hard palate in the anterior 2/3rd and in the posterior 1/3rd by soft palate. Adequate mouth opening is essential for SAD placement. Hard palate is shaped such that food is directed into the oropharynx with soft palate shielding the nasopharynx. SAD may be difficult to pass into oropharynx if angle of approach between the hard palate and posterior oropharyngeal wall is less than 90 degrees.

OROPHARYNX: SAD passes through the oropharynx to enter the laryngopharynx. It lies directly posterior to the oral cavity and it extends from below the soft palate to the upper border of the epiglottis. The posterior wall consists of the prevertebral fascia and the bodies of the second and third cervical vertebrae. The lateral walls contain the paired tonsillar fossae which are formed by the palatoglossal and palatopharyngeal folds and contain the palatine tonsils. If the palatine tonsils are grossly enlarged it may impede the passage of SAD into the oropharynx. Medial to the tonsillar fauces lies the base of the tongue. The tongue base is anterior to the laryngeal inlet and attaches to the epiglottis by the paired lateral glossoepiglottic folds and by the single median glossoepiglottic fold. Glossoepiglottic folds bind two spaces, the epiglottis and the valleculae.

LARYNGOPHARYNX AND HYPOPHARYNX: It extends inferiorly from the upper edge of the epiglottis to the inferior edge of the cricoid cartilage and communicates with the oropharynx, the laryngeal inlet and the oesophagus. A small pyriform fossa lies on each side of the laryngeal inlet, bounded medially by

the aryepiglottic folds and laterally by the thyroid cartilage and thyrohyoid membrane.

NEUROVASCULAR CONSIDERATIONS: There is risk of compression of several nerves and blood vessels within the tissues of the oropharynx due to malposition or over inflation of the cuff of laryngeal mask. Lingual artery at the base of the tongue, the glossopharyngeal nerve between the superior and middle constrictor muscles, recurrent laryngeal nerve deep to the border of the inferior constrictors and the lingual nerve below the inferior border of the superior constrictor against the periosteum of the mandible posterior to the third molar are the most common structures at risk of cuff related complications.

PHYSIOLOGICAL IMPLICATIONS:

CARDIOVASCULAR SYSTEM: Insertion of the SAD is associated with a smaller rise in blood pressure and heart rate as compared to ETT insertion. SAD can be inserted in the lighter planes of anaesthesia.

RESPIRATORY SYSTEM: Airway complications such as laryngospasm, bronchospasm, trauma and sore throat are less frequent with supraglottic airway than with endotracheal intubation. The SAD causes minimal triggering of the lung defences as there is no airway manipulation.

INTRACRANIAL PRESSURE: Use of SAD as a conduit to endotracheal intubation in patients undergoing neurosurgery, has a minimal effect on the intracranial pressure during insertion.

GASTROINTESTINAL SYSTEM:

THE SWALLOWING REFLEX: Insertion of the SAD in lighter planes of anaesthesia triggers variety of protective and digestive reflexes including coughing, gagging, retching, swallowing and hypersalivation. With increasing depth of anaesthesia, these reflexes are suppressed to a varying degree. Impact of SAD tip with the glottis results in coughing, but it may also occur due to irritation of the glottic opening by the secretions as supraglottic airway is inserted.

SAD insertion is successful as a blind technique as it utilizes normal existing physiological mechanism of swallowing to follow natural curve and the direction of the upper airway with inserting finger to guide LMA in the oral cavity. However, swallowing reflex is suppressed for insertion and tolerance of the LMA in the oral cavity.

OESOPHAGUS: The insertion and presence of mask in the pharynx involve various upper gastrointestinal tract reflexes. The pharynx contains mechanoreceptors and chemoreceptors, which play important role in triggering the primary peristaltic wave of deglutition. However, inappropriate stimulation of these trigger zones may produce a less coordinated response such as secondary peristalsis which lacks coordination of primary peristalsis and can result in relaxation of lower oesophageal sphincter without immediate restoration of the tone of the sphincter.

PHARYNGEAL MUCOSA: The inflated cuff causes compression of the pharyngeal mucosa and 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 mentioned in literature is the theoretical 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 44 mm Hg, which is the perfusion pressure of the capillaries of pharynx.

THE PROSEAL LARYNGEAL MASK AIRWAY(PLMA)^{18,42}

The Proseal laryngeal mask airway (PLMA; Intavent Orthofix, Maidenhead,UK), designed by Dr. Archie Brain, is based on the classic laryngeal mask airway(cLMA). It was introduced in 2000 and was specifically designed for positive pressure ventilation

The PLMA, like the cLMA, consists of airway tube, bowl and cuff . The airway tube is reinforced with similar calibre to an equivalent reinforced/flexible LMA (fLMA). Modifications compared to the cLMA are:

- 1) larger and deeper bowl
- 2) posterior extension of the mask cuff
- 3) drainage tube running parallel to the airway tube and exiting at the mask tip
- 4) integral silicone bite block
- 5) anterior pocket for seating an introducer or finger during insertion.

Characteristics of the PLMA design

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

- A drain tube communicates with the upper oesophageal sphincter and permits venting of the stomach and blind insertion of standard gastric tubes, in any patient position, without the need of Magill's forceps.
- A double tube arrangement reduces the likelihood of device rotation; the revised cuff profile, together with the two tubes, results in the device being more securely anchored in place.
- A built in bite block reduces the possibility of airway obstruction or tube damage.
- A strap for the PLMA introducer also accommodates the index finger or thumb for manual insertion.
- The position of the drain tube inside the cuff is designed to prevent the epiglottis from occluding the airway tube. This eliminates the need for aperture bars.

Table 1. PLMA selection guidelines

PLMA size	Weight of patient(kg)	Maximum inflation volume(ml.)	Orogastric tube(Fr.)
1	<5	4	8
1 1/2	5-10	7	10
2	10-20	10	10
2 1/2	20-30	14	14
3	30-50	20	16
4	50-70	30	16
5	70-100	40	18

Pre insertion preparation:

- Wear gloves
- Prior to insertion of the device, the cuff should be fully deflated to a flattened wedge shape which can be accomplished through use of the PLMA Cuff- Deflator.
- Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.

Insertion methods

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

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

Index finger insertion technique

Hold the LMA device like a pen, with the index finger tip placed in the introducer strap. The LMA is pressed against the hard palate and advanced into the hypopharynx until resistance is felt. The finger in the retaining strap is pushed towards the occiput, while the other hand exerts counter pressure to maintain the sniffing position. Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube. This prevents the PLMA from being pulled out of place when the finger is removed.

Introducer technique

This technique is recommended for PLMA size 1 to 2½. It can also be used for adult sizes. The distal end of the silicon coated metal introducer is placed in the introducer strap and the proximal end in the notch between airway tube and drain tube. Under direct vision, the bowl is placed into the mouth, guided against the hard palate and advanced in a smooth arc with the handle until resistance is encountered. The introducer is then removed, taking care to avoid dental damage.

Thumb insertion technique

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

Steps to facilitate correct mask position

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

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

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

Indications:

- For achieving and maintaining control of airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or positive pressure ventilation.
- It is also indicated for securing the immediate airway in known or unexpected difficult airway situations.
- May be used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes requiring artificial ventilation.

Contraindications:

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

- Patients who have not fasted, including patients whose fasting cannot be confirmed.
- Patients who are grossly or morbidly obese, more than 14 weeks pregnant or those with multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.
- Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the airway forms a low-pressure seal around the larynx.
- Patients where the peak airway inspiratory pressures are anticipated to exceed 30 cm H₂O with PLMA.

- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for use with PLMA

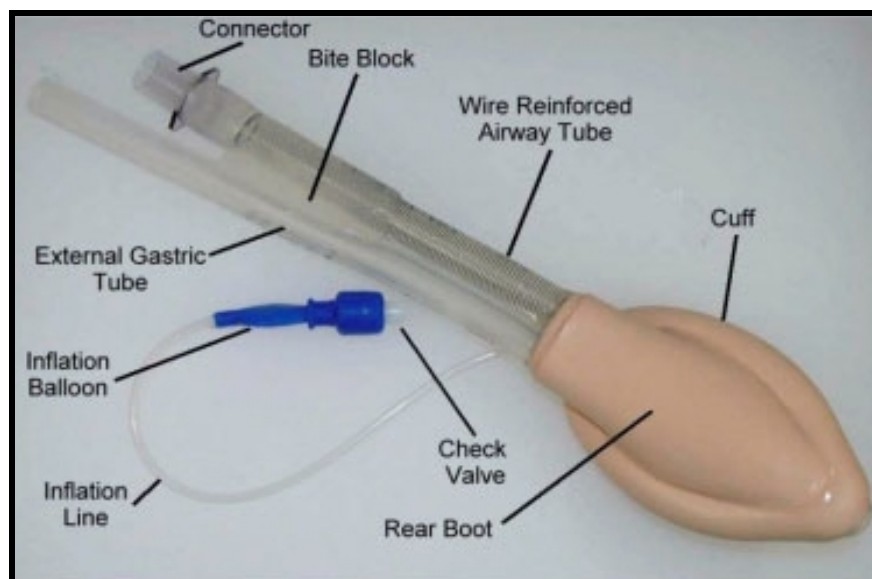
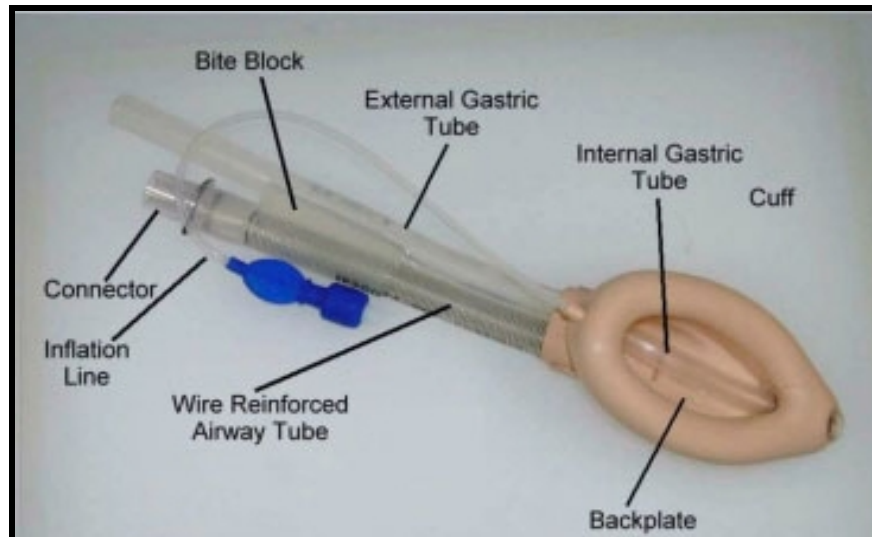


Figure 4 . PLMA

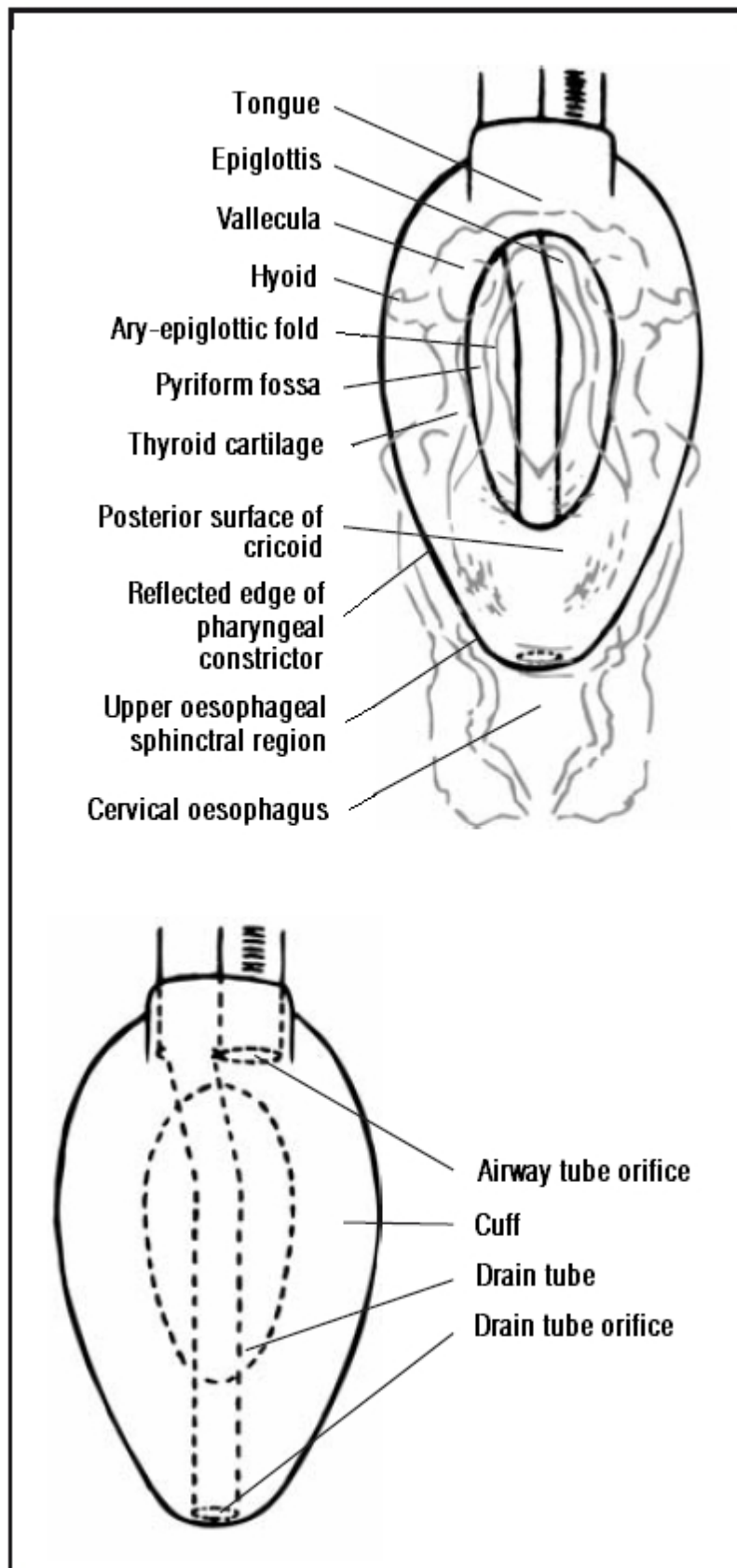


Fig 5.Schematic diagram showing PLMA in relation to pharyngeal anatomy

THE I GEL AIRWAY:⁴³

The i-gel is the innovative second generation supraglottic airway from Intersurgical launched in 2007. The first major development since the laryngeal mask airway, the i-gel changed the face of airway management and is now widely used in anaesthesia and resuscitation across the globe. It is a single use supraglottic airway device and was introduced into the market in January 2007. The credit of its invention goes to Dr. Muhammad Aslam Nasir.

Characteristics of i-gel :

- It is made of thermoplastic elastomer, which is soft, gel-like and transparent to create a non-inflatable anatomical seal over laryngeal framework providing a reliable perilaryngeal seal.
- An anatomical device, which achieves a mirrored impression of the pharyngeal, laryngeal and perilaryngeal structures.
- It causes minimal compression or displacement trauma to the tissues and structures in the vicinity.
- It is latex free, sterile, single patient use device
- The buccal cavity stabiliser has a widened, elliptical, symmetrical and laterally flattened cross sectional shape, providing good vertical stability and axial strength upon insertion.
- It has an integrated gastric channel that can provide an early indication of regurgitation, facilitates venting of gas from the stomach and allows for the passing of a nasogastric tube to empty the stomach contents.

- It has an artificial epiglottis and a protective ridge which helps to prevent the epiglottis from down folding or obstructing the distal opening of the airway

Pre-insertion preparation

- Wear gloves
- Open i-gel package and take out protective cradle containing the device
- Remove i-gel and transfer it to the palm of the same hand that is holding the protective cradle, supporting the device between the thumb and index finger. Place water based lubricant onto middle of the smooth surface of the cradle in preparation for lubrication.
- Grasp the i-gel with free hand along the integral bite block and lubricate the back, front and the sides of the cuff with a thin layer of lubricant. Avoid touching the cuff of the device with your hands.

Insertion technique

- Grasp the lubricated i-gel firmly along the integral bite block. Position the device so that the i-gel cuff outlet is facing towards the chin of the patient.
- Patient should be in sniffing position with head extended and neck flexed. The chin should be gently pressed down before proceeding to insert the i-gel.
- Introduce the leading soft tip into the mouth of the patient in a direction towards the hard palate.
- Glide the device downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt.

- It is not necessary to insert fingers or thumbs into the patient's mouth during the process of inserting the device.
- If there is early resistance during insertion a 'jaw thrust', 'insertion with deep rotation' or 'triple maneuver' is recommended.
- At this point the tip of the airway should be located into the upper oesophageal opening and the cuff should be located against the laryngeal framework. The incisors should be resting on the integral bite-block.
- The i-gel should be taped down from 'maxilla to maxilla'

Steps to facilitate ventilation

- Optimal depth of anaesthesia must be achieved prior to attempting insertion (i.e. absence of eyelash reflex, easy up and down movement of the lower jaw, no reaction to pressure applied to both angles of the mandible)
- After insertion, connect to anaesthesia circuit and check for leaks from the drain tube and airway tube
- Excessive air leak during manual ventilation is primarily due to sub-optimal depth of anaesthesia or sub-optimal depth of i-gel insertion.
- Verify position of the bite block
- Do not allow peak airway pressure of ventilation to exceed 40 cm H₂O.
- Do not leave the device in situ for more than 4 hours.

Table 2.i-gel airway selection guidelines

SIZE	PATIENT WEIGHT (Kgs)	MAXIMUM SIZE ENDOTRACHEAL TUBE (mm)	MAXIMUM SIZE OROGASTRIC TUBE (FG)
1	2-5	3.0	N/A
1.5	5-12	4.0	10
2	10-25	5.0	12
2.5	25-35	5.0	12
3	30-60	6.0	12
4	50-90	7.0	12
5	>90	8.0	14

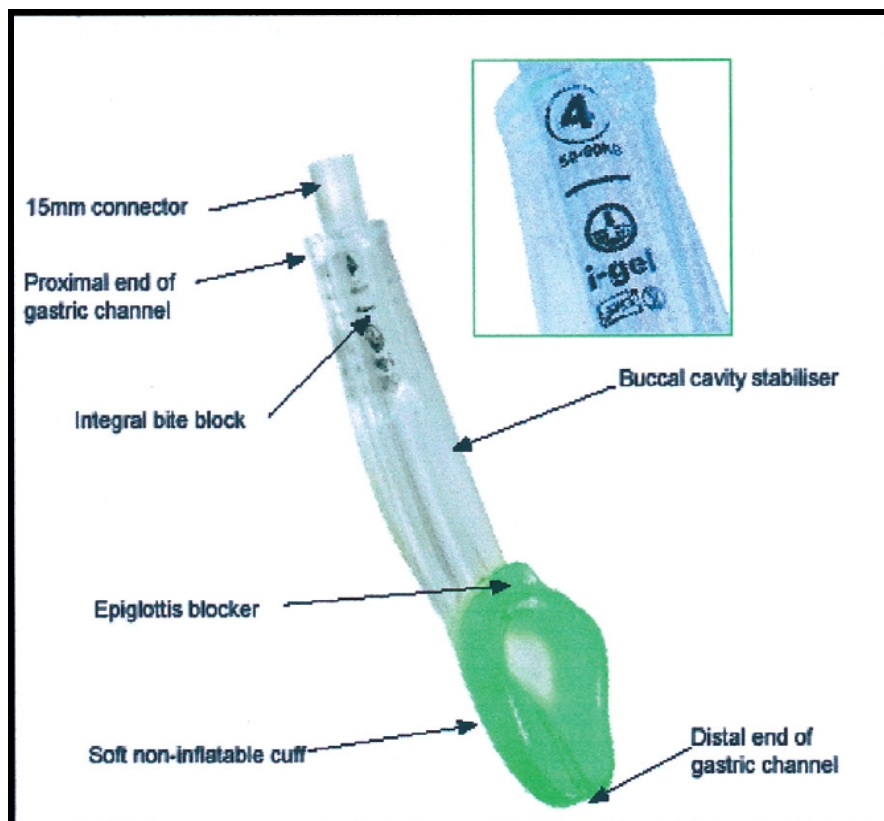


Figure 6.i-gel supraglottic airway

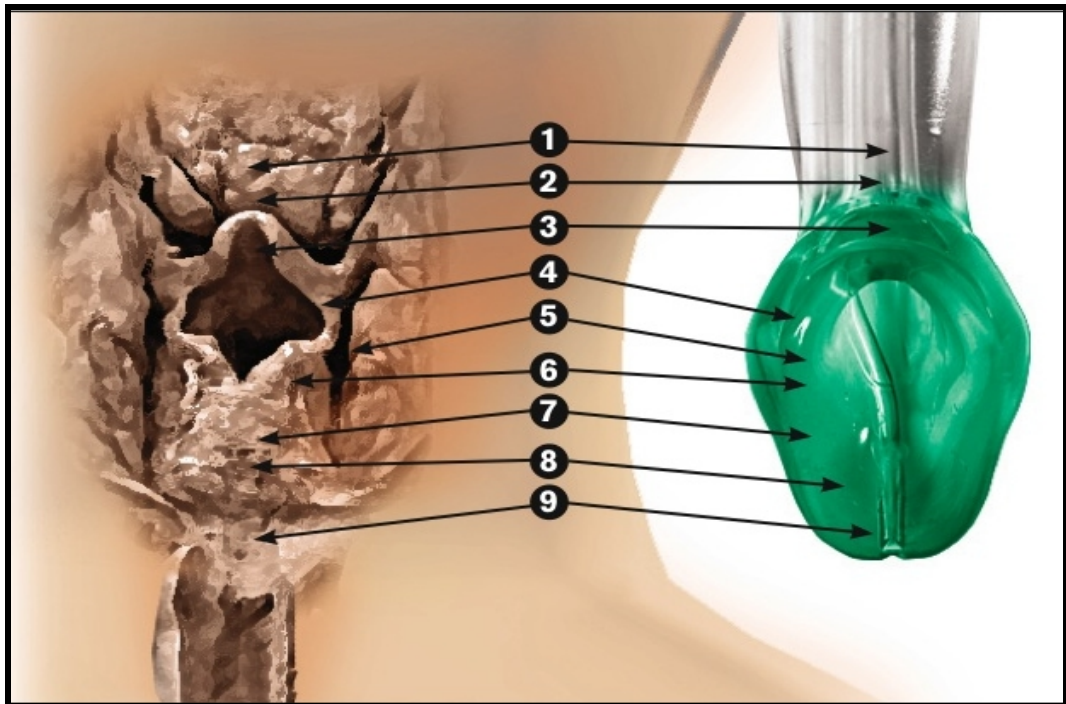
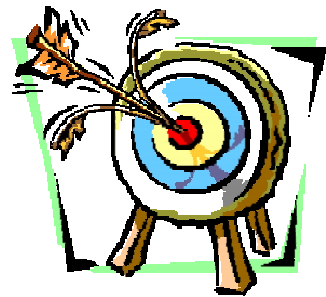


Figure7. View of the i-gel cuff in relation to the laryngeal framework

- | | |
|------------------------|------------------------------|
| 1. Tongue | 6. Posterior cartilages |
| 2. Base of tongue | 7. Thyroid cartilage |
| 3. Epiglottis | 8. Cricoid cartilage |
| 4. Aryepiglottic folds | 9. Upper oesophageal opening |
| 5. Piriform fossa | |



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Annexure-I



Annexure-II



Annexure-III



Annexure-IV

Chapter 5

Methodology



METHODOLOGY

This study was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital , Belgaum during the period of January 2013 to December 2013.

Study design

The study design was a one year randomized clinical trial.

Study Period

One year, from January 2013 to December 2013.

Place

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

Source of Data

Adult patients undergoing routine elective surgeries under general anaesthesia at KLES Dr. Prabhakar Kore Hospital, Belgaum.

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 the values in below stated formula:

Sample size was calculated using the formula as below;

$$n = \frac{(Z_1 + Z_2)^2 (S_1^2 + S_2^2)}{(x_1 - x_2)^2}$$

where,

Level of significance was taken as 5% ($\alpha=0.05$)

Power of the test was taken as 80% ($\beta=0.84$)

Hence

$$Z_1 = 1.96$$

$$Z_2 = 0.84$$

With these values, sample size obtained was 30 in one group. Hence a total of 60 patients equally distributed into two groups namely, **group A: i-gel** and **group B: PLMA**.

Selection criteria

Inclusion

- Elective surgeries under general anaesthesia in supine position, less than two hours duration.
- Age between 18 to 50 years.
- ASA status I or II.

- Weight 50-70 kgs

Exclusion

- Known or predicted difficult airway.
- Any pathology of the neck, upper respiratory tract or upper gastrointestinal tract.
- History of obstructive sleep apnea.
- Trendelenburg's position.
- History of cardiopulmonary disorders.
- Potentially full stomach patients (trauma, pregnancy, morbid obesity, hiatus hernia).
- Cervical spine disorders

Ethical clearance

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

Informed Consent

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

Method of collection of data

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

Investigations

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

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

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

Randomization

Patients were randomly allocated into one of the two groups by opening a computer generated 'sealed envelope' method into two groups of 30 each.

- **Group A:i-gel(n=30)**
- **Group B:PLMA (n=30)**

Procedure

In the operating room, a standard anaesthesia protocol was followed and routine monitoring was applied with electrocardiograph, non-invasive blood pressure, pulse oximetry (SPO₂) and end tidal CO₂ monitoring. The head and neck of the patient were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height.

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

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

Anaesthesia was induced with inj. Propofol 2mg/kg (IV) and neuromuscular blockade was achieved with inj. Vecuronium 0.1mg/kg (IV). Patient's were ventilated using a face mask for three to five minutes and then the airway device (size 4) was inserted in strict accordance with the manufacturer's recommendations. All insertions were performed by an experienced anaesthesiologist

Insertion technique:

PLMA: The standard index finger method as recommended by the manufacturer for size 4 was used. PLMA cuff was deflated, held like a pen, with the index finger tip placed in the introducer strap. It was then pressed against the

hard palate and advanced into the hypopharynx until resistance was felt. The finger in the retaining strap was pushed towards the occiput, while the other hand exerted counter pressure to maintain the sniffing position. Before removing the finger, the non-dominant hand was brought from behind the patient's head to press down on the airway tube. This prevents the PLMA from being pulled out of place when the finger is removed.

i-gel: The leading soft tip was introduced into the mouth of the patient in a direction towards the hard palate. The device was glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance was felt.

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

Failed insertion was defined by any of the following criteria.

- Failed passage into the pharynx.
- Malposition (air leaks).
- Ineffective ventilation (maximum expired tidal volume <6 ml/kg or/and end tidal CO₂ > 60 cm of H₂O).
- More than one attempt

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

For PLMA, the intra cuff pressure was set at 60 cm H₂O to obtain an effective airway seal for positive pressure ventilation, patients were ventilated at an inspired tidal volume of 8 ml/kg, respiratory rate of 12 breaths/minute and an inspiratory :expiratory ratio of 1:2. Anaesthesia was maintained with 1:1 oxygen-nitrous oxide mixture, isoflurane and inj. Vecuronium 0.025mg /kg(IV) boluses.

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

Study variables:

The ease of insertion was defined as:

- Easy- no resistance to insertion in the pharynx in a single maneuver.
- Difficult- resistance to insertion or more than one maneuver 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.

The duration of insertion was defined as the time between picking up the prepared PLMA or i-gel supraglottic airway and successful placement of the device.

Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 liter min⁻¹, and noting the airway

pressure in the anaesthetic breathing system at equilibrium (maximum allowed was 40 cm H₂O) using manometer.

The aetiology of failed insertion (if any) was documented.

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 were documented.

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

Statistical analysis

Data obtained was coded and entered into Microsoft excel spreadsheet. The categorical data was expressed in terms of rates, ratios and percentage and continuous data was expressed as mean \pm standard deviation (SD). The demographic data, duration of insertion and airway sealing pressure were analysed using unpaired 't' test. Sex and complications were compared using chi square test. The ease of insertion is analysed using fisher exact test. A probability value (p value) of less than or equal to 0.05 was considered as statistically significant.

Chapter 6

Results



RESULTS

The present study was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital , Belgaum during the period of January 2013 to December 2013.

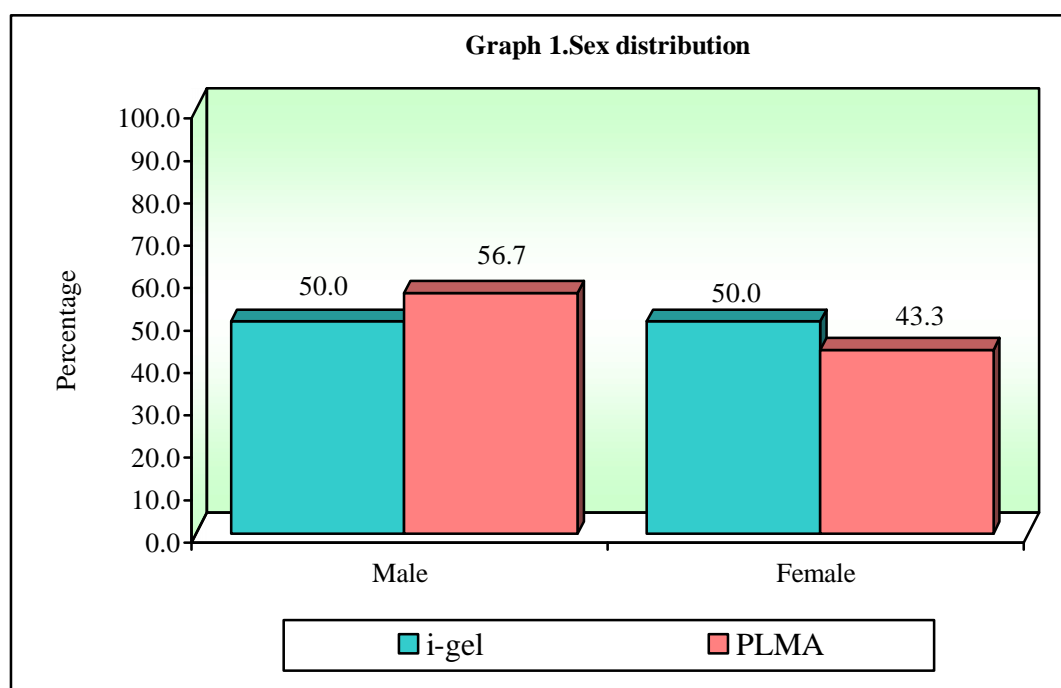
A total of 60 anaesthetized, paralysed adult patients, undergoing positive pressure ventilation were studied. Patients were randomly allocated into one of the two groups

- Group A:i-gel (n=30)
- Group B: PLMA (n=30)

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

Table 3. Sex distribution

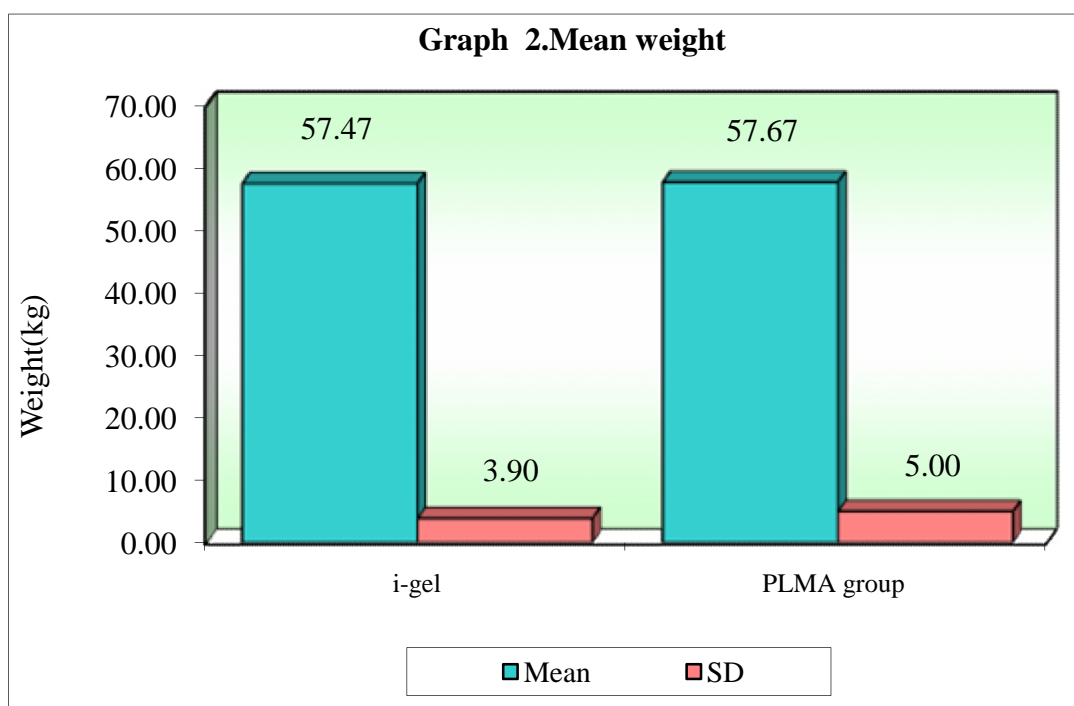
SEX	i-gel (n=30)		PLMA (n=30)	
	Number	Percent	Number	Percent
Male	15	50	17	56.67
Female	15	50	13	43.33
Total	30	100%	30	100%



In our study, there were 15 males, 15 female patients in i-gel group and 17 males, 13 female patients in PLMA group, male to female ratio being 1:1 in i-gel group and 1:1.307 in PLMA group.

Table 4. Mean weight

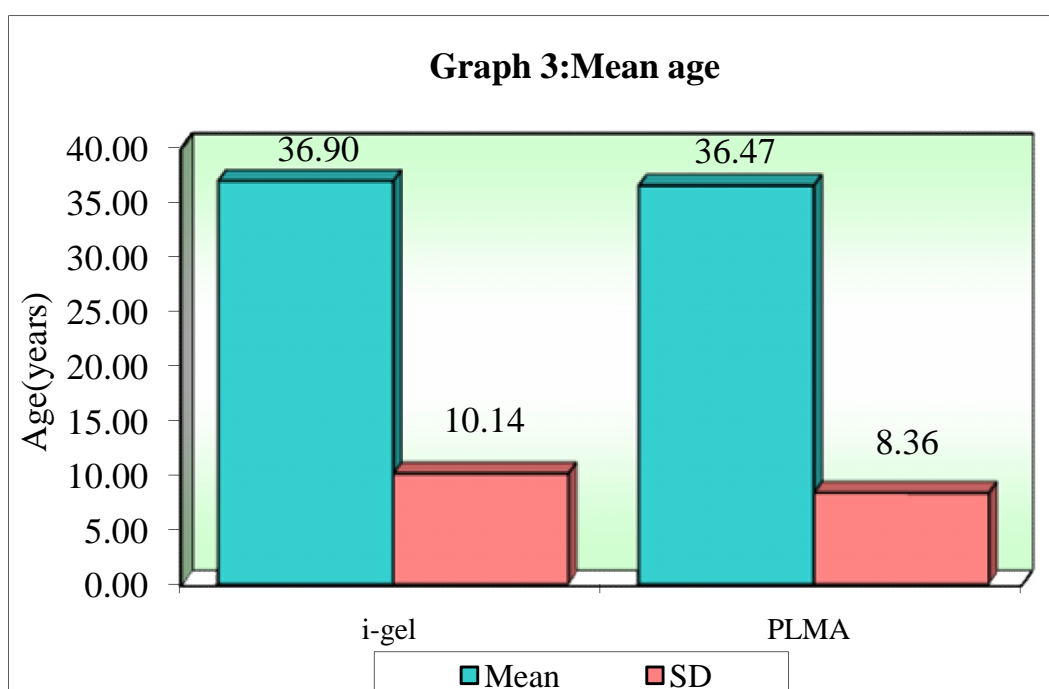
Groups	n	Mean(kg)	SD	t-value	p-value
i-gel	30	57.47	3.90	-0.1727	0.8635
PLMA	30	57.67	5.00		



The mean weight 57.47 ± 3.90 kg in group i-gel and was 57.67 ± 5.00 kg in group PLMA which was not statistically significant ($p=0.8635$). Both groups were comparable with respect to weight.

Table 5. Mean age

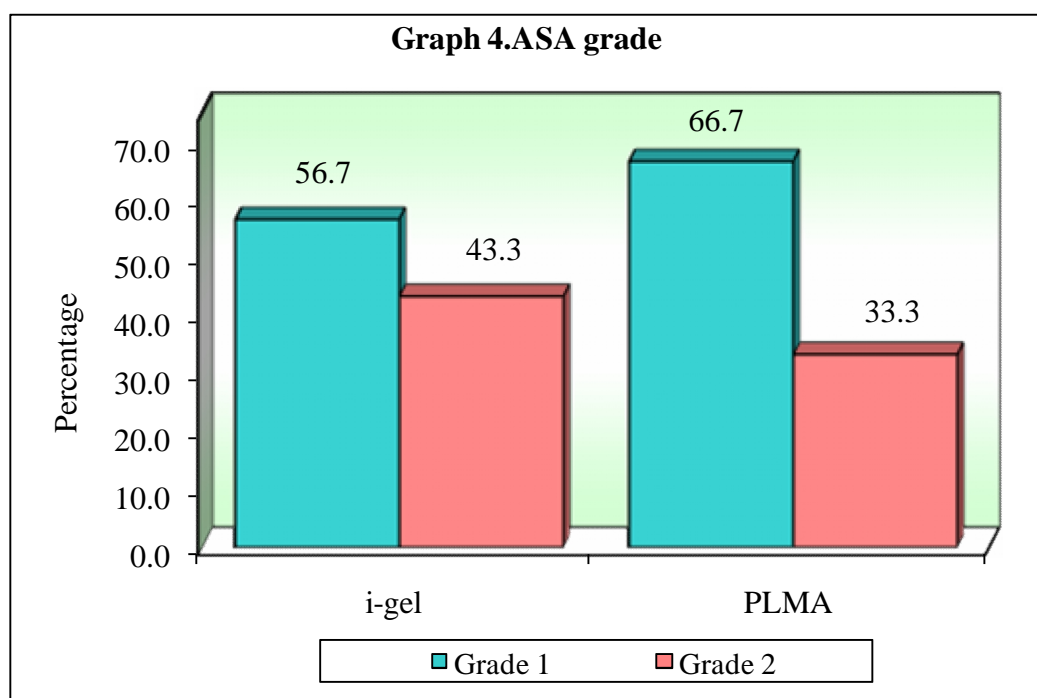
Groups	n	Mean(years)	SD	t-value	P-value
i-gel	30	36.90	10.14	0.1805	0.8574
PLMA	30	36.47	8.36		



The mean age was 36.90 ± 10.14 years in group i-gel and 36.47 ± 8.36 in group PLMA ($p=0.8574$). There was no statistically significant difference between both the groups. Both groups were well matched with respect to age.

Table 6. ASA grade

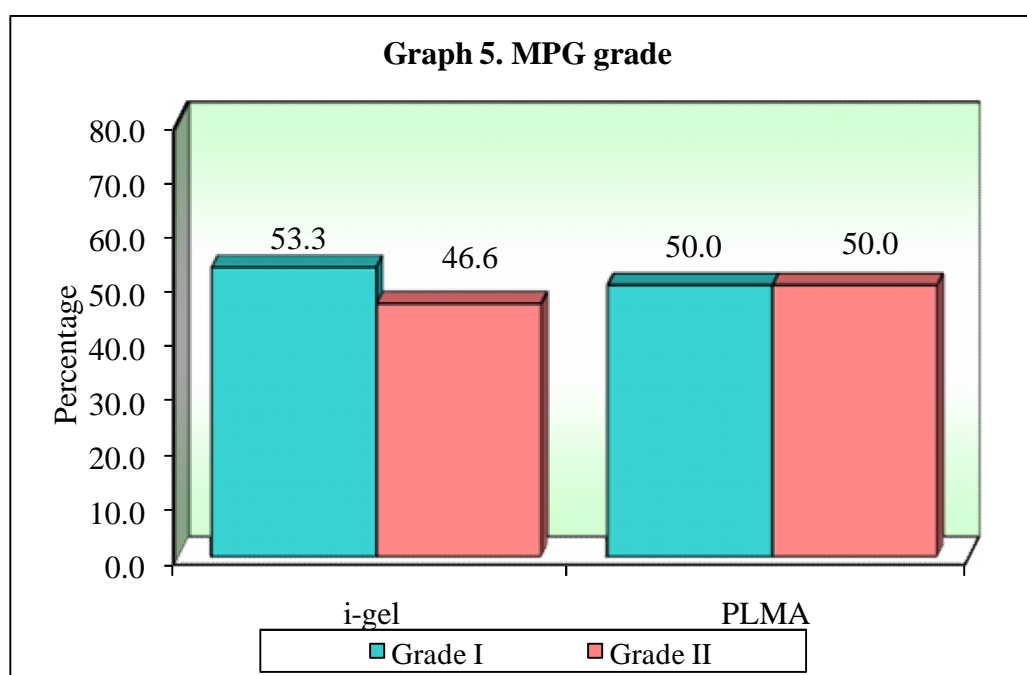
ASA grade	i-gel(n=30)	%	PLMA (n=30)	%
Grade 1	17	56.67	20	66.67
Grade 2	13	43.33	10	33.33
Total	30	100.00	30	100.00



In this study, among the patients that were scheduled for surgery 56.67% in the i-gel group belonged to ASA grade I compared to 66.67% in PLMA group($p=0.425$).

Table 7.MPG Grade

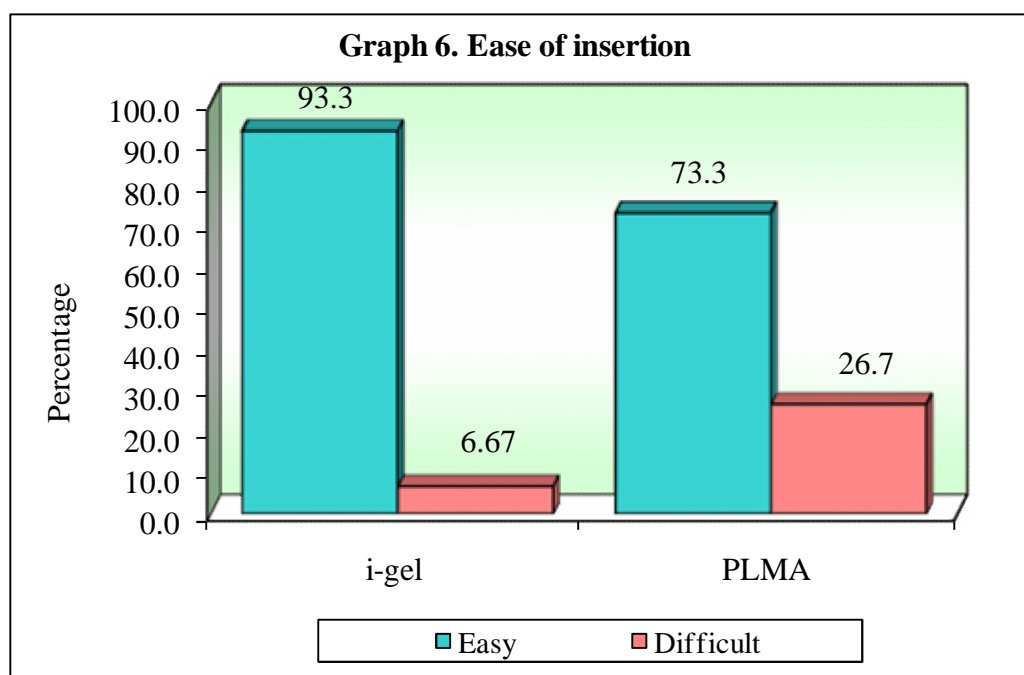
MPG grade	i-gel(n=30)	%	PLMA(n=30)	%
Grade I	16	53.28	15	50.00
Grade II	14	46.62	15	50.00
Total	30	100.00	30	100.00



In the present study, 53.28% of patients in i-gel group had Mallampati grade I in comparison to 50% of patients in PLMA group. Both groups were comparable with respect to MPG grading ($p=0.796$).

Table 8. Ease of insertion

Ease of insertion	i-gel(n=30)		PLMA(n=30)	
	Number	%	Number	%
Easy	28	93.33	22	73.33
Difficult	2	6.67	8	26.67
Total	30	100.00	30	100.00

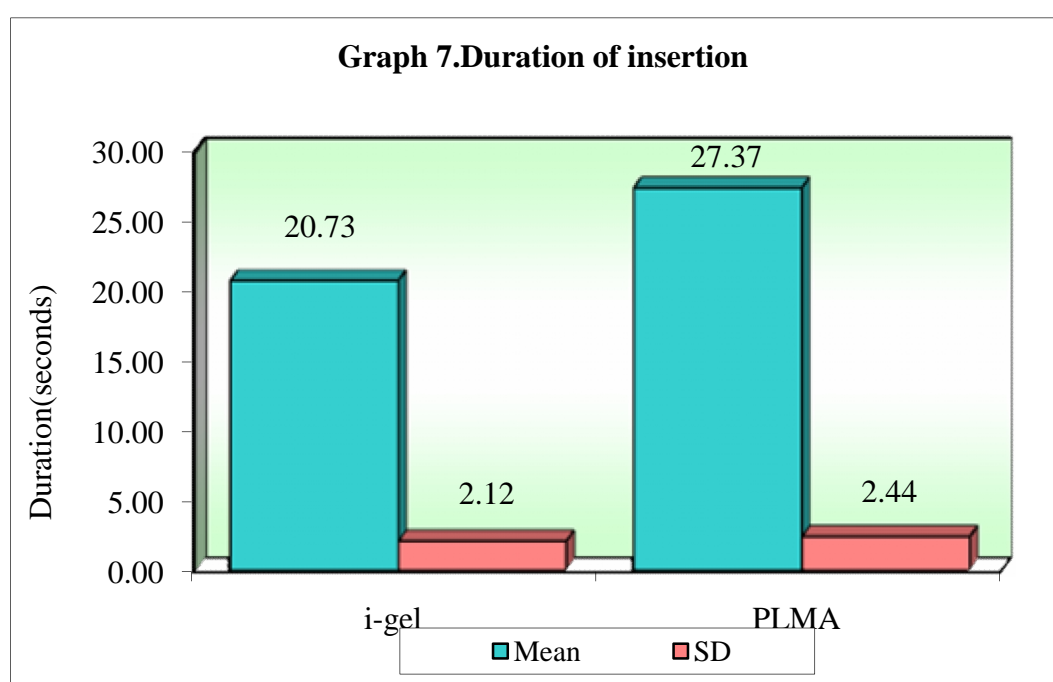


In our study, insertion was easy in and 28 patients in i-gel group(93.3%) and 22 patients in PLMA group(73.3%). Difficult insertion was seen in 2 patients in i-gel group(6.67%) and 8 patients in group PLMA(26.7%). This difference was not statistically significant. ($p=0.0832$). There were no failed insertions.

Table 9. Duration of insertion

Group	n	Mean duration (seconds)	SD	t-value	P-value
i-gel	30	20.73	2.12	-11.2432	0.00001*
PLMA	30	27.37	2.44		

*p<0.001

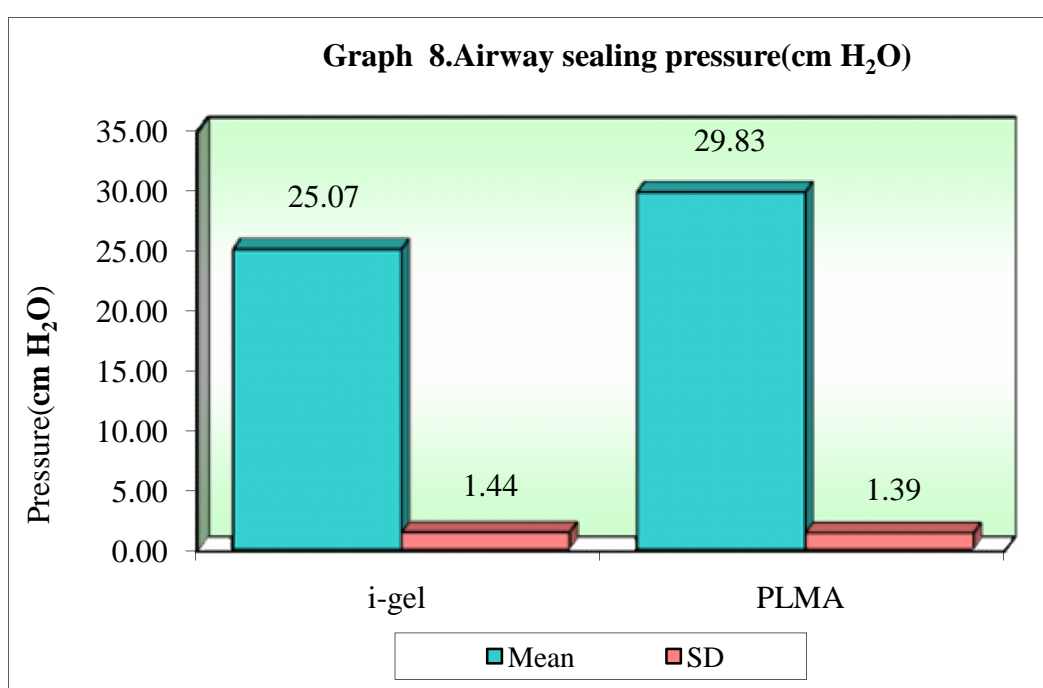


In our study, the mean duration of insertion was 20.73 ± 2.12 sec in i-gel group and 27.37 ± 2.44 sec in PLMA group. This difference was statistically significant ($p=0.00001$).

Table 10. Airway sealing pressure (cm H₂O)

Groups	n	Mean	SD	t-value	P-value
i-gel	30	25.07	1.44	-13.0522	0.00001*
PLMA	30	29.83	1.39		

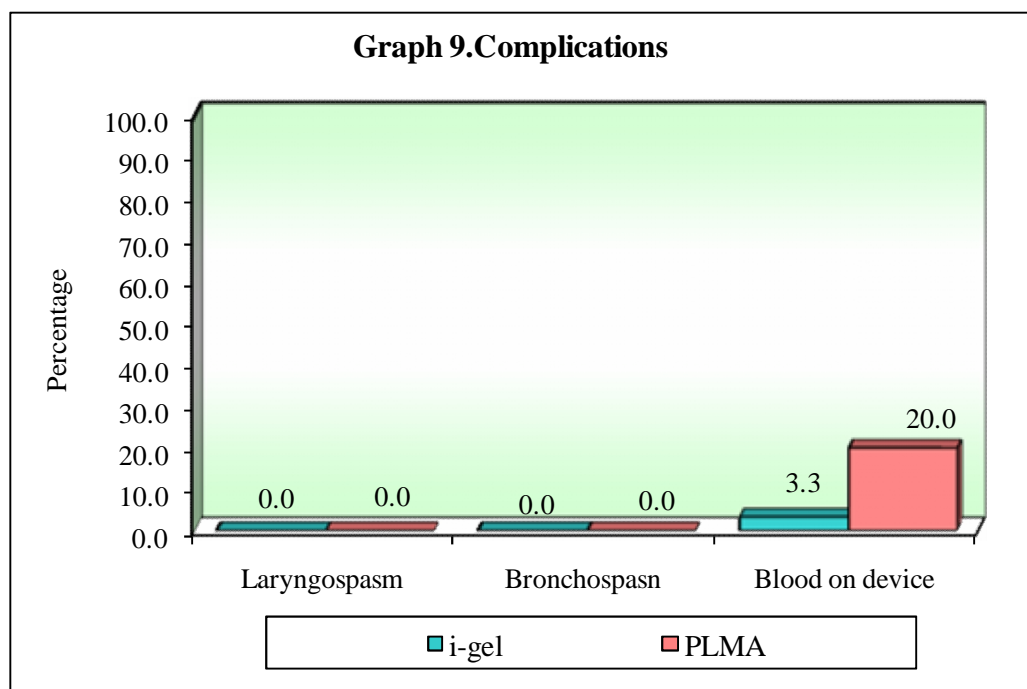
*p<0.001



The mean airway sealing pressure was and 25.07 ± 1.44 in i-gel group and 29.83 ± 1.39 in PLMA group. The airway sealing pressure was more in PLMA group which was statistically significant ($p < 0.001$).

Table 11. Complications

Complications	i-gel (n=30)		PLMA (n=30)		p value
	Number	%	Number	%	
Laryngospasm	0	0	0	0	-
Bronchospasm	0	0	0	0	-
Visible blood on the device	1	3.33	6	20	p=0.1



In our study, visible blood on the device was noted in 6 patients in PLMA group (20%) and 1 patient in i-gel group (3.3%) which was statistically insignificant. No bronchospasm and laryngospasm were noted in patients of either group.

Chapter 7

Discussion



DISCUSSION

Supraglottic airway devices (SADs) have been widely used as an alternative to tracheal intubation during general anesthesia.⁴⁴ They are easily inserted, better tolerated, with lesser hemodynamic changes, have favorable respiratory mechanics, and decreased airway morbidity.^{45,46} The current guidelines on cardiopulmonary resuscitation also recommend SADs as an alternative to tracheal intubation.^{47,48}

PLMA is a reusable supraglottic device that allows easy insertion, higher glottic seal pressures and permits the gastric drainage separating respiratory tract from alimentary tract.¹⁸

The i-gel is a recent novel second generation supraglottic airway device that consists of a noninflatable laryngeal mask made from a gel-like thermoplastic elastomer and an anatomically shaped cuff which is easier to insert.⁴³

This study was undertaken to compare the PLMA(size 4) and i-gel(size 4) for ease of insertion, airway sealing pressure and postoperative complications (blood staining of device, laryngospasm and bronchospasm) in anaesthetized, paralyzed patients on positive pressure ventilation.

A total of 60 ASA I and II patients aged 18-50 years weighing 50-70 kg posted for elective surgery under general anaesthesia, randomly divided into two groups of 30 each, were enrolled in our study.

In our study, there were 17 male, 13 female patients in PLMA group and 15 male, 15 female patients in i-gel group. The mean weight was 57.67 ± 5.00 kg in PLMA group and 57.47 ± 3.90 kg in i-gel group. The mean age was 36.47 ± 8.36 in PLMA group and 36.90 ± 10.14 years in i-gel group. Both groups were comparable with respect to sex, weight and age.

In the present study, 50% of patients in PLMA group had Mallampati grade I in comparison to 53.28% of patients in i-gel group.

In this study, among the patients in 66.67% in PLMA group were scheduled for surgery with ASA grade 1 compared to 56.67% in i-gel group.

Both groups were comparable with respect to MPG and ASA grading.

The supraglottic airway devices (SAD's) provide ease of placement and hands free maintenance, along with a relatively secure airway. Insertion of SADs may be less stimulating to sympathetic nervous system than laryngoscopy and tracheal intubation. It is also better tolerated at lighter levels of anaesthesia, potentially decreasing side effects and hospital stay.⁴⁹

In our study, insertion was easy in 22 patients in PLMA group (73.3%) and 28 patients in i-gel group (93.3%). Difficult insertion was seen in 8 patients in PLMA group (26.67%) and 2 patients in i-gel group (6.67%). This difference was not statistically significant. ($p=0.0832$). There were no failed insertions in our study.

The results of our study were similar to a study by Kini et al,⁵⁰ comparing i-gel with PLMA in adult patients undergoing elective surgical procedures under

general anesthesia without paralysis, where number of attempts for successful insertions were comparable and in majority, device was inserted in first attempt(19/24 in i-gel group and 18/24 in PLMA group)(p=0.918).

Gatward et al,²⁹ evaluated the size 4 i-gel airway in one hundred non-paralysed patients and concluded that the i-gel was successfully inserted in all patients and allowed effective controlled ventilation in 98%, with first time insertion success rate of 86%.

The inflatable cuff of PLMA may be the cause of various malpositions after insertion. The shape, softness and contour of i-gel accurately mirror the perilaryngeal anatomy to create the perfect fit, so that compression and displacement trauma are significantly reduced.⁵¹

The buccal cavity stabilizer of the i-gel has a widened, elliptical, symmetrical and laterally flattened cross sectional shape, providing good vertical stability upon insertion which is an advantage over LMA with inflatable cuffs where mechanical inflation can cause movement of the device, because the distal wedge shape of the mask is forced out of the upper oesophagus.⁵²

The i-gel is easier to insert as the large diameter cylindrical airway tube contained within buccal cavity stabiliser is anatomically widened and concave which eliminates the potential for rotation and provides vertical strength for insertion.⁵³

In our study, the mean duration of insertion was 27.37 ± 2.44 sec in group PLMA and 20.73 ± 2.12 sec in group i-gel. This difference is statistically significant(p<0.001).

In a study done by Das et al,⁵⁴ comparing PLMA and i-gel in ambulatory surgeries, i-gel insertion time was shorter than PLMA (14.9 vs. 20.0 sec respectively) and was statistically significant($p<0.05$). These results are similar to our study.

In another study by Tokgok et al,⁵⁵ comparing efficacies of i-gel and LMA Proseal for airway management in paediatric patients, insertion time was shorter for i-gel group than LMA Proseal group (19 ± 4 sec vs. 28 ± 5 sec, $p<0.01$).

The firmness of the tube section, its natural oropharyngeal curvature allows the device to be inserted by grasping the proximal end of i-gel and helps to glide the leading edge against the hard palate into the pharynx. It is not necessary to insert fingers into the mouth of the patient for full insertion. Apart from these factors, we can also say that the statistically significant higher time taken for placement in the group PLMA patients may be due to the additional time required to inflate the cuff of PLMA.

Oropharyngeal leak pressure values are commonly performed with SAD's to indicate the degree of airway protection, the feasibility for using positive pressure ventilation, and the likelihood of successful supraglottic airway placement.⁵⁶ Aspiration requires regurgitant fluid to reach the laryngeal inlet and it depends on the seal the SAD makes with oesophagus (oesophageal seal) combined with seal with pharynx (pharyngeal seal), which will determine the likelihood of spill into the larynx.

The mean airway sealing pressure in our study was 29.83 ± 1.39 in group PLMA and 25.07 ± 1.44 in group i-gel. The airway sealing pressure was more in PLMA group which is statistically significant ($p < 0.001$).

A study, comparison of Laryngeal Mask Airway Supreme and Laryngeal Mask Airway Proseal with respect to oropharyngeal leak pressure during laparoscopic cholecystectomy was done by Belena et al,⁵⁷ and the mean airway sealing pressure in the PLMA group was significantly higher than that in the LMA supreme group (30.7 ± 6.2 versus 26.8 ± 4.1 cmH₂O; $P < 0.01$). Similar to our study, PLMA achieved a better seal.

In a study done by Chauhan et al,⁵¹ comparing the clinical performance of PLMA and i-gel, i-gel was easier to insert with a better anatomic fit. 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) ($P = 0.001$). Also, mean airway sealing pressure in the PLMA group (29.55 ± 3.53 cm H₂O) was significantly higher than in the i-gel group (26.73 ± 2.52 cm H₂O; $P = 0.001$).

Wharton et al,⁵⁸ evaluated performance of i-gel supraglottic airway device in manikins and anaesthetized patients when used by novice medical students, non anaesthetist physicians and allied health professional all unfamiliar with the i-gel. 50 i-gel were placed in manikins. 88% (44/50) were placed on first attempt with median insertion time of 14 sec (range 7-45). I-gels were placed in 40 healthy anaesthetized patients and success on first attempt was 82.5% (33/40) and on the second attempt 15% (6/40). After three attempts, there were no

failures. Median insertion time was 17.4sec (range 7-197) median airway seal was 20cmH₂O (13-40).

The PLMA has been designed so that the larger, wedge shaped cuff would plug gaps in the proximal pharynx and the flat dorsal cuff would push the ventral cuff more firmly into the periglottic tissues. The wedge shaped proximal cuff is the more important new design feature with respect to improved seal. This latter concept was supported by the fact that OLP was higher at zero cuff volume when the dorsal cuff was deflated.⁵⁹

In our study, visible blood on the device was noted in 6 patients in PLMA group and 1 patient in i gel group which is statistically insignificant. No bronchospasm and laryngospasm were noted in patients of either group.

Singh et al,⁵² studied comparison of clinical performance of i-gel with PLMA in elective surgeries. 60 ASA grade I and II adult patients were randomly assigned into two groups. Group I (n=30) for i-gel and group P (n=30) for PLMA. The success rate at first attempt of insertion were 30/30 (100%) for I-gel & 28/30 (93.3%) for LMA – Proseal which was statistically not significant. However, in our study, only one attempt was allowed before recording failure of insertion. There were no failure of insertions in our study and both devices were placed in the first attempt in all patients. In the same study, the ease of gastric tube placement was more with group I (P >0.05). Blood staining of device and tongue, lip and dental trauma was more with group P (P > 0.05). There was no evidence of bronchospasm, laryngospasm, regurgitation, aspiration or hoarseness in either group. The results of this study are comparable with our study.

In a study done by Sardi et al,³⁵ postoperative throat and neck complaints after the use of the i-gel versus the traditional Laryngeal Mask was compared and they concluded that the group of patients where the i-gel was used presented lower incidence of sore throat (11% vs 27%) and cervical pain (3% vs 9%) and lower values of pressure on the airway tract compared with the group in which the conventional laryngeal mask was used. On the other hand, there was no difference in the presence of dysphonia, trauma or number of attempts used to insert the mask.

The i-gel airway is associated with fewer airway complications. This may be due to gel filled cuff which is less traumatic to the airway. Devices with an inflatable mask like the PLMA have the potential to cause tissue distortion, venous compression, and nerve injury, which explains the increased incidence of associated postoperative morbidity. Trauma on insertion, multiple insertions, and pressure exerted by cuff against the pharyngeal mucosa, cuff volumes and pressure have all been incriminated for postoperative complications of PLMA.⁶⁰

Thus, the results of these various studies comparing the efficacy of the i-gel with already established devices such as PLMA in adult patients are comparable to the results of our study with respect to higher airway sealing pressure in PLMA group and greater time taken for insertion. No significant difference was found in the ease of insertion between the groups. Minimal complications were observed in both the groups.

LIMITATIONS

Firstly, in our study, size 4 of both PLMA and i-gel were compared. Therefore the results may not be applicable to other sizes.

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

SCOPE FOR FURTHER STUDIES

Further studies can be done to evaluate the PLMA and i-gel in the difficult airway scenario.

They can also be studied in the ICU setting.

Chapter 8

Conclusion



CONCLUSION

The conclusions drawn from this study where we compared PLMA(size 4) and i-gel(size 4) are:

- The i gel was easier to insert than the PLMA in anaesthetized paralysed adult patients.
- Airway sealing pressures were higher for PLMA; therefore PLMA provided a more effective seal than i gel for positive pressure ventilation.
- The PLMA was associated with higher incidences of visible blood on the device and both devices had no incidences of laryngospasm and bronchospasm.

Chapter 9

Summary



SUMMARY

Our present study titled “**Comparison of Proseal Laryngeal Mask airway and i-gel supraglottic airway for ease of insertion and airway sealing pressure in adult patients under general anaesthesia-A one year randomized clinical trial**” was aimed to compare the PLMA and i-gel with regard to ease of insertion, duration of insertion, airway sealing pressure and complications.

The study was conducted in 60 ASA grade I and II adult patients of both sexes, aged between 18 and 50 years posted for elective surgeries under general anaesthesia in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2013 to December 2013. After obtaining the approval from the hospital ethical committee, the patients were randomly allocated to group A: i-gel (n=30) and group B:PLMA(n=30). The demographic data were comparable in both groups.

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

The ease of insertion , duration of insertion and airway sealing pressure were recorded. Anaesthesia was maintained with isoflurane in 1:1 oxygen-nitrous oxide mixture and vecuronium.

At the end of procedure, patient was reversed and the airway device was removed and examined for the presence of visible blood. Any incidences of laryngospasm and bronchospasm were noted.

In our study, the i-gel was easier to insert in comparison to PLMA. Difficult insertion was seen in 2 patients in i-gel group(6.67%) and 8 patients in PLMA group(26.7%).However, the difference was not statistically significant($p=0.0832$). There were no failed insertions in our study.

The mean duration of insertion was 20.73 ± 2.12 sec in i-gel group and 27.37 ± 2.44 sec in PLMA group. This difference was statistically significant ($p<0.001$). The PLMA provided a more effective seal than i-gel for positive pressure ventilation. The mean airway sealing pressure was 29.83 ± 1.39 in PLMA group and 25.07 ± 1.44 in i-gel group which was statistically significant ($p<0.001$).

In our study, visible blood on the device was noted in 6 patients in PLMA group and 1 patient in i-gel group which was statistically insignificant. No bronchospasm and laryngospasm were noted in patients of either group.

To summarise our study, the i-gel was easier to insert than PLMA in anaesthetized paralysed adult patients, but airway sealing pressures were higher for the PLMA. The PLMA provided a more effective seal than i gel for positive pressure ventilation. The PLMA was associated with higher incidences of visible blood on the device and both devices had no incidences of laryngospasm and bronchospasm.

Chapter 10

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Annexures

Annexure III



ANNEXURE II – PROFORMA

TITLE: “COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL SUPRAGLOTTIC AIRWAY FOR EASE OF INSERTION AND AIRWAY SEALING PRESSURE IN ADULT PATIENTS UNDER GENERAL ANAESTHESIA – A ONE YEAR RANDOMIZED CLINICAL TRIAL”

Patient’s name:

Age:

I.P no.:

Sex:

Occupation:

Address:

Anesthesiologist:

Preoperative diagnosis:

Name of the operation:

PRE-ANAESTHETIC EVALUATION

History in brief

Chief complaints:

Past history:

Personal history:

Drug therapy:

Previous anaesthetic experience:

General physical examination

Height :

Weight :

Pallor / Edema / Icterus / Cyanosis / Clubbing / Lymphadenopathy

P.R.:

R.R.:

B.P.:

Temperature:

Musculoskeletal system examination

Teeth:

Jaw movements:

Airway assessment:

Spine:

Systemic examination

CVS:

RS:

CNS:

GIT:

Investigations

Hb%:

Urine routine:

RBS:

Blood urea:

S. Creatinine:

ECG:

Chest X-ray:

ASA Grade:

Inclusion

- Elective surgeries under general anaesthesia in supine position, less than two hours duration.
- Age between 18 to 50 years.
- ASA status I or II.
- Weight 50-70 kgs

Exclusion

- Known or predicted difficult airway.
- Any pathology of the neck, upper respiratory tract or upper gastrointestinal tract.
- History of obstructive sleep apnea.

- Trendelenburg's position.
- History of cardiopulmonary disorders.
- Potentially full stomach patients (trauma, pregnancy, morbid obesity, hiatus hernia).
- Cervical spine disorders

Procedure

In the operating room, a standard anaesthesia protocol was followed and routine monitoring was applied with electrocardiograph, non-invasive blood pressure, pulse oximetry (SPO₂) and end tidal CO₂ monitoring. The head and neck of the patient were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height.

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

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

Anaesthesia was induced with inj. Propofol 2 mg/kg (IV) and neuromuscular blockade was achieved with inj. Vecuronium 0.1 mg/kg (IV). Patient's lungs were ventilated with a face mask for three to five minutes and then the airway device (size 4) was inserted in strict accordance with the manufacturer's recommendations.

Insertion technique :

PLMA: The standard index finger method as recommended by the manufacturer for size 4 was used. PLMA cuff was deflated, held like a pen, with the index finger tip placed in the introducer strap. It was then pressed against the hard palate and advanced into the hypopharynx until resistance was felt. The finger in the retaining strap was pushed towards the occiput, while the other hand exerted counter pressure to maintain the sniffing position. Before removing the finger, the non-dominant hand was brought from behind the patient's head to press down on the airway tube. This prevents the PLMA from being pulled out of place when the finger is removed.

i-gel: The leading soft tip was introduced into the mouth of the patient in a direction towards the hard palate. The device was glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt.

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

Failed insertion was defined by any of the following criteria.

- Failed passage into the pharynx.
- Malposition (air leaks).
- Ineffective ventilation (maximum expired tidal volume <6 ml/kg or/and end tidal CO₂ > 60 cm of H₂O).
- More than one attempt

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

For PLMA, the intra cuff pressure was set at 60 cm H₂O to obtain an effective airway seal for positive pressure ventilation and patient's lungs were ventilated at an inspired tidal volume of 8 ml/kg, at a respiratory rate of 12 breaths/minute and an inspiratory : expiratory ratio of 1:2. Anaesthesia was maintained with 1:1 oxygen-nitrous oxide mixture, isoflurane and inj. Vecuronium 0.025 mg kg⁻¹(IV) boluses.

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

Study variables:

The ease of insertion was defined as:

- Easy- no resistance to insertion in the pharynx in a single maneuver.
- Difficult- resistance to insertion or more than one maneuver 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.

The duration of insertion was defined as the time between picking up the prepared Proeal LMA or i-gel supraglottic airway and successful placement of the device.

Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 liter/min, and noting the airway pressure in the anaesthetic breathing system at equilibrium (maximum allowed was 40 cm H₂O) using manometer. .

The aetiology of failed insertion (if any) was documented.

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 were documented.

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

OBSERVATIONS:

Ease of Insertion	
Easy	Difficult

Duration of insertion (sec)	
Airway sealing pressure (cm of H₂O)	

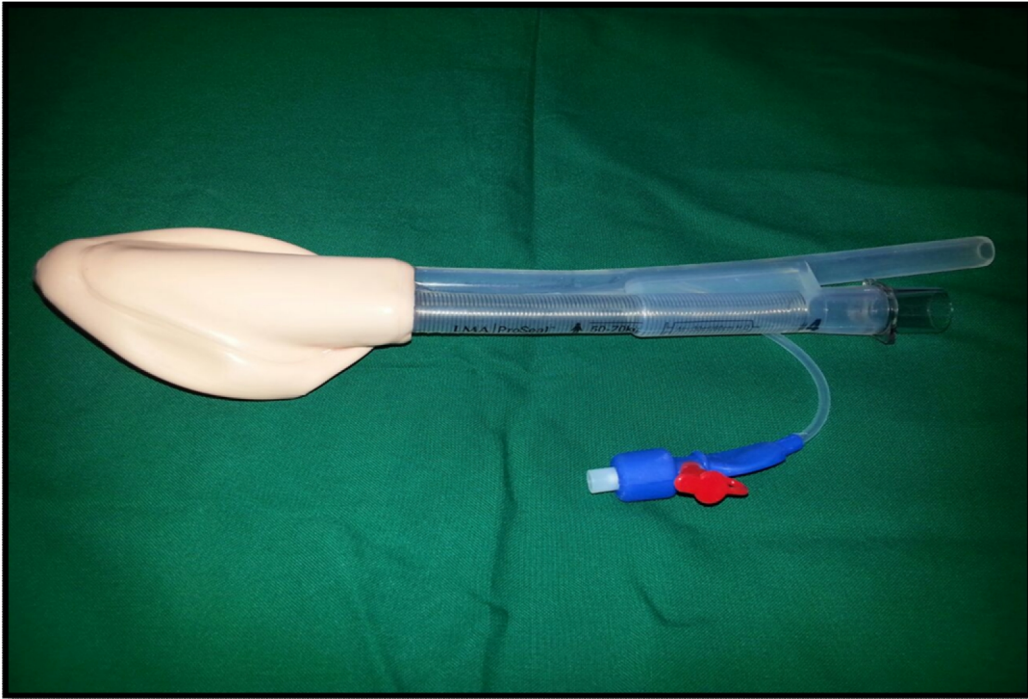
Complications (visble blood on device, bronchospasm and laryngospasm)	
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Annexures

Annexure III



ANNEXURE III – PHOTOGRAPHS



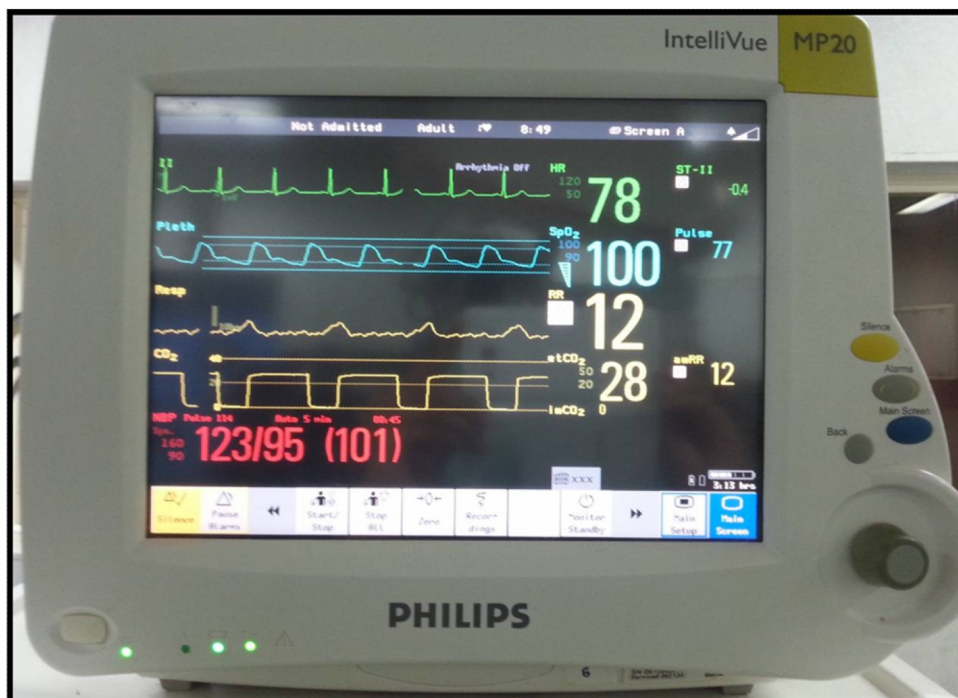
Photograph 1. Proseal Laryngeal Mask Airway



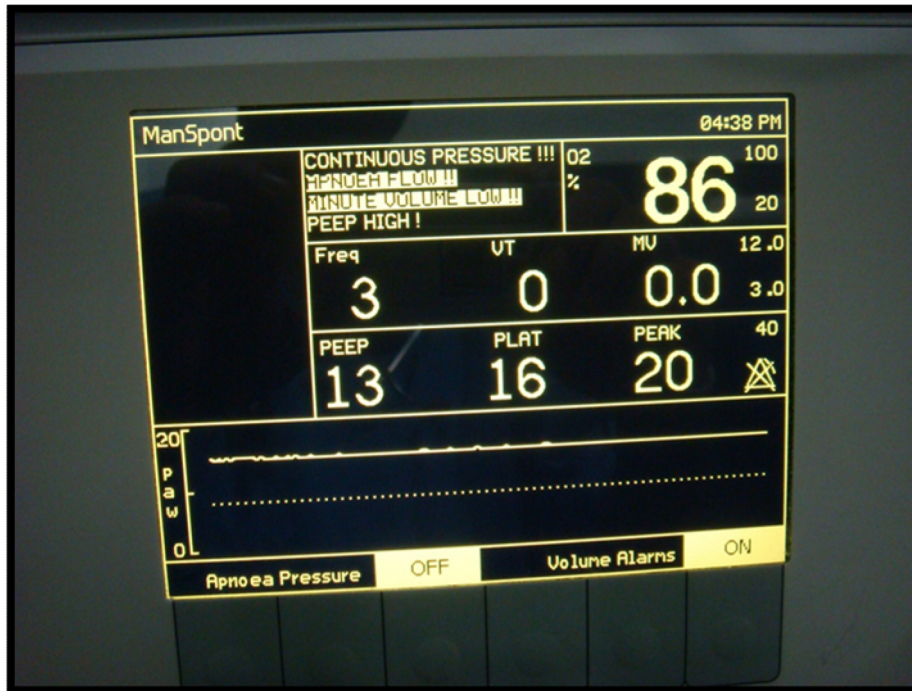
Photograph 2. i-gel supraglottic airway



Photograph 3. Anaesthesia work station(Drager Fabius plus)



Photograph 4. Monitor



Photograph 5. Measurement of oropharyngeal leak pressure



Photograph 6. Cuff pressure manometer

Annexures

<h2>Annexure IV</h2>



KEY TO MASTER CHART

ASA	-	American society of Anaesthesiologists
cm	-	Centimeter
F	-	Female
H ₂ O	-	Water
kg	-	Kilograms
M	-	Male
MPG	-	Mallampati grade
PBC	-	Post Burn Contracture
#	-	Fracture

Annexures

Annexure J



ANNEXURE I – CONSENT FORM

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled “**COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL SUPRAGLOTTIC AIRWAY FOR EASE OF INSERTION AND AIRWAY SEALING PRESSURE IN ADULT PATIENTS UNDER GENERAL ANAESTHESIA – A ONE YEAR RANDOMIZED CLINICAL TRIAL**” at KLES DR. Prabhakar Kore Hospital and Medical Research Centre, Belgaum conducted by Department of Anaesthesiology, J. N. Medical College, Belgaum under KLE university, Belgaum.

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

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

The purpose of research is to compare proseal laryngeal mask airway and i-gel supraglottic airway for ease of insertion and airway sealing pressure in adult patients under general anaesthesia.

Procedure Involved

If you agree to enroll yourself in my study, I will ask your present, past and family history. Then you will be clinically examined in detail and routine investigations like haemoglobin will be done. After administering general anesthesia with I.V induction agents and muscle relaxation with vecuronium, one of the randomized supraglottic airway devices will be inserted and connected to the mechanical ventilator system for positive pressure ventilation.

Risks and Benefits

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

Voluntary Participation / Withdrawal

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

Alternatives

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

Privacy and Confidentiality

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

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

Authorization to Publish Results

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

Financial Incentives for participation

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

Compensation:In the event of injury related to the study, treatment will be made available through KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Questions

If you have any questions about the research you may please contact:

1. Investigator, _____ Post Graduate student,
Department of Anaesthesiology, JNMC, Belgaum.
2. Guide, _____ Professor, Department of Anaesthesiology,
JNMC, Belgaum
3. _____ Principal, JNMC, Belgaum and Chairman,
Institutional Ethics Committee.

Consent for participation in research trial

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

Subject Name : _____

Signature or the Left Thumb Print of Subject: _____

Date:

Witness' Name : _____

Signature : _____

Date :

Investigator's Name : _____

Signature : _____

Date :

Place : _____

GROUP -A

S.No	IP NO.	SEX	WEIGHT (kg)	AGE (YEARS)	ASA GRADE	MPG GRADE	PROCEDURE	EASE OF INSERTION	DURATION OF INSERTION (seconds)	AIRWAY SEAL PRESSURE(cm H2O)	COMPLICATIONS		
											LARYNGO-SPASM	BRONCHO-SPASM	VISIBLE BLOOD ON THE DEVICE
1	542431	M	51	20	1	I	Umbilical hernia repair	difficult	25	26			
2	554678	F	53	26	2	I	Open tubectomy	easy	19	24			
3	543678	F	62	46	2	II	Dynamisation-tibia	easy	22	27			
4	553421	M	54	28	1	II	Humerus implant removal	easy	24	25			
5	543671	M	58	26	2	I	Inguinal hernia repair	easy	23	26			
6	558976	M	58	35	1	I	Ganglion excision	easy	20	27			
7	563476	F	57	38	1	II	Fibroadenoma excision	easy	21	25			
8	561023	M	56	46	2	I	Open appendicectomy	easy	22	24			
9	556383	F	54	36	1	II	Open cholecystectomy	easy	19	23			
10	544518	M	67	33	1	II	Circumcision	easy	23	26			
11	544519	F	64	31	1	II	Biopsy of axillary lymph node	difficult	26	27			
12	555643	M	63	42	1	II	Secondary suturing	easy	20	28			
13	563573	M	52	41	1	II	Scalp lipoma excision	easy	19	22			
14	558561	F	51	48	2	II	Scalp sebaceous cyst excision	easy	20	23			
15	557567	M	61	44	1	I	Inguinal hernia repair	easy	17	24			
16	555947	F	67	23	1	I	Umbilical hernia repair	easy	18	25			
17	551288	M	64	33	2	I	Open appendicectomy	easy	19	25			
18	556374	M	55	47	2	II	Cervical lymph node biopsy	easy	20	26			
19	557082	F	53	32	1	I	Open tubectomy	easy	19	26			
20	557014	F	52	36	1	II	Debridement and grafting	easy	20	26			
21	567091	F	60	48	1	I	Ganglion excision	easy	22	24			
22	542789	M	61	40	2	II	Radius #-open reduction	easy	20	25			YES
23	560009	F	51	39	2	I	PBC forearm-release	easy	22	24			
24	567901	M	54	28	1	II	Open appendicectomy	easy	23	26			
25	546789	F	53	22	2	I	uterine polypectomy	easy	18	25			
26	554321	F	55	35	1	II	Hand ulcer-debridement	easy	20	24			
27	564502	M	65	45	2	II	Exostosis excision	easy	21	25			
28	560076	M	62	48	2	I	Hydrocoele repair	easy	19	27			
29	560987	F	58	42	1	I	Foot ulcer-I &d	easy	21	23			
30	549800	F	59	36	2	I	Ulna #-open reduction	easy	20	24			

GROUP -B

S.No	IP NO.	SEX	WEIGHT (Kg)	AGE (YEARS)	ASA GRADE	MPG GRADE	PROCEDURE	EASE OF INSERTION	DURATION OF INSERTION (seconds)	AIRWAY SEALING PRESSURE (cm H ₂ O)	COMPLICATIONS		
											LARYNGO-SPASM	BRONCHO-SPASM	VISIBLE BLOOD ON THE DEVICE
1	557891	F	55	18	1	I	Fibroadenoma excision	easy	25	28			
2	560987	F	60	48	1	II	Cervical polypectomy	difficult	32	29			
3	547643	M	63	36	1	II	Excision of lipoma-thigh	easy	27	30			
4	550098	F	52	46	1	II	Open tubectomy	easy	27	29			
5	568907	M	63	49	1	I	Epigastric hernia repair	easy	28	32			
6	560074	M	55	48	2	I	Metacarpal #-kwire insertion	easy	26	30			YES
7	554000	M	55	42	2	II	Open appendectomy	easy	26	31			
8	560046	M	57	32	1	II	Dupytren's contracture release	difficult	31	32			
9	568345	F	60	34	1	I	Median nerve repair	easy	24	28			
10	543087	M	58	47	2	I	Cervical lymph node biopsy	easy	25	29			YES
11	548091	F	52	44	2	II	Breast abscess-i&d	difficult	32	30			
12	542000	F	53	41	2	II	Fibroadenoma excision	easy	25	30			
13	561090	F	62	23	1	I	Secondary suturing	easy	27	29			YES
14	567813	M	54	19	1	II	Inguinal hernia repair	easy	26	29			
15	553009	M	54	39	2	I	Open cholecystectomy	easy	25	31			
16	541086	F	61	25	1	II	# radius-closed reduction	easy	26	31			
17	547785	F	56	44	2	II	Ovarian cystectomy	difficult	30	32			YES
18	547001	M	57	46	2	I	Debridement and grafting	difficult	31	33			
19	548885	F	54	47	2	I	Abdominal hysterectomy	easy	26	29			YES
20	540980	M	58	21	1	II	Burns dressing	easy	25	29			
21	560963	M	51	45	2	I	Tibia dynamisation	easy	27	28			
22	543081	M	62	20	1	I	Open appendectomy	difficult	30	30			YES
23	561117	M	64	34	1	II	Inguinal hernia repair	easy	27	31			
24	567788	F	60	36	1	II	Fibroadenoma excision	easy	26	27			
25	549993	F	54	37	1	II	Open tubectomy	easy	24	30			
26	567106	M	53	38	1	I	Axillary lymph node biopsy	easy	26	30			
27	541074	M	63	49	1	I	Secondary suturing	difficult	29	31			
28	555512	F	59	44	1	I	Cervical polypectomy	easy	28	29			
29	542900	M	57	32	1	II	Debridement and grafting	easy	28	29			
30	549876	M	62	23	1	I	Hydrocoele repair	difficult	32	29			