"COMPARISON OF AIRWAY SEALING PRESSURE BETWEEN PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL SUPRAGLOTTIC AIRWAY IN ADULT PATIENTS UNDERGOING LAPAROSCOPIC SURGERIES REQUIRING GENERAL ANAESTHESIA – A ONE YEAR HOSPITAL BASED RANDOMIZED CLINICAL TRIAL"

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This is to certify that the dissertation entitled **"COMPARISON OF AIRWAY SEALING PRESSURE BETWEEN PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL SUPRAGLOTTIC AIRWAY IN ADULT PATIENTS UNDERGOING LAPAROSCOPIC SURGERIES REQUIRING GENERAL ANAESTHESIA – A ONE YEAR HOSPITAL BASED RANDOMIZED CLINICAL TRIAL"** is a bonafide research work done by **(REG NO. BA0116001).**

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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 gauge
GIT	-	Gastrointestinal tract
H_2O	-	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
PCV	-	Pressure controlled ventilation

ABSTRACT

Introduction: Airway management by anaesthesiologists has come a long way from the invention of endotracheal intubation. Invention of Supraglottic airway devices (SAD) provided alternate ways to establish definitive airway without hazards of direct laryngoscopy and intubation. First generations SAD were considered airway tubes, and hence modifications were made to make them better. The proseal laryngeal mask airway (PLMA) is a second generation SAD, which has a gastric drain port along with the airway tube. It has been a boon to anaesthesiologists ever since it came into clinical practice. The i-gel (intersurgical) is a recent novel second generation SAD 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 and i-gel for ease of insertion, duration of insertion, airway sealing pressure and complications in anaesthetized, paralysed adult patients undergoing positive pressure ventilation under general anaesthesia for laparoscopic surgeries.

Methodology: The present randomized clinical trial was conducted in 60 ASA I and II patients, aged between 18-60 years posted for elective laparoscopic surgeries under general anaesthesia in KLES Dr. Prabhakar Kore charitable Hospital and Medical Research Centre, Belagavi. Patients were allocated into two equal groups, Group P. PLMA (n=30) and Group I. i-gel (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 we observed that, i-gel was easier to insert in comparison to PLMA. Difficult insertion was seen in 10 patients in PLMA group (33%) and 4

patients in i-gel group (13%) with statistically significant difference (p=<0.0001). The mean duration of insertion was 16.9 ± 3.39 sec in PLMA group and 12.63 ± 2.04 sec in i-gel group which was statistically significant (p<0.0001). Soon after the insertion of SAD, PLMA provided a more effective seal than i-gel for positive pressure ventilation. But as the procedure progressed, effective seal was better with i-gel than PLMA. The mean airway sealing pressure soon after insertion was 25.3 ± 3.395 cm of H_2O in PLMA group and 21.933 ± 1.76 cm of H_2O in i-gel group which was statistically significant (p<0.0001). The mean airway sealing pressure after 30 min of pneumoperitoneum and after 30 min of trendelenburg position was 21.733 ± 2.016 cm of H_2O in PLMA group and 27.767 ± 1.716 cm of H_2O in i-gel group; 20.267 ± 1.617 cm of H_2O in PLMA group and 24.133 ± 2.097 cm of H_2O in i-gel group respectively. Incidence of post operative hoarseness of voice was higher in PLMA group than i-gel group, but was statistically insignificant.

Conclusion: To conclude, we observed that, i gel was easier to insert than PLMA in anaesthetized paralysed adult patients, and the time taken for successful insertion was shorter with i-gel than with PLMA. Mean airway sealing pressure was initially higher in PLMA group with statistical significance, but as the surgery progressed, airway sealing pressure of i-gel was significantly higher than with the PLMA group. Incidence of post-operative hoarseness of voice was higher in PLMA group, though statistically insignificant.

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

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INTRODUCTION

The most vital element in providing functional respiration, both in hospital and outside hospital settings, is establishing a patent airway. The primary goal of the anaesthesiologist is to maintain a patent airway. In addition to it, providing adequate oxygenation and ventilation is an important consideration in both emergency and elective situation.

Management of the airway has come a long way since the development of Endotracheal Intubation by Macewen in 1880, until the present day, where the usage of sophisticated devices has helped us securing a definitive airway [1]. Before general anaesthesia is administered, patients are induced and preoxygenated with a face mask. When a face mask is being used, the gap between the base of tongue and the glottis is not bypassed, which may cause obstruction during anaesthesia. This gap is overcome by traditional tracheal intubation with the aid of rigid laryngoscopes. However, laryngoscopy and tracheal intubation triggers adverse response such as increase in the level of plasma catecholamines, hypertension, tachycardia, arrhythmia, myocardial ischaemia and an increase in intracranial and intraocular pressure [2,3]. Apart from the above mentioned adverse effects, laryngoscopy and endotracheal intubation requires skill, continuous training and practice.

Dental damage remains to be the most common anaesthesia related injury, followed by respiratory related events. 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[4].

The Laryngeal Mask Airway (LMA) fills a niche between the face mask and Endotracheal tube in terms of both anatomical position and degree of invasiveness [5]. Since their introduction, LMA have evolved from an alternative airway management strategy, to a potential life saving tool integrated into American Society of Anaesthesiologists (ASA) guidelines for most difficult airway management algorithms [6].

First Supraglottic Airway Device (SAD) or Laryngeal Mask Airway (LMA) was described in 1983 by Dr. Archie Brain. Since the time of its discovery, though initially criticized, later was accepted worldwide by 1988 [3].

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

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

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]. Further few modifications were made on Classic LMA (cLMA) for easier and effective usage. These modifications led to invention of newer supraglottic airways namely LMA Supreme, Proseal LMA, LMA Fastrach, SLIPA, i-gel etc,.

Proseal Laryngeal Mask Airway (PLMA) is a second generation supraglottic airway device offering gastric access. It is a reusable device which was introduced into clinical practice in 2000. The Proseal LMA facilitates positive pressure ventilation as it offers higher glottic seal pressures than the cLMA. It has a built-in drain tube that allows passage of orogastric tube for draining of gastric contents and prevents aspiration. The drain tube also allows instant clinical diagnosis of device mispalcement. The Proseal LMA reduces the likelihood of throat irritation and stimulation, which inturn reduces postpoperative nausea and vomiting by as much as 40% compared to an ETT [10,11].

The i-gel supraglottic airway device (Intersurgical Ltd., Wokingham, Berkshire, UK) is made up of a thermoplastic elastomer (SEBS- Styrene Ethylene Butadiene Styrene) with a soft durometer (hardness), which has a gel-like feel. It was developed in 2007 and is a single use second generation supraglottic airway device [12]. The shape, softness and contour accurately mirror the perilaryngeal anatomy to cause a perfect fit. Trauma associated with cuff inflation and compression on the surrounding tissues is significantly reduced due to the 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].

Proseal LMA and i-gel have been used successfully in short procedures requiring general anaesthesia. In the recent time surgeries are progressing towards minimally invasive surgeries. Due to which, use of Laryngeal Mask Airway in

laparoscopic surgeries has been exclusively studied. Both Proseal LMA and i-gel have been used in laparoscopic surgeries successfully. The results of these studies showed varied results regarding ease of insertion, time taken for SAD insertion, airway sealing pressure during pneumoperitoneum [16,17].

Hence, we compared Proseal LMA and i-gel regarding ease of insertion, time taken for insertion and airway sealing pressure at different timing during the procedure in adult paralysed patients undergoing laparoscopic surgeries under general anaesthesia.

AIMS AND OBJECTIVES

The aims and objectives of the study were to compare the supraglottic airway devices, Proseal LMA and i-gel for:

1. Ease of insertion
2. Time taken for insertion
3. Airway Sealing pressure at different timings during the procedure like
    i. After insertion
    ii. 30 minutes after pneumoperitoneum
    iii. 30 minutes after trendelenberg
    iv. Before extubation (at neutral position)
4. Post-operative hoarseness of voice.

REVIEW OF LITERATURE

Endotracheal intubation is considered gold standard for establishment of a definite airway for positive pressure ventilation [5,18]. Tracheal intubation or ventilation with face mask were the only options available for airway management in 20th century. When a patient is ventilated using a face mask, the gap between the base of the tongue and the glottis can cause obstruction during anaesthesia as upper airway muscle tone decrease and gravity approximates the pharyngeal tissues. Tracheal intubation bypasses all these problems but has its own disadvantages as mentioned earlier [3,16].

To overcome these problems the LMA was invented and designed in 1981 by Dr.Archie Brain at the Royal London Hospital [3,19] . The first prototype was constructed using the cuff of a Goldman paediatric dental mask which was stretched onto the diagonally cut endotracheal end of a portex 10 mm clear plastic tube and fixed into position with acrylic glue [19] . 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 [3,4,19] .

First independent assessment of the LMA was made by Brodrick et al [17] ,in 1989, who obtained a clinically satisfactory and unobstructed airway in 98/100 patients. They described the LMA as the missing link between the face mask and tracheal tube. Three excellent features were described in this study: excellent airway patency, no manual support of jaw required which allowed to free anaesthesiologist hands for monitoring and documenting, and good for transfer of the patient to post

anaesthesia care unit and recovery. By 1993, the LMA was widely accepted and included in the ASA algorithm for unanticipated difficult airway [3] .

Invention of LMA, lead to their extensive usage in patients requiring controlled ventilation. First generation devices such as cLMA, flexible LMA and LMA-unique are simply 'airway tubes'. During their usage, they encountered certain drawback like gastric insufflations and gastric content aspiration. Hence modifications were made to increase the efficiency of LMA. This lead to invention of newer LMA classified as second generation LMA. Devices such as Proseal LMA, LMA Supreme and i-gel airway have inbuilt orogatsric tube port which drains gastric contents and protects patient from aspiration of gastric contents [8]

The Proseal Laryngeal Mask Airway (PLMA) is a second generation LMA which was introduced in the year 2000. PLMA is a reusable laryngeal mask device with a modified cuff, to improve seal and a drainage tube, to provide a channel for orogastric tube insertion and gastric content aspiration.

A study conducted by Ganzouri et al [20], compared Proseal LMA and Endotracheal tube (ETT) regarding ease of insertion, hemodynamic responses and emergence characteristics. Results of this study revealed that ease of PLMA insertion was rated excellent in 98% of patients. It was accomplished in 7± 14 sec. 19% of patients required reinsertion due to unsatisfactory initial positioning. Significant hemodynamic differences were observed between the groups in response to the airway device insertion. Maximum MAP and HR were significantly increased in ETT group when compared to PLMA group, during insertion and removal. During emergence, PLMA patients had significantly lower incidence of coughing (15% vs

86%, p<0.01). 24 hours postoperatively both PLMA and ETT patients had similar incidence of sore throat (48% vs 41% respectively)

A multicentre study was done by Brimacombe et al [21], compared the Proseal LMA (PLMA) and LMA Classic (cLMA) in anaesthetized non paralysed patients, revealed that the cLMA was easier and quicker to insert at the first attempt. Though insertion was difficult, success rates after three attempts for the PLMA were high (98%) and similar to that of cLMA (100%). PLMA formed a better seal, 5 cm H_2O above that formed by cLMA (27 $\pm$ 7 vs. 22 $\pm$ 6 cm of H_2O). Fiberoptically determined anatomic position was better with the cLMA than PLMA (P < 0.0001). Orogastric tube insertion was more successful after two attempts (88 *vs.* 55%; P < 0.0001) and quicker (22 $\pm$ 18 *vs.* 38 $\pm$ 56 s) with PLMA. There were no differences in total intraoperative complications.

In a randomized cross over study done to compare the Proseal LMA (PLMA) and Classic LMA (cLMA) in anaesthetized paralysed patients [22], conducted by Brimacombe et al, 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 cLMA. Airway sealing pressure was significantly higher in PLMA group (8-11 cm H_2O), at all cuff volumes (P <0.00001). Fiberoptic position was significantly better with the cLMA at all cuff volumes (P<0.00001), but vocal cord visibility was similar (cLMA-59/60 and PLMA- 56/60). When the devices were introduced with the introducer, first time success rates were comparatively higher (59 of 60 vs 53 of 60; P=0.03) and the effective airway time shorter (15 $\pm$ 13 sec vs 23 $\pm$ 18 sec; P=0.008).

A study compared Proseal LMA (PLMA) and Laryngeal Tube Airway (LTA) in paralyzed anaesthetized adult patients undergoing pressure controlled ventilation

(PCV) [23]. In this study, it was seen that first attempt success rates were similar in both the groups (PLMA-85%; LTA-87%), but after 3 attempts, success was higher for the PLMA (100% vs 92%, *P*=0.02). Effective airway time was similar in both the groups. Oropharyngeal leak pressure was higher for PLMA at 50% maximal recommended cuff volume (33 $\pm$ 7 vs 31 $\pm$ 8 cm H_2O). Tidal volumes (614 $\pm$ 173 vs 456 $\pm$ 207 ml, *P*<0.001) were significantly larger and EtCO2 (33$\pm$9 vs 40$\pm$11 mmHg, *P*=0.0001) significantly lower for 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 [24], studied Proseal LMA (PLMA) in 300 cases and concluded that the PLMA is a reliable airway management device which provides an effective glottic seal in both, paralysed and non-paralysed patients. Results of this study revealed successful insertion rate of 98% (294/300) of which 91 % were graded as easy (274). They didn't find any statistically significant difference for insertion with introducer or finger insertion method. Mean airway seal pressure was 29 cm of H_2O, with 20% patients having sealing pressures greater than 40 cm H_2O (59/294). Success rate of orogastric tube placement was 98.6% (290/294). Hemodynamic stability was observed during insertion of the device, with a small reduction in HR, 5 minutes after insertion and significant decreases in MAP at 1 and 5 minutes after insertion. 23 % of patients complained of sore throat immediately after surgery and 16% after 24 hours. 90% of the patients with sore throat described it to be of mild grade.

The i-gel airway is a recent supraglottic airway device, manufactured by Intersurgicals UK, brought into market in 2007. Its designed to fit the peripharyngeal and hypopharyngeal structure without use of an inflatable cuff. It is made of a

thermoplastic elastomer with a soft non-inflatable cuff which provides a seal in patients with a wide range of anatomical variations [25]. It is a single use supraglottic airway device (SAD) with a gastric port for OGT insertion, invented by Dr. Mohammed Aslam Nasir[26].

Richez et al [27], carried out one of the earliest studies to evaluate i-gel. They found that success rate for first attempt insertion was 97%, of which 93% was very easy and 7% was easy insertion. Only 2 failures were reported in the study, both of which were due to pharyngeal leak. Both the cases PLMA insertion also failed resulting in endotracheal intubation for securing the airway. Insertion of OGT was successful in all the cases. Hence this study concluded that i-gel was easily and rapidly inserted, to provide a reliable airway in over 90% of cases.

A study conducted by Uppal et al[28], compared i-gel with cuffed ETT for gas-leaks during pressure controlled ventilation (PCV). This study showed that there was no statistically significant difference between the leak fractions of the i-gel and ETT at 15 and 20 cm H_2O PCV. At 25 cm H_2O, the median difference in leak fraction was 0.02 (P= 0.014) and the median difference in leak volume was 26.5 ml (P= 0.006). Hence it was concluded that at moderate airway pressures, i-gel can be used as a reasonable alternative to ETT during PCV.

A comparative study was done by Teoh et al [29], between LMA Supreme and i-gel on 100 paralyzed adult patients undergoing laparoscopic surgeries in trendelenburg position on controlled ventilation. The results of this study showed that there was no statistically significant differences in oropharyngeal leak pressure between LMA Supreme and the i-gel (26.4 $\pm$ 5.1 vs 25.0 $\pm$ 5.7 cm of H_2O respectively). 47 LMA Supreme (94%) and 48 i-gel (96%) were successfully inserted

in the first attempt. Ease of insertion and time to achieve an effective airway successfully were similar in both the groups. Differences between expired and inspired tidal volumes after creation of pneumoperitoneum, were smaller with LMA Supreme (21.5/15.2 ml) than with the i-gel (31.2/23.5 ml). 2 LMA Supreme and 1 i-gel had blood staining at removal.

A study conducted by Gatward et al [30], evaluated size 4 i-gel in 100 non-paralyzed anaesthetized patients. They found that in 86% of patients successful insertion was obtained at first attempt. Whereas 11% of patients required second attempt and 3% required third attempt for successful i-gel insertion. Median insertion time was 15 sec. Median airway leak pressure was 24 cm H_2O. They concluded that i-gel is a newer SAD with easy and rapid insertion to provide a reliable airway in over 90%.

Similar results were observed in a study done by Acott C J [31], in which i-gel SAD was assessed during general anaesthesia. They reported that in majority of the patients first attempt was successful to establish a patent airway. All the i-gel insertions were done within 10 sec.

Schmidbauer et al[32], compared i-gel, cLMA and PLMA regarding airway sealing pressure in a cadaver model. It was observed that during the slow increase of pressure, the PLMA withstood an oesophageal pressure up to a median of 58 cm of H_2O, while the cLMA was able to block the oesophagus up to a median of 37 cm H_2O, and i-gel already lost its seal at 13 cm H_2O. One minute after maximum pressure was applied, the PLMA withstood an oesophageal pressure of 59 cm H_2O, the cLMA of 46 cm H_2O, and i-gel airway of 21 cm H_2O. A fast release of oesophageal fluid was accomplished through the gastric ports of both the PLMA and i-gel.

A randomized, non-crossover study conducted by Gasteiger et al[33], studied the ease of insertion using a duodenal tube guided insertion technique and the oropharyngeal leak pressure difference between the Proseal LMA (PLMA) and i-gel in non-paralysed, anesthetized female subjects. Insertion success rate, insertion time and oropharyngeal leak pressure were the parameters measured. First attempt successful insertion rate and overall insertion success rate were similar (PLMA- 75/76(99%) and 76/76 (100%); i-gel- 73/75 (97%) and 75/75 (100%) respectively). Mean (SD) insertion times with PLMA and i-gel were also similar without any statistically significant difference (PLMA- 40 (16) sec, i-gel- 43(21) sec). Mean oropharyngeal leak pressure was 7 cm H_2O higher with PLMA when compared to i-gel (P<0.0001). Method of insertion did not make any difference according to this study.

Shin et al [34], compared i-gel with Proseal LMA (PLMA) and Classic LMA (cLMA) in anaesthetized patients. Airway leak pressures of i-gel group (27.1 $\pm$ 6.4 cm H_2O) and PLMA group (29.8 $\pm$ 5.7 cm H_2O) were significantly higher than that of the cLMA group (24.7 $\pm$ 6.2 cm H_2O). The first attempt success rates were similar in all three LMA. Incidence of sore throat was observed to be higher in cLMA than PLMA or i-gel.

In one of the earliest studies comparingProseal LMA (PLMA), i-gel and LMA Supreme by Zundert and Brimacombe [35], it was reported that there were no differences in oxygen saturation, end-tidal CO_2 or hemodynamic data among groups. The LMA Supreme was easier (P<0.05) and quicker (P<0.01) to insert than the PLMA and i-gel. The first attempt success rates were 80% (i-gel), 84% (PLMA) and 100% (LMA Supreme). Oropharyngeal leak pressures were similar among groups

during apnoea (1 min) and spontaneous ventilation (at 30 and 60 min). Intracuff pressure increased slightly in both PLMA and LMA Supreme, and there were no differences in secondary variables among the groups.

In a study by Sardi et al [36], postoperative throat and neck complaints were compared after the use of i-gel vs cLMA. They concluded that the group of patients where the i-gel was used had lower incidence of sore throat (11% vs 27%) and cervical pain (3% vs 9%) compared with the cLMA group. On the other hand, number of attempts for insertion, and dysphonia were equal in both the groups. They summarized i-gel to be safe, with low incidence of morbidity to the airway during general anaesthesia.

In a randomized clinical trial conducted by Mishra et al [37], effect of pneumoperitoneum and trendelenburg position on airway sealing pressure of i-gel and PLMA were studied in adult patients undergoing laparoscopic gynaecological surgeries. This study revealed that the initial oropharyngeal leak pressure of i‑gel was significantly less than the PLMA (mean (SD) 24 (4) vs. 29 (4) cmH_2O, respectively; $P < 0.001$). After pneumoperitoneum, the leak airway pressure in i‑gel group was significantly less than that of PLMA group (mean (SD) 27 (3) vs. 34.0 (4) cmH_2O, respectively; $P < 0.001$). Peak airway pressure was increased after pneumoperitoneum compared to baseline in both the groups. From the above results, they concluded that both i‑gel and PLMA are effective for ventilation in gynecological laparoscopic surgeries. However, PLMA provides better sealing as compared to i‑gel.

In a study by Mukkader et al [38]Proseal LMA, LMA Supreme and i-gel were compared in gynaecological laparoscopic surgeries. The oropharyngeal leak pressures

were lower in i-gel group initially, (mean (SD)- 23.9 (2.4); 24.9 (2.9); and 20.9 (3.5) cm of H_2O resp.). But at 30 and 60 minutes of surgery and trendelenburg position, oropharyngeal leak pressures in i-gel group were greater than both LMA Proseal and LMA Supreme (25.0 (2.3); 25.0 (1.9); and 28.3 (2.3) cm of H_2O resp.) and (24.2 (2.1); 24.8 (2.2); and 29.5 (1.1) cm of H_2O resp.). The time taken for insertion of i-gel was significantly lower than that taken for insertion of PLMA or LMA Supreme. Hence the study concluded that initial oropharyngeal leak pressures obtained by i-gel were lower than PLMA or LMA Supreme, but increased over time. The ease of placement and lower airway morbidity made i-gel more favourable for such cases.

Jeon et al [39] conducted a similar study with PLMA and i-gel in gynaecological laparoscopy. It concluded that there exists no statistically significant difference between PLMA and i-gel in relation to ease of insertion, time for successful insertion of airway, mechanical ventilation, oropharyngeal leak pressures before and after pneumoperitoneum and trendelenburg position.

Thus, taking into consideration the data available in literature with respect to the supraglottic airway devices, Proseal LMA and i-gel, which provided different conclusions, we undertook this study to evaluate their clinical efficacy with regards to ease of insertion, duration of insertion, airway sealing pressure in laparoscopic surgeries before pneumoperitoneum, 30 min after creation of pneumoperitoneum, 30 min after trendelenburg position, and post-op hoarseness of voice in anaesthetized paralysed adult patients undergoing positive pressure ventilation.

BASIC SCIENCES

Anatomy [40,41,42]

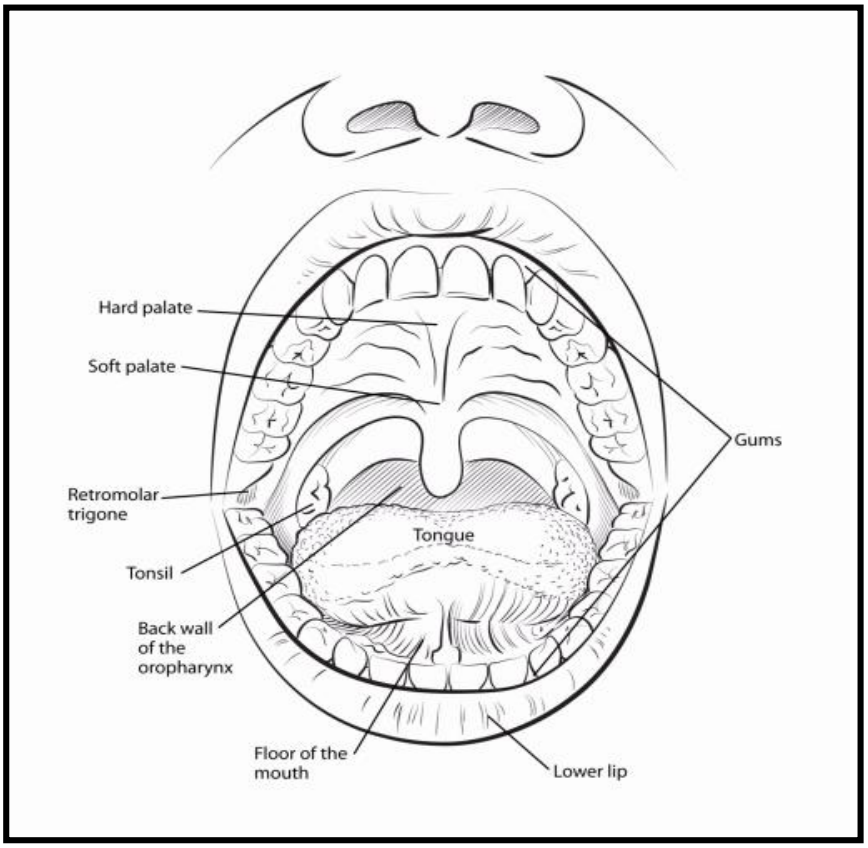


Figure 1. Anatomy of oral cavity

Oral cavity

The oral 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 bound externally by the lips and cheek, 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. Oropharyngeal isthmus is bound 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 2/3rd are formed by the palatine processes of the maxillae, and its posterior 1/3rd by the horizontal plates of 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; anteriorly 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.

Pharynx

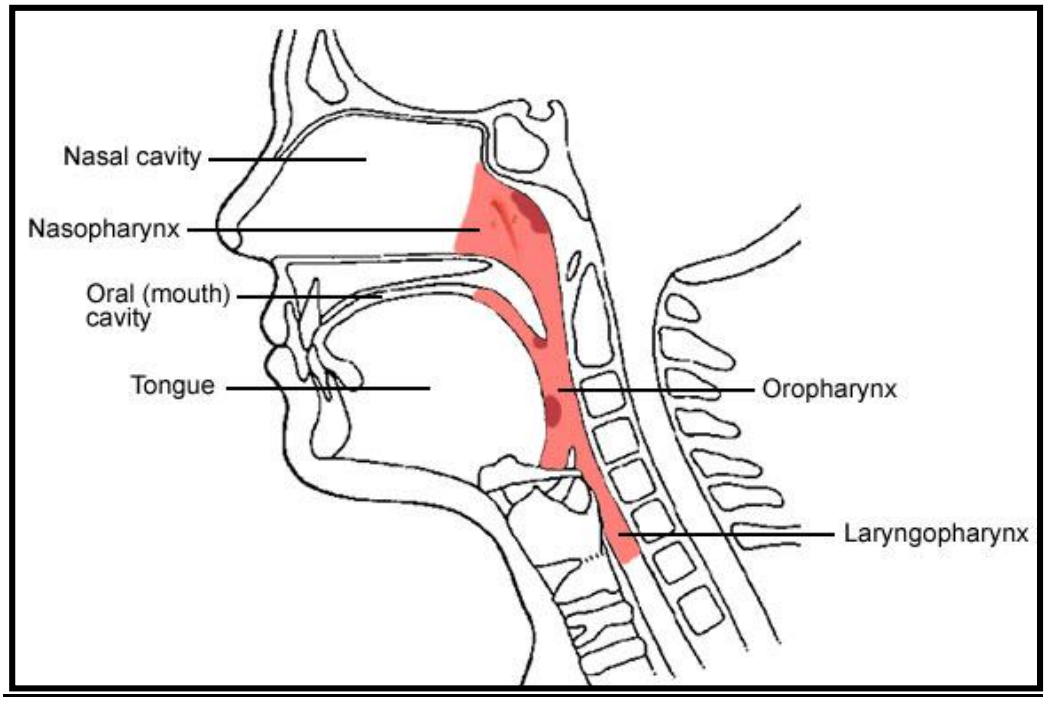


Figure 2. Anatomy of pharynx

The pharynx is a 12-14 cm long musculo membranous tube which is shaped like an inverted cone. It extends from the cranial base to the lower border of the cricoid cartilage (the level of the 6^{th} cervical vertebra), where it becomes continuous with the oesophagus.

Parts of pharynx

The cavity of the pharynx is divided into:

1. The nasal part- Nasopharynx.
1. The oral part- Oropharynx.
2. The laryngeal part- Laryngopharynx.

Nasopharynx

The nasopharynx lies above the soft palate and behind the posterior nares, which allows free respiratory passage between the nasal cavities and the nasopharynx. On 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, to the inferior border of the cricoid cartilage. At the superior border it is delineated from the oropharynx by the lateral glossoepiglottic folds and at the inferior border of the cricoids cartilage, it becomes continuous 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 inturn overlaps the superior. The longitudinal muscle coat of pharynx consists of Stylopharyngeus, Salphingopharyngeus 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.

Larynx

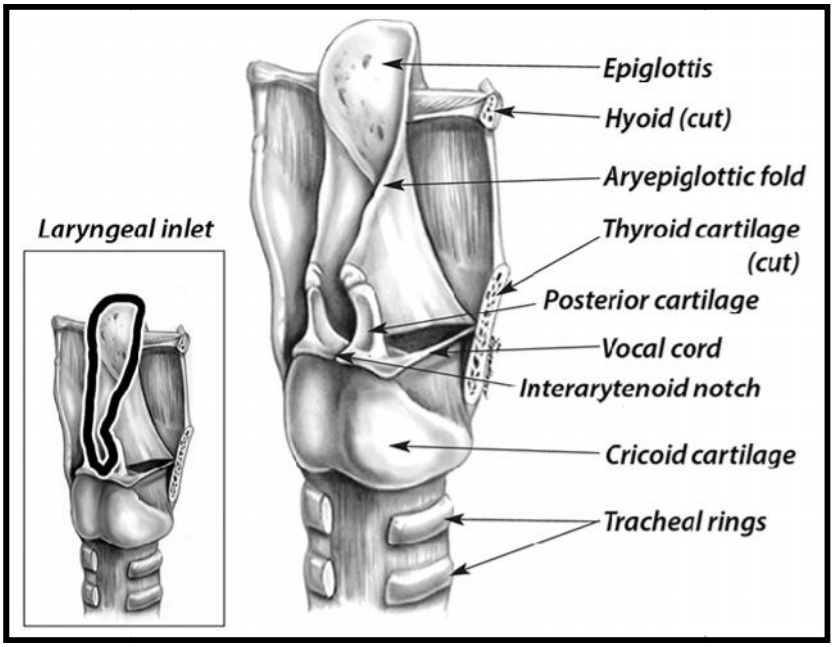


Figure 3. Anatomy of larynx

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 3^{rd} – 6^{th} 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

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 larynx
2. Ventricle of the larynx
3. Infraglottic part

Intrinsic muscles of larynx

1. Oblique arytenoids 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 are carried by 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)

Venous drainage

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

Lymphatic drainage

The lymph vessels draining the supraglottic 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 no

APPLIED ANATOMY*:*[43,44,45]

Anatomical structures relevant to supraglottic devices include mouth, oropharynx, laryngopharynx and hypopharynx[21].

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)[18,46]

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
11/2	5-10	7	10
2	10-20	10	10
21/2	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 H_2O 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.

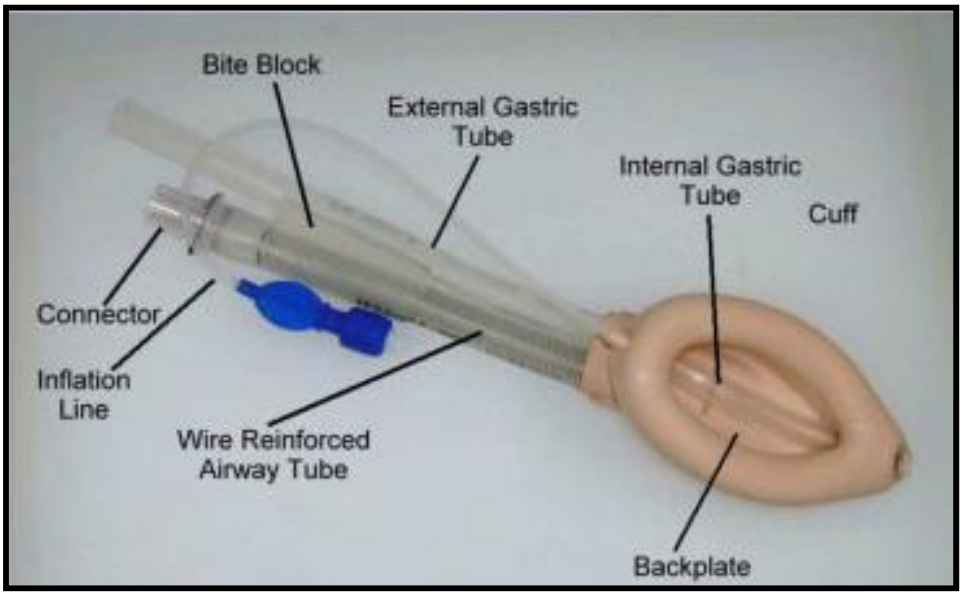
Indications:

- 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



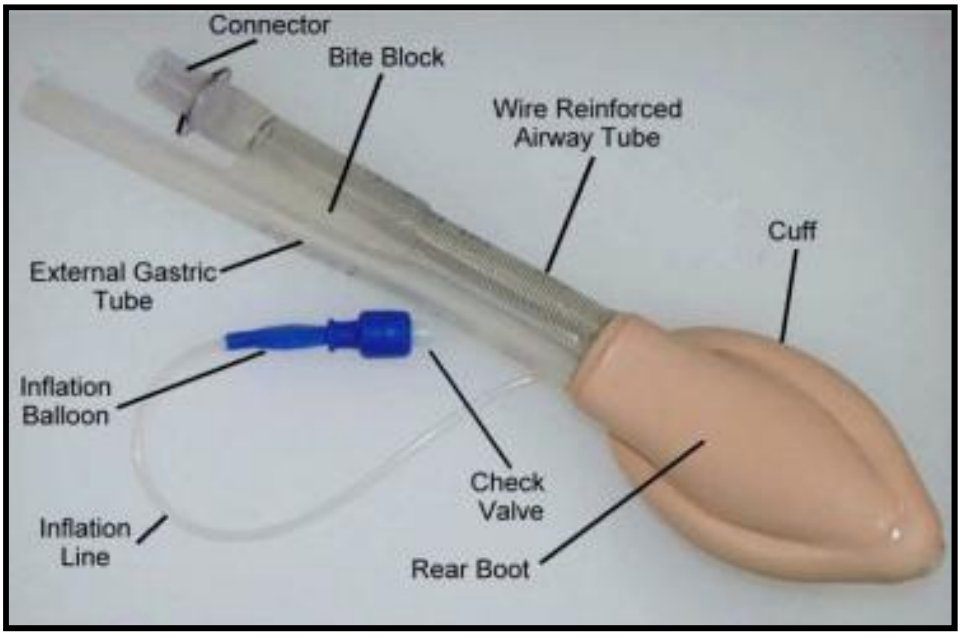


Figure 4 . PLMA

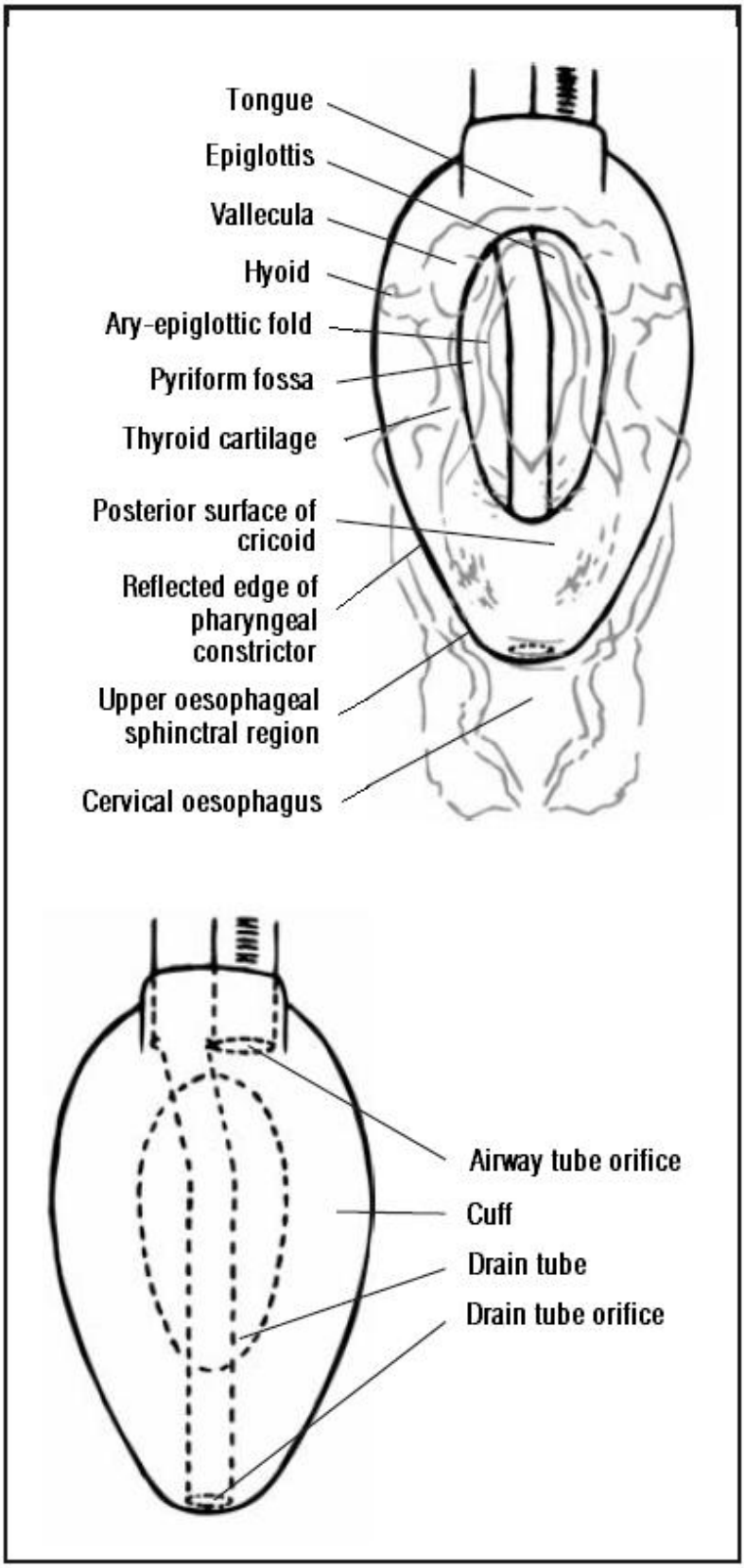


Fig 5.Schematic diagram showing PLMA in relation to pharyngeal anatomy

THE I GEL AIRWAY:[47]

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 Janury 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 H_2O.
- 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

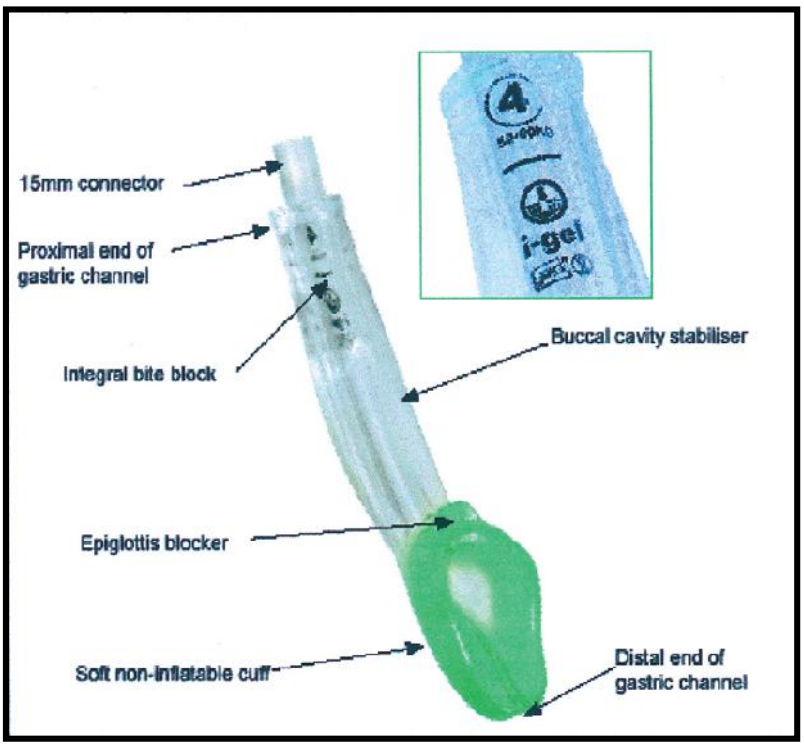


Figure 6.i-gel supraglottic airway

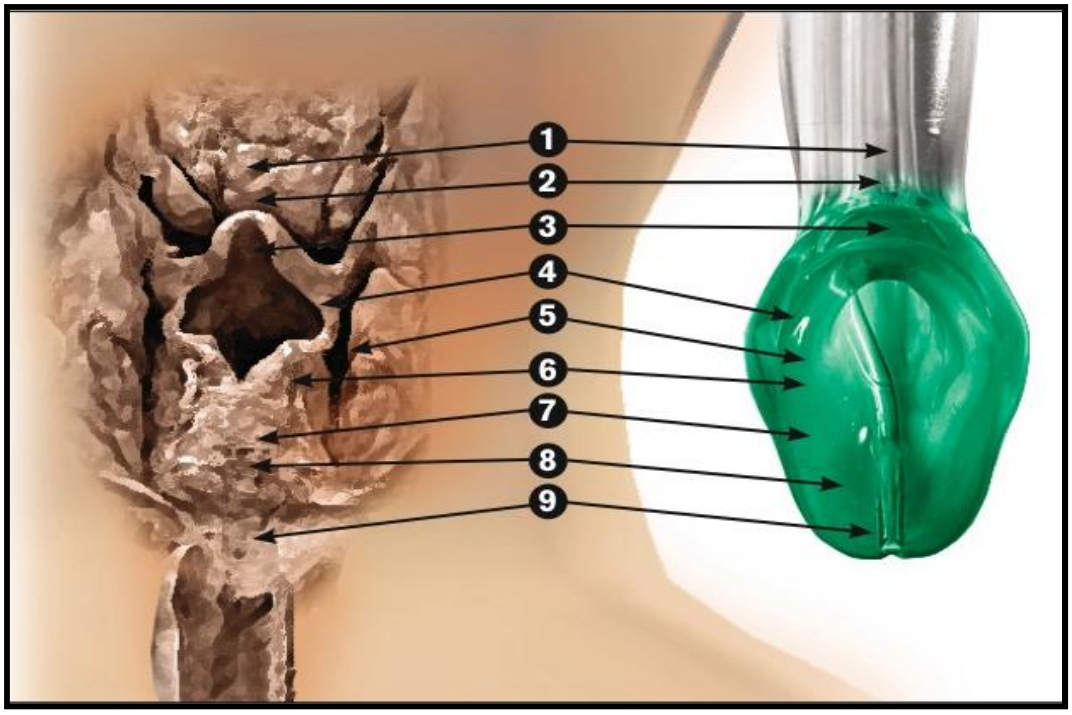


Figure 7. View of the i-gel cuff in relation to the laryngeal framework

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

METHODOLOGY

This study was conducted in the Department of Anaesthesiology, KLES Academy of Higher Education and Research, Belagavi during the period of January 2017 to December 2017.

Study design

The study design was a one year randomized clinical trial.

Study Period

One year, from January 2017 to December 2017.

Place

The present study was conducted at Department of Anaesthesiology, KLES Academy of Higher Education and Research , Belagavi a teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi.

Source of Data

Adult patients undergoing routine elective laparoscopic surgeries under general anaesthesia at KLES Academy of Higher Education and Research, Belagavi.

Sample Size

A total of 60 patients divided into two groups.

Sampling procedure

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

$$n = \frac{(Z\alpha + Z\beta)^2 \ (S_1^2+S_2^2)}{(x_1 - x_2)^2}$$

where,

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

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

Hence

$Z\alpha = 1.96$

$Z\beta = 0.84$

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

Group P- ProSeal LMA

Group I- i-gel.

Selection criteria

Inclusion

- Adult candidates aged 18-60 years.
- Laparoscopic surgeries lasting 90 min or less.
- Mallampati grade I and II
- ASA physical status I or II.
- Both male and female patients will be included.

Exclusion

- Presence of any significant acute or chronic lung disease.
- Pathology of the neck or upper respiratory tract with potential difficult intubation.
- Increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux or full stomach).
- Pregnant women
- BMI> 30 kg/m^2

Ethical clearance

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

Informed Consent

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

Method of collection of data

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

Investigations

All the patients were subjected to following investigations:

- Complete blood counts.
- 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 by opening a computer generated 'secret envelope' method into two groups of 30 each.

- **Group P: ProSeal LMA (n=30)**
- **Group I: i-gel (n=30)**

Procedure

In the operating room, a standard anaesthesia protocol was followed. Routine monitoring devices was applied- electrocardiograph (ECG), non-invasive blood pressure (NIBP), pulse oximetry (S_PO_2) and end tidal CO_2 ($EtCO_2$) monitoring. The head and neck of the patient were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height.

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

An IV access was established. All the patients were premedicated with Inj. Glycopyrrolate 0.005mg/kg (IV), Inj. Midazolam 0.05mg/kg (IV) and Inj. Fentanyl 2µg/kg (IV). Patient preoxygenated with 100% O_2 for 3 minutes.

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

Insertion technique:

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

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, 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 CO_2 > 60 cm of H_2O).
- More than three attempts.

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

For PLMA, the intra cuff pressure was set at 60 cm of H_2O 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 (1%) and Inj. Vecuronium 0.025mg /kg (IV) boluses. Intraoperative analgesia was taken care by Inj. Paracetamol 10 mg/kg IV.

At the end of the procedure, patients were adequately reversed 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:

- 1- Very easy- absolutely no resistance to LMA
- 2- Easy- no resistance to insertion in the pharynx in a single maneuver.
- 3- Difficult- resistance to insertion
- 4- Very difficult- 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 SAD and successful placement of the device confirmed by bilateral equal air entry and chest raise with square wave capnography.

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 H_2O) using manometer.

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

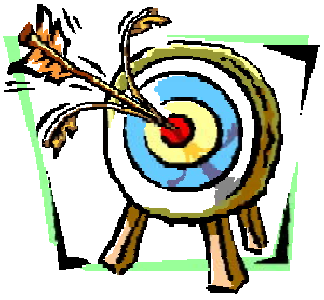
The presence/absence of oropharyngeal air leaks (detected by audible leak over the mouth), gastric air leaks (detected by auscultating over the epigastrium) were noted.

Any episodes of laryngospasm and bronchospasm, intraoperatively were documented. Postoperatively incidence of hoarseness of voice was recorded.

Statistical analysis

Data obtained was coded and entered into Microsoft excel spreadsheet. The categorical data was expressed in terms of rates, ratios and percentage and continuous data was expressed as mean ± standard deviation (SD). 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.

Introduction



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Discussion

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RESULTS

The present study was conducted in the Department of Anaesthesiology, KLE Academy of higher education and research, Belagavi during the period of January 2017 to December 2017.

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

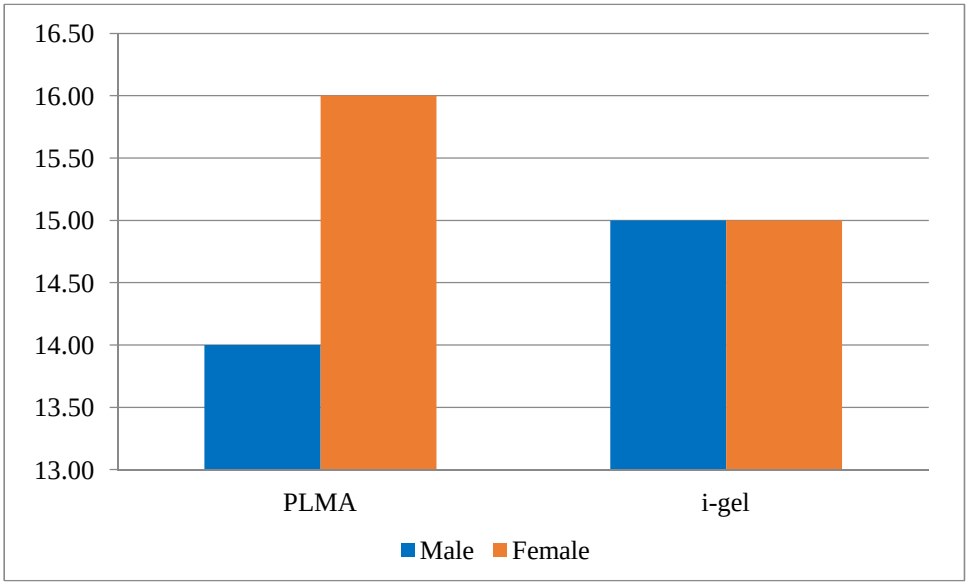
- Group P- PLMA (n=30)
- Group I- i-gel (n=30)

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	PLMA (n=30)		i-gel (n=30)	
	Number	Percent	Number	Percent
Male	14	46.66	15	50
Female	16	53.33	15	50
Total	30	100%	30	100%

Graph 1: Sex distribution

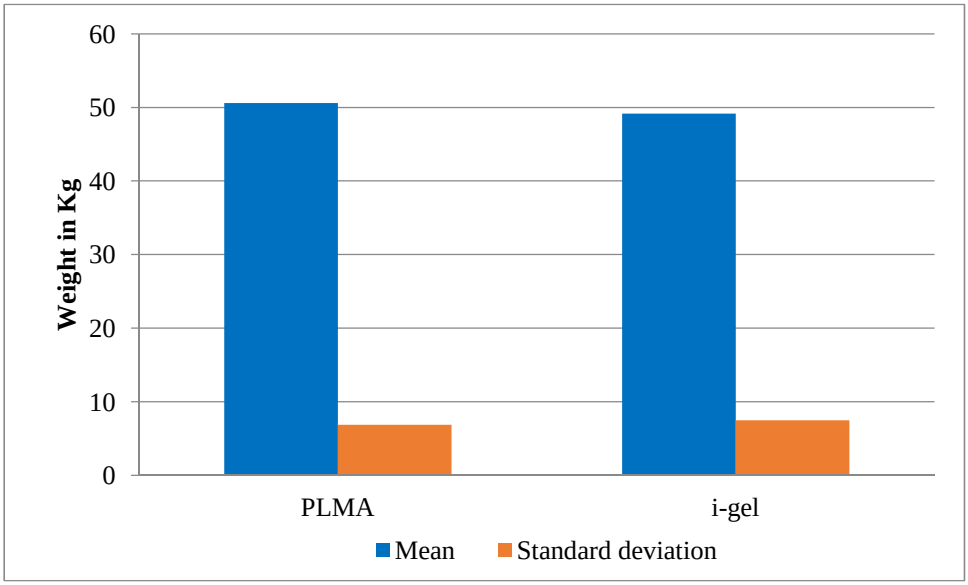


In our study, there were 14 males, 16 female patients in PLMA group and 15 male, 15 female patients in i-gel group, and sex distribution did not account to statistical significance.

Table 4. Mean weight

Groups	N	Mean(kg)	SD
PLMA	30	50.60	6.87
i-gel	30	49.17	7.49

Graph 2: Mean weight

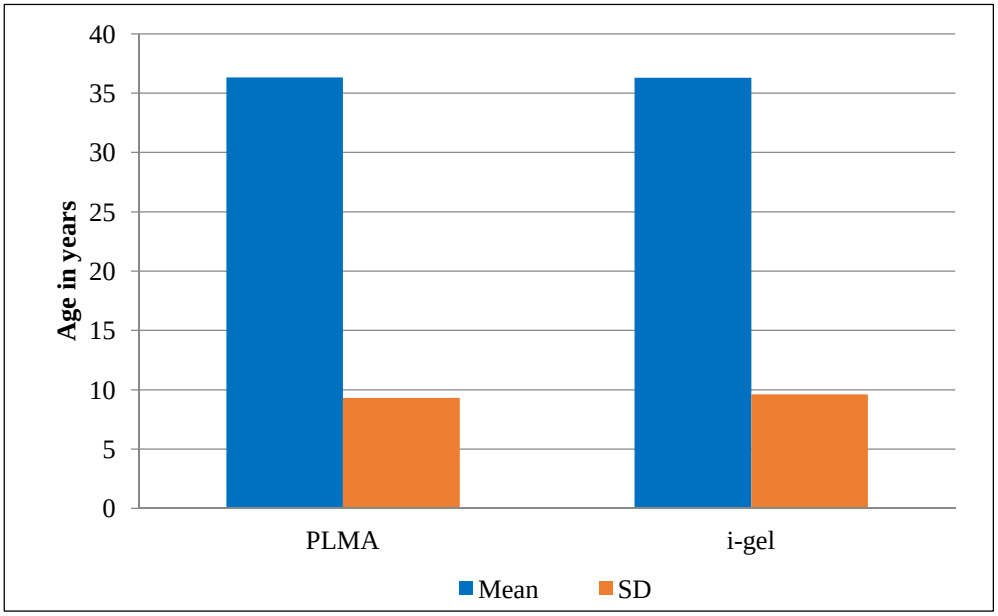


The mean weight in PLMA group was 50.60 $\pm$ 6.87 kg and in i-gel group was 49.17 $\pm$ 7.49 kg, which was not statistically significant (p= 0.443). Both groups were comparable with respect to weight.

Table 5. Mean age

Groups	N	Mean(years)	SD	P-value
PLMA	30	36.33	9.32	0.9892
i-gel	30	36.30	9.60	

Graph 3: Mean age

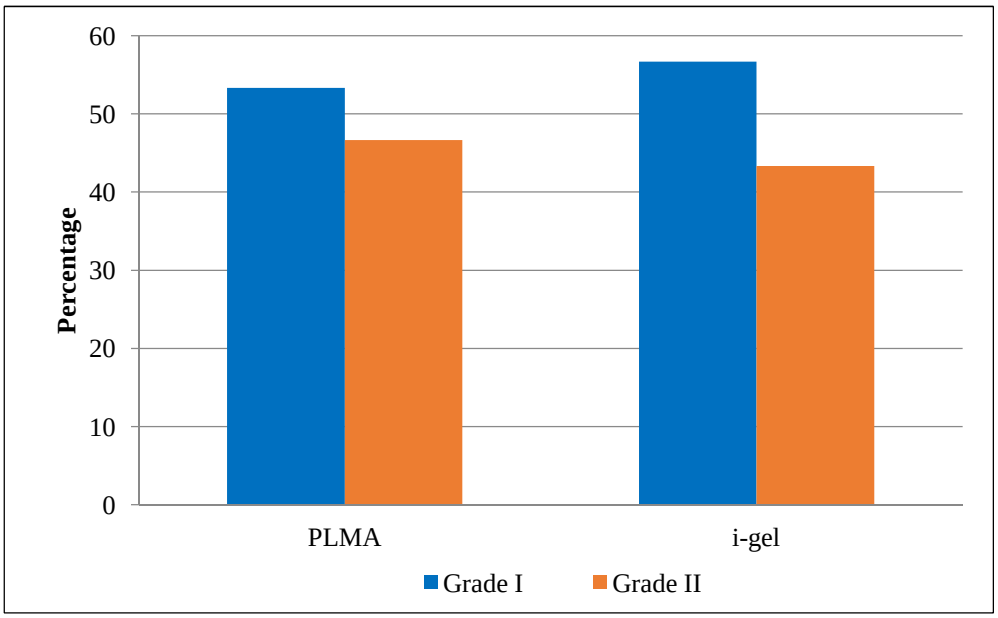


The mean age was 36.33 ± 9.32 years in group PLMA and 36.30 ± 9.60 years in group i-gel (p=0.9892). There was no statistically significant difference between both the groups. Both groups were well matched with respect to age.

Table 6. ASA grade

ASA grade	**PLMA(n=30)**	%	**i-gel (n=30)**	%
Grade 1	16	53.33	17	56.66
Grade 2	14	46.66	13	43.33
Total	30	100.00	30	100.00

Graph 4: ASA grade

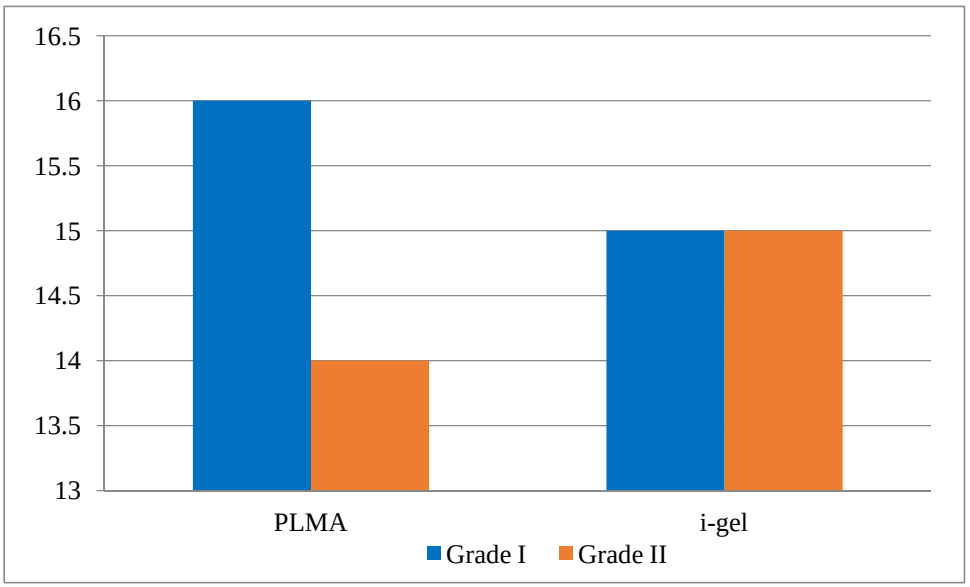


In this study, among the patients that were scheduled for surgery 53.33% in the PLMA group belonged to ASA grade I compared to 46.66% in i-gel group.

Table 7.MPG Grade

MPG grade	**PLMA (n=30)**	%	**i-gel (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

Graph 5: MPG Grade

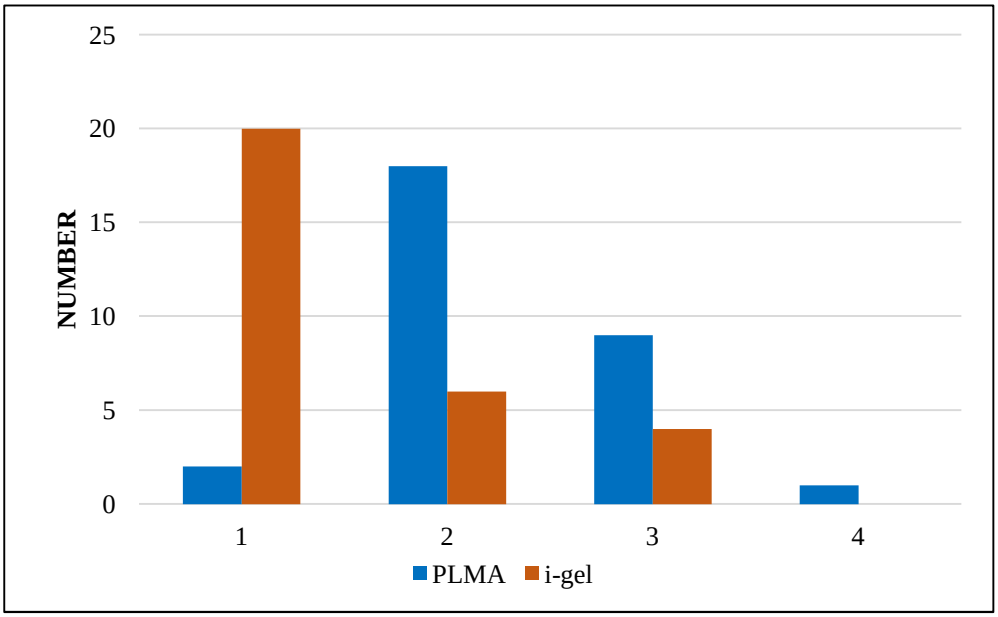


In the present study, 53.28% of patients in PLMA group had Mallampati grade I in comparison to 50% of patients in i-gel group. Both groups were comparable with respect to MPG grading (p=0.796).

Table 8. Ease of insertion

Ease of insertion	PLMA	i-gel	*P*-value
1 (very easy)	2	20	
2 (easy)	18	6	
3 (difficult)	9	4	
4 (very difficult)	1	0	
Total	30	30	<0.0001

Graph 6: Ease of insertion

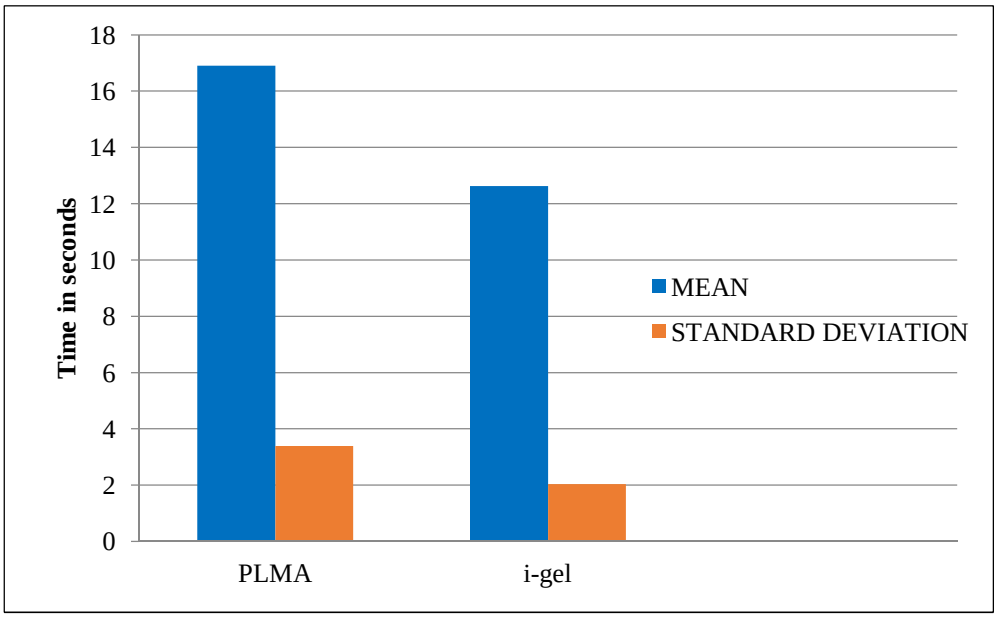


In our study, insertion was easy (1 and 2) in 20 patients from PLMA group and 26 patients in i-gel group. Difficult insertion (3 and 4) was seen in 10 patients in PLMA group and 4 patients in group i-gel. This difference was statistically significant. (*P*=<0.0001). There were no failed insertions.

Table 9. Time taken for insertion

Group	N	Mean duration (seconds)	SD	P-value
PLMA	30	16.9	3.39	<0.0001
i-gel	30	12.63	2.04	

Graph 7: Time taken for insertion

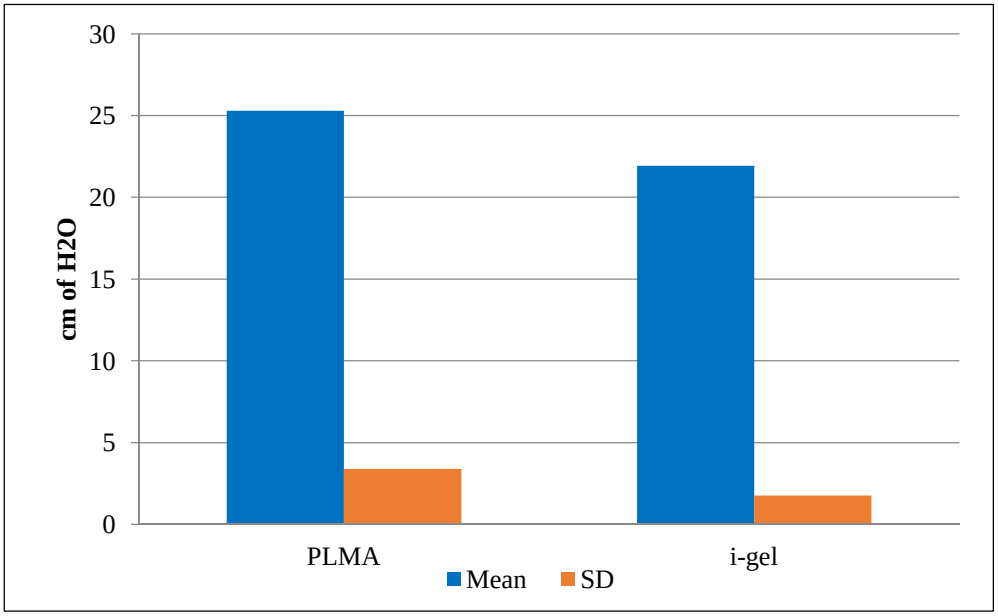


In our study, the mean duration of insertion was 16.9 ± 3.39 sec in PLMA group and 12.63 ± 2.04 sec in i-gel group. This difference was statistically significant (*P* <0.0001).

Table10.Mean Airway Sealing Pressure (cm H_2O)

Groups	Mean	SD	P-value
PLMA	25.3	3.395	<0.0001
i-gel	21.933	1.76	

Graph 8: Mean Airway Sealing Pressure

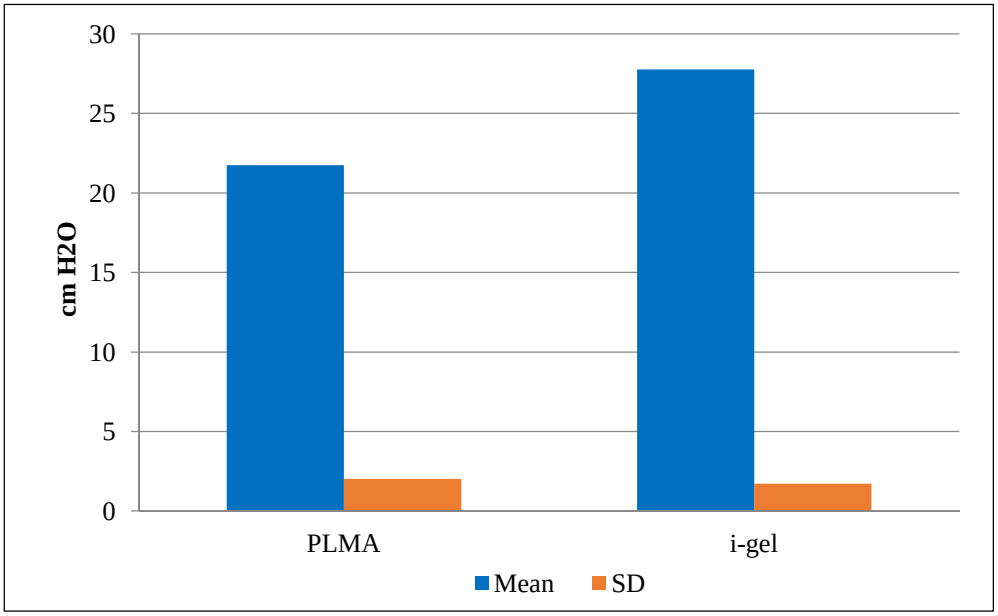


The mean airway sealing pressure was 25.3 $\pm$ 3.395 cm of H_2O in PLMA group and 21.933 $\pm$ 1.76 cm of H_2O in i-gel group. The airway sealing pressure was more in PLMA group which was statistically significant ($p<0.0001$).

Table 11. Mean Airway Sealing Pressure after 30 min of Pneumoperitoneum

Groups	**Mean**	**SD**	***P*-value**
PLMA	21.733	2.016	**<0.0001**
i-gel	27.767	1.716	

Graph 9: Mean Airway Sealing Pressure after 30 min Pneumoperitoneum

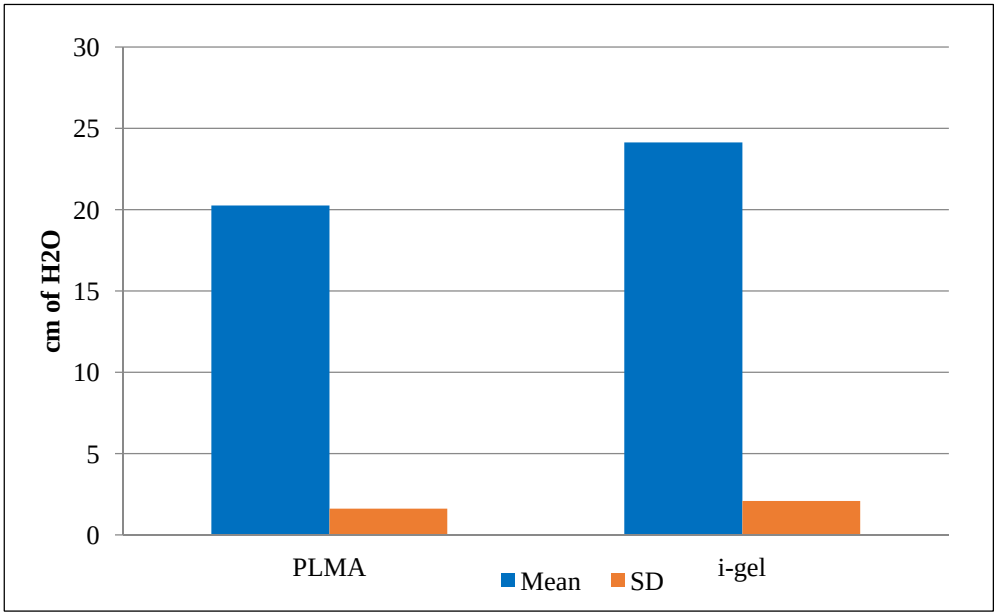


The mean airway sealing pressure following pneumoperitoneum was measured, 30 minutes after initiation of CO2 insufflation. Airway sealing pressure in PLMA group was 21.733 ± 2.016 cm of H_2O. Whereas in i-gel group it was 27.767 ± 1.716 cm of H_2O. The difference was statistically significant with a *p* value of <0.0001.

Table 12. Mean Airway Sealing pressure 30 min after Trendelenburg Position

Groups	**Mean**	**SD**	***P*-value**
PLMA	20.267	1.617	**<0.0001**
i-gel	24.133	2.097	

Graph 10: Mean Airway Sealing pressure 30 min after Trendelenburg Position

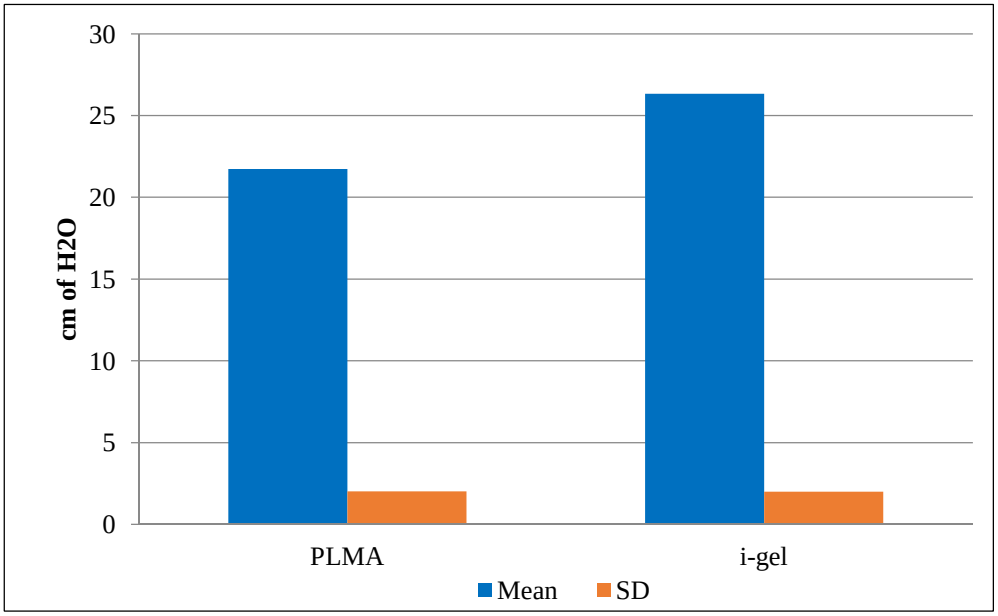


During the laparoscopic procedure, trendelenburg position was given. After which airway sealing pressure was measure to be 20.267 $\pm$ 1.617 cm of H_2O in PLMA group and 24.133 $\pm$ 2.097 cm of H_2O in i-gel group. This measurements were statistically significant with a *P* value of <0.0001.

Table 12. Mean Airway Sealing Pressure after Neutral Position

Groups	**Mean**	**SD**	***P*-value**
PLMA	21.733	2.016	**<0.0001**
i-gel	26.333	1.99	

Graph 11: Mean Airway Sealing Pressure after Neutral Position

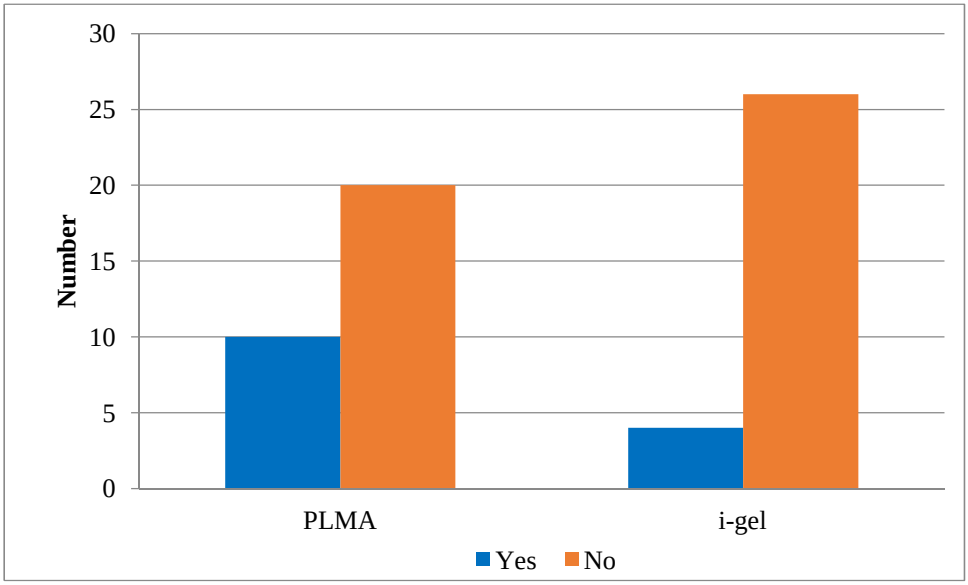


After the surgical procedure was completed, neutral position was assumed. The airway sealing pressures were 21.733 $\pm$ 2.016 cm of H_2O in PLMA group and 26.33 $\pm$ 1.99 cm of H_2O in i-gel group. The differences in sealing pressures were statistically significant (*P* value <0.0001).

Table 13: Post-operative Hoarseness of Voice

Groups	Yes	NO	*P*-value
PLMA	10	20	
i-gel	4	26	0.067

Graph 12: Post-Operative Hoarseness of Voice



In the recovery area, patients were assessed for hoarseness of voice. 10 patients in PLMA group and 4 patients in i-gel group complained of hoarseness of voice. Though the incidence of hoarseness of voice was more in PLMA group than in i-gel group, it was not of statistical significance (*P*=0.0670).

DISCUSSION

All through the 19th century, endotracheal intubation was considered as the only way of establishing a definitive airway. But invention of Supraglottic airway devices (SADs) has proven to effectively replace endotracheal tube in securing a definitive airway. SAD have various advantages like easy insertion, minimal hemodynamic changes, hands free maintenance, and lesser airway morbidity with relatively secure airway [49,50] . SAD are also better tolerated at lighter planes of anaesthesia. Because of the above mentioned advantages, SADs have been used widely as an alternative to tracheal intubation [48]. Current guidelines on cardiopulmonary resuscitation recommend SADs as an alternative to tracheal intubation [51,52,53]

PLMA is a reusable SAD that allows easy insertion, higher glottic seal pressures, and separation of respiratory tract from gastrointestinal tract via the gastric port which permits gastric drainage. [18]

The i-gel is a second generation SAD which consists of a noninflatable laryngeal mask made from a gel-like thermoplastic elastomer and an anatomically shaped cuff which is easier to insert and forms an effective seal around the perilaryngeal surface. [47]

In this study we compare PLMA and i-gel for ease of insertion, time taken for insertion, airway sealing pressure at insertion, 30 min after pneumoperitoneum, 30 min after trendelenburg position, after neutral position and postoperative hoarseness of voice in anaesthetized, paralyzed patients on positive pressure ventilation undergoing laparoscopic surgeries.

We enrolled a total of 60 ASA I and II patients aged 18-60 years, weighing 30-70 kg posted for elective laparoscopic surgeries under general anaesthesia. They were randomly divided into two groups of 30 each by computer generated secret envelope method.

Among the patients enrolled in the study, there were 14 male, 16 female patients in PLMA group and 15 male, 15 female patients in i-gel group. The mean weight was 50.60±6.87 kg in PLMA group and 49.17±7.49 kg in i-gel group. The mean age was 36.30±9.60 in PLMA group and 36.33±9.32 years in i-gel group. Both groups were comparable with respect to sex distribution, weight and age.

In our study, 53.28% of patients in PLMA group had Mallampati grade I in comparison to 50% of patients in i-gel group. 53.33% in PLMA group were scheduled for surgery with ASA grade 1 compared to 56.66% in i -gel group. Both groups were comparable with respect to MPG and ASA grading.

When comparing the ease of insertion, it was observed that, insertion was easy (1 and 2) in 20 patients in PLMA group (66.66%) and 26 patients in i-gel group (86.66%). Difficult (3 and 4) insertion was seen in 10 patients in PLMA group (33.33%) and 4 patients in i-gel group (13.33%).This difference was statistically significant. (P<0.0001).There were no failed insertions in our study.

The observations of our study were similar to a study by Kini et al, [54] comparing i-gel with PLMA in adult patients undergoing elective surgical procedures under general anesthesia without paralysis, where time taken for insertion was lower in i-gel group when compared to PLMA group (21.98 ± 5.42 and 30.60 ± 8.51 s in Group I and Group P, respectively) (P = 0.001) .

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. This is in accordance with our study where both i-gel and PLMA were inserted successfully in 100% of the patients.

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 [55,56,57]

Time taken for insertion of SAD in our study was observed to be 16.9 $\pm$ 3.39 sec in PLMA group and 12.63 $\pm$ 2.04 sec in i-gel group. This difference is statistically significant ($p<0.0001$).

In a study done by Chauhan et al, [55] 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 PLMA (15.13 ± 2.91 sec) (P = 0.001).Also, mean airway sealing pressure in the PLMA group (29.55 ± 3.53 cm H_2O) was significantly higher than in the i-gel group (26.73 ± 2.52 cm H_2O; P = 0.001). These results were similar to that found in our study.

Singh et al, [56] studied comparison of clinical performance of i-gel with PLMA in 60 ASA I and II adult patients undergoing elective surgeries. The success rate at first attempt of insertion were 30/30 (100%) for i-gel & 28/30 (93.3%) for PLMA, which was statistically not significant. In relation to this, our study had no failure of insertion, and both the devices were placed successfully in the first attempt.

In a study done by Das et al,[58] 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 the observations in our study.

In another study conducted by Tokgok et al, [59] where efficacies of i-gel and PLMA for airway management in paediatric patients were compared, insertion time was shorter for i-gel group than PLMA group (19 ± 4 sec vs. 28 ± 5 sec, $p<0.01$). The following result was similar to our finding. The airway leakage pressure of i-gel group was significantly higher than that of PLMA group (means ± SD: 28 ± 5 vs. 20 ± 4 cmH_2O, $P < 0.01$). Though, we found that the initial airway leak pressure was higher in PLMA group than in i-gel group in our study.

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 airway sealing pressure was higher at zero cuff volume i.e, when the dorsal cuff was deflated.[63]

The i-gel has a firm tube section with a natural oropharyngeal curvature which allows the device to be inserted relatively easily, by grasping the proximal end. It inturn helps to glide the leading edge against the hard palate into the pharynx. Hence the need of insertion of fingers into the mouth of the patient can be avoided. Apart from this, we can also assume 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.

When compared to the classic endotracheal intubation, the seal formed by SAD with the peripharyngeal and perilaryngeal tissue will determine the effectiveness of a definitive airway, degree of airway protection from gastric aspiration and feasibility of positive pressure ventilation during anaesthesia. Oropharyngeal leak pressure values are determinant of above mentioned seal. [56] Aspiration requires regurgitant fluid to reach the laryngeal inlet and it depends on the seal of the SAD in relation to oesophagus (oesophageal seal) combined with seal with pharynx (pharyngeal seal), which will determine the likelihood of spill into the larynx.

We observed that the initial mean airway sealing pressure after insertion of LMA was 25.3 $\pm$ 3.395 cm of H_2O in PLMA group and 21.933 $\pm$ 1.76 cm of H_2O in i-gel group. Mean airway sealing pressure measured 30 minutes after pneumoperitoneum (PLMA group 21.733 $\pm$ 2.016 cm of H_2O i-gel group 27.767 $\pm$ 1.716 cm of H_2O), 30 minutes after trendelenburg position (20.267 $\pm$ 1.617 cm of H_2O in PLMA group and 24.133 $\pm$ 2.097 cm of H_2O in i-gel group), and after neutral position (21.733 $\pm$ 2.016 cm of H_2O in PLMA group and 26.33 $\pm$ 1.99 cm of H_2O in i-gel group). The mean airway sealing pressure initially was significantly higher in PLMA group than i-gel group. But as the surgery progressed, mean airway sealing pressure was significantly higher in i-gel group rather than PLMA group. The resultant findings were statistically significant.

In a study done by Belena et al [61], where LMA Supreme and PLMA were compared with respect to oropharyngeal leak pressure during laparoscopic cholecystectomy, 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 cmH_2O; $P < 0.01$).Similarly, we found that PLMA achieved a better seal initially after insertion.

Wharton et al,[62] evaluated performance of i-gel supraglottic airway device in manikins and anaesthetized patients when used by novice medical students, non anesthetist 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). The 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) and median airway seal was 20cmH_2O (13-40). First attempt success rate for insertion of SAD in our study was 100% (30/30).

In a study by Sardi et al,[35] comparison of postoperative throat and neck complaints after the use of the i-gel versus the classic LMA (cLMA) was done. 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%) compared with the group in which the cLMA was used. These results are similar to our study where 10 patients in PLMA group and 4 patients in i-gel group complained of postoperative hoarseness of voice. Incidence of sore throat was higher in PLMA group than i-gel group, but was statistically insignificant.

Trauma on insertion, multiple attempts at insertion, pressure exerted by the cuff against the pharyngeal mucosa, cuff volumes have all been important factors as causative agents for post-operative hoarseness of voice. PLMA has an inflatable cuff which may have the potential to cause venous compression, tissue distortion and nerve injury. Hence PLMA has higher incidence of post-operative hoarseness of

voice. Due to gel filled cuff, which is less traumatic to the airway, i-gel is associated with fewer airway complications. [64]

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 where i-gel was easier to insert, with lesser time consumed to do the same. Though our study results were comparable to few studies which showed higher initial airway sealing pressure in PLMA group, but as the surgical procedure progressed, the airway sealing pressure in i-gel group was significantly higher than in PLMA group. This finding was against that was found in most other studies. Complications were observed more in PLMA group, but are statistically insignificant.

LIMITATIONS

Firstly, in our study, only two types of SAD were compared (PLMA and i-gel).

Type and duration of surgery was not mentioned.

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

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

Use of these SAD were done in adult healthy patients with no known comorbidities. Hence results cannot be projected to ASA III and IV patients.

SCOPE FOR FURTHER STUDIES

Further studies can be done to evaluate the PLMA and i-gel in the patients with associated cardiac comorbidities and difficult airway scenario.

They can also be studied in the ICU setting.

Use of SAD in prone and lateral position may be studied to increase the scope of their use.

CONCLUSION

The conclusions drawn from our study where we compared PLMA(size 3 and 4) and i-gel(size 3 and 4) are:

- When compared to PLMA, i gel was easier to insert in anaesthetized paralysed adult patients.
- Time taken for insertion of i-gel was lower than that taken by PLMA.
- Though initial airway sealing pressures were higher for PLMA, as the procedure progressed, airway sealing pressure was higher in i-gel than PLMA; therefore i-gel provided a more effective seal than PLMA for positive pressure ventilation in laparoscopic surgeries.
- The PLMA was associated with higher incidences of post-operative hoarseness of voice when compared to i-gel, but the difference was not statistically significant.

SUMMARY

Our present study was aimed to compare the PLMA and i-gel with regard to ease of insertion, duration of insertion, airway sealing pressure after insertion, 30 miutes after pneumoperitoneum, 30 minutes after trendelenburg position, after neutral position and complications.

The study was conducted in 60 ASA grade I and II adult patients of both sexes, aged between 18 and 60 years posted for elective surgeries under general anaesthesia in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi 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 P: PLMA (n=30) and group I:i-gel(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 Inj.propofol 2mg/kg(IV) and Inj. vecuronium 0.1mg/kg (IV). The airway device was inserted in strict accordance with the manufacturer's recommendations.

The ease of insertion, duration of insertion and airway sealing pressure at various times 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. Incidence of postoperative hoarseness of voice was recorded.

In our study, the i-gel was easier to insert in comparison to PLMA. Difficult insertion (3 and 4) was seen in 10 patients in PLMA group and 4 patients in i-gel

group. This difference was statistically significant(p=<0.0001). There were no failed insertions in our study.

Time taken for insertion was 16.9 ± 3.39 sec in PLMA group and 12.63 ± 2.04 sec in i-gel group. This difference was statistically significant (p<0.0001).

Soon after insertion of SAD, PLMA provided a more effective seal than i-gel for positive pressure ventilation. The mean airway sealing pressure after insertion was 25.3±3.395 cm of H_2O in PLMA group and 21.933±1.76 cm of H_2O in i-gel group which was statistically significant (p<0.0001).

When mean airway sealing pressure were recorded 30 minutes after pneumoperitoneum, 30 minutes after trendelenburg position and before extubation (neutral position), i-gel provided better seal than PLMA. Mean airway sealing were 21.733 ± 2.016: 20.267 ± 1.617 and 21.733 ± 2.016 cm of H_2O in PLMA group and 27.767 ± 1.716; 24.133 ± 2.097 and 26.33 ± 1.99 cm of H_2O respectively.

Intraoperatively no complications were encountered in either group. Incidence of postopertaive hoarseness of voice was higher in PLMA group than in i-gel (10/30 in PLMA group and 4/30 in i-gel group), but was not statistically significant.

To summarise our study, i-gel was easier to insert, and took lesser time than PLMA in anaesthetized paralysed adult patients. Airway sealing pressure soon after insertion were higher for the PLMA. Though as the procedure progressed, airway sealing pressures were significantly higher in i-gel group than PLMA group. We observed that i-gel provided a more effective seal than PLMA for positive pressure ventilation during laparoscopic surgeries. The PLMA was associated with higher incidences of postoperative hoarseness of voice.

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in **"COMPARISION OF AIRWAY SEALING PRESSURE BETWEEN PROSEAL LMA AND I-GEL SUPRAGLOTTIC AIRWAY IN ADULT PATIENTS UNDERGOING LAPAROSCOPIC SURGERIES REQUIRING GENERAL ANAESTHESIA- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL"** conducted by Department of Anaesthesiology, J.N. Medical College, Belagavi under KLE Academy of Higher Education and Research, Belagavi.

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

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

The purpose of the research is to evaluate efficacy of two different Supraglottic Airway Devices (SAD) regarding airway sealing pressure, ease of and time taken for their insertion, and post op hoarseness of voice.

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.

Benefits and Risks

These airway devices have become very popular because of their ability to maintain an airway without perturbing the trachea and can be used in patients without muscle relaxation who are only lightly anesthetized. There is incidence of postoperative sore throat and blood staining on the PLMA and I-Gel.

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 Dr. PrabhakarKore Hospital.

Alternatives

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

Confidentiality

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

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

Authorization to Publish Results:

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

Financial Incentives for participation

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

Compensation

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

Queries/ Contact details

If you have any queries about your right as a study subject, you may call Dr. Ganga Pilli, Prof. & Head of Pathology as Chairman of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No.9448863866 or Extension-4052 at J. N. Medical College, Belagavi

Consent for participation in research trial

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

Subject Name : _____

Signature or the Left Thumb Print :_____

Date: _____

Witness Name : _____

Signature:_____ Date:

Investigators Name: _____

Signature:_____

Date:_____ Place:_____

ANNEXURE II – PROFORMA

"COMPARISION OF AIRWAY SEALING PRESSURE BETWEEN PROSEAL LMA AND I-GEL SUPRAGLOTTIC AIRWAY IN ADULT PATIENTS UNDERGOING LAPAROSCOPIC SURGERIES - A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL".

Patient Name: IP No.:

Age: Gender:

Date of Operation: Occupation:

Address: Anaesthesiologist:

Preanesthetic Evaluation:

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

General physical examination

Pallor / Icterus / Clubbing / Cyanosis / Lymphadenopathy / Edema

Pulse Rate : BP :

Respiratory Rate : Temperature :

Systemic Examination

RS : CNS :

CVS : Abdomen :

Airway examination :

Jaw movements : Teeth :

Airway assessment : Spine :

Investigations

Hb : Total Leucocyte Count :

Platelet count : Serum Urea :

Serum.Creatinine: RBS:

ECG : Chest X-Ray:

Urine R/M : Others :

ASA GRADE : I II

Diagnosis :

Proposed Surgery :

Preoperative baseline values :

Pulse: BP:

Monitors attached :

Pulse oximetry :NIBP :

ECG :

- **Group of study belongs to :**

Proseal LMA group:

I-Gel group :

Inclusion

- The subjects are adult laparoscopic surgical candidates aged 18-60 years.
- Laparoscopic surgeries lasting 90 min or less.
- Mallampati grade I and II
- ASA physical status I or II.
- Both male and female patients will be included.

Exclusion

- Presence of any significant acute or chronic lung disease.
- Pathology of the neck or upper respiratory tract.
- Potential difficult intubation.
- Increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux or full stomach).
- Pregnant women
- BMI> 30 kg/m^2

Procedure

In the operating room, a standard anaesthesia protocol was followed. Routine monitoring devices was applied- electrocardiograph (ECG) , non-invasive blood pressure (NIBP) , pulse oximetry (SPO_2) and end tidal CO_2 ($EtCO_2$) monitoring. The head and neck of the patient were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height.

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

An IV access was established. All the patients were premedicated with inj. Glycopyrrolate 0.005mg/kg (IV), inj. Midazolam 0.05mg/kg (IV) and inj. Fentanyl 2µg/kg (IV). Patient preoxygenated with 100% O_2 for 3 minutes.

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

Insertion technique:

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

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 CO_2 > 60 cm of H_2O).
- More than three attempts.

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

For PLMA, the intra cuff pressure was set at 60 cm H_2O 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. Intraoperative analgesia was taken care of by inj. Paracetamol 10 mg/kg IV.

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:

  1- Very easy- absolutely no resistance to LMA

  2- Easy- no resistance to insertion in the pharynx in a single maneuver.

  3- Difficult- resistance to insertion

  4- Very difficult- 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 confirmed by bilateral equal air entry and chest raise with square wave capnography.

- 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 H_2O) using manometer.

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

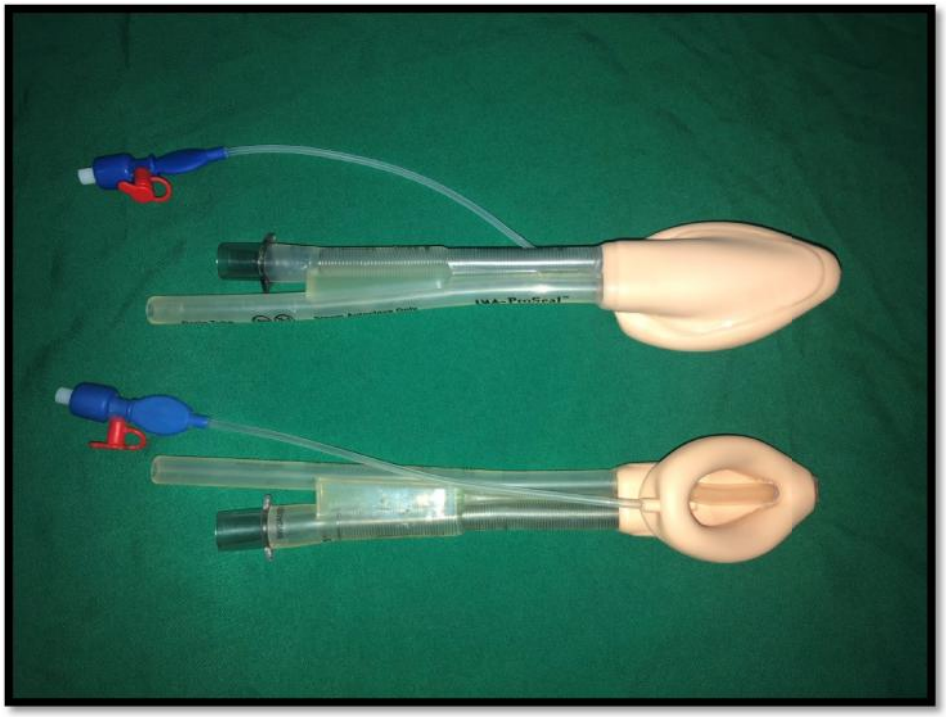
The presence/absence of oropharyngeal air leaks (detected by audible leak over the mouth), gastric air leaks (detected by auscultating over the epigastrium) were noted.

Any episodes of laryngospasm and bronchospasm were documented.

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

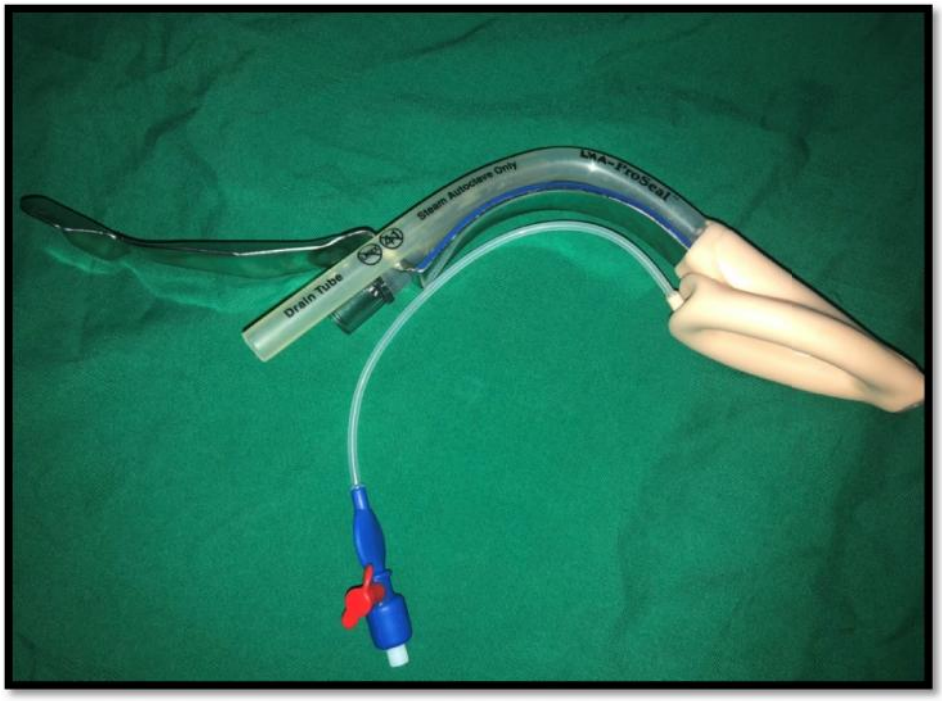
Mallampati grading	
Insertion time	
Airway sealing pressure(oropharyngeal leak pressure) after insertion of LMA	
Airway sealing pressure 30 min after pneumoperitoneum	
Airway sealing pressure 30 min after trendelenburg position	
Ease of insertion	
Post operative hoarseness of voice	

ANNEXURE III – PHOTOGRAPHS



Photograph 1: Proseal LMA size 3 and 4

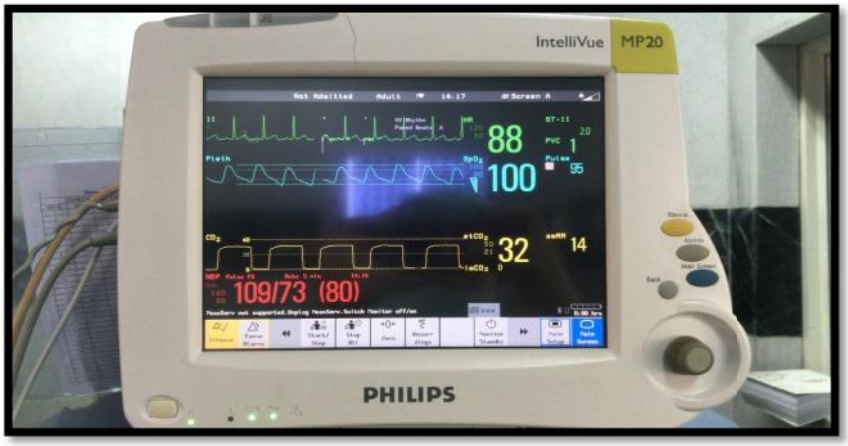
Photograph 2: Metal introducer of PLMA



Photograph 3: PLMA mounted on metal introducer

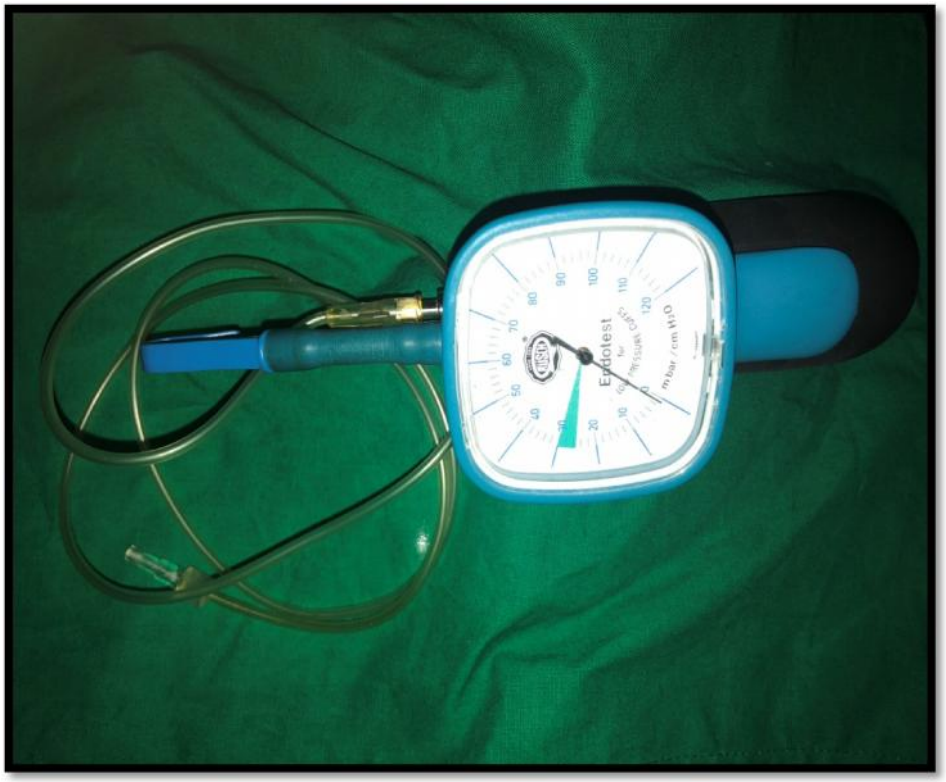
Photograph 4: i-gel SAD size 3 and 4

Photograph 5: Anaesthesia work station (Drager Fabius Plus)



Photograph 6: Monitor

Photograph 7: Measurement of airway sealing pressure



Photograph 8: Cuff pressure manometer

ANNEXURES IV - MASTER CHART

PRO SEAL

										Airway sealing pressures (cm of H20)							
S.no	IP no	Age	Weight	Height	Sex	ASA	MPG	Ease of insertion	Insertion time (Sec)	Oropharyngeal leak pressure	5 minutes after pneumoperitoneum	30 minutes after pneumoperitoneum	5 minutes after trendelenberg	30 minutes after trendelenberg	After neutral position	After releasing pneumoperitoneum	Post-op hoarseness of voice
1	877891	23	56	150	F	I	I	2	16	25	20	22	21	21	22	23	N
2	870987	45	60	155	M	I	I	3	20	20	15	18	15	17	18	18	Y
3	877643	39	45	160	F	II	I	1	12	22	18	20	18	18	20	20	N
4	870089	40	62	162	M	I	I	2	18	23	17	19	20	18	19	20	N
5	878907	42	55	145	F	II	I	2	18	21	19	20	22	18	20	20	N
6	870064	45	60	180	F	II	II	2	16	24	20	21	18	20	21	22	N
7	873000	55	48	162	M	II	I	3	22	30	24	24	22	22	24	25	Y
8	870034	32	50	170	F	I	I	3	20	22	20	21	20	20	21	20	Y
9	878345	34	60	172	M	I	II	2	16	30	24	24	22	22	24	26	N
10	873087	24	45	188	M	II	II	3	22	22	16	20	16	20	20	20	Y
11	878091	42	40	165	F	I	I	4	25	30	24	24	22	22	24	28	Y
12	872000	26	44	174	M	I	II	2	12	26	22	22	20	20	22	24	N
13	871090	49	45	165	F	II	II	2	13	25	20	20	18	18	20	22	N
14	877813	50	60	148	M	II	I	3	16	24	20	22	16	20	22	22	Y
15	873009	45	55	159	M	I	I	2	14	28	24	22	20	20	22	26	N
16	871086	21	40	167	M	II	II	2	12	20	16	18	16	18	18	20	N
17	877785	35	45	172	F	I	II	3	16	28	24	24	20	22	24	25	Y
18	877001	30	55	170	M	II	I	2	13	30	25	25	21	22	25	28	N
19	878885	34	52	168	F	I	I	2	18	26	22	22	20	20	22	24	N
20	870980	32	44	155	F	II	I	2	16	20	14	18	14	18	18	20	N
21	870963	31	58	150	M	I	II	3	20	28	24	24	20	22	24	24	Y
22	873081	40	40	160	M	I	I	3	22	24	20	22	20	20	22	22	Y
23	871117	54	57	164	F	II	II	2	16	28	22	22	20	22	22	24	N
24	878877	26	52	180	M	I	II	1	12	30	24	24	20	22	24	26	N
25	879993	30	45	172	F	II	II	2	18	26	22	22	18	20	22	24	N
26	877106	28	56	166	M	I	II	2	16	22	18	20	18	20	20	20	N
27	871074	40	43	165	F	II	I	3	20	23	20	22	16	22	22	20	Y
28	875512	22	50	154	M	I	II	2	16	24	20	22	17	20	22	22	N
29	872900	30	46	156	F	I	I	2	15	30	24	24	20	22	24	26	N
30	879876	45	50	165	M	II	II	2	17	28	24	24	22	22	24	24	N

I GEL

										Airway sealing pressures (cm of H20)							
S.no	IP no	Age	Weight	Height	Sex	ASA	MPG	Ease of insertion	Insertion time (Sec)	Oropharyngeal leak pressure	5 minutes after pneumoperitoneum	30 minutes after pneumoperitoneum	5 minutes after trendelenberg	30 minutes after trendelenberg	After neutral position	After releasing pneumoperitoneum	Post-op hoarseness of voice
1	872431	22	60	180	M	I	I	1	12	22	20	29	25	28	30	32	N
2	874678	32	45	176	M	I	II	1	16	25	19	25	20	24	26	30	N
3	873678	40	42	156	F	I	I	2	11	24	20	30	23	28	30	30	N
4	873671	43	44	163	F	I	I	1	13	21	21	28	20	25	27	31	N
5	878976	19	65	150	F	I	II	1	11	23	20	27	20	25	27	30	N
6	873476	35	50	153	F	II	II	2	12	25	21	30	22	24	26	31	N
7	871023	24	55	160	M	I	I	1	11	24	22	29	21	25	27	30	N
8	879800	54	65	165	M	I	I	2	11	22	20	27	22	24	26	30	N
9	870987	44	44	159	F	I	I	1	12	21	21	28	20	25	27	30	N
10	870076	42	52	180	M	II	I	2	14	23	23	30	20	24	28	30	N
11	874023	40	45	168	M	II	I	1	12	22	20	27	19	23	26	31	N
12	874321	39	46	169	M	II	II	3	16	23	22	29	19	25	27	30	Y
13	876789	23	39	156	F	I	II	1	11	21	18	26	20	22	24	31	N
14	877091	42	42	168	M	I	I	1	12	22	18	25	20	21	22	30	N
15	870090	46	48	160	F	II	I	1	12	21	20	28	18	24	26	31	N
16	872789	54	54	166	F	II	II	2	12	20	18	25	20	22	24	30	N
17	877091	46	46	168	F	II	II	1	13	21	18	30	20	26	28	30	N
18	877014	37	49	155	F	I	II	3	18	23	18	28	19	26	28	30	Y
19	876374	29	55	159	F	I	II	1	11	22	19	27	16	25	26	31	N
20	871288	31	43	160	F	I	II	1	12	24	18	28	20	26	28	32	N
21	875947	48	42	170	M	I	II	1	12	18	20	30	20	28	30	30	N
22	873573	36	44	169	M	II	I	2	12	20	19	27	18	25	26	32	N
23	875643	29	45	154	M	II	I	1	12	21	17	25	18	22	24	32	N
24	875637	40	65	159	M	II	II	3	17	22	16	27	20	21	24	31	Y
25	875859	31	54	160	M	I	II	1	11	24	19	30	21	24	26	30	N
26	876241	47	55	171	M	II	II	1	11	23	16	27	20	22	26	30	N
27	873156	27	50	169	F	II	I	1	12	22	20	28	22	21	26	31	N
28	874321	31	49	159	F	I	I	3	17	21	17	25	18	20	22	32	Y
29	873457	27	44	149	F	I	I	1	12	20	18	28	20	24	26	31	N
30	875263	32	38	165	M	II	II	1	11	18	19	30	21	25	27	32	N

KEY TO MASTER CHART

ASA	-	American Society of Anaesthesiologists
cm	-	Centimeter
F	-	Female
M	-	Male
H_2O	-	Water
Kg	-	Kilogram
MPG	-	Mallampati Grade

ANNEXURE V – ETHICAL CLEARANCE CERTIFICATE

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

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Ref: MDC/DOME/ 56 **Date: 17/10/2016**

To,

J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"COMPARISON OF AIRWAY SEALING PRESSURE BETWEEN PROSEAL LMA AND I-GEL IN ADULT PATIENTS UNDERGOING LAPAROSCOPIC SURGERIES REQUIRING GENERAL ANAESTHESIA – A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

(Dr. Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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