
**“COMPARISON BETWEEN LMA
PROTECTOR AND IGEL FOR
OROPHARYNGEAL LEAK PRESSURE IN
ADULT PATIENTS POSTED FOR
LAPROSCOPIC SURGERIES- ONE YEAR
HOSPITAL BASED RANDOMISED
CONTROL TRIAL.”**

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ABSTRACT

TITLE- COMPARISON BETWEEN LMA PROTECTOR AND IGEL FOR OROPHARYNGEAL LEAK PRESSURE IN ADULT PATIENTS POSTED FOR LAPROSCOPIC SURGERIES- ONE YEAR HOSPITAL BASED RANDOMISED CONTROL TRIAL

CONTEXT- Endotracheal intubation was considered as the only way of establishing a definitive airway. But it has its own complications such as laryngeal trauma, stressor response causing elevated pressures, etc. Invention of supraglottic airway devices (SAD) provide alternative airway, without hazards of direct laryngoscopy and intubation. Its advantages include easy insertion, minimal hemodynamic changes, hands free maintenance, and lesser airway morbidity with relatively secure airway.

Igel is a second-generation SAD made of thermoplastic elastomer non inflatable gel like cuff to create a seal with the peri laryngeal structures and avoid compression trauma. LMA Protector is a recently introduced, second-generation SAD with inflatable cuff, two gastric drainage tubes along with a lumen to pass an ET tube.

AIMS- To compare Oropharyngeal leak pressure of Igel (Group I) vs LMA Protector (Group P) in patients posted for laparoscopic surgeries. To compare Insertion time and Ease of insertion in the above mentioned groups.

SETTING AND DESIGN- A One year hospital based Randomised Clinical Trial

MATERIALS AND METHODS- The present randomized control trial was conducted in 60 ASA-1 and ASA-2, aged between 18-60 years posted for elective laparoscopic surgeries under general anaesthesia in KLES Dr.

Prabhakar Kore charitable hospital and medical research centre, Belagavi. Patients were allocated into two equal groups, Group I with Igel (n=30) and Group P with LMA Protector (n=30). All the data Collected were analysed. The demographic data, duration of insertion and airway sealing pressure were analysed using unpaired 't' test.

RESULT- The LMA Protector showed a significantly higher mean OLP after 5 minutes of insertion (37.5 ± 2.86 cm H₂O) in comparison to the Igel (27.33 ± 4.69 cmH₂O) ($p < 0.0001$). After 5 minutes of pneumoperitoneum, the OLP for LMA Protector was 34.83 ± 3.34 cm H₂O, whereas for Igel it dropped to 22.83 ± 4.49 cmH₂O ($p < 0.0001$) signifying that LMA Protector had a superior sealing pressure.

The mean insertion time of LMA Protector is 29.65 ± 7.39 sec, while that of Igel is 18.16 ± 3.62 sec. The study revealed that Igel took lesser time for insertion while being easier to insert as well.

CONCLUSION- The mean OLP was significantly higher in LMA Protector as compared to Igel both, after 5 min of insertion of the SAD and 5 min after creation of pneumoperitoneum. The ease of insertion of Igel was significantly higher than that in LMA Protector. The insertion time of Igel was significantly lower than that of LMA Protector.

KEYWORDS- Oropharyngeal leak pressure, LMA, laparoscopic surgeries, Igel, LMA Protector

LIST OF ABBREVIATIONS

ASA	-	American Society of Anaesthesiologists
ASP	-	Airway sealing pressure
BP	-	Blood Pressure
Cm	-	Centimetre
CNS	-	Central nervous system
CO ₂	-	Carbon dioxide
CVS	-	Cardiovascular system
EtCO ₂	-	End tidal carbon dioxide
ETT	-	Endotracheal tube
FG	-	French gauge
GIT	-	Gastrointestinal tract
H ₂ O	-	Water
Hb	-	Haemoglobin
Inj	-	Injection
IPPV	-	Intermittent positive pressure ventilation
IV	-	Intravenous

Kg	-	Kilogram
LMA	-	Laryngeal mask airway
mcg	-	Microgram
mg	-	Milligram
min	-	Minute
ml	-	Millilitre
OGT	-	Orogastric tube
OSP	-	Oropharyngeal sealing pressure
OLP	-	Oropharyngeal leak pressure
PAE	-	Pre anaesthetic evaluation
PCV	-	Pressure controlled ventilation
PPV	-	Positive pressure ventilation
PR	-	Pulse rate
RR	-	Respiratory rate
SAD	-	Supraglottic airway device
Sec	-	Seconds
SpO ₂	-	Saturation percentage of oxygen

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INTRODUCTION

General anesthesia (GA) has revolutionized surgical practice by allowing patients to undergo complex procedures without pain or awareness. Its development has been marked by key advancements, starting with the first recorded use of surgical anesthesia on October 16, 1846, at Massachusetts General Hospital. ^[1] During this historic event, a dentist known as William T.G. Morton used ether on a patient undergoing tumor excision, and successfully demonstrated the profound impact of anesthesia on medicine.

As surgical techniques progressed, the importance of effective airway management became increasingly apparent. Early methods, such as tracheotomy, were invasive and carried significant risks. By the late 19th and early 20th centuries, endotracheal intubation emerged as a safer and more effective technique, ensuring airway patency and facilitating ventilation. ^[2] Pioneers such as Sir Ivan Magill refined this method, making it a cornerstone of modern anesthesia practice.

Endotracheal intubation offers several benefits, main advantage being the airway protection it offers. It safeguards against aspiration of gastric contents, a critical consideration during surgery. Allows for Controlled Ventilation with precise management of respiratory parameters, essential in patients with compromised lung function.

Facilitates the delivery of inhalational anesthetics and oxygen directly to the lungs. Although ETT is considered gold standard, intubation is not without challenges. The procedure requires substantial skill and expertise, as improper insertion may lead to complications such as dental injury, vocal cord trauma, or tracheal damage. Additionally, intubation can

provoke a sympathetic nervous system response, resulting in hypertension and tachycardia, which may be problematic in certain patients.

To mitigate the challenges associated with intubation, supraglottic airway devices (SAD) were developed as an alternative airway management strategy. ^[4, 5] Introduced in the late 20th century, supraglottic airway devices sit above the vocal cords, offering a less invasive option than ETI. Among the earliest and most widely used SAD is the laryngeal mask airway (LMA), first introduced in the 1980s. They provide a middle ground between traditional mask ventilation and endotracheal intubation, facilitating ease of use while reducing airway trauma.

The advantages of Supraglottic Airway Devices include the ease to place them than endotracheal tubes, requiring less expertise. Also associated with a lower risk of injury to airway structures. It is less likely to provoke significant cardiovascular responses during insertion. Often better tolerated during emergence from anesthesia, with reduced coughing and sore throat.

However, SADs have their limitations most significant being the risk of aspiration. Unlike ETI, SADs do not completely prevent gastric contents from entering the airway, making them less suitable for patients who have had a recent meal, pregnant women. These devices may not achieve as tight a seal as endotracheal tubes, potentially leading to air leakage during positive pressure ventilation. Not ideal for procedures requiring high airway pressures or those involving the airway itself.

^[6] The development of second-generation SADs aimed to address some of these limitations, incorporating features such as improved sealing pressures and gastric drainage channels for better protection. Devices like

the LMA Protector and the Igel have been specifically designed to enhance airway security and ventilation efficiency, making them viable alternatives to ETI, particularly in laparoscopic surgeries.

[7] In the context of laparoscopic surgeries, where pneumoperitoneum and patient positioning can alter respiratory mechanics, the choice of airway device is crucial. Second-generation LMAs, including the LMA Protector and the Igel, are specifically designed to provide better airway sealing and increased protection against aspiration, making them suitable alternatives to endotracheal intubation. They offer better airway sealing and reduced aspiration risk, making them suitable options for maintaining ventilation in such surgeries.

Igel – A second-generation SAD made of thermoplastic elastomer with a gel-like, non-inflatable cuff, is designed to conform to the airway and minimize compression trauma.

LMA Protector – A more recent second-generation SAD that includes an inflatable cuff, two gastric drainage tubes, and an additional lumen for endotracheal tube insertion, providing enhanced airway management capabilities.

[8, 9] Recent studies have compared the efficacy of these two devices in laparoscopic surgeries. Findings suggest that the LMA Protector provides superior airway sealing but requires longer insertion times and has a higher incidence of blood staining upon removal. In contrast, the Igel has demonstrated more stable airway sealing and easier gastric tube insertion, particularly in laparoscopic cholecystectomy.

The evolution of airway management—from early tracheotomies to endotracheal intubation and modern supraglottic devices—reflects the

ongoing pursuit of safer and more effective strategies in anesthesia. The choice between ETI and LMAs, particularly advanced devices like the LMA Protector and Igel, should be guided by the specific clinical context, including the type of surgery, patient characteristics, and the clinician's experience. Understanding the advantages and limitations of each airway management strategy is essential for optimizing patient outcomes in laparoscopic surgeries.

OBJECTIVES OF THE STUDY

PRIMARY OBJECTIVE: Comparing oropharyngeal leak pressure of Igel vs LMA Protector in patients posted for elective laparoscopic surgeries under general anesthesia.

SECONDARY OBJECTIVE: Comparing ease of insertion and insertion time of Igel vs LMA Protector in patients posted for elective laparoscopic surgeries under general anesthesia.

REVIEW OF LITERATURE

Endotracheal intubation is considered gold standard for establishment of a definite airway for positive pressure ventilation.^[1] Tracheal intubation or ventilation with face mask was the only option available for airway management in the 20th century. During induction, as the upper airway muscle tone decreases and as the tongue falls back on to the pharyngeal tissues due to gravity, it causes obstruction of trachea while ventilating with the face mask. Tracheal intubation bypasses all these problems but has its own disadvantages as mentioned earlier.

In 1981, to overcome these problems, LMA was designed by Dr Archie Brain.^[3] The prototype of LMA was first made using Goldman paediatric dental mask's cuff. A 10mm portex clear plastic tube was taken and its endotracheal end was diagonally cut. The cut cuff of the dental mask was then stretched and fixed to the portex tube by acrylic glue. The first documented use of the LMA in a human subject occurred during a routine hernia repair, where it was inserted under halothane anesthesia and successfully supported positive pressure ventilation. The initial results of this new device were published in the British Journal of Anaesthesia in 1983.

First independent assessment of the LMA was made by Brodrick *et al*, in 1989, who obtained a clinically satisfactory and unobstructed airway in 98/100 patients. ^[3, 38] They described the LMA as the “missing link between the face mask and endotracheal tube.” Their excellent features were described in this study, 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 (PACU) and recovery. By 1993, the LMA was widely accepted and was included in the ASA algorithm for unanticipated difficult airway.^[8]

Invention of LMA, led to their extensive usage in patients requiring controlled ventilation. First generation devices such as cLMA, flexible LMA and LMA-unique are simply ‘airway tubes’.^[5, 39] During their usage, they encountered certain drawbacks like gastric insufflations and gastric content aspiration. Hence changes were made to increase the efficiency of LMA. This led to invention of newer SAD, LMA Supreme and Igel airway which have inbuilt orogastric tube port which drains gastric contents and protects patient from aspiration of gastric contents.

Several clinical studies have evaluated the effectiveness, ease of use, and safety of different SADs.^[17] A study by “D.E. Ari et al” assessed the Igel and LMA Protector during laparoscopic cholecystectomy in 64 patients (ASA I–III). Key parameters included ease and speed of insertion, number of attempts, gastric tube (GT) insertion time, airway sealing efficiency, postoperative complications like nausea, sore throat, hoarseness and pain on swallowing.

Findings revealed that Igel had a significantly faster insertion time (13 ± 7.4 seconds) compared to the LMA Protector (18.8 ± 9.8 seconds, $P = 0.020$). Additionally, gastric tube insertion was quicker and easier with Igel ($P < 0.05$). During pneumoperitoneum, the oropharyngeal leak pressure (OLP) remained stable in the Igel group but declined in the LMA Protector group, suggesting that Igel maintained a better airway seal. Both devices had comparable first-attempt success rates and postoperative complication profiles, confirming their suitability for laparoscopic surgeries.

[37] “Berthold Moser et al” examined the LMA Protector and LMA Supreme supraglottic airway devices, focusing on their effectiveness in maintaining airway seal and ventilation pressure. The aim was to determine whether LMA Protector provides a higher OLP than LMA Supreme, which could be clinically significant for patients requiring higher ventilation pressures.

Total of 96 patients were allocated randomly to either the LMA Protector or LMA Supreme group. OLP was measured 5 minutes after device was inserted, with a standardization of 60 cm H₂O cuff pressure. Other parameters included insertion time, number of attempts for device, placement of gastric tube, volume of gastric content, peak airway pressure, pulse oximetry levels throughout the surgery. After device removal, researchers also assessed blood staining and postoperative airway complications three hours postoperatively.

Key findings of the study showed that OLP was higher in the LMA Protector group (30.9 ± 7.4 cmH₂O) compared to LMA Supreme (25.6 ± 4.4 cmH₂O) thereby providing a superior airway seal. LMA Protector also maintained a higher ventilation peak pressure (19.6 ± 7.7 cmH₂O) compared to LMA Supreme (14.0 ± 4.4 cmH₂O)

The differences observed in insertion time, placement of RT, volume of gastric content or postoperative morbidity between the two groups were not statistically significant.

[10] A study by “So Ron Choi et al” evaluated the Baska Mask and Igel in 97 patients undergoing laparoscopic cholecystectomy randomly distributed in two groups: Baska Mask (n = 48) and Igel (n = 49).

Researchers assessed insertion characteristics, OLP, heart rate, blood pressure, airway pressures and compliance of the lung during different surgical phases. Pneumoperitoneum was induced to observe how the airway devices handled increased intra-abdominal pressure.

Results showed that Baska Mask achieved a higher OLP (29.6 ± 6.8 cmH₂O) than Igel (26.7 ± 4.5 cmH₂O), indicating superior airway sealing. However, insertion times, fiberoptic positioning, and need for airway adjustments were comparable between both groups. The differences noted in heart rate, blood pressure, PAP, or lung compliance were not significant. Complication rates, including sore throat, dysphonia, and minor airway trauma, were also similar.

[11] “André A J van Zundert et al” studied the LMA Supreme and LMA Protector supraglottic airway devices, focusing on their airway sealing capability when inserted using a vision-guided technique with a video laryngoscope. Since these devices are typically placed blindly, which can lead to suboptimal positioning, researchers aimed to determine whether LMA Protector provides a superior airway seal compared to LMA-Supreme in surgical patients under general anesthesia.

In a study involving 100 patients undergoing non-thoracic surgery, participants were randomly assigned to either the LMA Supreme group or the LMA Protector group. The devices were inserted under direct visualization using a video laryngoscope, following an "insert-detect-correct-as-you-go" technique with standardizations. Findings indicated that the OLP was significantly higher in the LMA Protector group (31.7 ± 2.9 cmH₂O) compared to the LMA Supreme group (27.7 ± 3.5

cmH₂O). Both devices achieved similar fiberoptic positioning (94% for LMA Protector vs. 96% for LMA-Supreme). No major differences were observed in insertion success rate, alignment, or final anatomical positioning between the two groups. However, LMA-Supreme required significantly more adjustments. Proximal cuff folding occurred in 90% of LMA-Supreme cases vs. only 2% in LMA Protector. The cuff pressure adjustments were needed in 80% of LMA-Supreme cases vs. 48% in LMA Protector. Size corrections were required in 18% of LMA-Supreme insertions vs. only 4% in LMA Protector.

They concluded that when inserted using vision-guided techniques, LMA Protector achieves a higher OLP than LMA-Supreme, while requiring fewer adjustments to achieve optimal positioning. This suggests that LMA Protector may be a preferable choice for patients needing higher OLP during surgery.

[12] “Abhyuday Kumar et al” compared three devices Igel, Proseal LMA and Ambu AuraGain to assess their effectiveness in pediatric laparoscopic surgeries. The objective included determining differences in oropharyngeal leak pressure (OLP), which influences airway sealing and ventilation efficiency.

90 pediatric male patients (ASA I, aged 6 months to 10 years) undergoing laparoscopic surgery were assigned randomly to a group- Igel, Proseal LMA and Ambu AuraGain. The outcomes assessed in the study was OLP, number of attempts, time for insertion, need for airway adjustments and perioperative/ postoperative complications.

Study revealed that Igel achieved a significantly higher OLP than the other two devices. Before pneumoperitoneum: Igel vs. Proseal LMA: $27.36 \pm$

5.72 cmH₂O vs. 23.24 ± 4.35 cmH₂O respectively. OLP for Igel was 27.36±5.7 cmH₂O and for Ambu AuraGain was 23.56 ± 5.7 cmH₂O.

After pneumoperitoneum: Igel OLP was 31.58 ± 4.3 cmH₂O and that of Proseal 27.03±3.8 cmH₂O. Igel OLP was 31.58 ± 4.35 cmH₂O and of Ambu AuraGain 26.83 ± 5 cmH₂O respectively.

Proseal LMA and Ambu AuraGain had similar OLP values before and after pneumoperitoneum. Postoperative complications were similar across all groups, with no cases of regurgitation or aspiration related issues. In conclusion the Igel exhibited the highest airway sealing pressure (OLP), making it the preferred choice for situations requiring greater ventilatory support, such as in obese patients, trendelenburg position, or high airway resistance cases. However, all three devices were safe and effective, with no significant postoperative complications.

[13] “Chang, JE et al” compared two SADs, the Igel and LMA Protector, to evaluate their effectiveness in anesthetized, under general anesthesia. Total of 110 patients undergoing elective surgery were received either the LMA Protector or the Igel after randomization. Researchers evaluated oropharyngeal leak pressure, time for insertion, ease of insertion, fiberoptic glottic view, difficulty in gastric tube insertion, presence of blood staining and complain of sore throat.

Key findings showed LMA Protector achieved an airway leak pressure of 31±7 cmH₂O compared to Igel 27±6 cmH₂O, P = 0.016, suggesting better airway sealing with LMA Protector. The insertion time of Igel was quite less (19±16s) as that of the LMA Protector (27±16s, P < 0.001). Additionally, the cords had better fiberoptic visibility in Igel group, with 80% showing a direct view compared to only 16% in LMA Protector. Igel

had significantly easier gastric tube placement while LMA Protector had more failures in tube placement. Blood staining was more commonly seen with LMA Protector (24%) than Igel (7%), suggesting greater mucosal trauma ($P = 0.033$). The severity of postoperative sore throat was not statistically significant.

The study concluded that while LMA Protector provided superior airway sealing, it required more insertion time, had poorer fiberoptic visibility, and resulted in more mucosal injury as compared to Igel. Igel demonstrated advantages in insertion speed, ease in placement of gastric tube, and lower trauma risk, making it a favorable choice for routine airway management in anesthesia.

[7] The study by “Chih-Jun Lai et al”, compared the effectiveness of the Igel (SAD) as an alternative to the conventional endotracheal tube (ETT) in laparoscopic surgeries requiring pneumoperitoneum and the Trendelenburg position (LPT). The primary outcome of the study included determining whether Igel could provide a reliable airway seal and maintain adequate ventilation in non-obese patients undergoing elective laparoscopic gynaecologic procedures. Additionally, the study aimed to compare respiratory parameters, such as airway resistance, peak and mean airway pressures, pulmonary compliance, and postoperative complications, including sore throat and pulmonary aspiration.

This study included forty patients classified as ASA I-II, posted for gynaecologic laparoscopic surgeries. Participants were allocated groups after randomization, with twenty patients receiving an Igel and twenty receiving an ETT. The primary outcome measure was “the leak fraction”, defined as “the ratio of leak volume to inspired tidal volume” assessed in both the supine and LPT positions. Secondary outcomes included

assessments of pulmonary resistance, airway pressures, compliance, and the incidence of postoperative complications. Standardized anesthetic management, including neuromuscular blockade and volume-controlled ventilation, was applied to all patients.

Findings from the study indicated that the performance of Igel was comparable to the ETT in maintaining an effective airway seal. In LPT position, the median leak fraction was 6.20% [IQR: 3.49] in the Igel group and 6.38% [IQR: 3.71] in ETT group, showing as statistically not significant. Notably the leak fraction of Igel group was lower in the LPT position as compared to supine position (7.01% [IQR: 3.73]), which may suggest that increased intra-abdominal pressure and cephalic organ displacement enhance the airway seal. Pulmonary resistance was lesser in Igel group in comparison to ETT group in both positions, possibly due to the Igel's wider internal diameter. The mean and peak airway pressures remained similar between the two groups in LPT position, demonstrating that the Igel facilitated adequate ventilation without increasing barotrauma risk.

Postoperative complications were also assessed, revealing that sore throat occurred significantly less frequently in patients belonging to the Igel group compared to those who were intubated with an ETT (3/17 vs. 9/11, $p = 0.038$). No instances of pulmonary aspiration, regurgitation, or respiratory distress were observed in either group. The integrated gastric channel in may have contributed a role in reducing the aspiration risk by allowing passive drainage of gastric contents.

In summary, this study supports the Igel as a viable substitute to endotracheal intubation to secure airway in non-obese patients. It provides comparable ventilation efficacy while offering advantages such as reduced

pulmonary resistance and reduced occurrence of sore throat postoperatively.

[26] The study by “Das et al” compares the clinical performance of the Igel (SAD) with the LMA ProSeal in patients who underwent ambulatory surgery. The primary objective was comparison of airway sealing efficacy, intraoperative ventilation parameters and postoperative complications. Given the increasing preference for SADs over endotracheal tubes in ambulatory anesthesia due to reduced airway trauma and faster recovery, the study aimed to determine whether the Igel offers distinct advantages over the LMA ProSeal.

This study included 100 adult patients listed for elective ambulatory surgeries. The patients were assigned one of the groups randomly. 50 patients received the Igel and 50 received the LMA ProSeal. Standard anesthesia protocols were followed, and the devices were inserted by experienced anesthesiologists. The primary objective was to assess insertion time, number of attempts required for successful placement, and oropharyngeal leak pressure (OLP). Secondary outcomes included intraoperative ventilation parameters such as tidal volume and peak airway pressure, success rates of gastric tube placement, and postoperative complications including sore throat, dysphagia, and mucosal trauma.

The findings demonstrated that the Igel had a significantly shorter mean insertion time (11.32 ± 2.19 s) compared to the LMA ProSeal (14.56 ± 2.74 s, $p < 0.001$). Although Igel group had a superior first-attempt success rate (96%) than in the LMA ProSeal group (88%), it was statistically insignificant ($p = 0.17$). LMA ProSeal demonstrated a slightly higher mean OLP (28.26 ± 2.18 cmH₂O) compared to the Igel (26.48 ± 2.16 cmH₂O, $p = 0.001$), indicating a superior airway sealing pressure.

However, both devices facilitated adequate positive-pressure ventilation with no significant difference in peak airway pressure or tidal volume.

Gastric tube placement had a 100% success rate in the LMA ProSeal group, whereas it was successful in 92% of cases in Igel group. This demonstrates that in comparison to LMA ProSeal, Igel may require additional maneuvers for gastric tube placement. Postoperative sore throat was reported in 16% of patients in the LMA ProSeal group, in contrast to 6% in Igel group. Additionally, dysphagia was observed in 8% of patients using the LMA ProSeal but in only 2% of those with the Igel ($p = 0.03$). This suggests that the softer thermoplastic elastomer of the Igel applies less pressure on the surrounding mucosa.

In conclusion, the findings indicate that the Igel provides significant advantages over the LMA ProSeal for ambulatory surgery, including a shorter insertion time and a higher first-attempt success rate, and lower incidence of postoperative airway discomfort. Although the LMA ProSeal provides a slightly superior airway seal and easier gastric tube placement, both devices ensure effective ventilation without major complications. The study supports the use of the Igel as an alternative option to the LMA ProSeal in ambulatory anesthesia, particularly in cases where rapid placement and patient comfort are priorities. Further research was recommended to explore the applicability of the Igel in more complex surgeries and high-risk populations.

[31] “Joly et al” conducted a study aimed to compare the Igel and LMA Supreme in anesthetized patients listed for elective surgeries. The primary objective was to evaluate oropharyngeal leak pressure (OLP) as a measure

of airway sealing effectiveness. Secondary objectives included assessing number of attempts needed for successful placement, fiberoptic visibility of vocal cords, ventilation efficiency, and postoperative complications.

This prospective, randomized trial included 96 patients posted for surgeries under general anesthesia. Half of these patients received Igel the other half, LMA-Supreme after randomization. Standardized anesthetic induction was administered, including neuromuscular blockade, and experienced anesthesiologists inserted the devices and OLP was studied. Secondary outcomes evaluated included time of insertion, first-attempt success rate and fiberoptic glottic visualization. Additionally, any airway related complications were documented postoperatively.

The findings revealed the LMA Supreme had a mean oropharyngeal leak pressure (OLP) of 27 ± 5 cmH₂O compared to that of Igel 24 ± 5 cmH₂O ($p = 0.01$), indicating a more effective airway seal with the LMA Supreme. The successful placement of Igel in first attempt was 98% and for the LMA Supreme, 96% ($p = 0.6$). However, the Igel took a significantly brief time for its insertion (12 ± 5 s) in comparison to the LMA Supreme (16 ± 6 s, $p = 0.002$), suggesting that the Igel allows for quicker and easier placement.

Fiberoptic evaluation of the glottic view revealed that the Igel provided a superior view of the vocal cords compared to the LMA Supreme ($p = 0.04$), which may be attributed to its anatomical fit and lack of an inflatable cuff. Ventilation parameters, including peak airway pressure, were comparable in both the devices, ensuring effective ventilation during surgery. However, blood stained device after the surgery was associated more frequently with the LMA Supreme (29%) compared to Igel (12%, $p = 0.03$), indicating that the LMA Supreme may exert greater pressure on

airway tissues. Additionally, postoperative sore throat was reported in 14% of patients who received the LMA Supreme, whereas 6% of those with the Igel experienced this complication.

In conclusion, both the Igel and LMA Supreme were effective for anesthetized and paralyzed patients, with each having distinct advantages. The LMA Supreme provided a higher oropharyngeal leak pressure, indicating a better airway seal, which may be beneficial in scenarios requiring positive pressure ventilation. Conversely, the Igel offered a faster insertion time and superior fiberoptic glottic visualization, along with a lower incidence of mucosal trauma. These findings suggest that the Igel may be preferable in cases where rapid and atraumatic insertion is a priority, while the LMA Supreme may be advantageous in situations requiring a more secure airway seal. Further research is recommended to evaluate their comparative performance in high-risk patient populations and prolonged surgical procedures.

Given these findings, selecting the appropriate SAD should be guided by surgical requirements, patient condition, and operator experience. In laparoscopic surgeries, second-generation devices such as Igel and LMA Protector offer viable alternatives to traditional endotracheal intubation.

BASIC SCIENCES

Anatomy [18, 21, 32]

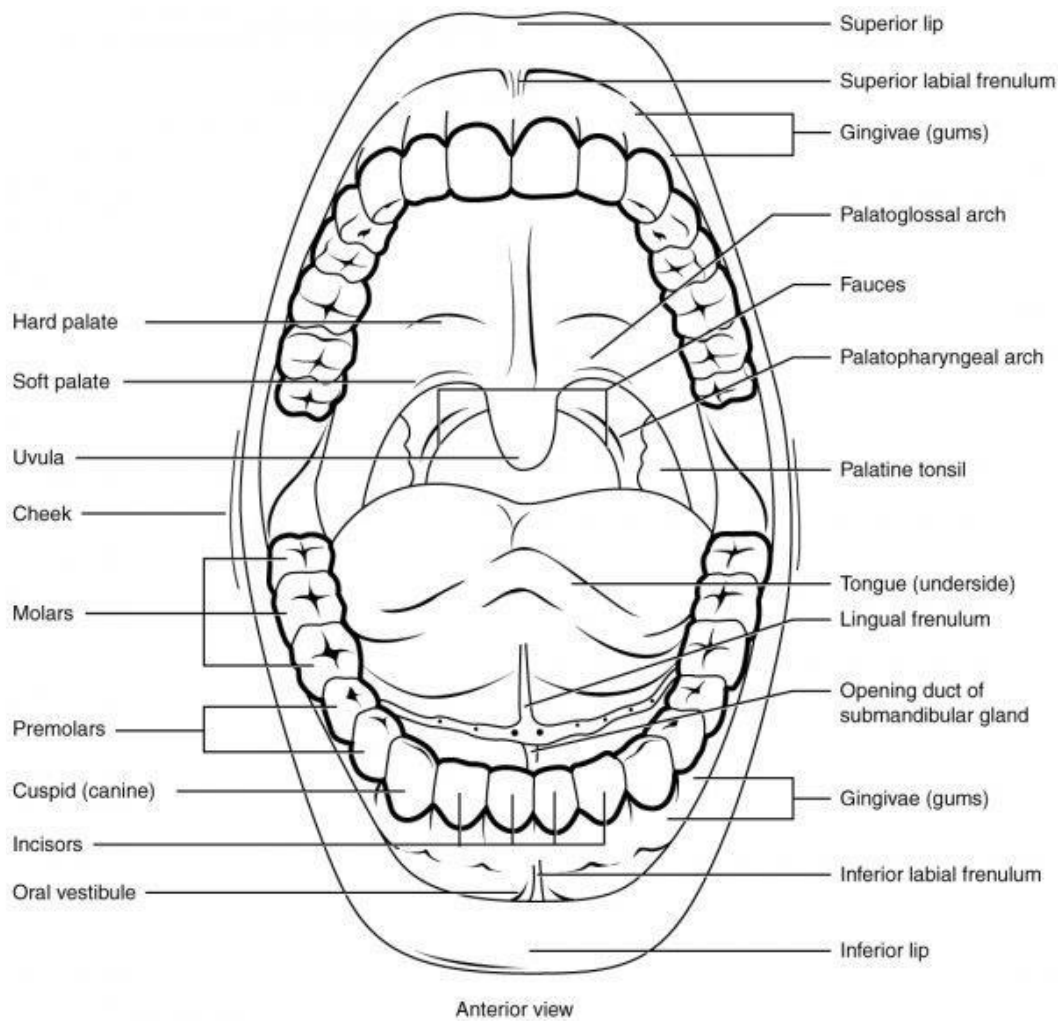


Figure 1: Anatomy of oral cavity

Oral cavity:

It has two parts,

- Vestibule
- Oral cavity proper

Vestibule: It is a narrow space.

Boundaries:

- o External: lips and cheek
- o Internal: the teeth and gums.

Oral cavity proper:

- Boundaries include the teeth, gums and the jaw's alveolar arches.
- Roof: Hard and Soft palate.
- Floor:
 - o Posterior: Tongue.
 - o Anterior: Sublingual region (below the tongue's tip).
- Posterior: Oro-pharyngeal isthmus (pharyngeal communication): It is bounded by soft palate superiorly, tongue inferiorly and palato-glossal arches on the sides.

Hard palate:

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

Soft palate:

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

Muscles of the palate:

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

Tongue:

- It is a muscular organ.
- It has two parts that are separated by sulcus terminalis- oral and pharyngeal
- Attachment of the tongue's inferior surface to the mouth is by frenulum.
- Muscles of the tongue:

Tongue is divided into left and right halves by a fibrous septum in the middle. Each half consists of 4 intrinsic and 4 extrinsic muscles.

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

Nerve supply:

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

Arterial supply:

External carotid artery's branches: The maxillary, facial and lingual arteries.

Venous drainage:

- o Pterygoid plexus
- o Tonsillar plexus
- o Pharyngeal plexus

□ Lymphatic drainage:

- o Upper deep cervical lymph nodes.
- o Retropharyngeal lymph nodes.

Pharynx:

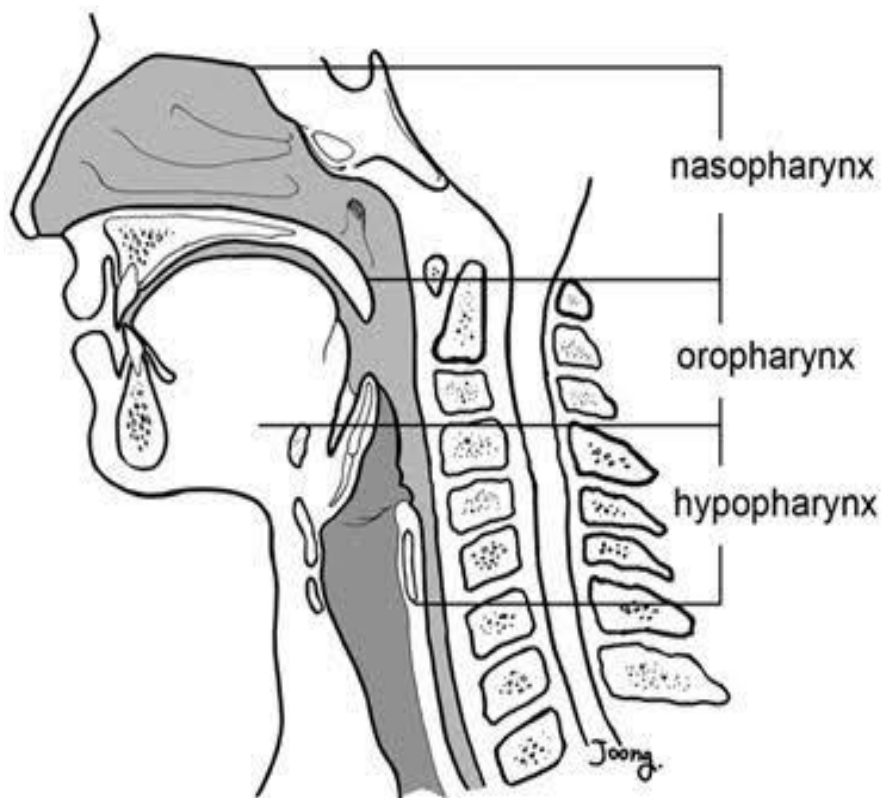


Figure 2: Anatomy of pharynx

- The pharynx is a 12-14 cm long musculo-membranous tube.
- Inverted cone in shape.
- Extension:
 - o Superiorly: Base of cranium.

o Inferiorly: Cricoid cartilage's lower border.

Parts of pharynx: It includes naso-, oro- and laryngo-pharynx.

Nasopharynx:

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

Oropharynx:

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

Laryngopharynx:

It forms the posterior part of the pharynx in its entire length.

Extension:

- superior –epiglottis
- inferior –cricoid cartilage

Borders:

- Superior:

- Lateral glosso epiglottic folds. Delineates oropharynx and laryngopharynx
- Inferior: continuous with oesophagus.

On either side of the inlet of larynx lies the pyriform fossa. Its boundaries are:

- Medial: Aryepiglottic fold.
- Lateral: Thyroid cartilage and thyrohyoid membrane.

Muscles of the pharynx:

□ Constrictors:

- Superior
- Middle
- Inferior

□ Longitudinal muscle coat:

- The Palato-pharyngeus muscle.
- The Stylopharyngeus muscle
- The Salpingo-pharyngeus muscle.

Nerve supply of pharynx:

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

Arterial supply:

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

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

Lymphatic drainage:

- Retropharyngeal lymph nodes
- Upper deep cervical lymph nodes

Larynx:

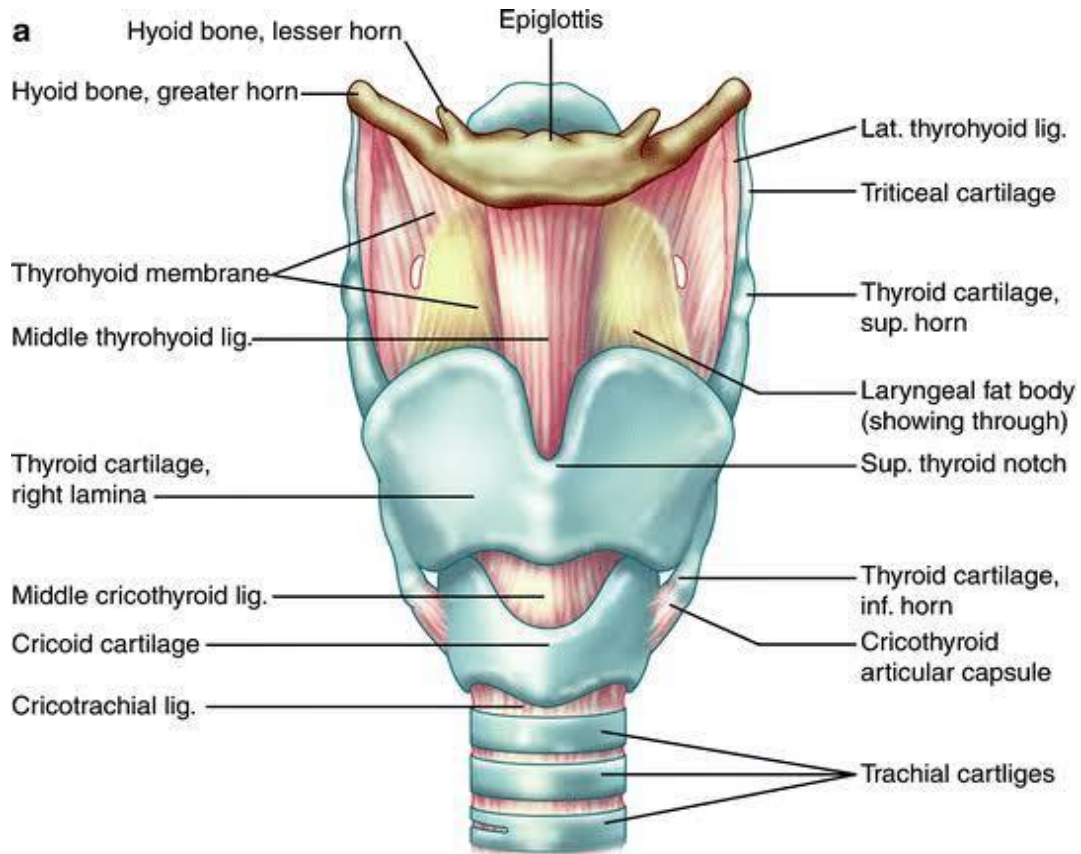


Figure 3: Anatomy of larynx

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

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

Cartilages

Paired cartilages:

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

Unpaired cartilages:

1. Epiglottis
2. Thyroid Cartilage
3. Cricoid Cartilage

Laryngeal joints

1. Cricothyroid joint
2. Cricoarytenoid joint

Laryngeal ligaments and membranes:

Extrinsic ligaments

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

Intrinsic ligaments

1. Quadrate membrane
2. Cricothyroid membrane and conus elasticus.

Cavity of larynx

The larynx is divided into:

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

Muscles of larynx

Intrinsic muscles of larynx

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

Extrinsic muscles of larynx

1. Suprahyoid muscles:

- a. Stylohyoid.
- b. Digastric
- c. Mylohyoid
- d. Geniohyoid

2. Infrahyoid muscles:

- a. Sternohyoid
- b. Omohyoid

c. Sternothyroid

d. Thyrohyoid

Nerve supply of larynx:

- Motor supply- Vagus nerve via recurrent laryngeal nerve to all intrinsic muscles except cricothyroid (supplied by external laryngeal nerve)
- Sensory supply- Mucosal membrane is supplied by internal laryngeal nerve upto the level of cords and below the vocal cord is supplied by recurrent laryngeal nerve.

Arterial supply:

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

Venous drainage:

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

Lymphatic drainage

The supraglottic part of the larynx is drained by lymph vessels into the upper deep cervical lymph nodes and the infraglottic part of larynx;

lymph vessels reach pre and para tracheal lymph nodes and join the lower deep cervical lymph nodes

Applied anatomy [33,40,41]

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

Mouth:

Hard palate makes up anterior 2/3rd of roof of oral cavity and soft palate forms the posterior 1/3rd. Supraglottic airway device needs optimum opening of the mouth. Upon entry of food into oral cavity, it is diverted into oropharynx by the shape of hard palate whereas the soft palate protects food from entering the nasopharynx. If the angle formed by hard palate and the posterior oropharyngeal wall is below 90 degrees, it might be difficult to place the SAD.

Oropharynx:

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

Neurovascular considerations:

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

Cuff related complications commonly affect

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

Physiological implications:

Cardiovascular system:

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

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

Respiratory system:

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

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

Gastrointestinal system:

The swallowing reflex:

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

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

Oesophagus:

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

Pharyngeal mucosa:

The inflated cuff causing compression of the pharyngeal mucosa results in tissue trauma. No major pharyngeal trauma has been associated with supraglottic airway insertion and airway complications are less as

compared to the endotracheal intubation. A very rare complication is risk of ischemia of the pharyngeal mucosa produced by the pressure of the mask over it. This can be avoided by keeping cuff pressure values under 60 cm of H₂O, which is perfusion pressure of the capillaries of pharynx.

The LMA Protector ^[14, 34]

The LMA Protector is a supraglottic airway device (SAD) designed for airway management, providing an alternative to endotracheal intubation. It is typically used when a secure airway is required, especially under general anesthesia. The device is structured to fit comfortably over the laryngeal inlet, preventing aspiration and ensuring that the airway remains patent throughout the procedure. Unlike traditional endotracheal tubes, the LMA Protector features enhanced anatomical shaping and a seal around the larynx. This feature is crucial in preventing aspiration, especially during surgeries where patients may be at risk of regurgitation, such as abdominal surgeries or those involving patients with a full stomach.

LMA[®] Protector[™] Airway with Cuff Pilot[™] Technology

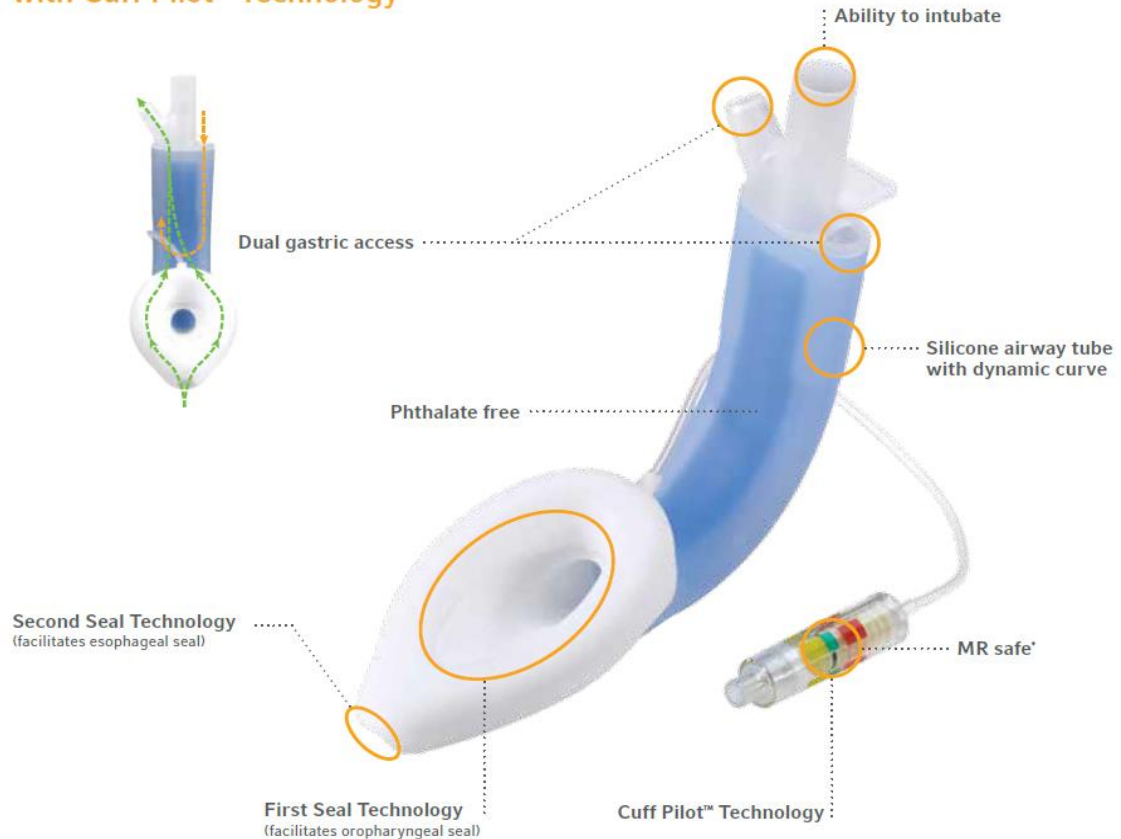


Figure 4 : LMA Protector

Advantages of LMA Protector:

The LMA Protector is composed of soft, medical-grade silicone, phthalate free and is designed to be inserted into the patient's mouth and advanced until it fits snugly over the laryngeal opening. This process generally requires minimal discomfort for the patient. Silicone cuffs have been shown to reduce risk of sore throat and achieve higher seal pressures compared with PVC cuffs.

To ensure a secure fit, the device includes a cuff that can be inflated once it is correctly positioned, creating a seal that helps maintain ventilation and protects the airway. It has an integrated cuff pressure indicator (green, yellow, red) that enables continuous cuff pressure monitoring at a glance and facilitates easy, accurate adjustment when necessary. It is an effective option for airway management, particularly in cases where traditional endotracheal intubation may be difficult or unnecessary. It can also be used in emergency situations when quick and non-invasive airway management is required.

For optimal use, the device should be checked for integrity before insertion to ensure there are no defects. Lubrication is recommended for easier insertion, minimizing discomfort for the patient. Once inserted, confirmation of correct placement is essential. This can be achieved by observing signs of adequate ventilation, such as chest rise and monitoring end-tidal CO₂ levels. Additionally, it has a channel through which a fiberoptic bronchoscope may be passed to visualize the airway and verify that the device is properly positioned, and secure an endotracheal tube under vision if required. Continuous monitoring during the procedure is important, as the LMA Protector may need adjustments if displacement occurs.

LMA® Protector™ Airway with Cuff Pilot™ Technology

MASK SIZE	PRODUCT CODE WITH CUFF PILOT™ TECHNOLOGY	PRODUCT CODE WITH PILOT BALLOON	PATIENT WEIGHT IN KG	MAXIMUM INTRACUFF PRESSURE** IN CM H ₂ O	MAXIMUM ETT ID IN MM	LARGEST SIZE OG TUBE IN FR.
3	192030	195030	30-50	60	6.5	16
4	192040	195040	50-70	60	7.5	18
5	192050	195050	70-100	60	7.5	18

ETT=ENDOTRACHEAL TUBE | OG=OROGASTRIC TUBE

Table 1 : LMA Protector Size Chart

Company recommendations emphasize proper patient selection when considering the LMA Protector for airway management. It is particularly suited for patients undergoing short to medium-duration procedures, those who do not require deep tracheal intubation, or situations where minimizing airway trauma is a priority. The device is well-suited for surgeries like laparoscopic procedures or those where it is critical to maintain a clear airway without significant discomfort or complications.

Disadvantages of LMA Protector:

While the LMA Protector offers numerous advantages, such as ease of insertion, reduced irritation compared to endotracheal tubes, and decreased risk of aspiration, there are limitations. It may not provide as secure a seal as an endotracheal tube, especially in patients with high aspiration risks. It is also not ideal for long-duration surgeries or situations requiring extensive airway pressure, and it may be displaced if not carefully managed.

The device's use may also be restricted in certain patient populations, such as those with difficult airways or severe obesity. It is not suitable for all types of surgeries, especially those that require positive pressure ventilation or in patients with anatomical abnormalities that may complicate its insertion. Moreover, patients at high risk of aspiration, such as those with severe gastroesophageal reflux disease, may not be ideal candidates for this device. Additionally, while it is an effective alternative in some cases, availability and cost can vary by hospital or clinic, limiting its widespread use in certain regions.

The Igel [15,16]

The Igel is a second generation supraglottic airway device with non-inflatable cuff, widely used for securing a patient's airway, particularly in emergency and anesthetic settings. It is designed to provide an alternative to traditional endotracheal intubation, offering a simpler and quicker method of airway management, especially during critical situations. The device is a popular choice in both the operating room and pre-hospital care because of its ease of use, quick insertion, and effective airway sealing.

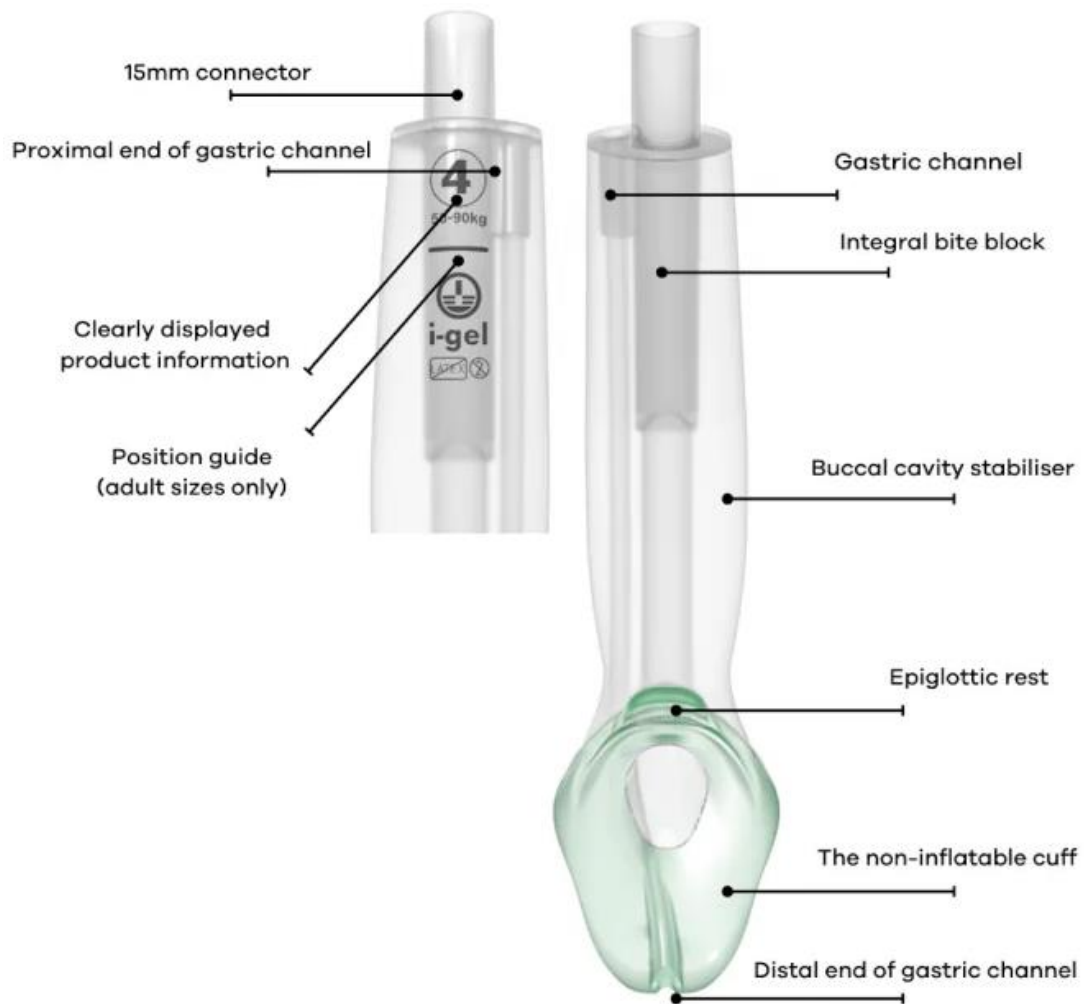


Figure 5 : Igel

Uses of Igel:

The Igel device is commonly employed in a variety of clinical settings. In emergency airway management, it is used when a patient needs rapid airway control, such as in cases of trauma, cardiac arrest, or respiratory failure. Its design allows it to be inserted quickly and effectively, which can be a life-saving advantage when time is crucial. Igel serves as a safe airway device for maintaining ventilation during general anesthesia. It is particularly useful in cases where traditional intubation might be difficult or unnecessary, especially when the risk of complications is high.

The Igel is also employed in pre-hospital care, where paramedics and emergency medical teams rely on it for securing the airway of patients in ambulances. Its ease of use is especially beneficial in pre-hospital settings, where there is limited time for complex procedures. Additionally, in postoperative care, the Igel is used to maintain airway stability in patients recovering from surgery, ensuring they can breathe effectively until they regain full consciousness.

Advantages of Igel:

One of the most significant advantages of the Igel is its ease of insertion. Unlike traditional endotracheal tubes, which require the use of a laryngoscope for visualization of the vocal cords, the Igel is designed to be inserted directly into the patient's pharynx with minimal manipulation. This reduces the risk of trauma and complications during the procedure, making it an attractive option for healthcare providers, especially in high-pressure situations. Additionally, the Igel does not require laryngoscopy, making it a more accessible airway management option for healthcare providers with varying levels of experience.

The device also provides a secure airway. Its unique shape and design form a tight seal in the pharynx, which minimizes the risk of air leakage and prevents aspiration of stomach contents. It incorporates a gastric channel that allows passage of nasogastric tube to empty the stomach contents. Furthermore, the Igel is highly compatible with mechanical ventilation, making it a reliable choice in surgeries and critical care scenarios where mechanical ventilation is necessary to maintain proper oxygenation and ventilation. Another advantage is its reduced risk of injury. Because it is non-invasive and easy to insert, there is a lower chance of causing harm to the patient's airway compared to more invasive methods like endotracheal intubation. Finally, the Igel's versatility is noteworthy, as it comes in various sizes, making it suitable for use in both adult and paediatric patients.

Description	Size	Weight	Colour
i-gel [®] supraglottic airway, large adult	5	90+ kg	orange
i-gel [®] supraglottic airway, medium adult	4	50 - 90 kg	green
i-gel [®] supraglottic airway, small adult	3	30 - 60 kg	yellow
i-gel [®] supraglottic airway, large paediatric	2.5	25 - 35 kg	white
i-gel [®] supraglottic airway, small paediatric	2	10 - 25 kg	grey
i-gel [®] supraglottic airway, infant	1.5	5 - 12 kg	light blue
i-gel [®] supraglottic airway, neonate	1	2 - 5 kg	pink

Table 2 : Igel Size Chart

Disadvantages of Igel:

Despite its many benefits, the Igel is not without its limitations. One significant disadvantage is that it provides limited airway control compared to endotracheal intubation. While it effectively secures the airway and ensures adequate ventilation, it does not offer the same level of protection against aspiration, particularly in patients with a full stomach or those who are prone to regurgitation. This means that in cases where the risk of aspiration is high, endotracheal intubation might be a more appropriate choice. Additionally, the Igel device cannot be used for suctioning. If the patient has significant secretions, vomit, or blood in the airway, suctioning might be necessary, but this is not possible with the Igel.

Another disadvantage is that the Igel is not suitable for all patients. For individuals with abnormal airway anatomy, such as those with significant facial trauma, high BMI, or challenging anatomical features, the Igel may not provide a secure fit. In such cases, more invasive procedures, such as endotracheal intubation, may be required to ensure the airway is properly managed. The limited duration of use is another consideration; while the Igel is effective for short-term airway management, it may not be appropriate for prolonged use, such as in extended surgeries or for long-term ventilation. In such situations, an endotracheal tube might be necessary for better airway protection and extended support. Finally, as with any medical device, there is a risk of malpositioning.

While the Igel is easier to insert than traditional intubation devices, it still requires proper technique to ensure it is placed correctly. If inserted improperly, it could fail to secure the airway effectively, leading to

complications. Healthcare providers must receive proper training to minimize this risk and ensure the device is used correctly.

METHODOLOGY

STUDY DESIGN: A One Year Hospital Based Randomised Control Trial

STUDY PERIOD: A year (January 2024 – December 2024)

PLACE: “Department of Anaesthesiology, KLE’S Dr. Prabhakar Kore Hospital and Medical Research Centre, KAHER, Belagavi”.

SOURCE OF DATA: 18 to 60 years old patients listed for elective laparoscopic surgeries under general anesthesia at “KLE’s Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi.”

SAMPLE SIZE: A total of 60 patients.

SAMPLING PROCEDURE:
$$n = \frac{(Z\alpha + Z\beta)^2 (SD_1^2 + SD_2^2)}{(x_1 - x_2)^2}$$

Where,

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

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

Hence,

$Z\alpha = 1.96$, $Z\beta = 0.84$

In view of these calculations a total of 60 patients were evenly assigned to two groups, namely

Group I – Igel

Group P – LMA Protector

Inclusion Criteria:

- Adults undergoing Elective Laparoscopic surgeries under general anaesthesia aged 18-60 years.
- Surgeries lasting up to 120 min or less.
- American Society of Anaesthesiologist- ASA grade I and II.
- Mallampati grade I and II.

Exclusion Criteria:

- Upper airway obstruction.
- Potential difficult intubation.
- Surgeries which lasted more than 120 minutes.

Ethical Clearance:

The approval was obtained from “The institutional Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi” on 01/04/2023, before starting the study. CTRI registration number was obtained as follows- CTRI/2023/09/057613

Informed Consent:

All patients fulfilling the selection criterias were informed about the study's nature and the planned intervention. Written informed consent was obtained from each participant in their own vernacular language before enrolment.

Method of Collection of Data:

Thorough preanesthetic evaluation was done one day before surgery. On the day of the procedure, an eight-hour nil-by-mouth status was confirmed, and an intravenous cannula was secured. Aspiration prophylaxis was given with Inj pantoprazole 40mg and Inj ondansetron 8mg.

Group P- LMA Protector was used

Group I- Igel was used

After shifting to operation theatre, standard monitors were attached. All the patients were initially pre-oxygenated for 3minutes by 100% oxygen. They were pre-medicated with intravenous Inj. Glycopyrrolate at 0.005mg/kg, Inj. Midazolam at 0.05mg/kg and Inj. Fentanyl at 2mcg/kg.

Intravenous propofol (2 mg/kg) was used to administer anesthesia, and neuromuscular blockade using atracurium (0.5 mg/kg) subsequently. The airway device of the appropriate size was inserted as indicated by the guidelines from manufacturer. Oropharyngeal leak pressure (OLP) was measured five minutes after device insertion and again five minutes after the establishment of pneumoperitoneum. To determine OLP, the expiratory relief valve was closed at a fixed flow rate of 6 liters/minute, and the airway pressure at which a gas leak occurred was recorded. The leak was identified by placing the stethoscope lateral to the thyroid cartilage and detecting an audible leak.

The ease of insertion was defined as:

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

If an effective airway could not be established, the device was removed, the insertion failure was documented, and endotracheal intubation was performed. Such cases were excluded.

The insertion duration was defined as the time from when the LMA contacted the incisors to successful placement, confirmed by square-wave capnography, bilateral equal air entry, and symmetric chest rise.

The inspired tidal volume was set at 6–8 mL/kg, a respiratory rate of 12–14 cycles per minute. Maintenance of anesthesia was delivered by 1:1 oxygen and nitrous oxide mixture, isoflurane (0.6–1%), and administration of intravenous doses of atracurium (0.15 mg/kg).

At the conclusion of the procedure, reversal of neuromuscular blockade was done using intravenous glycopyrrolate (0.01 mg/kg) and neostigmine (0.05 mg/kg) once extubation criteria were met. The airway device was removed once the protective airway reflexes and consciousness returned, followed by ventilation with a facemask for five minutes.

Statistical analysis:

The collected data was entered into Microsoft excel spread sheet. The qualitative variables were presented as percentages, rates, ratios, while continuous variables were represented as mean \pm standard deviation (SD). The unpaired 't' test was used in analysis of demographic data, duration of insertion and OLP. Fisher's Exact Test was used for ease of insertion scores. The probability value (p value) of ≤ 0.05 was deemed to be statistically significant.

RESULTS

The study included a total of 60 adult patients, between 18 to 60 years of age, who underwent elective laparoscopic surgeries under general anesthesia. Participants were distributed equally into groups using a computer-generated randomization pattern.

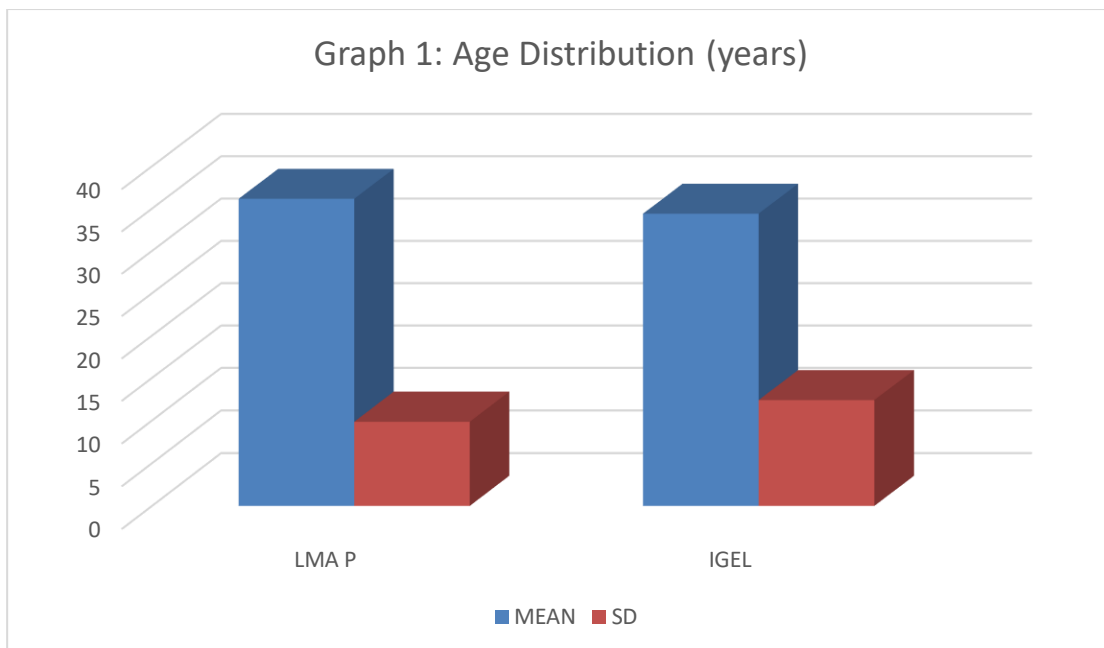
Group P- LMA Protector (n=30)

Group I- Igel (n=30)

The collected data was transcribed into a Microsoft Excel spreadsheet for perusal. The results were processed and presented in tabular format.

Table 3 : Age distribution (years)

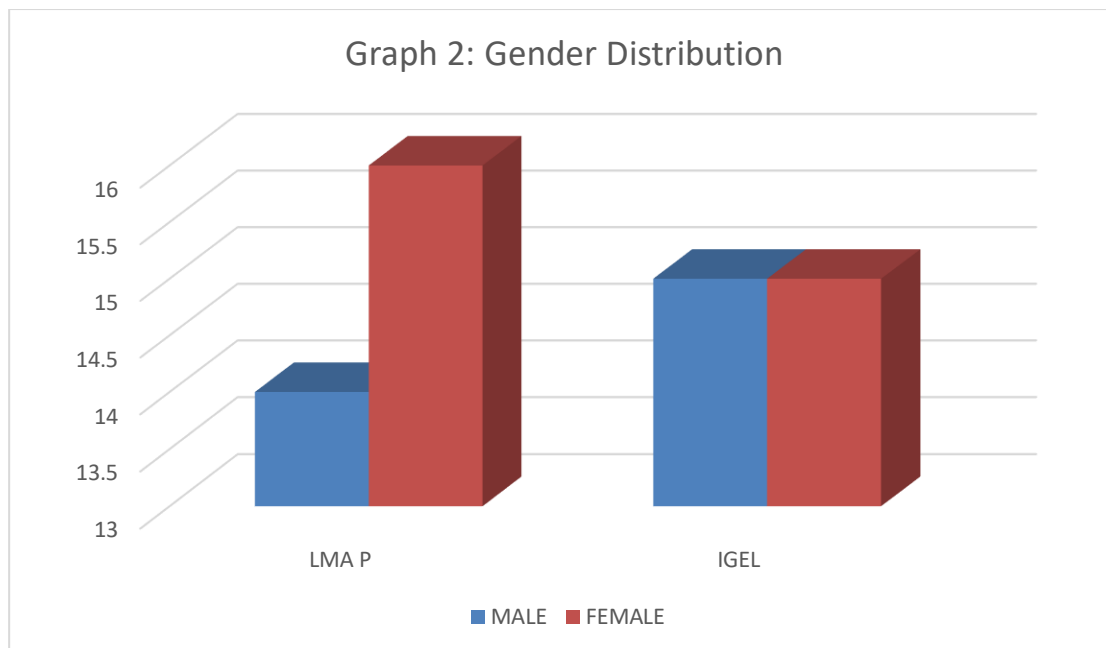
GROUP	Mean Age	SD	MIN	MAX	P VALUE
LMA P	36.16	9.85	22	55	0.5437
IGEL	34.4	12.39	18	60	



The mean age was 36.16 ± 9.85 in LMA Protector group and 34.4 ± 12.39 in Igel group. The two groups did not show a statistically significant difference.

Table 4 : Gender Distribution

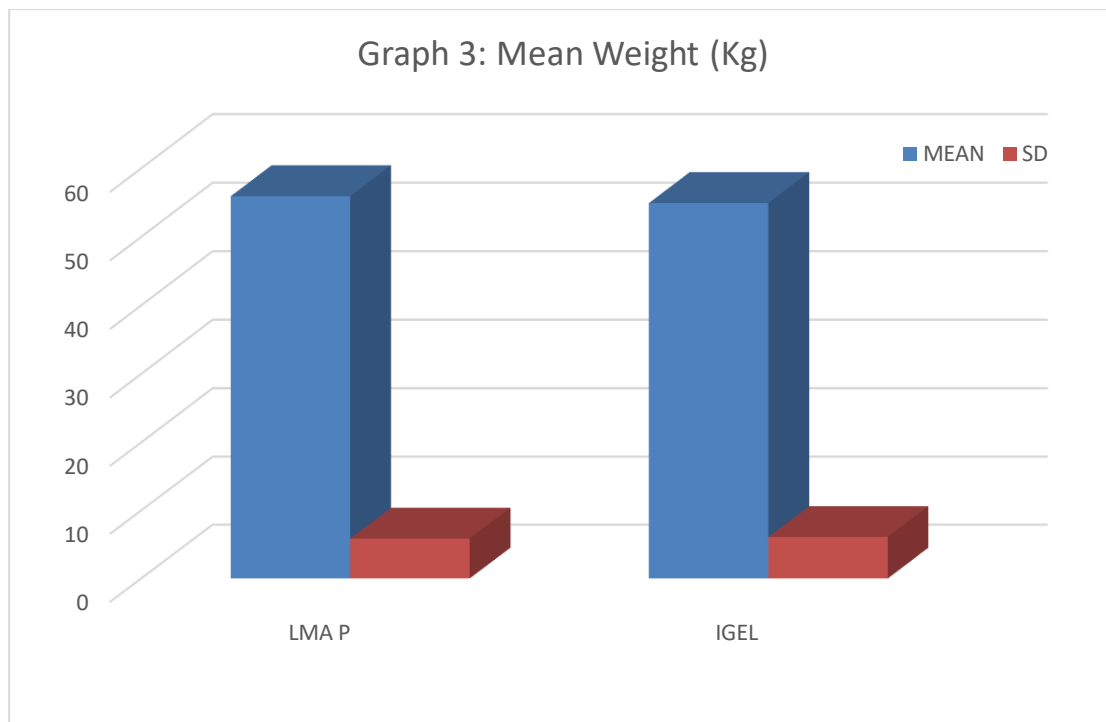
Groups	LMA P		Igel		P value
	Number	Percentage	Number	Percentage	
Male	14	46.66	15	50	0.899
Feale	16	53.33	15	50	
Total	30	100	30	100	



In the study, there were 14 males and 16 females under LMA Protector group, while 15 males as well as females in Igel group. This gender distribution was not statistically significant to the study.

Table 5 : Mean Weight (Kg)

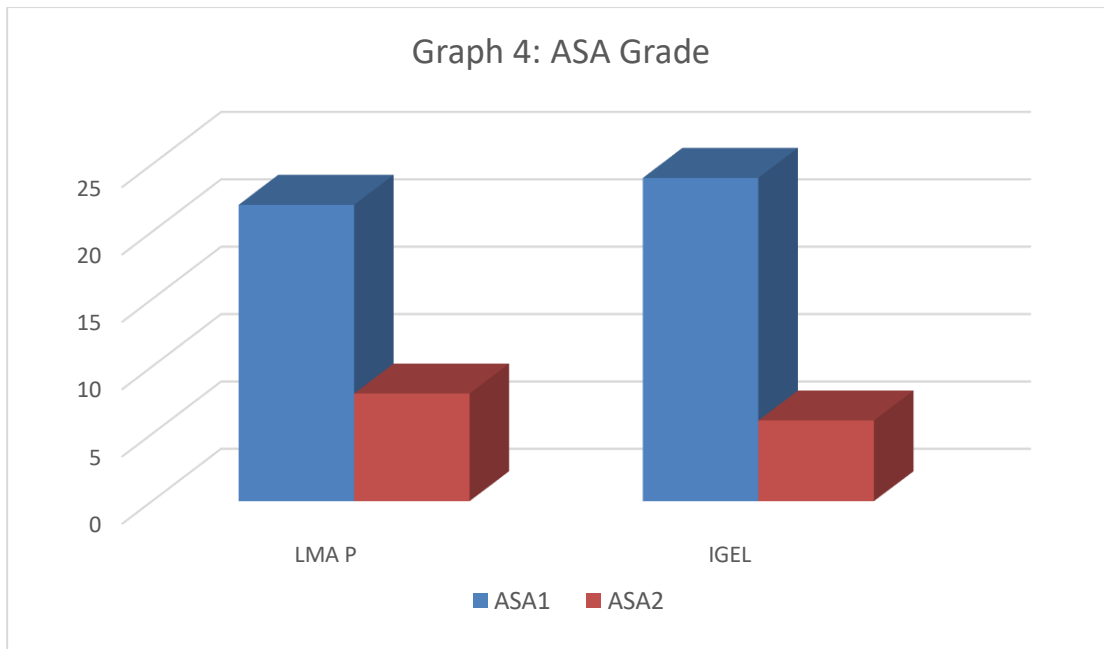
Groups	N	Mean Weight	SD	P Value
LMA P	30	55.93	5.87	0.5207
IGEL	30	54.93	6.10	



The mean weight in LMA Protector group was 55.93 ± 5.87 and that in Igel group was 54.93 ± 6.10 with the p value of 0.5207 rendering it statistically not significant.

Table 6 : ASA Grade

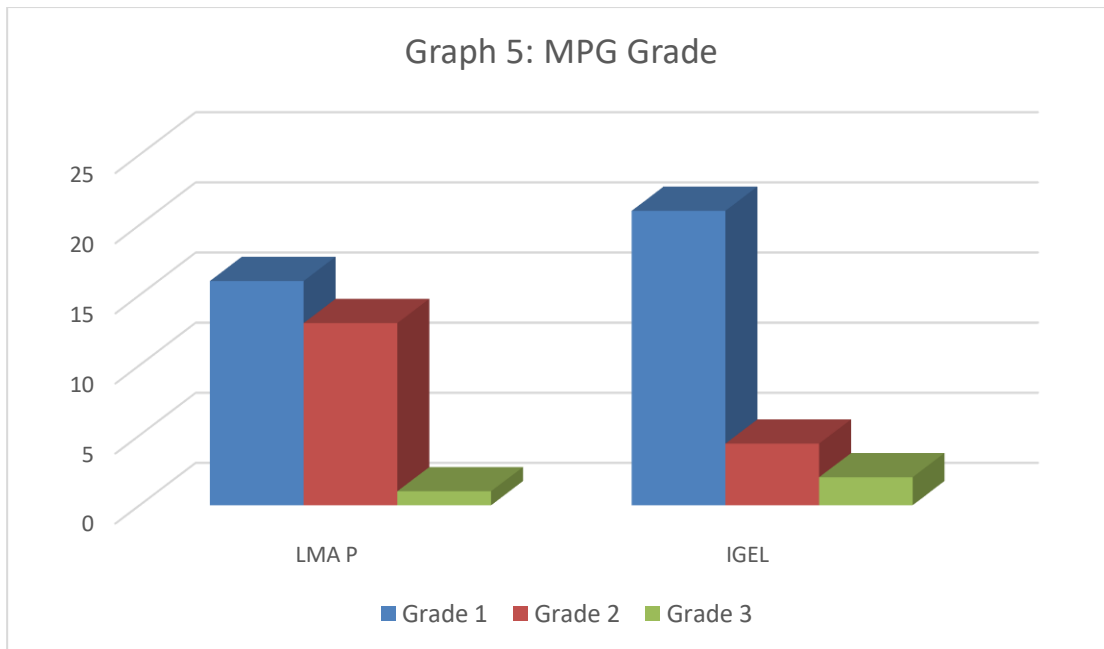
ASA Grade	LMA P	Percentage	IGEL	Percentage	P value
Grade 1	22	73.33	24	80	0.55
Grade 2	8	26.67	6	20	
Total	30	100	30	100	



Out of 30 patients in each group, 73.33% in LMA Protector Group belonged to ASA grade 1 while 80% in Igel Group. While ASA grade 2 of LMA Protector was 26.67% and 20% of Igel. With p value of 0.55 there is no statistical significance between two groups.

Table 7 : Mallampati Grade (MPG)

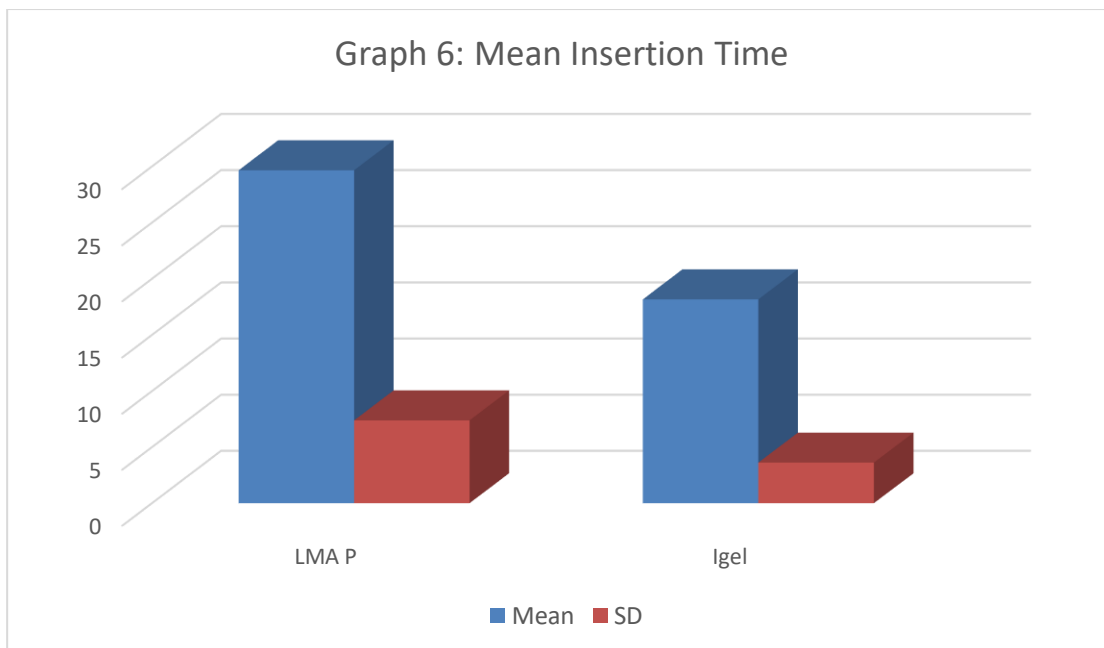
MPG Grade	LMA P	Percentage	Igel	Percentage	P Value
Grade 1	16	53.33	21	70	0.39
Grade 2	13	43.33	7	23.33	
Grade 3	1	3.34	2	6.67	
Total	30	100	30	100	



In our study 53.33% patients had MPG 1, 43.33% had MPG 2 and only 3.34% had MPG 3 in LMA Protector group. While Igel group had 70% patients with MPG 1, 23.33% with MPG 2 and 6.67% with MPG 3. P value being 0.39, both groups were comparable.

Table 8 : Mean Insertion Time (seconds)

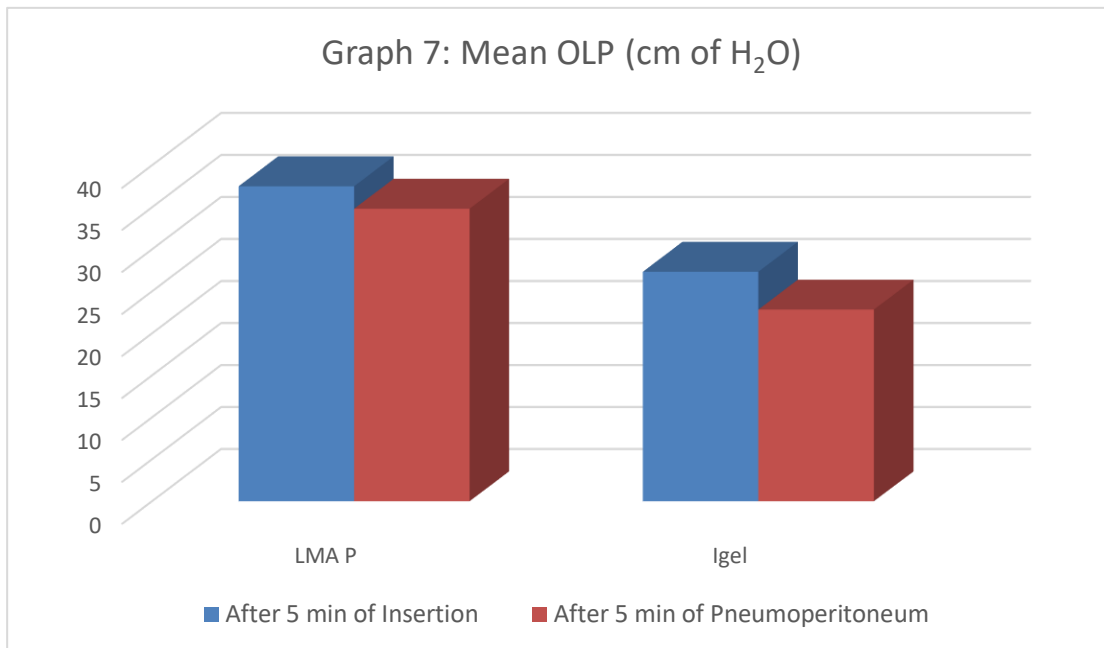
Group	Mean	SD	Min	Max	P value
LMA P	29.6553	7.39	25.87	47.53	<0.0001
Igel	18.1633	3.62	16.73	27.87	



The mean insertion time of LMA Protector is 29.65 ± 7.39 sec, while that of Igel is 18.16 ± 3.62 sec. P value being <0.0001 , this is a statistically significant difference.

Table 9: Mean Oropharyngeal Leak Pressure (OLP in cm of H₂O)

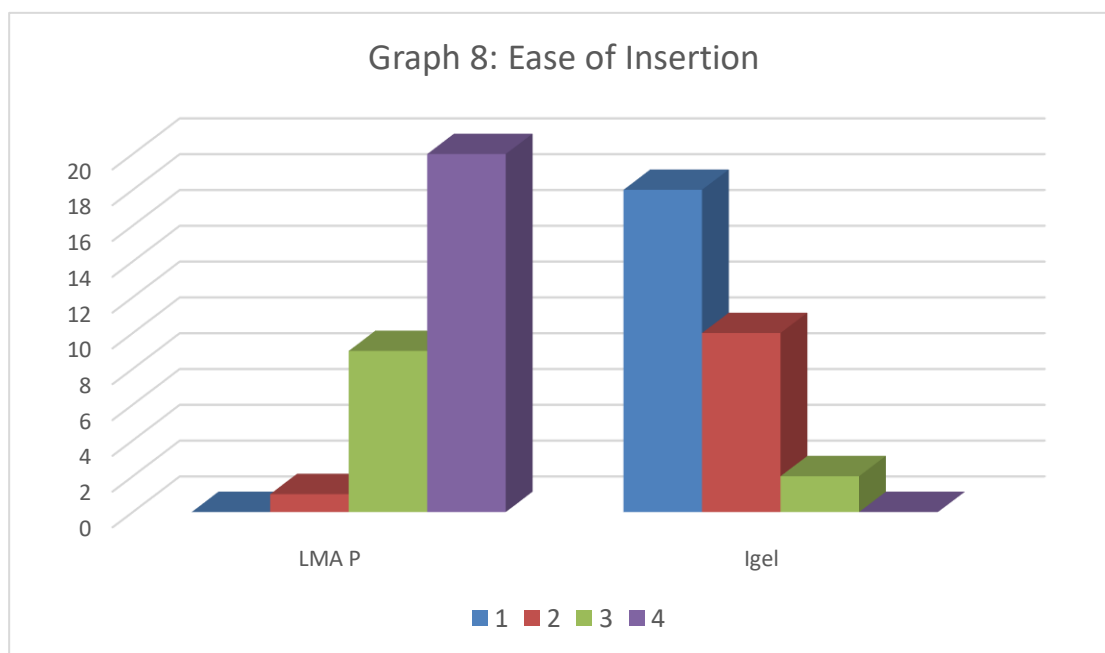
OLP	LMA P				Igel				P value
	Mean	SD	Min	Max	Mean	SD	Min	Max	
After 5 min of insertion	37.5	2.86	30	40	27.33	4.69	15	40	<0.0001
After 5 min of pneumo-peritoneum	34.83	3.34	30	40	22.83	4.49	10	35	<0.0001



In our study, after 5 min of insertion the mean OLP in LMA Protector group was 37.5 ± 2.86 cm of H₂O and that in Igel Group was 27.33 ± 4.69 cm of H₂O. While the mean OLP after 5 min of creating pneumoperitoneum was 34.83 ± 3.34 cm of H₂O in LMA Protector group and 22.83 ± 4.49 cm of H₂O in Igel group. In both conditions the p value was <0.0001 indicating this difference was statistically significant.

Table 10 : Ease of Insertion

Ease of Insertion	LMA P		Igel		P value
	Number	Percentage	Number	Percentage	
1	0	-	18	60	<0.0001
2	1	3.33	10	33.33	
3	9	30	2	6.67	
4	20	66.67	0	-	
Total	30	100	30	100	



This study showed that Igel was very easy to insert with 18 patients graded at '1', 10 graded at '2' and only 2 graded at '3'. On the other hand insertion of LMA Protector was quite difficult with 20 patients graded at '4', 9 graded at '3', only 1 patient with grade of '2' and none graded as '1'. The p value being <0.0001 , this difference was concluded to be statistically significant.

DISCUSSION

Supraglottic airway devices (SADs) have revolutionized airway management, particularly in anesthesia and emergency medicine. Over the years, multiple variations of LMAs have been developed with unique structural and functional modifications aimed at improving sealing pressure and patient safety. Unlike traditional LMAs, Igel lacks an inflatable cuff, relying instead on its gel-like structure for an effective seal. The LMA Protector incorporates features such as an integrated bite block and gastric access for improved airway protection and reduced aspiration risk.

The study aimed to compare and evaluate the performance of the LMA Protector and Igel in patients undergoing elective laparoscopic surgeries under general anesthesia. The primary objective was to evaluate the oropharyngeal leak pressure (OLP) before and after pneumoperitoneum, which is crucial in ensuring adequate ventilation during laparoscopic procedures where intra-abdominal pressure is increased.

The secondary objectives included comparison of insertion time between the two devices and assessment of ease of insertion. A total of 60 patients between 18 to 60 years of age undergoing elective laparoscopic surgeries were included, with 30 allotted to the LMA Protector group and 30 to the Igel group randomly. Both groups had comparable age distribution pattern (36.16 ± 9.85 years for LMA Protector vs. 34.4 ± 12.39 years for Igel, $p = 0.5437$).

There were 14 males and 16 females under LMA Protector group, while 15 males as well as females in Igel group. The mean weight in LMA Protector group was 55.93 ± 5.87 and that in Igel group was 54.93 ± 6.10

with the p value of 0.5207. None of which showed statistically significant differences.

Similarly, out of 30 patients in each group, 73.33% in LMA Protector Group belonged to ASA grade 1 while 80% in Igel Group. While ASA grade 2 of LMA Protector was 26.67% and 20% of Igel. With p value of 0.55 and 53.33% patients had MPG 1, 43.33% had MPG 2 and only 3.34% had MPG 3 in LMA Protector group. While Igel group had 70% patients with MPG 1, 23.33% with MPG 2 and 6.67% with MPG 3. Thus, ASA grades and Mallampati classifications were evenly distributed across both groups. This comparability in baseline characteristics ensured that differences observed in performance metrics could be attributed to the devices rather than confounding patient factors.

OLP is a key parameter in SAD performance, as it determines the ability of the device to maintain airway patency and prevent gas leakage, particularly in positive pressure ventilation settings.

After 5 minutes of insertion, the LMA Protector showed a significantly higher mean OLP (37.5 ± 2.86 cm H₂O) in comparison to the Igel (27.33 ± 4.69 cmH₂O) ($p < 0.0001$).

After 5 minutes of pneumoperitoneum, the OLP for LMA Protector was 34.83 ± 3.34 cm H₂O, whereas for Igel it dropped to 22.83 ± 4.49 cmH₂O ($p < 0.0001$).

This significant difference was indicative of the LMA Protector providing a superior airway sealing even under increased intra-abdominal pressure conditions, making it a preferable choice for laparoscopic procedures where higher ventilatory pressures may be required.

[19] “Bhardwaj M et al” conducted a study to determine whether the LMA Protector offered superior airway sealing compared to the well established LMA ProSeal. In agreement with our study, the results demonstrated that the LMA Protector had a significantly higher median oropharyngeal leak pressure (33 cm H₂O) in comparison to the LMA ProSeal (29.5 cm H₂O), suggesting that it provided a more effective airway seal. However, both devices showed comparable performance of successful placement on first-attempt, ease of insertion, and fiberoptic view. The LMA Protector required fewer cuff pressure adjustments during use, indicating better cuff stability. Despite these differences, both the groups had similar postoperative complications such as blood staining and sore throat, indicating that both devices were equally safe in clinical practice.

[20] “Kerai S et al” compared the impact of different head and neck positions on the oropharyngeal leak pressure (OLP) of LMA Protector and the LMA ProSeal (PLMA). The study revealed that the OLP for the LMA Protector in the neutral head position was 32.24 ± 7.02 cmH₂O. In head flexion and rotation, OLP values were 38.14 ± 5.11 cm H₂O and 32.97 ± 6.58 cm H₂O, respectively for LMA Protector and LMA ProSeal. The study concluded that the LMA Protector and PLMA exhibit similar OLPs across various head and neck positions.

[22] “Singh I et al” compared the Igel and LMA ProSeal supraglottic airway devices based on their clinical performance during elective surgeries. Corresponding to the findings of our study, this study showed OLP of Igel was 25.27 cm H₂O compared to 29.6 cm H₂O for LMA Proseal. The Igel had a significantly lesser mean insertion time of 11.2 ± 2.5 seconds, whereas the LMA ProSeal had a mean insertion time of 14.8 ± 3.6 seconds. The difference in first-attempt success rate and postoperative

complications like dysphagia, hoarseness and sore throat was not statistically significant.

The time required for successful insertion of the device is a critical factor, especially in emergency airway management. The mean insertion time for LMA Protector was 29.65 ± 7.39 sec, whereas for Igel it was significantly shorter at 18.16 ± 3.62 sec ($p < 0.0001$). This may be attributed to the bulkier design of LMA Protector and requirement for more precise positioning compared to the pre-shaped, cuffless structure of Igel, which allows for easier and faster insertion.

[23] “Chauhan G et al” compared the clinical performance of the Igel and ProSeal (PLMA) in anesthetized patients who underwent elective surgeries. The mean insertion time for Igel (11.12 ± 1.81 seconds) was notably less as compared to PLMA (15.13 ± 2.91 seconds). Additionally, the mean oropharyngeal leak pressure (OLP) was found to be significantly higher in PLMA group (29.55 ± 3.53 cm H₂O) as compared to the Igel group (26.73 ± 2.52 cm H₂O; $P = 0.001$). Insertion of RT was also notably easier in the Igel than in the PLMA ($P = 0.001$). Although the insertion time of Igel was quite less, the mean OLP reflected similar results as our study.

[24] “Jeon WJ et al” evaluated efficacy of ProSeal and Igel. In parallel to our study, the mean insertion time of Igel was found to be 26.4 ± 0.83 sec while that of Proseal was 26.64 ± 1.44 sec. They also concluded that OLP 10 min after insertion for PLMA and Igel were 25.9 ± 5.2 and 24.3 ± 3.4 cmH₂O respectively, rendering them comparable. On a “5-point scale”, the median ease of insertion score was 4, suggesting that clinicians found the device relatively easy to insert.

[25] “Kini G et al” evaluated the efficacy of the Igel and the ProSeal (PLMA) in patients listed for elective surgeries under general anesthesia. Study revealed the time required for insertion of Igel (21.98 ± 5.42 sec) was quite lesser as compared to Proseal LMA (30.60 ± 8.51 sec). They also found that OLP of Igel was 23.58 ± 4.9 cm H₂O while that of Proseal LMA was 21.83 ± 5.92 cm H₂O. This is in alignment with our findings. The difference in quality of the fiberoptic view of the glottis, ease of RT insertion, occurrence of postoperative sore throat was not statistically insignificant.

[26] “Das A et al” did a research comparing the clinical performance of Igel and LMA ProSeal (PLMA). Their findings showed that the Igel group had a significantly shorter mean insertion time (12.42 ± 2.36 seconds) than the PLMA group (17.23 ± 2.82 seconds). However, the first-attempt insertion success between the two devices was comparable. Additionally, the occurrence of sore throat was less frequent in the Igel group (6.67%) in comparison to the PLMA group (13.33%), but was statistically insignificant.

[27] According to “Ní Eochagáin A et al”, the median time taken to insert LMA Protector was 31 sec. The LMA Protector demonstrated an effective seal, with a mean oropharyngeal leak pressure of 37 mmHg. 74.8% of their patients needed jaw thrust and 67.5% needed neck extension, depicting the difficulty in inserting the SAD. This is in accordance with our study.

Ease of insertion was assessed using a grading system where lower scores indicated greater ease. Igel was significantly easier to insert, with 60% of patients scoring 1 (easiest) and only 6.67% scoring 3 (moderately difficult). Conversely, the LMA Protector was more challenging to insert, with 66.67% of patients scoring 4 (most difficult) and none achieving a

score of 1. The difference was statistically significant ($p < 0.0001$). This suggests that while Igel offers a user-friendly design that facilitates rapid placement, the LMA Protector requires more expertise and technique for proper insertion.

[28] “Eckardt F et al” evaluated the LMA Protector’s clinical performance. The median seal pressure with head in the neutral position was 34 cm H₂O. Notably, passive neck extension did not reduce the seal pressure; instead, a slight increase to a median of 34.7 cm H₂O was observed. Fiberoptic-guided tracheal intubation through the LMA Protector was successful, indicating its utility in such procedures.

[29] “Shariffuddin II et al” assessed the clinical efficacy of the LMA Protector in moderately obese patients. Their study concluded that mean OLP of LMA Protector was 31.8 ± 5.4 mmHg. The mean insertion time was 21.0 ± 4.0 seconds. And out of 29 patients, 26 were assessed as ‘easy’ grade of insertion and 3 patients as ‘fair’. A clear view of the glottic opening was achieved in 93% of subjects upon fiberoptic evaluation, suggesting proper anatomical positioning of the device.

[30] “Sng BL et al” in their clinical evaluation of LMA Protector concluded its mean OLP as 25.5 ± 4 cmH₂O and the median time to insert the LMA was 19 sec, with ease of insertion graded as ‘easy’. The first-attempt insertion success rate was 94%. This is on contrast to the findings of our study.

[31] “Joly N et al” compared the LMA-Supreme and Igel. Their study concluded that median OLP for Igel was 23 ± 7 cmH₂O while LMA Supreme was 21 ± 8 cmH₂O. Insertion time for Igel was 19 ± 7 sec and was 27 ± 17 sec for LMA Supreme. They also concluded that Igel was

associated with a slightly faster insertion time and better Fiberoptic visualization of the glottis. Both devices had comparable rates of mild postoperative discomfort and complications between the groups.

[35] “Gatward JJ et al” studied clinical performance of Igel in 100 patients and in 92 patients took 30sec or less for securing the airway, with an overall median duration being 15sec. To achieve a clear airway, 26% of patients required manipulations, with a median of one manipulation per patient. While the median OLP was 24 cmH₂O. Fiberoptic examination through the device revealed visible vocal cords in 91% of patients.

[36] “Chan WK et al” compared clinical performance of LMA Supreme and LMA Protector. Mean OLP was 30.72 ± 8.60 cm H₂O for the LMA Protector Cuff Pilot group and 27.23 ± 8.09 cm H₂O for the LMA Supreme group. The mean insertion time was 27.72 ± 9.45 seconds for the LMA Protector Cuff Pilot™ and 24.37 ± 6.46 seconds for the LMA Supreme. The successful placement of gastric tube in first-attempt was significantly lower with LMA Protector. This resonates with the findings established by our study.

[37] “Moser B et al” compared the oropharyngeal leak pressure (OLP) of LMA Protector and LMA Supreme. Their study concluded that the LMA Protector had mean OLP of 30.9 ± 7.4 cmH₂O (95% CI) vs 25.6 ± 4.4 cmH₂O for LMA Supreme with a mean difference of 5.2 cm H₂O. The mean insertion time was similar for both devices.

Clinical Implications:

The LMA Protector demonstrated superior sealing ability, making it the better option for surgeries where higher airway pressures are required, such as laparoscopic ones. The significantly higher OLP ensures reduced gas leakage and minimizes the risk of inadequate ventilation.

The Igel was easier and quicker to insert, making it a preferred option in emergency situations where rapid airway management is crucial. Its cuffless design eliminates the need for inflation, reducing procedural complexity and minimizing potential cuff-related complications.

Given its longer insertion time and higher difficulty score, the LMA Protector requires more skill for proper placement. Both have gastric drainage channel, reducing risk of aspiration.

Limitations:

1. The study was conducted on a total of 60 patients (30 in each group) which is a relatively smaller sample size.
2. Only size 3 and 4 of SAD were used. Thus, the results may not be applicable to other sizes.
3. The ease and time for insertion are operator dependent. More skilled anesthetists or ones familiar with the device may need shorter time and be able to secure the device with ease.
4. Only ASA 1 and 2 grade patients were selected for the study and hence performance of the device cannot be projected on patients with ASA grade 3 or 4.
5. This was a single centre study which may limit a generalized findings to different population and healthcare settings.

CONCLUSION

In our study we compared LMA Protector (size 3 and 4) and Igel (size 3 and 4) and it was concluded that:

- The mean OLP was significantly higher in LMA Protector as compared to Igel both, after 5 min of insertion of the SAD and 5 min after creation of pneumoperitoneum.
- The ease of insertion of Igel was significantly higher than that in LMA Protector.
- The insertion time of Igel was significantly lower than that of LMA Protector.

SUMMARY

Our current study was done to compare LMA Protector and Igel with respect to Oropharyngeal leak pressure (OLP) 5min after insertion of SAD and 5min after creation of pneumoperitoneum, ease of insertion and time for insertion.

The study was conducted with 60 ASA 1 and 2 adult patients of both sex, aged between 18 and 60 years posted for elective laparoscopic surgeries under general anaesthesia in the “Department of Anaesthesiology, KLE’S Dr. Prabhakar Kore Hospital and Medical Research Centre, KAHER, Belagavi, during the period of January 2024 to December 2024. After obtaining the approval from the hospital ethical committee, the patients were randomly allocated to group P: LMA Protector (n=30) and group I: Igel (n=30). The demographic data were comparable in both groups.

All the patients were initially pre-medicated with intravenous Inj. Glycopyrrolate at 0.005mg/kg, Inj. Midazolam at 0.05mg/kg and Inj. Fentanyl at 2mcg/kg. Pre-oxygenation with 100% oxygen was given for 3 minutes. Anaesthesia was induced with Inj Propofol 2mg/kg and neuromuscular blockade by Inj Atracurium 0.5mg/kg. Airway device of appropriate size was inserted in accordance with manufacturer’s recommendation.

In our study, LMA Protector gave a better sealing pressure after 5 minutes of insertion with mean OLP (37.5 ± 2.86 cm H₂O) compared to the Igel (27.33 ± 4.69 cm H₂O) ($p < 0.0001$). After 5 minutes of pneumoperitoneum, the OLP for LMA Protector was 34.83 ± 3.34 cm

H₂O, whereas for Igel it dropped to 22.83 ± 4.49 cm H₂O ($p < 0.0001$). The OLP was significantly higher in LMA Protector at both times.

The insertion of Igel was much easier, with 60% patients at score of 1. Compared to LMA Protector with 66.67% patients at score 4. In our study the mean insertion time was 29.65 sec for LMA Protector while that for Igel was 18.16 sec. These findings were statistically significant.

To summarise our study, Igel took lesser time to insert and was much easier to insert in comparison to LMA Protector. The mean OLP was higher after 5 min of insertion and 5 min of pneumoperitoneum in LMA Protector as compared to Igel.

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ANNEXURE 1 – CONSENT FORM**CONSENT FOR PARTICIPATION IN RESEARCH STUDY**

Mr. /Mrs. /Miss. _____ we are requesting you to enroll you in the study titled “**COMPARISON BETWEEN LMA PROTECTOR AND IGEL FOR OROPHARYNGEAL LEAK PRESSURE IN ADULT PATIENTS POSTED FOR LAPROSCOPIC SURGERIES- ONE YEAR HOSPITAL BASED RANDOMISED CONTROL TRIAL**”

Respected Sir/Madam, we request you to participate in our study as you are eligible for it. During the study you will be asked some questions regarding your medical history and you are supposed to answer to the best of your knowledge. Your participation in this 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

Purpose of the study:

The purpose of the research is to evaluate efficacy of two different supraglottic airway devices Igel and LMA Protector regarding oropharyngeal leak pressure, time of insertion and ease of insertion in adult patients undergoing laparoscopic surgeries under general anesthesia.

Explanation of Procedure:

If you agree to enroll yourself in my study, you will be premedicated with inj. Pantoprazole 40 mg, inj. Ondansetron 8 mg intravenously 15 min before surgery.

Inj. Glycopyrrolate 0.005 mg/kg, inj. Midazolam 0.05 mg/kg, inj. Fentanyl 1mcg/kg, will be administered intravenously. Following pre-oxygenation for 3 minutes,

Anaesthesia will be induced with inj. Propofol titrated to loss of verbal contact with the patient, loss of eyelash reflex and relaxation of jaw. If coughing, gagging or body movement occurs during insertion of device, inj. Propofol 1mg/kg will be added to achieve an adequate level of anaesthesia. For the safety reason of patients before the insertion of any of the devices after loss of verbal contact, the anaesthetist will check that hand-ventilation with a face mask is possible. Once the patient becomes apneic and LMA insertion depth is achieved on the basis of clinical judgment, (i.e. jaw relaxation), the deflated LMA Protector or Igel SAD of appropriate size based on weight will be inserted.

Withdrawal from participation in the study:

Taking part in the study is voluntary. You may choose not to enrol yourself in this study. Your decision will not change any health care services offered to you or your ward at K.L.E. S Hospital & MRC.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality:

The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions:

In case of any questions with regard to this study, you are free to contact: Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study
“Comparison between LMA Protector and Igel for Oropharyngeal Leak Pressure in adult patients posted for Laproscopic surgeries- one year hospital based Randomised Control Trial”. My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE 2 – PROFORMA

“Comparison between LMA Protector and Igel for Oropharyngeal Leak Pressure in adult patients posted for Laproscopic surgeries – A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL”.

Patient Name: Date of Operation:
IP No: Address:
Age: Anaesthesiologist:
Gender:

Preanesthetic Evaluation:

3. Chief Complaints:

4. Past History:

HTN / DM / Asthma / Epilepsy / Rx allergy/Other relevant history.

5. Treatment / Drug intake history:

6. History of previous surgeries and anaesthetic exposure

General physical examination

Pallor / Icterus / Clubbing / Cyanosis / Lymphadenopathy / Edema

Pulse Rate:

BP:

Respiratory Rate:

Temperature:

Systemic Examination

RS: CVS:

CNS: P/A:

Airway examination:

Teeth:

Jaw movements:

Airway assessment:

Spine:

Investigations

Hb: RBS:
 Total Leucocyte Count: ECG:
 Platelet count: Chest X-Ray:
 Serum Urea: Urine R/M:
 Serum Creatinine: Others:

ASA GRADE: I II**Diagnosis:****Proposed Surgery:****Preoperative baseline values:**

Pulse:
 BP:

Monitors attached:

Pulse oximetry:
 NIBP:
 ECG:

Group of study belongs to:

Group P:

IP No	Age	Sex	ASA	MPG	OLP 5min after insertion	OLP 5min after pneumo-peritoneum	Time for insertion	Ease of insertion (0-4)

Group I:

IP No	Age	Sex	ASA	MPG	OLP 5min after insertion	OLP 5min after pneumo-peritoneum	Time for insertion	Ease of insertion (0-4)

Signature of Anaesthesiologist: _____

Signature of Principal Investigator: _____

ANNEXURE 3 – PHOTOGRAPHS



Photograph 1: Igel



Photograph 2: Ventilation with Igel



Photograph 3: LMA Protector



Photograph 4: Ventilation with LMA Protector



Photograph 5: Anesthesia Workstation

ANNEXURE 4 – MASTER CHART (GROUP P)

Sr No	Randomization No	IP No	Age (yrs)	Sex	Wt (Kg)	ASA	MPG	OLP 5min after (cm of H ₂ O)		Time for insertion (sec)	Ease of insertion (0-4)
								Insertion	Pneumo-peritoneum		
1	3	10069815	24	F	51	1	1	40	40	41.43	4
2	5	10073144	27	M	57	1	1	40	35	47.53	4
3	11	10069504	36	M	60	1	2	35	30	40.73	4
4	20	10051415	32	M	58	1	1	40	35	38.63	4
5	13	10049958	48	F	54	2	2	35	30	36.03	4
6	2	10047340	28	F	43	1	1	40	35	32.95	4
7	22	10033159	36	F	48	1	1	40	40	33.59	4
8	30	10033212	30	F	51	1	1	35	35	34.73	4
9	19	10030644	33	M	59	1	1	40	30	30.84	4
10	1	10023374	55	F	55	2	3	40	40	33.25	4
11	21	10017251	24	M	64	1	1	40	35	28.95	4
12	18	10018497	49	F	60	2	2	35	30	27.45	3
13	12	10019593	43	F	65	2	2	35	35	25.87	3
14	29	10018813	47	M	60	2	2	35	35	24.46	3
15	6	10016167	31	M	57	1	1	40	35	31.17	4
16	28	10081007	23	F	48	1	1	35	35	44.73	4
17	23	10079129	44	F	56	1	2	40	30	26.74	4
18	10	10077989	40	M	67	1	1	40	35	27.75	4
19	14	10077944	46	M	62	2	2	40	35	24	3
20	24	10078126	22	M	57	1	2	35	35	25.74	4
21	16	10077447	35	F	47	1	2	35	30	23.94	4
22	7	10075753	39	F	44	1	2	40	35	26.45	4
23	25	10076252	22	M	59	1	1	35	35	22.84	4
24	15	10076136	52	M	53	2	2	40	40	21.74	3
25	27	10073270	41	F	55	1	1	35	30	20.63	3
26	8	10081432	23	M	60	1	1	40	40	22.45	3
27	17	10096541	31	M	58	1	1	40	35	17.39	2
28	9	10099571	35	F	54	1	2	35	35	25.66	3
29	4	10101709	51	F	60	2	2	30	40	27.02	3
30	26	10102810	38	F	56	1	1	35	35	24.97	4

ANNEXURE 4 – MASTER CHART (GROUP I)

Sr No	Randomization No	IP No	Age (yrs)	Sex	Wt (Kg)	ASA	MPG	OLP 5min after (cm of H ₂ O)		Time for insertion (sec)	Ease of insertion (0-4)
								insertion	Pneumo-peritoneum		
1	8	10078248	25	F	44	1	1	30	25	22.43	2
2	16	10080380	38	M	56	1	1	30	25	27.87	3
3	2	10081687	52	M	58	1	2	25	20	23.54	2
4	26	10094440	50	M	60	2	3	25	20	23.84	2
5	15	10093878	40	F	55	1	1	25	25	21.17	1
6	7	10094150	24	F	42	1	1	30	25	20.86	1
7	30	10095576	42	F	57	1	1	30	20	22.14	1
8	27	10096616	25	M	58	1	1	25	20	19.94	1
9	24	10096619	29	M	60	1	1	30	25	20.21	1
10	1	10096801	21	F	43	1	1	25	25	19.36	1
11	28	10097045	51	F	50	1	3	25	25	16.73	1
12	14	10096824	18	M	55	1	1	30	25	18.57	1
13	10	10098545	51	M	57	2	2	25	25	17.25	1
14	17	10098503	40	F	48	2	2	20	15	15.37	2
15	23	10099216	28	F	50	1	1	30	20	17.95	2
16	29	10099052	25	F	52	1	1	30	25	14.65	1
17	11	10099930	24	M	58	1	1	25	20	15.47	1
18	6	10099945	34	M	59	1	1	20	20	13.53	1
19	18	10098849	42	M	60	2	2	25	20	18.61	2
20	3	10099825	25	F	54	1	1	30	25	15.18	1
21	12	10101316	44	M	62	1	2	30	25	16.64	2
22	25	10101734	18	F	44	1	1	25	25	14.15	1
23	22	10102061	18	F	50	1	1	30	25	16.22	1
24	19	10102044	39	F	53	1	1	40	35	17.39	2
25	13	10102691	20	M	60	1	1	35	30	18	2
26	21	10102567	29	M	58	1	1	25	20	13.43	1
27	5	10103259	60	F	60	2	2	30	20	20.87	3
28	9	10103935	37	M	64	1	1	15	10	16.88	2
29	20	10105217	56	M	63	2	2	25	20	14.43	1
30	4	10105543	27	F	58	1	1	30	25	12.22	1

ANNEXURE 5 - KEY TO MASTER CHART

ASA	-	American society of Anaesthesiologist
Cm	-	Centimeter
F	-	Female
H2O	-	Water
Kg	-	Kilogram
M	-	Male
MPG	-	Mallampati Grade
Sec	-	Seconds
Wt	-	Weight
Yrs	-	Years