COMPARISON OF CLINICAL PERFORMANCE OF I-GEL WITH PROSEAL LARYNGEAL MASK AIRWAY IN SURGICAL PROCEDURES

By

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IN

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ABBREVIATIONS

Abbreviation	Full-Form
ASA	American Society of Anesthesiologists
APL Valve	Adjustable pressure limiting valve
BMI	Body Mass Index
bpm	Beats per min
cc	Cubic centimeter
CNS	Central nervous system
cm	Centimeters
CPR	Cardiopulmonary resuscitation
ECG	Electrocardiogram
Ect	Etcetera
ETT	Endotracheal tube
FR	French
HR	Heart Rate
g	Grams
Hr	Hours
IV/i.v	Intravenous

I-Gel	Intersurgical Ltd Gel
Kg	Kilograms
LMA	Laryngeal Mask Airway
cLMA	Classic Laryngeal Mask Airway
LMA-U	Laryngeal Mask Airway-Unique
LTS-D	Laryngeal Tube Suction-D
ml	Milliliters
mg	Milligrams
µg/mcg	Micrograms
Min	Minutes
mm of Hg	Millimeter of mercury
NIBP	Non-invasive blood pressure
NG Tube	Nasogastric Tube
OT	Operation theater
OLP	Oropharyngeal Leak Pressure
PPV	Positive pressure ventilation
PR	Pulse rate
PLMA	Proseal Laryngeal Mask Airway
PVC	Poly Vinyl Chloride

s	Seconds
SAD/SGA	Supraglottic Airway Device
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
MAP	Mean arterial pressure
SpO_2	Percentage of oxygen saturation
Tab	Tablet
Inj/ inj	Injection
b/w	Between
Vs.	Versus

ABSTRACT

COMPARISON OF CLINICAL PERFORMANCE OF I-GEL WITH PROSEAL LARYNGEAL MASK AIRWAY IN SURGICAL PROCEDURES

AIMS AND OBJECTIVES:

The objective of the study is to compare two supraglottic airway devices: I-Gel and Proseal LMA in patients undergoing elective surgeries under General Anesthesia in terms of airway leak pressure, number of attempts for insertion, time taken for the placement of the device, ease of insertion of gastric drainage tube, hemodynamic changes.

MATERIALS AND METHODS:

A randomized prospective comparative clinical study was conducted in R.L.Jalappa Hospital and Research center, Tamaka, Kolar during the period from January 2018 to May 2019. Seventy-two patients belonging to age group 18-6o years with ASA grade I OR II of either sex, admitted for elective surgery done under general anesthesia were included in the study.

Each patient was visited pre-operatively and the procedure was explained, written and informed consent was obtained. The patients were counseled for overnight fasting for at least 6 hours and oral Tab. Ranitidine

150mg was given on the night before the surgery and repeated 2 hours before the surgery.

On arrival patient was secured with an 18G i.v cannula and shifted to O.T. Inside the operation room, monitors were attached and baseline HR, NIBP, ECG, SPO2 were recorded.

All patients were pre-medicated with i.v Glycopyrrolate 0.005mg/kg and i.v Fentanyl 2mcg/kg. Preoxygenation was done for 3 mins. Then the patient was induced with i.v Propofol 2mg/kg and motor blockade was achieved with i.v.Succinylcholine 2mg/kg. After induction, the patient vital is noted again.

In group A- Proseal LMA was inserted by using Index finger insertion technique and cuff was inflated with 20ml of air before connecting the circuit.

In group B- I-Gel was inserted

PARAMETERS OBSERVED:

Airway leak pressure, the number of insertion attempts, time taken for each attempt, ease of insertion of gastric tube and hemodynamics at insertion, 1 min, 3min, and 5 min post-insertion.

RESULTS:

In our study of comparing the Proseal and I-Gel LMA, the mean age, weight, BMI and sex ratio were comparable among both the groups.

The mean airway leak pressure of the Proseal group was 30 cm H2O and significantly higher than I-Gel 23cm H2O.

There was no statistical difference in the ease of insertion in both the devices. The overall success rate was 100%.

In our study the mean insertion time was significantly less for I-Gel (14s) when compared to Proseal (24s).

The gastric tube could be inserted easily in all the cases of both the group in our study.

The hemodynamic response recorded at insertion and at one, three, and five minutes was comparable between the two groups with no statistical significance.

CONCLUSION:

We hereby conclude that Proseal has a higher airway leak pressure of 30cm H20 compared to I-Gel which has an acceptable airway leak pressure of 23cm H2O. However, I-Gel is better than Proseal in terms of faster and easier insertion. Hence I-Gel is a cheap and effective alternative supraglottic device to Proseal LMA.

KEYWORDS: Proseal, I-Gel, Supraglottic devices, Airway leak pressure.

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INTRODUCTION

The main responsibility of the anesthesiologist is to render adequate ventilation to the patient.

Airway management has been drastically improved from the development of endotracheal intubation (ETT) by Macewen in 1880, up to the present day use of other modern and sophisticated airway devices[1].

Using ETT to secure airway is still the gold standard [2, 11] but the laryngeal mask airway has revolutionized the anesthetic practice of securing the airway. It has been recognized worldwide as an acceptable substitute device for securing the airway of patients under General Anesthesia and also in emergency airway management within the hospital environment.

The inventor of the "classic LMA", Dr. Archie Brain, devised it to provide a substitute for the face mask ventilation and Intubation.

When compared to ETT they sit outside the trachea sealing the supraglottic structures and thereby minimizing laryngeal trauma[3] and unwanted laryngeal reflexes[4]. It requires less skill and training is needed as it does not require laryngoscopy for insertion[5].

It enables a relatively "hands-free" method for leak-free airway and is also less probable to cause gastric insufflations which is a relatively common complication with face mask ventilation[5]

For all these reasons, the ASA has endorsed LMA as a rescue airway, and as a first-line airway management in those with limited airway management experience. But this LMA had a low-pressure seal making positive pressure ventilation difficult

and it did not assure airway protection in as it increased the chances of gastric regurgitation and pulmonary aspiration.

To overcome the above-said problems Dr. Archie Brain designed the LMA Proseal at the beginning of the millennium with certain modifications targeted to separate the Gastro-intestinal tract from the Respiratory tract[5], to increase airway sealing pressure and to allow positive pressure ventilation[6, 7]. A gastric drainage tube reduces the risk of gastric insufflation and consequently regurgitation and pulmonary aspiration of stomach contents[8, 9].

I-gel is a recently developed supraglottic device designed by Dr.Mohammed Nasir. It has successfully combined the concept of uncuffed supraglottic devices like SLIPA and the gastric drain tube design of LMA ProSeal, yet works in coherence with the patient's anatomy[10, 11]. Like LMA Proseal it also decreases the risk of stomach insufflation consequently, regurgitation and pulmonary aspiration of stomach contents[12].

Against this backdrop, the study was outlined to practically compare the Performance of I-gel and Proseal LMA in elective surgeries.

OBJECTIVES

The objectives of the current study are to compare two supraglottic airway devices, I-gel and LMA Proseal in patients posted for elective surgeries under General Anesthesia in terms of:

1. Airway leak pressure.
2. Number of attempts for insertion.
3. Time taken for the device placement.
4. Ease of insertion of gastric drain tube.
5. Hemodynamic changes.

APPLIED ANATOMY

THE UPPER AIRWAYS

Anatomically Airway is a passage through which air passes during respiration. It is divided into the upper and lower airway. The upper airway comprises of the Nasal Cavity, Oral Cavity, Nasopharynx, Oropharynx, Pharynx and Larynx[13].

Nasal cavity:

The nose is composed of bone and cartilage attached to the facial bone. The nasal cavity extends from the nares up to the end of the Turbinates. It is divided by nasal septum which forms the medial wall. The roof is formed by the cribriform plate and inferiorly by the Palatal Processes of the Maxilla. The three bony turbinatesforms the lateral wall. The important functions of filtering, warming and humidification of air occur. Paranasal sinuses open into the nasal cavity via the lateral wall.

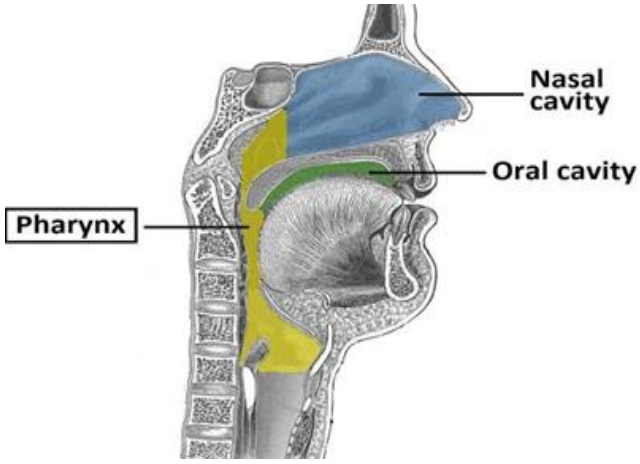


Figure1: Upper Airway

Oral cavity:

It extends from lips to the anterior tonsillar pillar. The roof of the mouth is bounded by the hard palate anteriorly and soft palate posteriorly. Contracture of mouth, teeth and tongue can lead to difficult laryngoscopy. The tongue takes up most of the cavity. It may fall back and the lower mandible may slide down leading to obstruction of the airway when the patient is anesthetized.

Pharynx:

The Pharynx is a U-shaped fibro-muscular funnel that extends from the base of the skull to Cricoid cartilage (lower border). It joins the nasal and oral cavities above, with Larynx and Oesophagus below. It is divided into Nasopharynx and Oropharynx.

The nasopharynx:

Extends from the base of the skull up to the soft palate and communicates with the nasal cavity anteriorly.

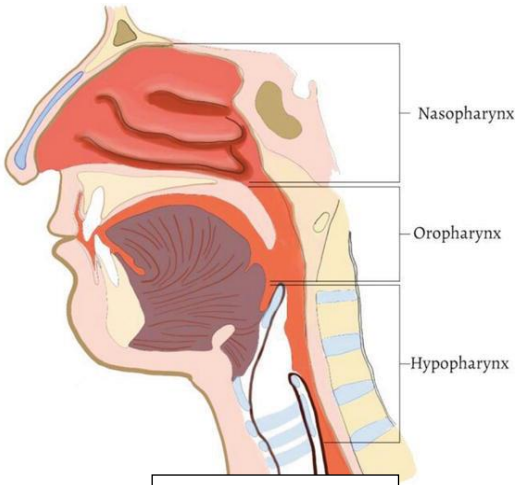


Figure2: Pharynx

The oropharynx:

Extends from the soft palate above till the Epiglottis below; and anteriorly from tonsillar pillar to posterior pharyngeal wall. It includes the Tonsils, Uvula, and Epiglottis. Space behind the epiglottis is called Valeculla.

Hypopharynx:

Extends from the level of the Hyoid bone to the opening of the Oesophagus. It functions to guide food into the esophagus and away from the larynx, during normal swallowing

Larynx:

The larynx, which lies at the level corresponding to 4^{th} to 6^{th}Cervical Vertebrae extending from the Epiglottis up to the lower border of the Cricoid, serves as the organ of phonation. It also acts as a valve to protect the lower airways from gastric contents.

The larynx is made up of 9 cartilages:

UNPAIRED CARTILAGES	PAIRED CARTILAGES
Epiglottis	Arytenoid
Thyroid	Corniculate
Cricoid	Cuneiform

Table: 1 Cartilages of Larynx

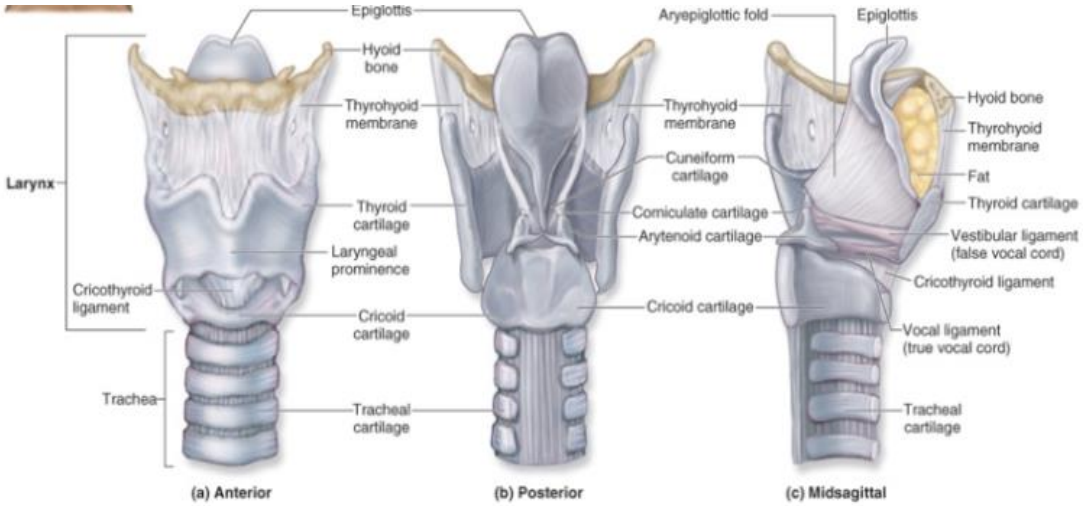


Figure3: Larynx

Inside the laryngeal cavity, one first encounter the vestibular folds also referred to as the false vocal cords, which are narrow bands of fibrous tissue on each side. They play a significant role in the maintenance of the laryngeal functions of breathing and preventing food from entering the airway during swallowing.

True vocal cords are pale white ligamentous structures that attach to the Thyroidanteriorly and posteriorly to the Arytenoids. The triangular fissure between these vocal cords is termed the Glottic opening, which represents the narrowest segment of the larynx in adults.

The Cricoid cartilage is complete ring-shaped cartilage and continues with the trachea[13].

Ligaments of the larynx:

Extrinsic ligaments are: Hyoepiglottic, Thyrohyoid, and Cricotracheal ligament. Intrinsic ligaments are the capsules of tiny synovial joints in between arytenoids and cricoid and also thyroid and cricoid cartilages.

Gentle upward pressure on the Valeculla with laryngoscope blade tenses the Hyoepiglottic ligament and indirectly elevates the larynx and helps in the alignment of laryngeal and pharyngeal axes.

Muscles of the larynx:

The muscles of larynx can be broadly classified into the extrinsic and intrinsic group of muscles.

Extrinsic group of muscles	Intrinsic group of muscles are:
1. Sternohyoid	1. Posterior cricoarytenoid
2. Thyrohyoid	2. Lateral cricoarytenoids
3. Mylohyoid	3. Interarytenoid
4. Stylohyoid	4. Aryepiglottic
5. Geniohyoid	5. Thyroarytenoid
	6. Cricothyroid
	7. Vocalis

Table: 2 Muscles of Larynx

Blood supply of larynx:

1. Above the cords, the Superior Laryngeal Artery, a branch of the Superior Thyroid Artery supplies blood.

2. Below the cords, the Inferior Laryngeal Artery, a branch from the Inferior Thyroid Arterysupplies blood.

Sensory nerve supply of larynx:

1. Mucous membrane above cords and the cricothyroid membrane is supplied chiefly by the Superior Laryngeal Nerve.

2. Mucous membrane below cords and all other membranes are supplied by the Recurrent Laryngeal Nerve[13].

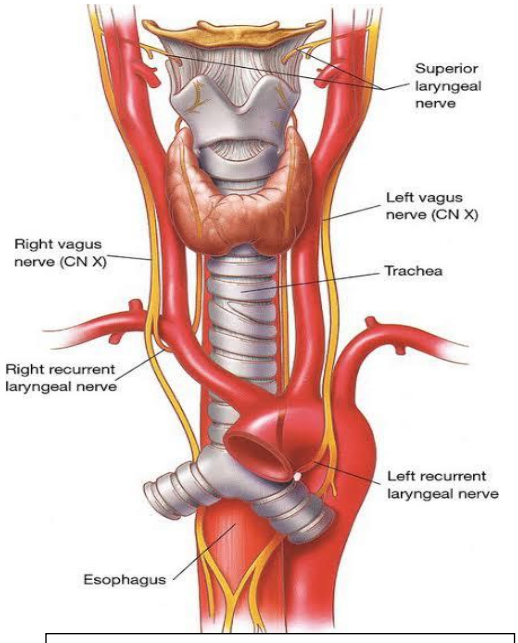


Figure: 4 Laryngeal Nerve Supply

HEMODYNAMIC RESPONSE TO INTUBATION AND LARYNGEAL MASK AIRWAY INSERTION

The main cause of hemodynamic response to laryngoscopy is the stimulation of the base of the tongue activating somato-visceral reflexes.

The prime response is seen in the form of tachycardia and hypertension. Further, intubation by an ETT and subsequent stimulation of the glottic region recruits more receptors and augments the hemodynamic response and increased catecholamine release and also some vagal inhibition of the heart.

All these responses can be attenuated by LMA by avoiding laryngoscopy and tracheal intubation[14].

LARYNGEAL MASK AIRWAY

BIOGRAPHY

Archie Ian Jeremy Brain was born in Kobe, Japan on 2nd July 1942 to Sir Henry Norman Brain who worked as British Consul in Kobe. Archie Brain had a reputation as an athlete and a poet, who found physics interesting. He built his own guitar in 1956. He finished his preclinical studies and graduated in 1970. Then, in 1971, he began his career as an anesthesiologist at the Royal East Sussex Hospital.

Figure: 5 Dr. Archie Brain

INVENTION OF LARYNGEAL MASK AIRWAY

While working at the East End London Hospital in the Anaesthesia department, in 1981, he extensively studied the anatomy and physiology of the upper respiratory tract. During that period, the management of the airway was done in 2 ways. First, was to secure an oral/nasal tracheal tube. Second, was to ventilate with a face mask, along with oral or nasopharyngeal airways.

He imagined the respiratory tract to resemble a tube with glottis as its opening. Now, he required a device that could connect the Anaesthesia machine and this tube to complete the circuit.

For that he used the Goldman Dental Mask, to make the first supraglottic airway device. The Goldman mask had a detachable vulcanized rubber cuff. A 10mm diameter plastic tube was attached to it. This occupied the hypopharynx forming a seal and the anesthetic agents and gases could now be administered in this device.

Figure: 6 First Laryngeal Prototype

CONCEPTS AND DESIGNS OF LMA

The1st commercially available classic LMA is a prototype and fills a niche between the face mask and also the ETT[15].

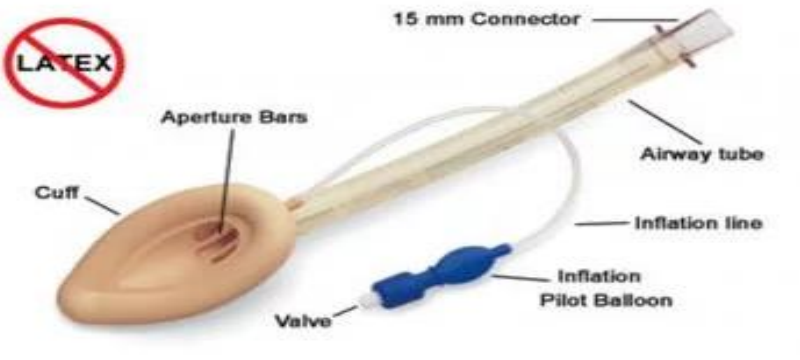


Figure: 7 Classic LMA

The anatomical position occupied is as follows:

The hypopharynx is occupied by the tip of the cuff, and it forms a circumferential low-pressure seal around the glottis.

The broad proximal portion of the cuff lies behind the base of the tongue. The epiglottis lies inside the bowl. The aperture bars prevents it from folding in and obstructing the airway.

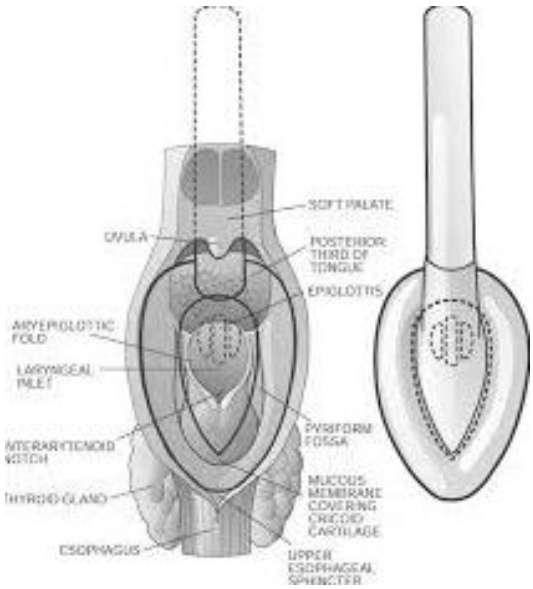


Figure: 8 Supraglottic Position of LMA

INDICATIONS OF LMA

1. LMA is used as a substitute for an ETT for securing the patient's airway.
2. It is useful in anticipated difficult airway situations like edentulous patients, facial injury, and burns16.
3. as a component in unanticipated difficult airway management algorithm. In case of inability to intubate or ventilate LMA may be life-saving either as primary means of securing the patient's airway or to facilitate passage of ET tube[17].
4. It is also used in diagnostic bronchoscopy as an excellent aid for fiberoptic scopes into the laryngeal opening,
5. During CPR, for rapid securing of patient's airway[18].

ADVANTAGES OF LMA OVER ENDOTRACHEAL TUBES:

1. Rapid and easy access to airway

2. Reduces stress response to laryngoscopy, intubation, and emergence[4].
3. Reduce the requirement of anesthetic agents for airway tolerance[19].
4. Neuromuscular blockers are not required for insertion[7].
5. Minimal training, particularly during CPR[18].
6. Lesser extent of postoperative sore throat compared to ETT[15].
7. In patients where immobilization is necessary, thus a contraindication for laryngoscopy as in cervical spinal injury LMA is preffered[20].

ADVANTAGES OF LMA OVER FACE MASK:

1. It is easier to obtain airtight seal with LMA when a good seal with a face mask is difficult
2. The anesthesiologist's hands are relatively free and do not require jaw support
3. Used easily during CPR by clinician/non-clinician staff as it requires minimal training.
4. When compared to face mask ventilation there is a lesser incidence of gastric insufflation and consequently aspiration[5].

DISADVANTAGES OF LMA:

1. Patients with glottis/ subglottic obstruction can't be managed with LMA.

3. Postoperative sore throat[21].

2. The airway is not secured against aspiration but is superior to a face mask.

3. LMA has a low airway sealing pressure than ETT.

CONTRAINDICATIONS[22]:

1. In patients not maintaining NPO or in morbidly obese, > 14 weeks pregnant, any other condition associated with delayed gastric emptying.

2. Patients with a condition like a Hiatus Hernia unless effective measures are made to empty the stomach

3. Patients with a condition like pulmonary fibrosis that reduces pulmonary compliance. Only a low-pressure seal is formed by the LMA cuff around the laryngeal inlet whereas these patients need higher pressure to adequately ventilate.

4. Patient with major oral, perioral pathology such as a tumor, abscess, grossly enlarged tonsils

6. Mouth opening < 2cms

TYPES OF LMA:-

- 1st Generation SGA: Simple breathing tube, usually with some form of mask or opening at the larynx.

Examples: Classic LMA, LMA-Unique, SureSeal LM, Cobra PLA, Laryngeal Tube Airway

- 2ndGeneration SGA: Above, plus provision for gastric drainage and improved protection against aspiration.

Examples: Combitube, **Proseal LMA**, LMA-Supreme, AuraGain, **I-Gel**

- 3rd Generation: with dynamic cuff.

Example: SIPLA

PROSEAL LMA

In 2000, Dr. Archie Brain devised a new Proseal with the main goal of constructing a device that offered protection against gastric insufflation, regurgitation and had better features for ventilation[5].

DEVICE DESCRIPTION:

The principle new attributes were as previously described, a modified inflatable cuff and a for gastric tube channel.

Medical grade silicone is used to craft Proseal making it reusable.

It has four main components:

1. Mask
2. Pilot balloon connected to the cuff by an inflation line.
3. Airway tube
4. Gastric tube channel

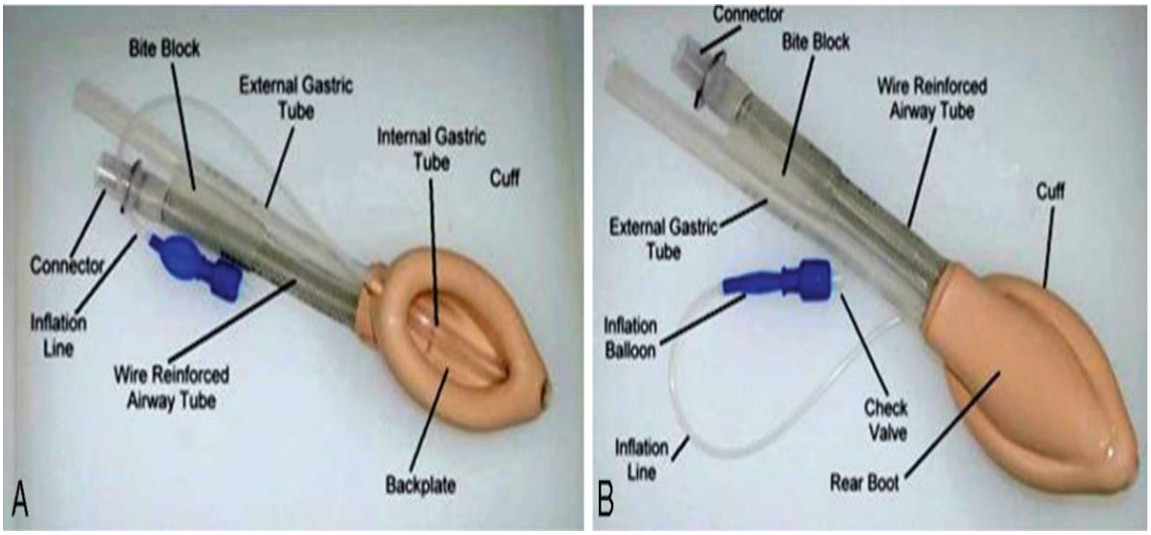


Figure: 9 Parts of Proseal LMA

Modified Feature's Intended Purpose[5, 6, 7]

1. The elliptical cuff that is proximally broader	The glottic structures are enclosed inside the bowl when compared to older devices where the cuff and inlet opposed each other.
2. The ventral cuff is conical shaped distally	It forms a tighter seal in the hypopharynx.
3. Second dorsal cuff- Rear boot.	Improves the seal by pushing the ventral cuff more anterior.
4. A wire reinforced airway tube	Makes it is more rigid and flexible and prevents it from kinking.

5. A drainage channel	To prevent gastric insufflation. To facilitate Ryle's tube insertion through which gastric contents can be suctioned out.
6.A plastic supporting ring around the distal drainage tube	To prevent the drainage tube from collapsing when the cuff is inflated
7.Integral bite block	To prevent compression or damage of airway tube resulting in obstruction during biting
8.Introducer strap	To prevent slipping of the finger from the tube during insertion
9. No aperture bars	It reduces flow resistance.

Table: 3 modified features and intended purpose of Proseal

SIZES:

Proseal LMA size	*Patient selection Guidelines*	*Proseal LMA airway tube ID(mm)*	*Maximum cuff inflation Volume (Air)*	*Gastric Tube*
1 ½	5 – 10 kg	6.4	7ml	10 Fr
2	10 – 20 kg	6.4	10ml	10 Fr
2 ½	20 – 30 kg	8.0	14ml	14 Fr
3	30 – 50 kg	9.0	20ml	16 Fr
4	50 – 70 kg	9.0	30ml	16 Fr
5	70 – 100 kg	10.0	40ml	18 Fr

Table 4: Proseal Size

Proseal LMA intracuff pressure should be <60cm H2O**.**

PROSEAL USE:

Preparation:

With proper handling Proseal LMA can be used up to40 times.

Cleaning:

The LMA should be washed with lukewarm water and diluted sodium bicarbonate solution. The inside of the tubes is cleaned using a soft bristle brush.

Sterilization:

The only sterilization method that is recommended is Steam autoclaving. Deflate the cuff completely and sterilize at 135^0C or 275^0F.

Performance Tests:

It is conducted prior to every use of the device.

1. Visual inspection:

The integrity of the thin-walled drain tube portion inside the bowl should be checked. Ensure that it is not perforated or damaged. Make sure the LMA in not discolored so that the gastric contents may be seen clearly.

2. Cuff check:

Deflate the LMA completely and check for spontaneous re-inflation occurring immediately which suggests a leak in the cuff.

Insertion Techniques:

1. Digital insertion

- The Proseal is held like a pen with an index and thumb finger.

- Jaw is pushed open
- The index finger is advanced along the palatopharyngeal curve into the hypopharynx until definite resistance was felt.
- The finger is removed while maintaining counter pressure on the LMA with the other hand to avoid accidental removal of LMA.
- This technique was used in this study[23].

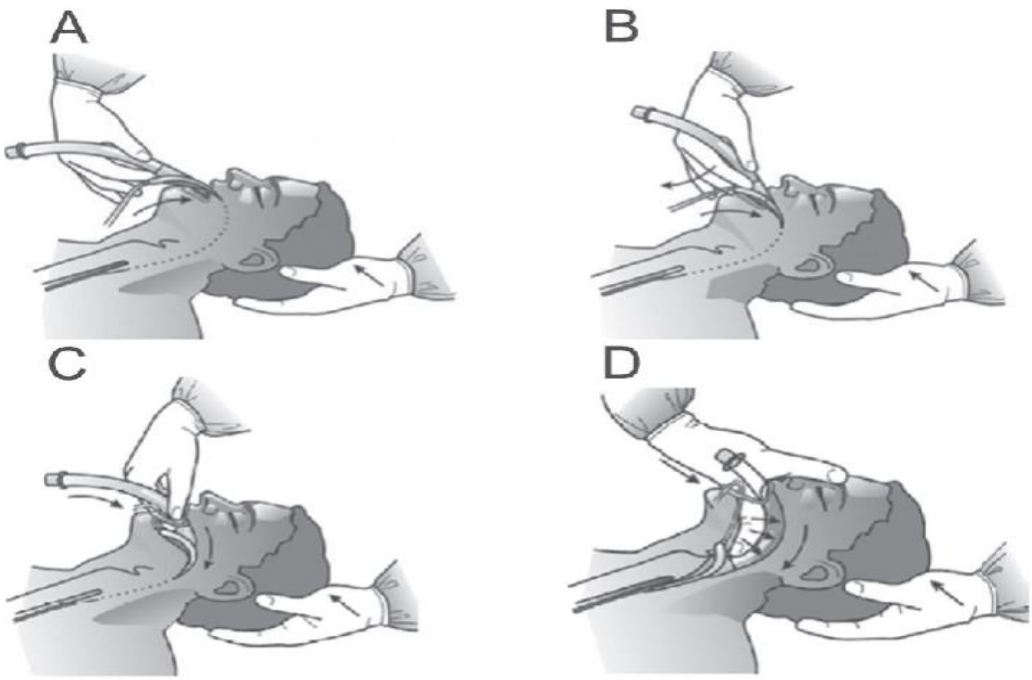


Figure: 10 Digital Insertion of Proseal LMA

2) Introducer-guided insertion.

3) Gum elastic bougie-guided insertion[24, 25].

Device Inflation: [5, 6]

The cuff is inflated with recommended maximum volume of air or at least 50% for an effective seal.

The indications of proper placement of the device: [26]

1. After inflation, there is a slight outward movement of the device.

2. Proper Ryle's tube placement is possible if only the device is placed properly
3. Chest expansion on bag compression
4. Capnography- Square wave pattern.
5. Fibreoptic examination
6. Gel displacement test - a blob of water-soluble jelly (1ml) is placed over the drain tube opening. Expulsion of the gel on gentle pressure on the bag indicates a leak.

Device Fixation:

The device is fixed by taping it from maxilla to maxilla.

Insertion of the Gastric Drain Tube:

The main advantage of the drain tube is that it provides a separate channel connecting the GIT. The Ryle'stube is slightly lubricated with water-soluble jelly and then advanced down the drain channel without any inadvertent force.

Difficulty in insertion may be due to the following reasons[26]:

1. Improper size of gastric tube
2. Inadequate lubrication
3. Very cold and stiff gastric tube
4. Cuff over-inflation
5. Malposition of Proseal LMA

Advantages of inserting a gastric tube are:

1. It allows suctioning of gastric fluid and venting of gas.
2. Confirms device placement

3. Functions like a bougie or a guide along which the PLMA can be reinserted if accidental displacement occurs.

Disadvantages of inserting a gastric tube are:

1. Accidental intratracheal placement of the nasogastric tube.
2. The gastric tube itself might trigger regurgitation
3. Closed or obstructed Ryle's tube blocks draining of gas and fluid from the esophagus.

I –GEL

I-gel is the new supraglottic airway device that is developed by Intersurgical Ltd., (Wokingham, and Berkshire, UK).

DEVICE DESCRIPTION

The I-gel LMA is a unique single-use, latex and PVC free airway Device. It is made up of medical-grade thermoplastic elastomer, which is soft, gel-like transparent and designed to anatomically fit the perilaryngeal &hypopharyngeal structures without an inflatable cuff[10, 27,28].

Its key components are:

1. Soft non-inflatable cuff
2. Gastric channel
3. Epiglottic rest
4. Buccal cavity stabilizer
5. Proximal connector
6. Integral bite block

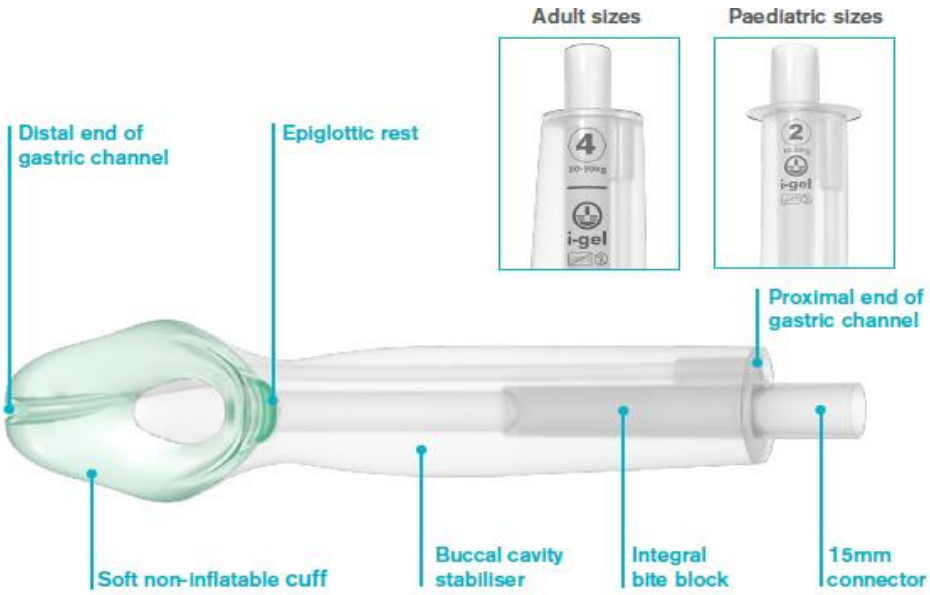


Figure: 11 Parts of I-Gel LMA

FEATURES AND THEIR INTENDED PURPOSE[30].

1. Soft non-inflating cuff	Fits snugly onto the perilaryngeal framework, mirroring the anatomical shape Reduced possibility of neurovascular compression
2. Gastric channel	Runs lateral to the airway from its proximal end at the side of the flat connector wing up to the distal tip of the cuff. A Ryle's tube can be inserted to empty the stomach contents and enables the venting of gas.
3. Epiglottic rest	A protective ridge help prevent the epiglottis from down-folding or Obstructing the distal opening of the airway.
4. Buccal cavity stabilizer	Natural curvature and an inherent propensity to adapt its shape to the oropharyngeal curvature of the patient. Widened and concaved to eliminate the potential for rotation and keeps the device in place
5. Bite block	To prevent occluding of the airway channel due to biting. As a marker for the correct position.

Table: 5 Modified Features and intended purpose of I-Gel

SIZES: [30]

It is latex free LMA and available in seven variable sizes 1, 1.5, 2, 2.5, 3, 4, 5.

i-gel size	Patient Size	Patient weight guidance (kg)
1	Neonate	2-5kg
1.5	Infant	5-12kg
2	Small paediatric	10-25kg
2.5	Large paediatric	25-35kg
3	Small adult	30-60kg
4	Medium adult	50-90kg
5	Large adult	90+kg

Table: 6 I-Gel Size Selection

I-GEL Use:

Preparation: [30]

1. Wear gloves.
2. I-gel is unpacked and the protective cradle is removed
3. In the final minute of pre-oxygenation, place a small blob of a water-based jelly onto the cradle
4. Lubricate the back, sides, and front of the non-inflatable cuff with a very thin layer of jelly.
5. Replace the LMA back onto the cradle in preparation for insertion

INSERTION TECHNIQUE[30]

Figure: 12 I-Gel Insertion Technique

1. In sniffing position the mouth is opened by gently pressing down the chin.
2. The device is held with the cuff facing out.
3. Introduce the distal soft tip into the oral cavity directing towards the hard palate.
4. Slide the LMA downward and backward alongside the anterior hard palate with a gentle, continuous pressure until resistance is encountered.
5. At this juncture, the incisors can be seen resting on the integral bite block
6. It is taped firmly from maxilla to maxilla.
7. An appropriate size nasogastric tube passed down through the gastric channel.

i-gel size	Maximum size of Nasogastric Tube (FG)
1	N/A
1.5	10
2	12
2.5	12
3	12
4	12
5	14

Table 7: I-Gel Gastric Tube

The indications of proper placement of I-gel LMA may include one or more of the following:

1. The horizontal line on the bite-block corresponds with the incisors.

2. Proper Ryle's tube placement is possible if only the device is placed properly

3. Chest wall expansion on bag compression

4. Capnography-square wave pattern.

5. Fibreoptic examination

REVIEW OF LITERATURE

Brain Al, et al[31] discussed and reported about the Proseal LMA in a preliminary study in 30 patients. There was no distinction in insertion, quality of airway or trauma. At cuff pressure of 60 cm H20, Proseal gave increased sealing pressure than the ordinary device and allowed a very effortless insertion of a drain tube in all cases.

Levitan RM, Kinkle WC[10], studied the anatomical positioning and functioning of the I-Gel LMAin 65 non-embalmed cadavers with 73 endoscopies(8 repeat insertion), neck dissections, and neck X-rays. A 100% glottic view occurred in 44/73 insertions. Only 3/73 had an epiglottis-only view. More than 50% of glottic view was obtained in all 65 cadavers. The overall score was 82%. In all neck dissections and X-rays, the mask edge lined the glottis opening. Despite the lack of an inflatable cuff, I-Gel achieved proper positioning for adequate ventilation.

Brimacobe J, Keller C[32], conducted a study in 60 anesthetized patients where they studied the ease of insertion, Oropharyngeal Leak Pressure (OLP), and fiberoptic scope position varying between the standard LMAand PLMA. The first-time success rates were higher and duration for insertion is shorter in standard LMA. But sealing pressure of PLMA was about 8-11 cm H2O more than standard LMA. The fiberoptic vocal cord visibility was similar for both. Ryle's tube was easily inserted in all the cases but they felt it was more difficult to insert the device without an introducer.

A study compared the classic LMA (cLMA) and PLMA in 180 patients who were anesthetized without neuromuscular blocking drugs. ProSeal took much longer to

insert and more attempts was needed than the cLMA. ProSeal also had higher sealing pressure 29 cm H2O compared to cLMA (18 cm H2O). Gastric tube insertion was successful in 92% of cases[7].

Singh I, Gupta M, TandonM[3], compared I-gel and PLMA in elective surgeries. They studied the airway sealing pressure, first-time successful insertion rate, ease of insertion, gastric tube placement, postoperative complication and cost of the device. The airway sealing pressure was higher with Proseal (29.6Cm H2O) than I-Gel (25.27 CM H2O) which still was within the normal range to prevent aspiration. In ease of insertion, the first-time rate of successful insertion and ease of Ryle's tube placement was higher with I-Gel. Blood tinging of the device, oral-dental trauma, was more with Proseal. There was no evidence of hoarseness, bronchospasm, laryngospasm, regurgitation or aspiration in either group.

Gatward JJ, Cook TM, Seller C[28], reported the performance of I-GEL in 100 patients comparing it to other devices they had studied. They successfully inserted I-gel in all patients and it allowed controlled ventilation in 98%. The first-time successful insertion rate was 86%, which is similar to the PLMA but lower than cLMA. The average insertion time was 15s. Median airway leak pressure was 24 cm H2O. There was one incident of regurgitation but without aspiration.

Uppal V, Gangaiah S, FlectherG[34,] compared I-GEL and LMA-Unique in terms of OLP, insertion time and attempts, reposition, leak volumes, and leak fractions. They found the OLP of both devices to be similar. The median insertion time for the I-GEL (12.2 vs. 15.2s) was significantly lesser than LMA-U. One attempt and the same

number of repositions were enough to insert both LMA. I-Gel is a similar alternative to the LMA-U for controlled ventilation.

Shin WJ, Cheong YS, Yang HS[35], compared I-Gel with Classic and Proseal LMA. They assessed hemodynamic data, OLP, Leak volume, success rate, and postoperative complications. There was no difference in hemodynamic data among the three groups at insertion. The OLP of I-GEL and PLMA (27 and 29 cm H2O) were significantly higher than the cLMA group (24.7cm H2O). Successful insertion rate was similar in all but a higher incidence of sore throat in cLMA. They concluded IGEL has comparable OLP as that of PLMA but higher than that of cLMA and not associated with adverse events.

Chauhan G, Nayar P, Seth A[36], compared Proseal and I-gel LMA in 80 patients in terms of OLP, ease of insertion and attempts, fiberoptic glottis view, ease of Ryle's tube placement, and airway complications. The I-gel's average insertion time (11.12s) was significantly lesser and easier than PLMA (15.13s). Proseal had significantly higher sealing pressure (29cm H2O) than I-Gel (26 cm H2O) but drain tube insertion was easy in the I-gel group.

Kini G, Devanna GM, Mukkapati KR[37], compared I-gel and Proseal in terms of insertion ease and attempts, OLP, fiberoptic glottis view, ease of Ryle's tube placement, and other airway morbidities. They found average insertion time for the I-gel (21.98s) was significantly lesser and easier than PLMA (30.60s). The mean airway leak pressures were comparable. All other parameters were comparable.

Kapoor S, Jethava DD, Gupta P[38,] compared blind tracheal intubation via I-Gel and LMA Fastrach was assessed in 100 patients. Successful first-attempt and overall intubation success rates, the time required for intubation, and complications were studied. They found adequate ventilation possible via both the LMAs. The successful first attempt rate by I-Gel was only 66% but 74% via LMA Fastrach. The overall successful intubation rate was only 82% with I-gel when compared to 96% with Fastrach LMA. The duration for intubation was also less through LMA Fastrach (20.96 s) than I-gel (24.04 s). Complication incidence was similar. I-gel is a better LMA in emergency rescue ventilation for its easy and quick insertion but a poor intubating LMA compared to LMA Fastrach.

Jadhav PA, Dalvi NP, Tendolkar BA[39]compared I-Gel with PLMA in patients undergoing short surgical procedures in terms of ease of insertion and duration for insertion, OLP, and complications. I-gel was easier to insert, requiring significantly less time for it (29s) than Proseal (41s). The first- successful insertion rate was more with I-gel. The airway sealing pressure was considerably higher with Proseal (25.73vs. 20.07cm of H2O). But complaints of sore throat were also more with Proseal.

Schälte G, Bomhard L, Rossaint R[40]. A hundred laymen were presented with a manikin and a package containing I-gel and a mouthpiece with a filter that could be connected to the LMA and an instruction manual. They attempted to ventilate the manikin through the LMA. The ease of usage, time taken to ventilate and the success rate were recorded. 90% of them handled the LMA in the proper way, 79% of participants were able to adequately ventilate the manikin. 85% of participants felt

their inhibition from performing resuscitation was lowered. This encourages the initiation of LMA into BLS courses and the placements of LMAs in units with public automatic external defibrillators.

Chauhan G, Syal K, Prasad V[41], compared I-gel and Proseal in 80 patients who are undergoing laparoscopic cholecystectomy in terms of ease of insertion and time of device placement, insertion attempts, OLP, and ease of Ryle's tube placement and postoperative complications. They found both LMA can be safely used for laparoscopic cholecystectomy, but ProSeal provides better sealing while I-gel is easier to use practically and has fewer hemodynamic variations.

Das B, Varshney R, Mitra S[42], conducted a prospective, randomized, double-blind study in which PLMA, I-gel or Laryngeal Tube Suction-D (LTS-D) was inserted randomly in 150 patients undergoing elective surgical procedures. The chief aim was to measure airway sealing pressure. Ease and duration of insertion, insertion attempts, and first successful insertion rate were also evaluated. The airway sealing pressure was lower with I-Gel (23 cm H2O) when compared to LTS-D and Proseal (26cm H2O vs. 28cm H2O). The time of insertion was more in Proseal (38s) compared to I-gel (27s) and LTS-D (21s). The first-successful insertion rate was comparable between the 3 groups

Banerjee G, Jain D, Bala I, Gandhi K et al[43]**.**While inserting LMA the manipulation of head and neck changes the shape of the pharynx resulting in changes in sealing pressure. In 70 children this effect was compared between I-Gel and

PLMA. OLP in neutral position, maximum flexion, and extension were recorded. They found no difference of the same between PLMA and I-Gel in any position.

Singh A, Bhalotra AR, Anand R[44], compared PLMA, Supreme LMA and I-gel in 84 patients, in terms of insertion time and attempts, hemodynamic changes, ease of both LMA and Ryle's tube placement, OLP and airway morbidity. OLP was higher with PLMA (32cm H2O) than Supreme (29 cm H2O). At insertion, the OLP of I-Gel was 26cm H2O, and it increased to 27 cm H2O, half-hour later and it further increased to 27.50 cm H2O towards the end of surgery. Albeit these increases were not statistically significant. Proseal took the longest time for insertion whereas I-gel took the longest time for gastric tube insertion. There were no differences in hemodynamic changes and complications in any of the three devices.

Chaudhary UK, Mahajan SR, Mahajan M[45], compared Baska mask versus I-gel in 100 patients posted for laparoscopic cholecystectomy. They also assessed OLP, ease of insertion and removal, time for insertion and number of attempts, leak fraction, airway morbidity. Average OLP of Baska mask was notably higher than I-gel (29cm H2O vs. 23cm H2O) but duration for insertion was more in Baska mask 12.33s and its insertion was easy only in 58% of patients whereas time for device placement was only11.31s in I-Gel and insertion was easy in 76% of participants, though the leak fraction was considerably less in Baska mask than I-gel. Airway morbidity was comparable between the two groups.

Joshi R, Rudingwa P, Kundra P[46]**,** compared Ambu AuraGain and Proseal in 94 children posted for elective surgical procedures in terms of OLP. They also assessed

the duration for insertion, number of attempts, ease of insertion, ease of drain tube placement, and fiberoptic glottis view. They found that the OLP of Ambu AuraGain was notably higher than PLMA (23.3 cm H2O vs. 20.6 cm H2O). The insertion time was shorter and gastric tube placement was easier in Ambu AuraGain when compared to the PLMA. Ambu AuraGain could be a disposable alternative to PLMA for ventilation in children.

Watanabe A, Edanaga M, Ichinose H[47], compared Air-Q with I-Gel in 37 patients undergoing surgical procedures. The time of insertion and attempts, hemodynamic response, tidal volume, fiberoptic scope tip position in the glottis, and postoperative complications was evaluated. They showed no statistical difference in any parameters evaluated between the 2 groups. With Air-Q, the fiberoptic tip was likely to be in the center, whereas with I-gel it took a 6-o'clock position in the glottis. They concluded Air-Q is a similar alternative to I-Gel and the distributions of tips of fiberoptic scope is different in each of them.

MATERIALS AND METHODS

Source of data:

This study was conducted on 72 patients posted for elective surgery done under general anesthesia at R. L. Jalappa Hospital and Research center, Tamaka, Kolar during the period from January 2018 to May 2019.

Study Design:

A randomized controlled prospective comparative study.

Method of collection of data:

The approval for commencement of this study was obtained by our Ethical committee. A written informed consent was taken from all the patients satisfying the below inclusion criteria

Inclusion Criteria:

1. Adult patient-18 to 60 years
2. Mallampatti 1 and 2
3. ASA physical status 1 or 2
4. Patients undergoing elective surgery under General Anesthesia expected to last less than 2 hours.

Exclusion Criteria:

1. Patients with restricted mouth opening (less than 2 cm) and anticipated difficult airway
2. Abnormality of the neck, the upper respiratory tract or the upper alimentary tract.
3. Patients with increased risk of aspiration, or having a history of symptomatic gastro-oesophageal reflux or hiatus hernia.
4. Patients with a history of obstructive sleep apnea.
5. Pathology of the cervical vertebra.

STUDY METHOD

Included patients were randomized by computer-generated random table into one of the two groups:

- Group A: Proseal for airway management
- Group B: I-Gel for airway management

The patients were counseled for overnight fasting for at least 6 hours and oral Tab.Ranitidine 150mg was given on the night before the surgery and repeated 2 hours before the surgery.

On arrival patient was secured with an 18G i.v cannula and shifted to O.T. Inside the operation room, monitors were attached and baseline HR, NIBP, ECG, SPO2 were recorded.

All patients were pre-medicated with i.v Glycopyrrolate 0.005mg/kg and i.v Fentanyl 2mcg/kg. Preoxygenation was done for 3 mins. Then the patient was induced with i.v

Propofol 2mg/kg and motor blockade was achieved with i.v.Succinylcholine 2mg/kg. After induction, the patient vital is noted again. An appropriate size of the LMA was inserted by the author.

Group A-Proseal

Size 4 Proseal LMA was inserted by using the Index finger insertion technique described before. Cuff was inflated with 20ml of air before connecting the circuit.

Group B- I-Gel

Size 4 I-gel was inserted gently as described before.

Position of both the devices were confirmed by:

1. Bilateral chest movement
2. Square EtCO2 waveform
3. Absence of oral leak

Anesthesia was maintained with oxygen-nitrous oxide and Isoflurane. A 16 F Ryle's tube was inserted through the drain channels of both the devices.

Datex Ohmeda has an in-built pressure gauge that was used for measuring Airway leak pressure.

Following parameters were observed:

1. AIRWAY LEAK PRESSURE[48]

It was measured by regulating the fresh gas flow to a minimum of 3L/min and the Adjustable Pressure Limiting Valve of the circle system was completely closed. Airway pressures were not allowed to exceed 40 cm of water. The manometer stability test was used which requires observation of the aneroid manometer dial in the ventilator, as the pressure in the breathing system increases and recording the pressure at which the dial reading stabilizes i.e., the airway pressure at which the leak will be in equilibrium with the fresh gas flow.

2. EASE OF INSERTION

Easy insertion: Defined as no resistance is encountered against insertion in a single attempt.

Difficult insertion: Defined as the one where resistance was encountered against insertion or more than one attempt was needed.

3. NUMBER OF INSERTION ATTEMPTS

A strict protocol was followed. An attempt was considered unsuccessful if the device had to be removed because of any of the following:

- Absence of chest raise.
- An audible leak.
- Capnography- Absence of square wave pattern.

  Same device or a different size of LMA would be placed. Two more attempts were allowed. If unsuccessful, endotracheal intubation would be done.

4**. TIME TAKEN FOR INSERTION**

It was defined for this study as the point when Proseal LMA or I-gel was inserted into the patient oral cavity until the confirmation of the proper positioning of the airway.

4. **HEMODYNAMIC RESPONSES**

The patient's HR, NIBP, MAP, SPO2 were recorded just before insertion and 1min, 3min and 5min after the initiation of insertion attempts.

After the end of surgery Ryle's tube suctioning was done. When spontaneous breathing efforts were present, a thorough oral suction was done, and LMA was removed.

Then the patient was shifted to the recovery room and monitored for an hour before shifting to the ward.

STATISTICAL ANALYSIS

The collected data was coded in the excel spreadsheet and SPSS version 22 was used for analysis.

Demographic data, the time taken for device placement and airway leak pressure and hemodynamic variables among the groups were analyzed with unpaired independent student's T-test. P values <0.05 is considered statistically significant.

Fisher's exact test or Chi-square was used to compare categorical data.

Qualitative data are presented in the form of Proportions and pie diagrams, bar charts are used to represent graphically. Quantitative data are presented as mean and standard deviation.

Sample size:

r = ratio of control to cases, 1 for equal number of case and control

$$Samplesize = \frac{r+1}{r}\frac{(p^*)(1-p^*)\left(Z_\beta + Z\alpha_{/2}\right)^2}{\left(p_{1-p_2}\right)^2}$$

p*= average proportion exposed = proportion of exposed cases + proportion of control exposed/2

Zβ= standard normal variate for power = for 80% power it is 0.84 and for90% value is 1.28. Researcher has to select power for the study.

Zα/2= standard normal variate for level of significance as mentioned in previous section.

p1-p2= effect size or different in proportion expected based on previous studies. p1 is proportion in cases and p2 is proportion in control

According to the reference article & using above formula estimated sample size was 72.

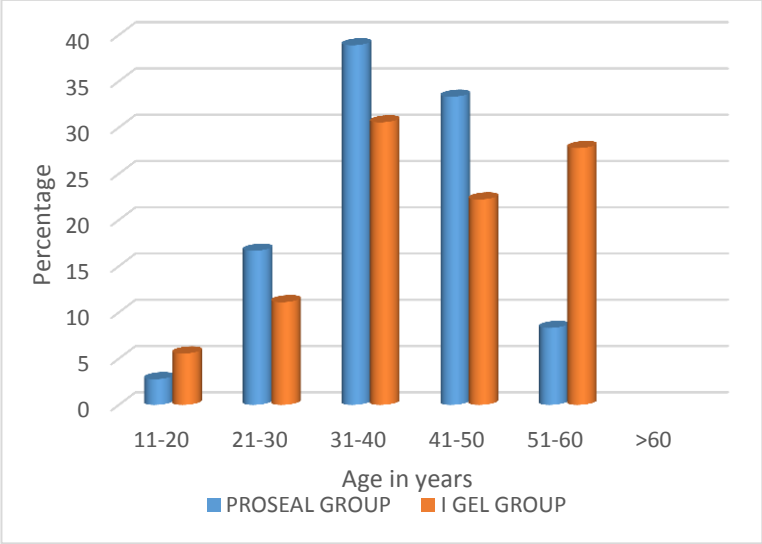
RESULTS

Table 8: Age Distribution of Subjects

Age (years)	PROSEAL	I-GEL
11-20	1	2
21-30	6	4
31-40	14	11
41-50	12	8
51-60	3	10
Total	36	36
Mean ± SD	**38.58±9.02**	**41.42±5.01**

P=0.205, Student's T-test

The mean age in both groups was around 40 years. Both the groups were comparable with regard to age and there was no statistically significant difference between the two groups.



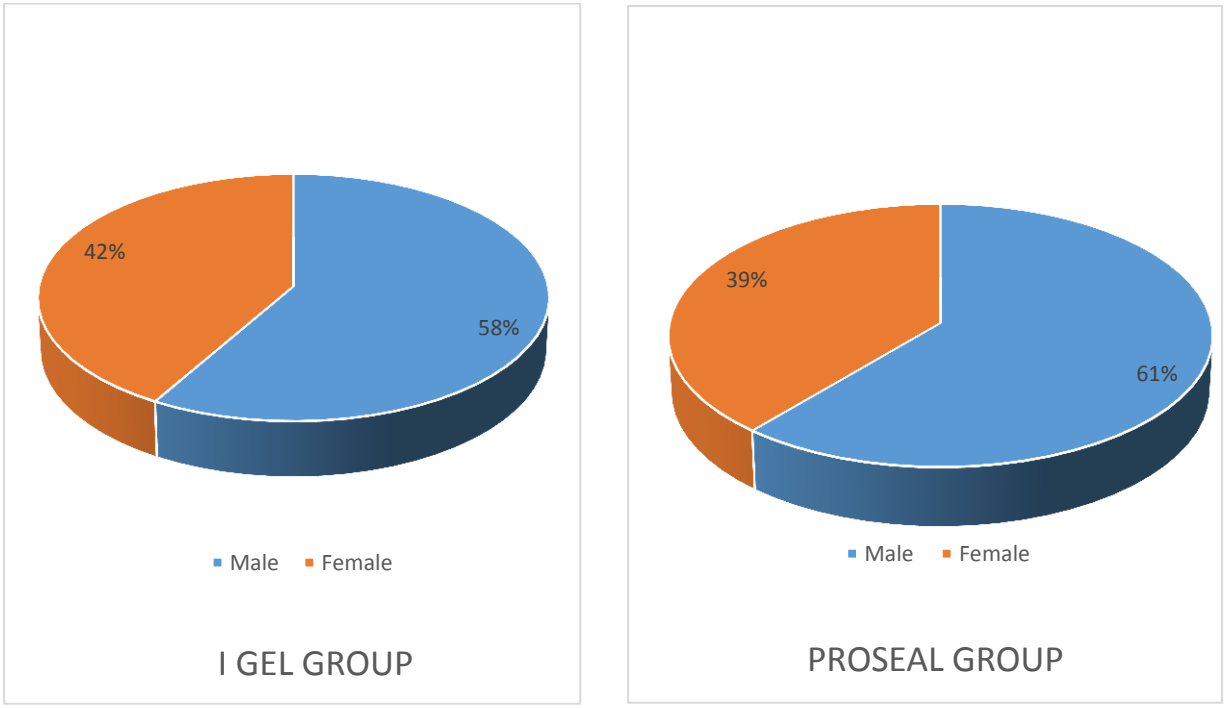
Graph: 1 Age Distribution

Table 9: Gender Distribution of Subjects

Gender	Total	PROSEAL	I GEL
Male	**43**	22	21
Female	**29**	14	15
Total	72	36	36

P=0.889, Student's T-test

Both the groups were comparable with regard to gender. There was no statistical difference between the two groups in terms of gender.



Graph 2: Gender Distributions

Table 10: BMI (Kg/m^2) Distribution of Subjects

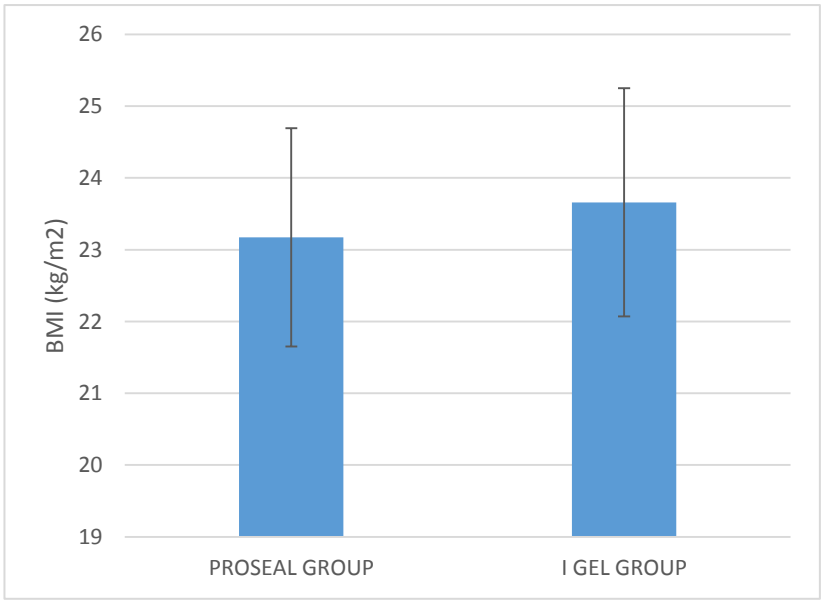
BMI (kg/m^2)	PROSEAL	I-GEL
<18.5	0	0
18.5-25	34	32
25-30	2	4
>30	0	0
Total	36	36

Table 11: Comparison of Clinical Variables of Subjects

Variable	Total	PROSEAL	I-GEL	P-value
BMI (kg/m^2)	**23.42±1.56**	23.17±1.52	23.66±1.59	**0.189**

P=0.189, Student's T-test

The mean BMI in both the groups was around 23.42 Kg/m^2. Both the groups were comparable with regard to BMI. There was no statistical difference between the two groups in terms of BMI.

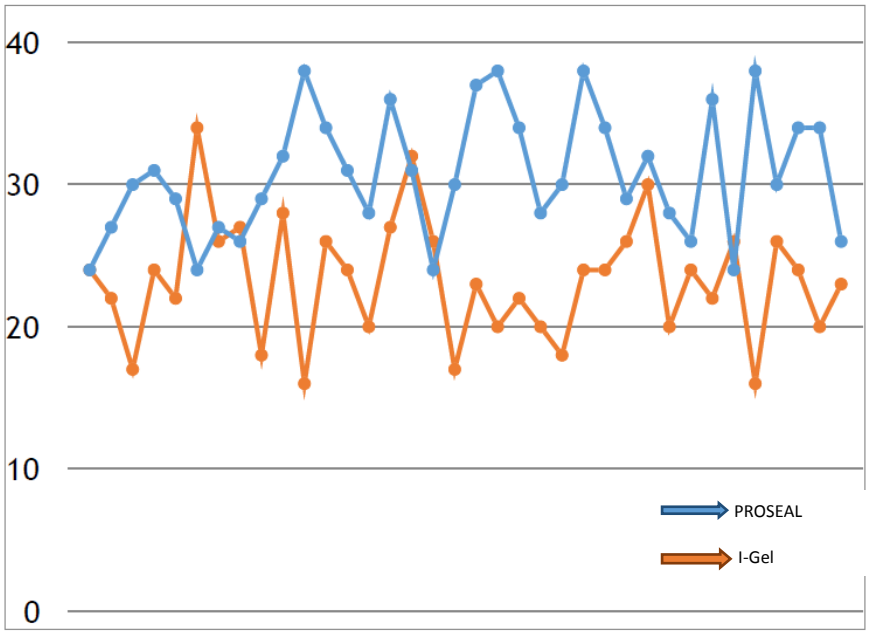


Graph: 3 BMI Distributions

Table 12: Airway Leak Pressure Distribution in between the two groups

Airway leak pressure (cm H2O)	PROSEAL	I-GEL
11-20	0	11
21-30	19	23
31-40	17	2
Total	36	36
Mean ± SD	**30.75±4.38**	**23.28±4.26**

P<0.001**, significant, Student's T-test



Graph: 4 Airway Leak pressure in Both Group

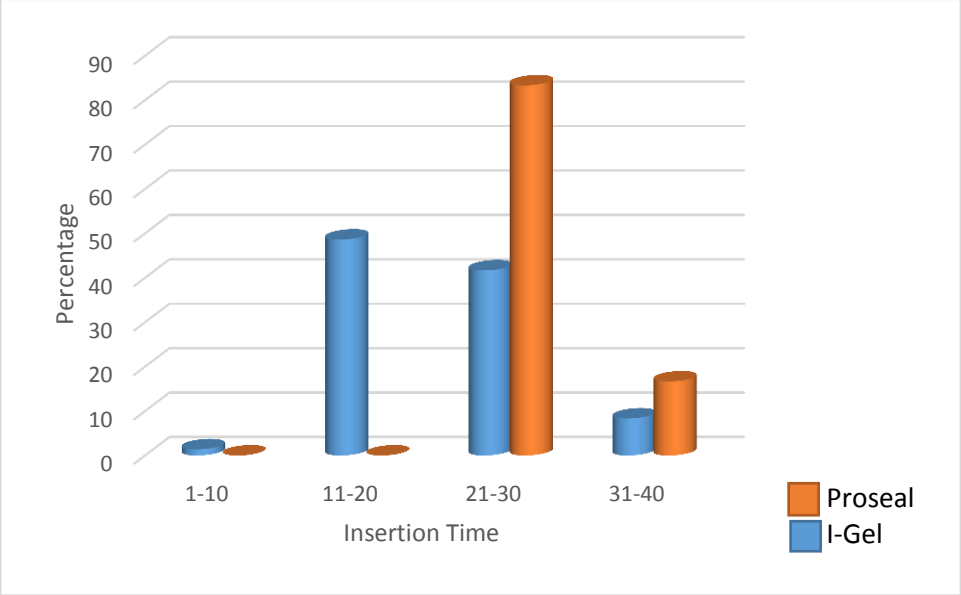
The mean airway pressure in the Proseal group was 30.75cm H2O compared to 23.28cm H2O in the I-Gel group. The p-value was <0.001 and is statistically significant.

Table 13: Insertion Time Distribution in between the two groups

Insertion Time(s)	PROSEAL	I GEL
1-10	0	1
11-20	0	35
21-30	30	0
31-40	6	0
Total	36	36
Mean ± SD	**26.17±3.33**	**14.33±2.23**

p<0.001**, significant, Student's T-test

The mean insertion time for Proseal placement was 26.1s compared to 14.12s in the I-Gel group. The p-value in <0.001 and is statistically significant.

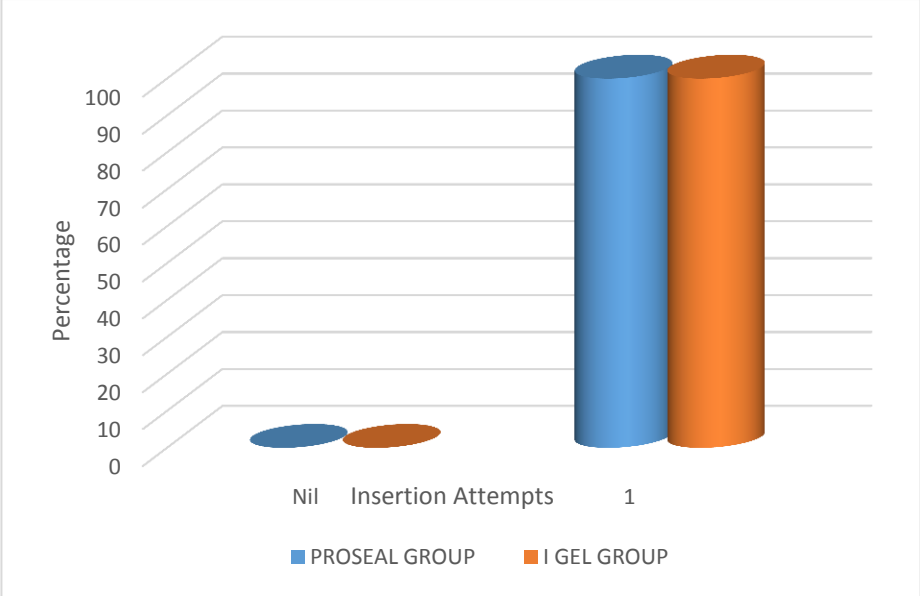


Graph 5: Insertion Time of LMA in Both Groups

Table 14: Insertion Attempts in between the two groups

Insertion Attempts	PROSEAL	I GEL
Nil	0	0
1	36(100%)	36(100%)
Total	36	36

In both, proseal and I-Gel group the placement of the airway device was done successfully in the first attempt. Effective ventilation was possible in all cases.

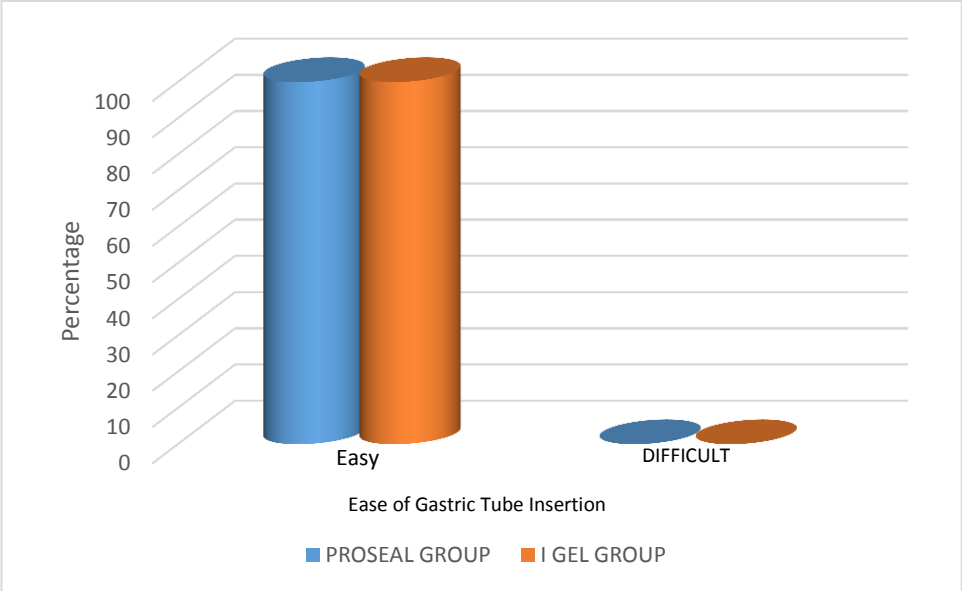


Graph 6: Insertion Attempts in both groups

Table 15: Ease Of Insertion of Gastric Drainage Tube in between the two groups

Group	Number	Easy	Difficult	Failure
Proseal	36	36	0	0
I-Gel	36	36	0	0

Out of the 36 cases, the drainage tube could be easily inserted in all the cases in Proseal group grading it easy. In the I-Gel group also drainage tube could be easily inserted in the first attempt in all the 36 cases. In none of the cases, was there any failure to insert it.



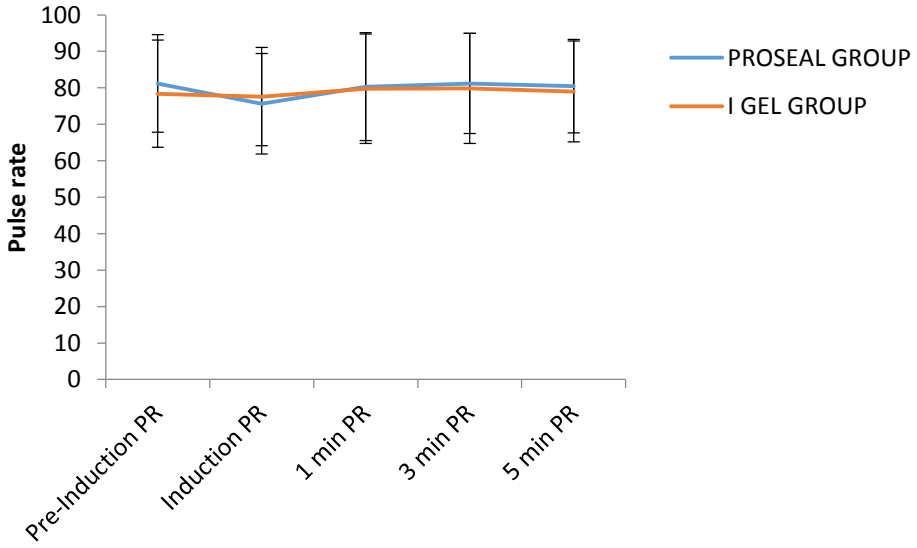
Graph 7: Ease of Gastric Tube Insertion

Table 16: Pulse Rate in Two Groups of Subjects

Pulse rate (bpm)	PROSEAL	I GEL	P-value
Pre-Induction PR	81.17±13.39	78.39±14.71	**0.405**
Induction PR	75.64±13.82	77.61±13.49	**0.542**
1 min PR	80.33±14.76	79.78±15	**0.875**
3 min PR	81.19±13.73	79.83±15.12	**0.690**
5 min PR	80.47±12.8	79±13.85	**0.641**

P>0.05, Student's T-test

When compared between the two groups, there was no statistically significant difference in terms of pulse rate.



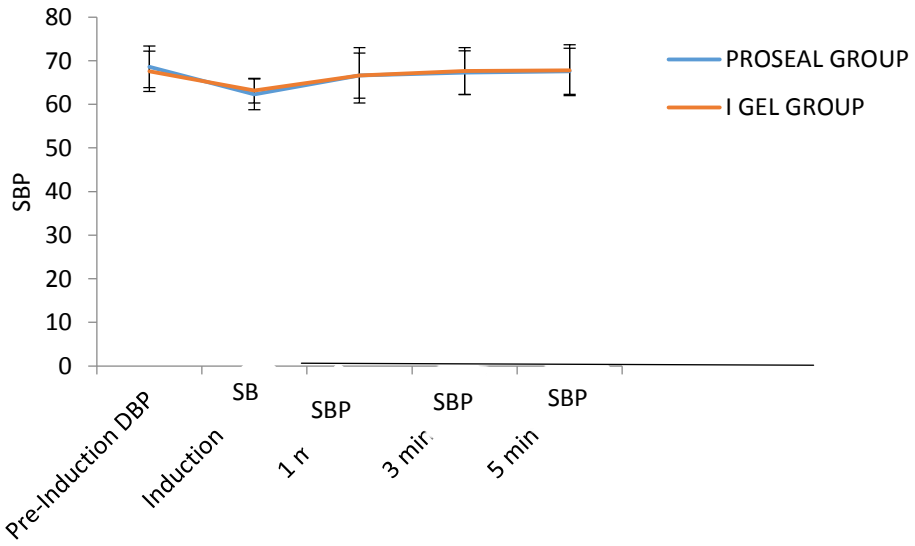
Graph 8: Pulse Rate in both groups

Table 17: Systolic Blood Pressure in Two Groups of Subjects

SBP (mm Hg)	PROSEAL	I GEL	P-value
Pre-Induction SBP	112.86±9.09	110.14±7.29	**0.160**
Induction SBP	103.75±6.17	101.97±4.53	**0.160**
1 min SBP	108.19±10.58	108.78±10.48	**0.815**
3 min SBP	108.44±10.28	109.14±9.23	**0.764**
5 min SBP	108.36±10.99	109.69±9.54	**0.584**

P>0.05, Student's T-test

When compared between the two groups, there was no statistically significant difference in terms of SBP.



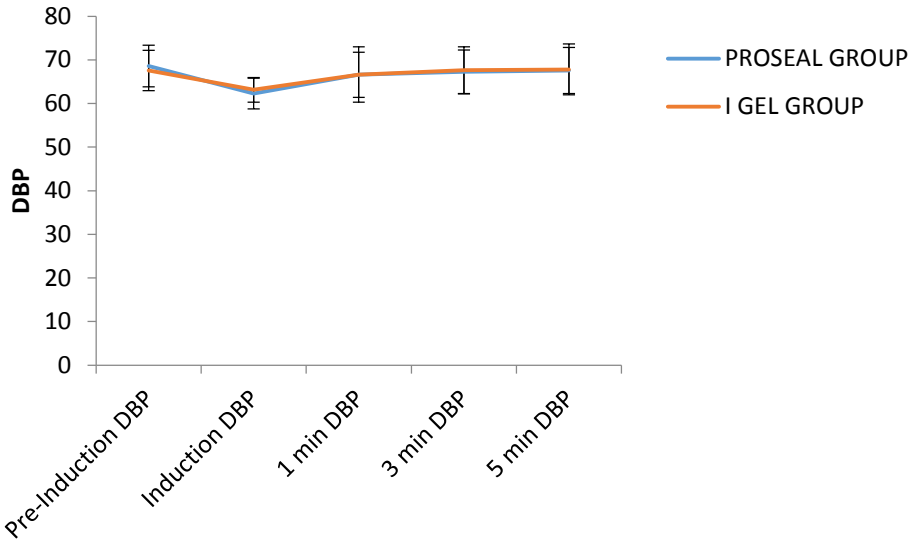
Graph 9: Systolic BP in Both Groups

Table 18: Diastolic Blood Pressure in Two Groups of Subjects

DBP (mm Hg)	PROSEAL	I GEL	P-value
Pre-Induction DBP	68.58±4.75	67.58±4.64	**0.369**
Induction DBP	62.25±3.52	63.14±2.82	**0.241**
1 min DBP	66.64±6.34	66.58±5.15	**0.968**
3 min DBP	67.25±5.04	67.64±5.39	**0.753**
5 min DBP	67.56±5.25	67.81±5.82	**0.849**

P>0.05, Student's T-test

When compared between the two groups, there was no statistically significant difference in terms of DBP.



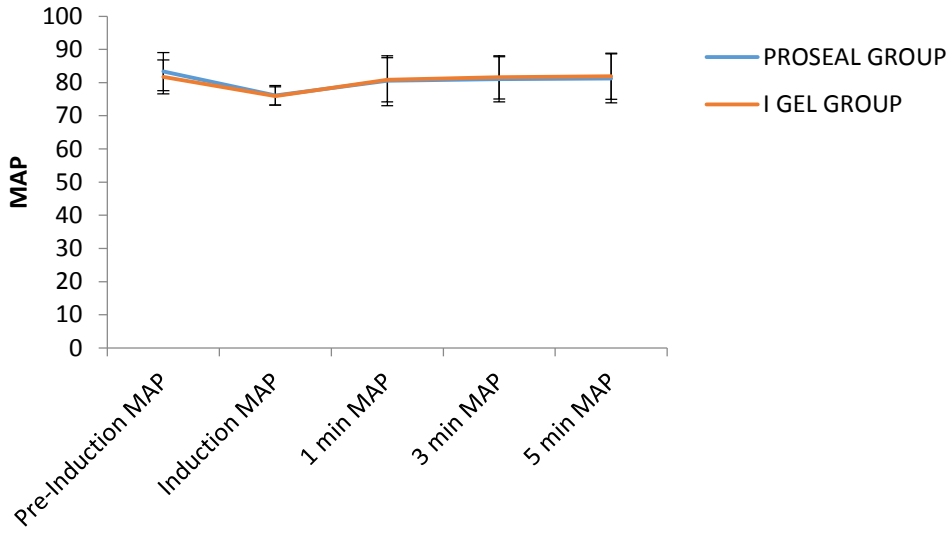
Graph 10: Diastolic BP in both

Table 19: Mean Arterial Pressure in Two Groups of Subjects

MAP (mm Hg)	PROSEAL	I-GEL	P-value
Pre-Induction MAP	83.33±5.75	81.69±5.13	**0.206**
Induction MAP	76.17±2.91	75.97±2.78	**0.773**
1 min MAP	80.56±7.57	80.81±6.66	**0.882**
3 min MAP	81±6.83	81.58±6.47	**0.711**
5 min MAP	81.28±7.39	81.92±6.95	**0.707**

P>0.05, Student's T-test

When compared between the two groups, there was no statistically significant difference in terms of MAP.



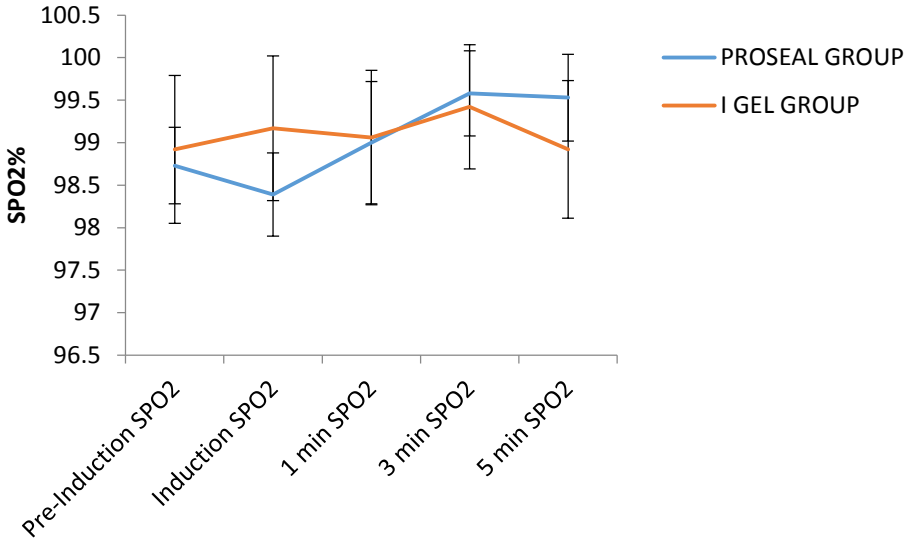
Graph 11: Mean Arterial pressure in both

Table 20: Arterial Saturation in Two Groups of Subjects

SPO2 (%)	PROSEAL	I GEL	P-value
Pre-Induction SPO2	98.73±0.45	98.92±0.87	**0.240**
Induction SPO2	98.39±0.49	99.17±0.85	**<0.001****
1 min SPO2	99±0.72	99.06±0.79	**0.756**
3 min SPO2	99.58±0.50	99.42±0.73	**0.263**
5 min SPO2	99.53±0.51	98.92±0.81	**<0.001****

P<0.05 for SPO2 at Induction and Student t-test

When compared between the two groups, though there is a statistical difference at induction and 5mins it is clinically not significant.



Graph 12: Arterial Saturation in both groups

DISCUSSION

This study was outlined to compare the clinical performance of the Proseal and I-Gel in terms of airway sealing pressure, ease of insertion, time for insertion and hemodynamic changes. It was conducted in 72 patients of ASA grade I or II, aged >18years and < 60 years undergoing elective surgeries.

In our study the mean age, weight, BMI and sex ratio were comparable among both the groups.

The mean airway leak pressure was measure by manometer stability test (with circle gas flow of 3L/min and APL valve closed and measuring the equilibrium on the aneroid pressure gauge on the Datex Ohmeda machine). **Keller**[C48] compared this with 3 other methods 1. Detection of audible noise by listening over the mouth. 2. By ETCO2 by placing the sample line in the mouth. 3. Detection of leak noise on the neck by auscultation 4. Manometric stability test as described before and found this method to be more reliable.

In our study, the mean airway leak pressure of the Proseal group was 30 cm H2O and higher than I-Gel. This is similar to the results of **Brain**, **Chauhan G, Das B, Miller DM** [31, 36, 42, 49] **.** The large capacity of Proseal LMA may result in the increased seal pressure by enabling the walls of the cuff to conform with the contours of the pharyngolaryngeal structures more effectively[31]. It forms a tighter seal without increasing the directly measured mucosal pressure[50]. The bulky cuff of Proseal LMA provides a good seal for positive pressure ventilation[7, 8]**.**

In our study, the mean airway leak pressure in the I-Gel group was 23 cm H2O. This is like many studies including, **Gatward JJ**, **Singh I, Uppal V, Shin. W.J, Das B**[28, 33,34,35,42] . But **Kini G**[37] found that the airway sealing pressure was comparable between these two LMA.

A preliminary study by **Levintan**[10] in cadavers has shown that the I-Gel is capable of achieving a good- perilaryngeal seal needed for adequate ventilation without an inflatable cuff. Its potential advantages include minimal risk of tissue compression [51, 52, 53] whereas supraglottic devices with inflatable cuff can absorb anesthetic gases leading to increased mucosal pressure [54]. I- Gel is made of thermoplastic elastomer with a soft gel-like material designed anatomically to fit the perilaryngeal and hypopharyngeal structures[55]. **Singh A**[44] found that the sealing pressure improved over time. This is probably due to the warming of the thermoplastic cuff to the body temperature[56].

No statistical difference in the ease of insertion in both the devices. The overall success rate was 100%. This may be due to our prior experience with the devices. One major study[57] also found the overall successful insertion rate of I-gel to be 97% irrespective of the anesthesiologist's previous experience of using the device. There is an overlap of sizing guidelines for in I-Gel size 3(30–60 kg) and size 4(50–90 kg) which might be confusing. **Janakiraman**[58] concluded that resizing the I-Gel improved its overall success rate.

Our result was the same as with studies of **Kini G, SHIN, Gatward,** [28, 35, 37]who found the overall insertion success rate of I-Gel was comparable to PLMA.

In contrary to our study **Singh I, Chauhan G, Jadhav PA** [33,36,39]et al found the ease of insertion and successful first-attempt insertion rate more in the I-Gel group than the

PLMA group. This may be because the I-Gel insertion does not require the finger into the oral cavity as the device is simply pushed into place[56]. Whereas Proseal has a large and flaccid cuff making it difficult to insert. **Brimacombe, Keller[25]** showed the first-time successful insertion rate was higher with lesser duration for insertion when the Proseal was inserted with an introducer than when digitally inserted which was not done in our study.

In our study the mean insertion time was significantly less for I-Gel (14s) when compared to PLMA (24s). This was in concurrence to many studies including **Gatward, Uppal, Singh A[28, 34, 44]**. As no cuff inflation is required in the I-gel, shorter time was required to achieve an effective airway[33, 55]

The gastric tube could be inserted easily in all the cases of both the group in our study. This is in concurrence **with Kini G, Bimla S[37, 59].**

In our study, the hemodynamic response recorded at insertion and at one, three, and five minutes was comparable between the groups, with no statistical significance. This is in concurrence to Shin **WJ, Singh A, Agarwal P, Acharya R, [35,44,60,61]**.

CONCLUSION

Based on the results of our study we conclude that Proseal has a higher airway leak pressure of 30cm H20 compared to I-Gel which still has an acceptable airway leak pressure of 23cm H2O. However, I-Gel is better than Proseal in terms of faster and easier insertion. Hence I-Gel is a cheap and effective alternative supraglottic device to Proseal LMA.

SUMMARY

Insertion of a supraglottic airway device may be indicated where conventional laryngoscopy fails. The I-Gel, a relatively new device has some benefits: disposable, cheap and wide bore facilitate direct passage of the standard size tracheal tube and its gastric channel also facilitates gastric drainage. It can be a useful adjunct to tracheal intubation in patients with difficult airway as documented in severe case reports[56, 62].

The Proseal LMA is used as a safe alternative to a tracheal tube for many laparoscopic procedures with good airway sealing pressures[63]. A second posterior cuff is present to improve the seal. It has an incorporated gastric channel for drainage of gastric contents.

A prospective randomized single-blind study was designed to compare the supraglottic airway devices I-Gel and Proseal in patients undergoing elective surgery under general anesthesia.

After obtaining the Institutional Ethical Committee approval, seventy-two adult patients of ASA physical status 1 and 2 of either sex undergoing elective surgical procedures under general anesthesia were randomly allocated into two groups, Group A: Proseal (n=36) and Group B: I-Gel(n=36).

Airway leak pressure, number of attempts, the time required for the device placement, ease of gastric tube insertion and hemodynamic response to insertion were studied.

The study showed no significant difference between the two groups based on the demographic variables. The airway leak pressure of Proseal was significantly higher when

compared with I-Gel ($p<0.05$). The mean insertion time for I-Gel was significantly less than Proseal ($p<0.05$). There was no statistical difference between the two groups in the number of attempts required for the placement of the supraglottic airway device and the ease of insertion of the gastric tube. There was no significant hemodynamic response to insertion when compared between the two groups.

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INFORMED CONSENT

TITLE OF THE STUDY: **COMPARISON OF CLINICAL PERFORMANCE OF I-GEL WITH LMA PROSEAL A PROSPECTIVE CLINICAL STUDY**

I, the undersigned, agree to participate in this study and to undergo the mentioned procedure as outlined in this consent form.

I have been explained /readout in my local language i.e. in _____ and understand the purpose of this study and the confidential nature of the information that will be collected and disclosed during this study. I have had the opportunity to ask questions regarding the various information collected will be used only for research.

I understand that I remain free to withdraw from this study at any time. Participation in this study is under my sole discretion and does involve any cost to me.

Signature of attending Doctor:

Signature/Left thumb impression of the patient:

Witness 1: Date:

Signature:

Witness 2:

Signature:

ANNEXURE-1

CASE PROFORMA

Comparison of Clinical Performance of I-Gel with Proseal Laryngeal Mask Airway in Surgical Procedures.

INVESTIGATOR- Dr. S. ARPITHA MARY

GUIDE- Dr. DINESH K.

NAME: AGE: SEX:

DEPT: HOSPITAL NO:

PRE OPERATIVE EXAMINATION:

GENERAL PHYSICAL EXAMINATION

PR	SBP	DBP	RR	SPO_2	HEIGHT	WEIGHT	TEMP

AIRWAY:

SYSTEMIC EXAMINATION:

CVS:

RS:

OTHERS:

INVESTIGATIONS:

Hemoglobin: Platelet Count:
Bleeding time: Clotting Time:
Blood urea: Serum Creatinine:
Serum sodium: Serum Potassium:
ECG: Chest X-Ray:
Random blood sugar:
Urine analysis:
Others:

DIAGNOSIS:

PROPOSED SURGERY:

ASA PHYSICAL STATUS:

PREMEDICATION: Tab. Alprazolam 0.5mg, Tab. Ranitidine 150mg

OBSERVATION:

Parameters	**Group**
Airway sealing pressure (cm H2O)	

Parameters	**Group**
Ease of insertion Easy Difficult	
Insertion attempts 1. 2. Failed	
Time taken for placement of device	

INTRAOPERATIVE MONITORING

	PR	**SBP**	**DBP**	**MAP**	**SPO_2**
Pre induction					
Induction					
1 Min					
3 Min					
5 Min					

Comparison of other parameters

Parameters	**Group**
Gastric tube placement Easy Difficult	

ANNEXURE-2

INFORMATION SHEET:

I, Dr. S. Arpitha Mary, Post Graduate in the Department of Anaesthesiology, Sri Devaraj Urs Medical College, Kolar. We are carrying out a study on "Comparison of Clinical performance of I-gel with LMA Proseal inpatients undergoing elective short surgeries under general anesthesia". The study has been reviewed by the Institutional ethical committee and has been started only after their formal approval.

Supraglottic airway devices have become one of the standard fixtures in airway management. These devices sit in the supraglottic space and achieve a better air seal than the face masks and lesser complications than the endotracheal tube.

The Proseal laryngeal mask airway and I-gel airway are two recently introduced devices for maintaining the airway during controlled ventilation under general anesthesia.

In this study, we aim to compare I-gel and Proseal LMA in adults for airway sealing pressure, ease of insertion, insertion attempts and ease of gastric tube placement.

Adverse effects reported are

During induction – apnea, laryngospasm, hiccup

During LMA insertion – cough, gagging, laryngospasm,

Postoperatively – nausea, vomiting, sore throat

Participation in this study doesn't involve any cost for the patient.

All the information collected from the patient will be strictly confidential and will not be disclosed to any outsider unless compelled by law. This information collected will be used only for research.

I request you to kindly give consent for the above-mentioned procedure.

There is no compulsion to participate in this study. You are required to sign only if you voluntarily agree to participate in this study. Further, you are at the liberty to withdraw from the study at any time, if you wish to do so. Be assured that your withdrawal will not affect your treatment by the concerned surgeon in any way. It is up to you to decide whether to participate.

For any further clarification you are free to contact,

Dr. S Arpitha Mary(Postgraduate in Anesthesiology); Mobile No: 7619306125

Dr.Dinesh K (Assistant Professor in Anesthesiology); Mobile No:9880463098

ANNEXURE-3

KEY TO MASTERCHART

Ht	**Height**
Wt	**Weight**
BMI	**Body Mass Index**
Ca	**Carcinoma**
R	**Right`**
L	**Left**
PR	**Pulse Rate**
HR	**Heart Rate**
SBP	**Systolic Blood Pressure**
DBP	**Diastolic Blood Pressure**
MAP	**Mean Arterial Pressure**
SPO2	**Arterial Oxygen Saturation**
SSG	**Split Skin Grafting**
P/o C/o	**Post-operative case of**
#	**Fracture**

PLMA GROUP	IP NO	AGE	SEX	DIAGNOSIS	PROCEDURE	BMI	AIRWAY LEAK PRESSURE	INSERTION ATTEMPTS	INSERTION TIME	EASE OF GASTRIC TUBE PLACEMENT	PRE INDUCTION PR	INDUCTION PR	1 MIN PR	3 MIN PR	5 MIN PR	PRE INDUCTION SBP	PRE INDUCTION DBP	PRE INDUCTION MAP	PRE INDUCTION SPO2	INDUCTION SBP	INDUCTION DBP	INDUCTION MAP	INDUCTION SPO2	1 MIN SBP	1 MIN DBP	1 MIN MAP	1 MIN SPO2	3 MIN SBP	3 MIN DBP	3 MIN MAP	3 MIN SPO2	5 MIN SBP	5 MIN DBP	5 MIN MAP	5 MIN SPO2
1	255704	42	M	Epigastric Hernia	Meshplasty	22.2	24	1	24	EASY	83	74	80	82	81	110	69	83	98	100	65	77	98	103	67	78	100	107	66	80	100	106	66	79	100
2	358260	38	F	Lipoma-anterior abdominal Wall	Excision Biopsy	20.1	27	1	22	EASY	74	69	71	72	71	110	71	83	98	100	60	73	98	102	60	74	100	107	68	81	100	112	72	85	99
3	370624	32	F	L-Breast Abscess	Incision And Drainage	28.8	30	1	32	EASY	93	77	83	91	86	109	72	84	98	96	66	76	98	107	71	82	99	110	74	85	100	112	74	86	99
4	453542	45	M	Crush injury of Left Hand	Wound debridment	23.1	31	1	24	EASY	61	56	61	64	63	114	71	85	98	110	63	79	98	117	71	87	100	118	74	89	100	112	70	84	100
5	529620	19	M	R-Fibroadenoma	Excision Biopsy	23.1	29	1	25	EASY	100	97	102	103	109	110	68	82	98	111	61	78	98	104	63	77	98	112	67	83	100	109	64	80	99
6	329442	35	F	R-Fibroadenoma	Excision Biopsy	21.8	24	1	28	EASY	76	70	78	79	83	124	74	91	98	110	55	73	98	122	74	91	100	126	70	91	99	128	77	96	100
7	389507	30	M	L-Both Bone# Forearm	ORIF And LCP insertion	25.4	27	1	25	EASY	83	66	76	81	87	104	66	79	99	98	63	75	99	106	66	79	100	110	68	82	99	109	67	81	99
8	398857	41	M	R- Distal Radius #	CRIF And K-Wire insertion	23	26	1	26	EASY	89	90	103	97	88	99	63	75	99	102	64	77	99	99	63	74	99	96	61	72	99	97	62	73	100
9	521151	50	F	Incisional Hernia	Meshplasty	22.1	29	1	28	EASY	61	59	66	72	65	109	60	76	99	100	62	75	99	117	63	83	99	114	66	83	99	117	63	83	99
10	398858	35	F	Breast abcess	Incision aAnd Drainage	24	32	1	32	EASY	89	81	87	88	83	114	66	82	99	116	60	79	99	124	66	88	99	120	66	86	99	122	64	86	99
11	344810	24	M	L-Humerus # with implant in situ	implant Removal	23	38	1	26	EASY	102	101	116	107	103	97	63	74	98	100	62	75	98	91	67	72	98	93	63	71	100	96	64	73	99
12	425561	40	M	L-clavicle #	CRIF And TENS Nailing	23.1	34	1	24	EASY	98	96	103	101	102	109	66	80	98	97	63	74	98	109	69	82	98	107	69	81	100	109	66	81	100
13	533112	56	F	Epigastric Hernia	Meshplasty	24.5	31	1	33	EASY	67	61	93	71	69	112	64	80	99	102	58	73	99	112	63	81	98	112	64	81	99	116	66	84	100
14	593268	38	M	Anterior abdominal wall abscess	Incision And Drainage	24.7	28	1	23	EASY	99	86	78	91	104	119	77	91	99	101	66	78	99	113	72	86	98	110	71	84	99	112	74	86	100
15	618359	35	M	Scrotal Wall Abscess	Incision And Drainage	22.8	36	1	24	EASY	74	72	66	74	71	110	70	83	98	94	60	71	98	103	71	80	99	106	68	80	100	109	73	84	99
16	576620	44	F	R-Lump in Breast	Lumpectomy	22.7	31	1	26	EASY	62	55	67	67	63	96	65	75	98	102	64	77	98	96	61	72	99	93	61	70	100	96	64	73	100
17	453317	55	F	Right arm abcess	Incision and drainage	24	24	1	24	EASY	63	62	84	63	64	107	66	80	98	100	63	75	98	92	66	72	99	102	69	79	100	109	69	82	99
18	511211	40	M	Post-cricoid growth	Gostrostomy And Feeding jejunostomy	22.3	30	1	22	EASY	83	80	92	87	86	128	74	92	99	108	64	79	99	122	74	91	99	124	77	94	99	128	73	94	99
19	562888	23	F	L-Fibroadenoma	Excision Biopsy	24.5	37	1	22	EASY	90	86	60	96	91	116	64	81	99	100	55	70	99	104	55	73	100	106	54	73	99	105	55	73	100
20	585903	30	M	R-Lipoma In Axillary Region	Excision Biopsy	24	38	1	24	EASY	57	51	92	62	59	120	74	89	98	98	68	78	98	113	74	87	100	116	77	90	99	120	77	92	100
21	559405	34	M	L-Galeazzi #	ORIF And LCP insertion	21.4	34	1	26	EASY	96	94	68	98	72	110	68	82	98	100	63	75	98	110	74	85	99	102	60	74	99	99	63	74	100
22	532475	32	F	Fibroadenoma	Excision Biopsy	21.1	28	1	24	EASY	68	62	85	66	74	110	68	82	99	97	63	74	99	107	71	82	99	106	66	79	100	102	69	79	99
23	600657	28	M	L- indidect inguinal hernia	Herniorraphy	22.3	30	1	27	EASY	98	86	76	84	82	128	66	88	99	110	64	79	99	114	66	83	99	113	72	86	100	109	66	81	99
24	489636	28	F	R-Breast abcess	Incision And Drainage	24.5	38	1	28	EASY	62	78	74	78	79	119	77	91	98	110	72	85	98	117	63	83	99	112	63	81	100	97	62	73	99
25	574157	42	M	L-Incisional Hernia	Meshplasty	24	34	1	24	EASY	82	74	78	82	84	128	74	92	98	116	60	79	98	112	67	83	98	107	69	81	100	96	64	73	100
26	564848	42	M	Epigastric Hernia	Meshplasty	24.3	29	1	26	EASY	72	76	80	69	68	107	66	80	99	97	63	74	99	122	74	91	99	122	64	86	100	120	77	92	99
27	533044	50	F	Epigastric Hernia	Meshplasty	23	32	1	22	EASY	78	82	84	86	82	104	66	79	99	102	60	74	99	124	66	88	98	120	66	86	100	116	66	84	100
28	707481	42	M	L- Lacerated wound arm	Wound exploration and proceed	21.5	28	1	32	EASY	90	80	63	66	86	119	77	91	98	100	62	75	98	96	64	73	99	92	66	72	100	91	67	72	99
29	511282	60	F	L-Healing Ulcer forearm	Split Skin Graft	23.2	26	1	32	EASY	82	62	66	62	72	110	63	79	98	110	60	77	98	90	50	63	99	91	67	72	100	94	67	76	100
30	721011	38	M	L-Lymphangioma of Axilla	Excision Biopsy	24	36	1	28	EASY	67	56	62	68	68	114	65	81	99	104	68	80	99	100	62	75	100	107	69	81	99	112	63	81	100
31	532608	42	M	L-Both Bone # Forearm	ORIF And LCP insertion	21.8	24	1	28	EASY	76	70	78	79	83	124	74	91	98	110	55	73	98	122	74	91	100	126	70	91	99	128	77	96	100
32	614498	38	M	Lipoma- anterior Chest Wall	Excision Biopsy	23	38	1	26	EASY	102	101	116	107	103	97	63	74	98	100	62	75	98	91	67	72	98	93	63	71	100	96	64	73	99
33	562192	38	F	Incisional Hernia	Meshplasty	22.3	30	1	22	EASY	83	80	92	87	86	128	74	92	99	108	64	79	99	122	74	91	99	124	77	94	99	128	73	94	99
34	733771	36	M	R-Closed Radial Head #	ORIF And Radial Head Excision	21.4	34	1	26	EASY	96	94	68	98	72	110	68	82	98	100	63	75	98	110	74	85	99	102	60	74	99	99	63	74	100
35	715176	42	M	Umblical Hernia	Meshplasty	24	34	1	24	EASY	82	74	78	82	84	128	74	92	98	116	60	79	98	112	67	83	98	107	69	81	100	96	64	73	100
36	550211	45	M	L- Lipoma in Axillary Region	Excision Biopsy	23.2	26	1	33	EASY	84	65	66	63	74	110	63	79	98	110	60	77	98	90	50	63	99	91	67	72	100	94	67	76	100

I GEL GROUP	IP NO	AGE	SEX	DIAGNOSIS	PROCEDURE	BMI	AIRWAY LEAK PRESSURE	INSERTION ATTEMPTS	INSERTION TIME	EASE OF GASTRIC TUBE PLACEMENT	PRE INDUCTION PR	INDUCTION PR	1 MIN PR	3 MIN PR	5 MIN PR	PRE INDUCTION SBP	PRE INDUCTION DBP	PRE INDUCTION MAP	PRE INDUCTION SPO2	INDUCTION SBP	INDUCTION DBP	INDUCTION MAP	INDUCTION SPO2	1 MIN SBP	1 MIN DBP	1 MIN MAP	1 MIN SPO2	3 MIN SBP	3 MIN DBP	3 MIN MAP	3 MIN SPO2	5 MIN SBP	5 MIN DBP	5 MIN MAP	5 MIN SPO2
1	563655	47	M	Epigastric hernia	Meshplasty	25	24	1	15	EASY	68	60	72	74	72	110	64	79	99	112	60	77	99	103	67	78	100	107	66	80	99	106	66	79	99
2	680243	35	F	Lipoma over R lateral chest wall	Excision Biopsy	23.1	22	1	12	EASY	99	93	98	114	104	109	64	79	98	96	61	73	99	102	60	74	99	107	68	81	100	112	72	85	99
3	546246	28	F	Fibroadenoma	Excision Biopsy	22.7	17	1	14	EASY	69	73	74	76	73	109	72	84	98	102	61	75	99	107	71	82	99	110	74	85	100	112	74	86	98
4	595094	58	F	L-Lump in Breast	Lumpectomy	24.7	24	1	13	EASY	83	79	78	79	81	128	78	95	98	100	60	73	98	117	71	87	100	118	74	89	100	112	70	84	98
5	615485	23	M	R-Degloving injury of leg	Wound debridment	21.1	22	1	16	EASY	117	117	120	123	119	106	72	83	99	100	64	76	100	104	63	77	100	112	67	83	99	109	64	80	100
6	439340	20	F	Fibroadenoma	Excision biopsy	24.7	34	1	10	EASY	73	74	77	77	76	113	67	82	99	106	65	77	100	122	74	91	100	126	70	91	99	128	77	96	100
7	580271	45	F	Lump in RIGHT Breast	lumpectomy	25	26	1	16	EASY	86	97	103	98	97	109	63	78	99	98	62	74	99	106	66	79	99	110	68	82	100	109	67	81	98
8	569833	47	M	Lacerated Wound Over Right Foream	Wound Closure	20.5	27	1	12	EASY	87	88	93	87	89	109	59	77	100	100	60	73	98	99	63	74	100	96	61	72	100	97	62	73	99
9	498981	41	F	L- Fibroadenoma	Excision Biopsy	24.4	18	1	17	EASY	63	59	63	66	65	109	70	83	100	98	64	75	100	117	63	83	99	114	66	83	99	117	63	83	98
10	445004	35	F	R- Ulna #	ORIF And Semitubular Plating	24.7	28	1	15	EASY	71	66	70	72	75	95	62	73	100	96	60	72	100	124	66	88	98	120	66	86	98	122	64	86	100
11	546576	52	M	Supra Umblical Hernia	Meshplasty	23.1	16	1	19	EASY	82	79	78	76	80	113	71	85	99	101	62	75	99	91	67	72	98	93	63	71	98	96	64	73	99
12	618359	23	M	Scrotal Abscess	Incision And Drainage	19.6	26	1	11	EASY	87	83	87	86	84	104	62	76	98	100	66	77	98	109	69	82	99	107	69	81	99	109	66	81	98
13	565667	60	F	L- # Lateral Condyle Humerus	CRIF And K Wire Fixation	26.8	24	1	14	EASY	69	68	71	67	66	118	70	86	100	102	62	75	98	112	63	81	100	112	64	81	100	116	66	84	99
14	628190	33	M	L-Lump in Breast	lumpectomy	25	20	1	14	EASY	76	70	72	77	74	100	62	75	98	102	68	79	100	113	72	86	99	110	71	84	100	112	74	86	100
15	487386	36	M	R-Rolando #	ORIF And K wireFixation	24.4	27	1	12	EASY	79	77	76	74	73	112	67	82	99	109	61	77	100	103	71	80	100	106	68	80	99	109	73	84	99
16	576074	55	F	L-Distal Radius #	CRIF And K Wire Fixation	23.1	32	1	11	EASY	91	85	89	90	90	122	74	90	100	107	74	85	98	96	61	72	99	93	61	70	100	96	64	73	98
17	465623	60	M	Dupuytrens Contracture	Fasciotomy And Z-plasty	22.3	26	1	14	EASY	54	60	57	55	59	108	64	77	98	100	63	75	100	92	66	72	98	102	69	79	100	109	69	82	100
18	370402	52	M	Sebaceous cyst	Excision Biopsy	24.7	17	1	13	EASY	101	99	96	101	106	102	67	79	98	102	62	75	99	122	74	91	98	124	77	94	99	128	73	94	98
19	370624	32	F	L- Breast Abcess	Incision And Drainage	25.4	23	1	14	EASY	70	77	74	72	71	104	71	82	100	101	60	74	98	104	55	73	99	106	54	73	100	105	55	73	99
20	704380	54	M	Epigastric hernia	Meshplasty	24.8	20	1	14	EASY	59	68	71	69	66	106	64	78	98	101	67	78	100	113	74	87	100	116	77	90	99	120	77	92	99
21	447183	20	F	R-Fibroadenoma	Excision Biopsy	24	22	1	12	EASY	68	60	74	76	73	104	62	76	98	102	66	78	98	103	71	80	100	110	71	84	98	112	74	86	99
22	586568	37	F	L-Fibroadenoma	Excision Biopsy	23.2	20	1	16	EASY	83	79	78	79	81	122	74	90	100	100	64	76	100	124	66	88	99	116	77	90	98	122	64	86	98
23	589558	32	M	R-Closed Galeazzi #	ORIF and plating	22.7	18	1	14	EASY	73	74	77	77	76	113	71	85	100	112	62	78	99	112	63	81	98	110	71	84	99	112	74	86	98
24	569878	35	M	Epigastric Hernia	Meshplasty	21.5	24	1	15	EASY	83	79	74	79	73	122	74	90	98	106	65	79	100	122	74	91	98	120	66	86	100	120	77	92	100
25	534363	28	F	R-Fibroadenoma	Excision Biopsy	22.1	24	1	18	EASY	71	66	63	66	70	104	62	76	98	98	62	74	99	109	69	82	99	106	68	80	100	109	66	81	100
26	672045	45	M	L-Non Healing Ulcer Foot	Wound debridment	24.8	26	1	12	EASY	117	102	120	110	102	112	67	82	100	100	65	84	100	124	66	88	100	120	66	86	100	122	74	91	100
27	601433	55	F	L-Ca Breast	Incisional biopsy	25.4	30	1	14	EASY	61	59	63	66	65	109	64	79	98	98	64	75	98	96	61	72	100	93	61	70	99	96	64	73	98
28	626564	36	M	Paraumblical Hernia	Meshplasty	23.2	20	1	13	EASY	70	74	77	72	71	102	67	79	100	100	63	75	100	117	63	83	99	113	72	86	100	97	62	73	98
29	671063	52	M	Right Indirect Inguinal Hernia	Herniorraphy	24.5	24	1	118	EASY	76	78	74	72	72	113	67	82	99	100	64	76	98	99	63	74	98	91	67	72	100	92	66	72	99
30	500734	60	M	Incisional hernia	Meshplasty	24.7	22	1	17	EASY	91	85	90	92	90	120	72	88	98	116	61	73	100	122	74	91	100	117	71	87	99	107	66	80	99
31	704140	45	F	Umblical Hernia	Meshplasty	25	26	1	16	EASY	86	97	103	98	97	109	63	78	99	98	62	74	99	106	66	79	99	110	68	82	100	109	67	81	98
32	527615	35	M	L-# Radius	ORIF And LCP Fixation	23.1	16	1	19	EASY	82	79	78	76	80	113	71	85	99	101	62	75	99	91	67	72	98	93	63	71	98	96	64	73	99
33	736521	48	F	Incisional Hernia	Meshplasty	22.3	26	1	14	EASY	54	60	57	55	59	108	64	77	98	100	63	75	100	92	66	72	98	102	69	79	100	109	69	82	100
34	491185	32	M	R- Bartons #	CRIF And K Wire Fixation	21.5	24	1	15	EASY	83	79	74	79	73	122	74	90	98	106	65	79	100	122	74	91	98	120	66	86	100	120	77	92	100
35	588276	45	M	Soft tissue swelling over the chest	Excision Biopsy	23.2	20	1	13	EASY	70	74	77	72	71	102	67	79	100	100	63	75	100	117	63	83	99	113	72	86	100	97	62	73	98
36	566656	38	M	P/O C/O Left Radius # With LCP in-situ	Implant Realignment	25.4	23	1	14	EASY	70	77	74	72	71	104	71	82	100	101	60	74	98	104	55	73	99	106	54	73	100	105	55	73	99