COMPARISON OF CLINICAL PERFORMANCE OF SUPRAGLOTTIC AIRWAY DEVICES I–GEL VS LMA-PROSEAL IN PAEDIATRIC ELECTIVE SURGERIES

Dissertation Submitted to the

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In partial fulfilment of the requirements

for the award of degree of

M.D. (Branch-X)

ANAESTHESIOLOGY

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APRIL 2013

DECLARATION BY THE CANDIDATE

I, **Dr. R. PUNIDHA VARDHANI** Solemnly declare that the dissertation entitled **"COMPARISON OF CLINICAL PERFORMANCE OF SUPRAGLOTTIC AIRWAY DEVICES I–GEL VS LMA-PROSEAL IN PAEDIATRIC ELECTIVE SURGERIES",** is a bona fide work done by me during the period of October 2011 to September 2012 at Government Stanley Medical College and Hospital, under the guidance of **Dr.S.PONNAMBALANAMASIVAYAM**,**M.D.,D.A.,DNB**., Professor, Department of Anaesthesiology at Stanley Medical College, Government Stanley Medical College, Chennai.

This thesis is submitted to The Tamil Nadu Dr .M.G.R. Medical University in partial fulfilment of the rules and regulations for the M.D. degree examinations in Anaesthesiology to be held in April 2013.

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This is to certify that the dissertation presented herein **"COMPARISON OF CLINICAL PERFORMANCE OF SUPRAGLOTTIC AIRWAY DEVICES I–GEL VS LMA-PROSEAL IN PAEDIATRIC ELECTIVE SURGERIES",** by Dr**. R. PUNIDHA VARDHANI.,** is an original work done in the Department of Anaesthesiology, under the guidance of **Dr.S.PONNAMBALANAMASIVAYAM**, **M.D.,D.A.,DNB**., Professor, Department of Anaesthesiology, Government Stanley Medical College and Hospital, Chennai in partial fulfilment of regulations of the Tamilnadu Dr. M.G.R. Medical University for the award of degree of M.D. (Anaesthesiology) Branch X, under my supervision during the academic period 2010-2013.

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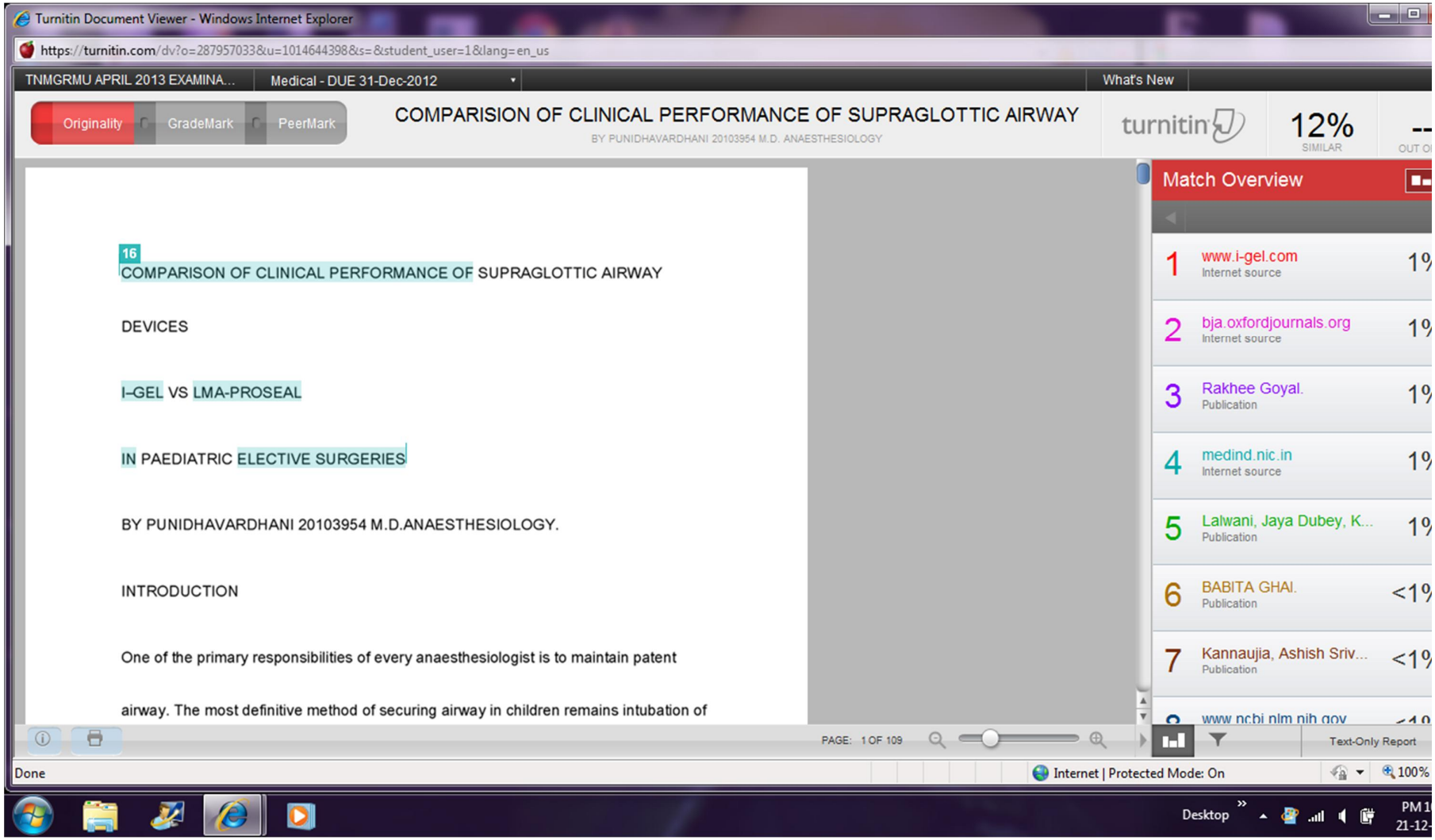
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INTRODUCTION
One of the primary responsibilities of every anaesthesiologist is to maintain patent
airway. The most definitive method of securing airway in children remains intubation of
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INTRODUCTION

INTRODUCTION

One of the primary responsibilities of every anaesthesiologist is to maintain patent airway. The most definitive method of securing airway in children remains intubation of trachea.[1]

Paediatric patients have specific airway characteristics that are rather different from those of adults, and their intubation therefore has a number of unique features. [2] This age group is more commonly associated with higher rates of complications of laryngoscopy and intubation.[3]

Supraglottic airway devices have been shown to be safe & effective in paediatric anaesthesia.[4] It has many advantages over endotracheal tube by producing less sympathetic stimulation, less airway irritability and they are well tolerated at lighter plane of anaesthesia.[5] Due to its large calibre, supraglottic airway devices produce less airway resistance compared to an endotracheal tube and decreased work of breathing during spontaneous ventilation under anaesthesia . [6]

Laryngeal mask airway, a supraglottic airway device is designed to provide and maintain a seal around the laryngeal inlet that could overcome the complications associated with endotracheal intubation. [7,8] The laryngeal mask airway provides a useful alternative to the tracheal

tube when it is necessary to administer anaesthesia to children with an upper respiratory infection.[9] However, classic LMA widely used in paediatric anaesthesia [10] has many limitations like, less stability after insertion and does not contain drainage tube.[11]

The relatively new supraglottic airway devices, LMA-Proseal & I-Gel [12, 13] have been introduced recently and are safely used in children during spontaneous or controlled ventilation without complications.[14-18]

LMA-ProSeal is a specialized laryngeal mask device that has an integral bite block.[19] It has two cuffs. The cuff design is modified to improve the seal with the larynx, which allows ventilation at much higher airway pressures. [20] In the smaller paediatric sizes, there is no second dorsal cuff but mask profile has been modified to improve the seal. [21] LMA-Proseal has an oesophageal drainage tube [22], placed lateral to the main airway tube which reduces the risk of gastric insufflations and pulmonary aspiration.[23] Monitoring devices, Doppler probe, and medications can be passed into the oesophagus through the oesophageal drain tube.[24,25]

I-Gel a novel supraglottic airway device with a non-inflatable cuff, [26] is composed of transparent, soft gel like, thermoplastic elastomer. The shape and contour of the cuff accurately mirrors the peri-laryngeal

structures to attain a perfect seal.[27] Airway seal tend to improve with time likely due to the warming of the thermoplastic cuff to body temperature. [28] Due to its stability, the I-Gel device allows the child to be placed in the lateral decubitus position to perform caudal anaesthesia, without causing a leak or the displacement of the supraglottic device.[29] Since I-Gel can be used in spontaneously breathing patients, it also has gastric channel and posses greater stability, it is a useful device for MRI suite in children. [30] I-Gel has been used as a rescue device in difficult, failed intubation situation [31] and resuscitation.[32-34]

Although it has all the advantages and more stability, [35] there are very few controlled randomized studies comparing I-Gel with LMA-Proseal in children.

We chose the I-Gel supra glottic airway device in comparison with the LMA-Proseal because both devices attain an effective airway seal associated with higher oropharyngeal seal pressures and both have gastric channel for the drainage of gastric contents.

Therefore, a prospective randomized single blind study was designed and the I-Gel was compared with LMA-Proseal with respect to ease of insertion, number of insertion attempts, insertion time, oropharyngeal leak pressure, and possible complications in paediatric elective surgeries under general anaesthesia.

AIM OF THE STUDY

AIM OF THE STUDY

The aim of this study is to compare the clinical performance of I-Gel and LMA -Proseal in anaesthetized, spontaneously breathing, paediatric age group patients posted for elective, below umbilical surgical procedures. The following parameters are compared between two devices

1. Ease of insertion

2. Success rate to place at first attempt

3. Number of insertion attempts

4. Time taken for device insertion

5. Airway seal pressure

6. Ease of gastric tube placement

7.Occurrence of complications like bronchospasm, aspiration, cough, hoarseness, blood staining of the device, mucosal/ lip trauma.

PAEDIATRIC AIRWAY ANATOMY

PAEDIATRIC AIRWAY ANATOMY

Airway of a child differs from an adult in many ways including size, shape, position, epithelial lining and supporting structures. The major differences in the upper airway are,

1. The head is relatively larger and the occiput is prominent. This difference in size and shape naturally position the head in sniffing the morning air position, when the child lying in supine position it also causes neck flexion lead to possible airway obstruction.

2. Decreased muscle tone and large tongue that easily collapses against the posterior pharynx, and obstruct the airway.

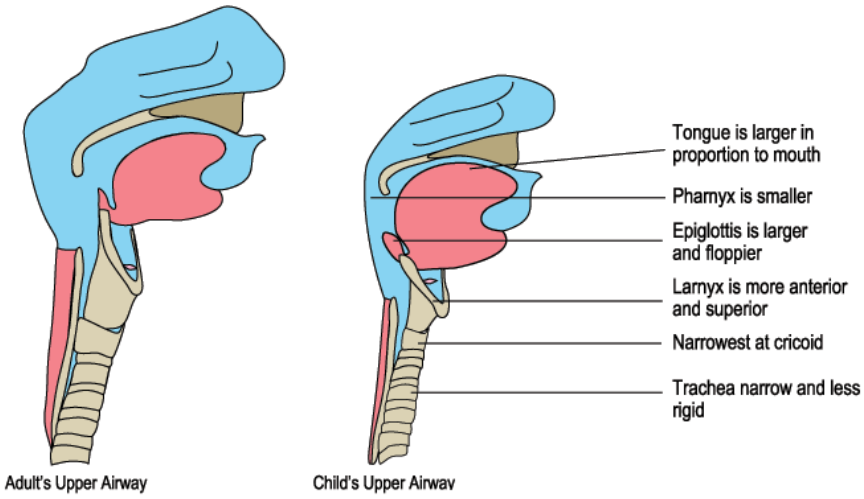
3. The nasal passages which offer 50% of total resistance offered by the respiratory system are narrower and prone for obstructions.

4. The tongue is larger and occupies much of the oropharynx

5. The palate is non-ossified relatively high arched

6. The epiglottis is large omega shaped. It projects at an angle of 45^0 to the base of the tongue, it is only 15^0 in adults

7. The neck is shorter, hyoid cartilage lies in close proximity to the thyroid cartilage



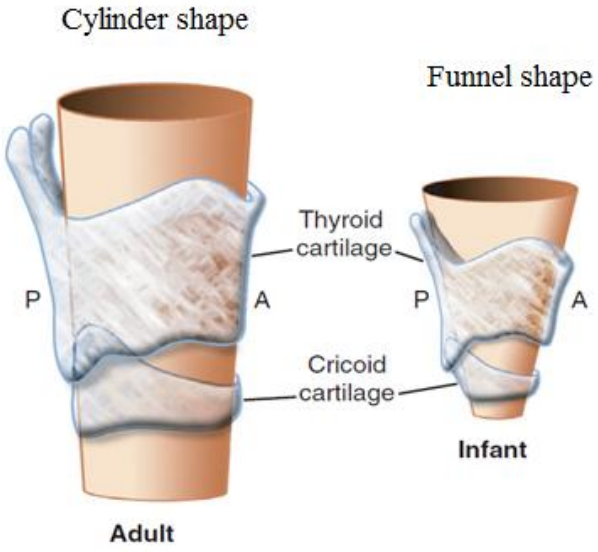
8. The larynx is situated more cephalad at the level of mid C_3 in preterm, C_3-C_4 in full-term neonate, C_4-C_5 in older children. The larynx is placed more anteriorly. The vocal cords are bow shaped, being cephalad anteriorly and rostral posteriorly.

9. The cricoid ring is situated immediately below the vocal cords and it is important in three ways

    a. It is only circumferentially solid cartilage within the airway

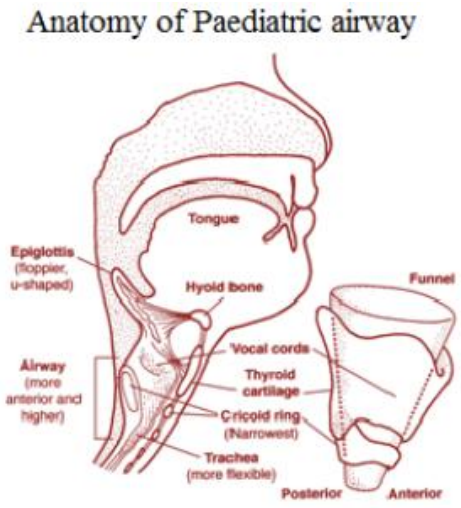
    b. It is funnel shaped with the caudal aperture being narrowest part of the pediatric airway.

    c. It is covered with loose pseudo stratified columnar epithelium, which is susceptible to both inflammation and edema



10. The length of the trachea is 4-5cm and is supported by non-calcified, soft cartilaginous tracheal rings

11. Angulations of bronchus are more horizontal than in adults. Right bronchus being 32^0 to the tracheal axis, while left bronchi being 47^0.



LMA-PROSEAL

LMA-PROSEAL

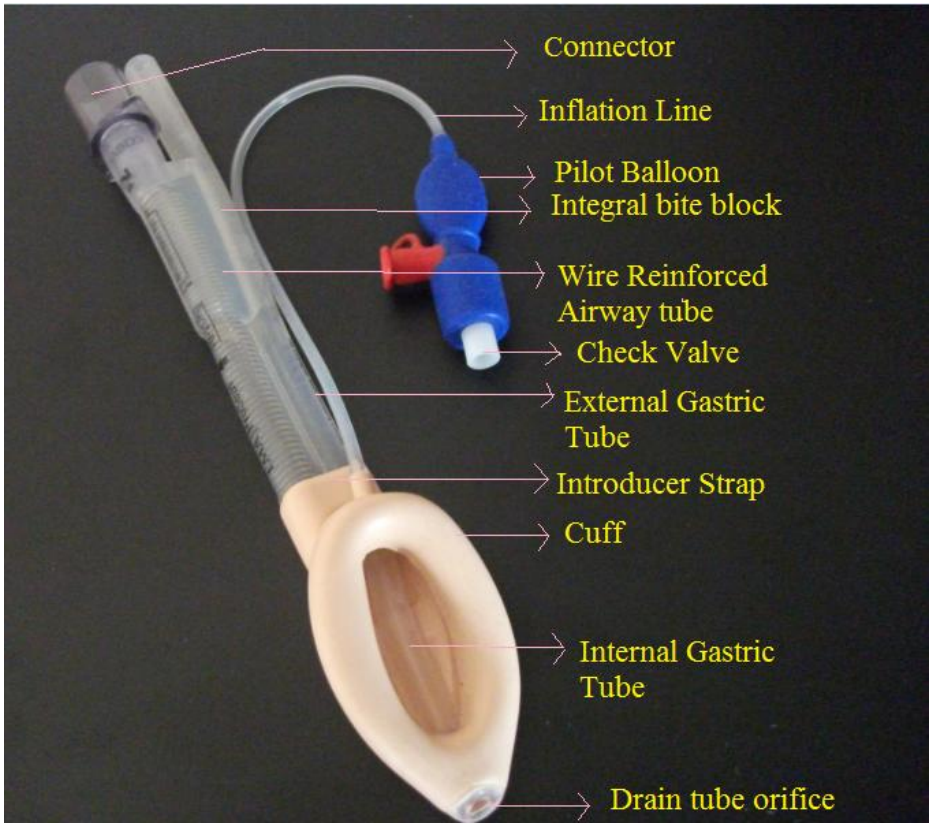
Archie Brain never regarded the Classic LMA as the best form of the device[36] .He found that increasing the force against the periglottic tissues, or increasing the surface area over which this force is applied would produce a more effective seal; a drainage tube could be incorporated to divert regurgitated fluid away from the respiratory tract. Between 1981 and 1996, a variety of prototypes were constructed and tested, that proved the feasibility of these concepts, but none were developed because they were complex, bulky, and difficult to insert. In 1998, however, Brain made a series of design breakthroughs, which resulted in a batch of ProSeal LMAs produced for the purposes of clinical testing and released in 2000.

The LMA-Proseal has been designed so that, it helps to effectively separate the gastro intestinal tract and respiratory tracts, improve the airway seal and enables better-controlled ventilation.

Concept and Design [37, 38, 39]

The LMA-ProSeal is made of medical-grade silicone and does not contain latex. It is a reusable supraglottic airway device.

COMPONANTS OF LMA-PROSEAL



The LMA-ProSeal has four main parts:

1. The cuff

2. Inflation line with pilot balloon

3. An airway tube with universal 15mm adapter

4. The drain (gastric access) tube

The cuff

LMA-Proseal has two cuffs, large ventral cuff, and dorsal cuff. It has deeper bowel and does not contain aperture bar. Bowel contains accessory vent under the drainage tube. It prevents secretions from pooling and acts as an accessory ventilation port. Once the dorsal cuff is inflated, it improves the seal by pressing the ventral cuff more firmly into the periglottic tissue. Properly placed pLMA can withstand a leak pressure of approximately 30 cm H_2O.

Airway tube

Airway tube is flexible and wire reinforced. This helps in preventing the double tube configuration from becoming too stiff, also provide stability to the device once placed in the oral cavity. A built -in bite block has been added at the proximal end of the two tubes to prevent patient from biting and collapsing the airway. A locator strap has been added at the junction of the bowel with the shaft of the tube. 15 mm universal adaptor present in the proximal end of the airway tube.

Drain tube

The drain tube traverses through the bowel, opens most distally. The purpose of the drain tube is to facilitate the gastric tube insertion, to

divert regurgitated fluid away from respiratory tract and prevent gastric insufflation. The drain tube in the bowel helps to eliminate the aperture bar. Distal aperture sloped anteriorly and is supported by a plastic ring to prevent it from collapsing when the cuff is inflated. Drain tube also helps inn confirming the correct positioning of the LMA-Proseal.

Introducer

LMA-Proseal comes with reusable introducer. It is an easily clip-on, clip-off device. It is a curved blade made of malleable metal with a guiding handle. Inner surface and the curved tip is coated with a layer of silicone to prevent trauma. The distal end of the introducer fits into the locator strap and proximal end clips between two tubes above the bite block area.

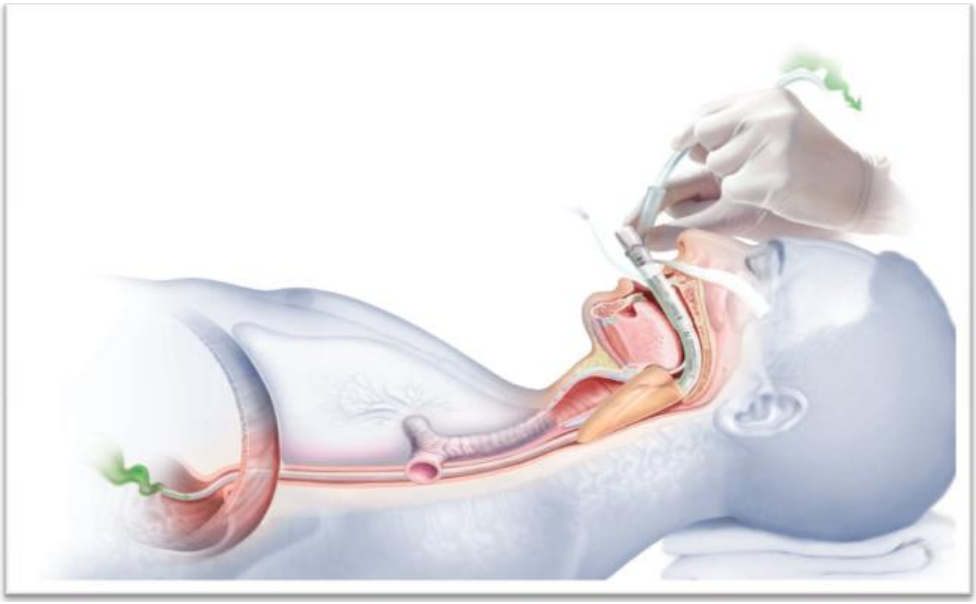
Appropriate size selection

LMA-Proseal available in seven sizes: 1, 1.5, 2, 2.5, 3, 4, and 5. Size selection can be either weight based[40] or gender based[41] (size 4 for female patients and size 5 for male patients). It is the recommended method of device selection given by Dr. Archie brain. The recommendations also have the maximum amount of air that can be used for mask inflation of particular size LMA-Proseal and largest size of the gastric tube and ETT tube that can be used.

LMA-Proseal sizes and recommended maximum size of the gastric tube and Endo Tracheal Tube

LMA SIZE	PATIENT WEIGHT IN KILOGRAMS	MAXIMUM INFLATION VOLUME (ML)	Largest Size OG Tube	Largest ETT tube ID
1	Neonates/Infants up to 5kg	4ml	8Fr	3.5Uncuffed
1.5	Infants 5-10kg	7 ml	3.5mm/10Fr	4.0 Uncuffed
2	Infants/Children 10-20kg	10ml	3.5mm/10Fr	4.5 Uncuffed
2.5	Children 20-30kg	14 ml	4.9mm/14Fr	4.5 Uncuffed
3	Small adult 30-50kg	20 ml	5.5mm/16Fr	5 Uncuffed
4	Adults 50-70kg	30 ml	5.5mm/16Fr	5 cuffed
5	Adults 70-100kg	40 ml	6mm/18Fr	6 cuffed

Schematic diagram of the LMA-Proseal in situ



Indications

The LMA-ProSeal can be used for both spontaneous and controlled ventilation.

However, it is more suitable for controlled ventilation. The sealing pressure is higher than with the LMA-Classic in adult and paediatric patients, making it a better choice for situations,

1. Where higher airway pressures are required, where better airway protection is desirable, and surgical procedures necessitating intraoperative gastric drainage like,

Laparoscopic surgeries,

Prone position anaesthesia,

Gastro oesophageal disease,

Obesity

Restrictive pulmonary disease

Upper abdominal surgery

2) Situations where mask ventilation is difficult or not possible

3) Anticipated and unanticipated difficult airway

4) Cardiopulmonary resuscitation[42 43]

5) To aid diagnostic and therapeutic fibre optic bronchoscope.

Contraindications

1) Full stomach patients,

2) Patients with restricted mouth opening (less than 2 cm)

3) Intraoral surgery

4) The patient with glottic and sub glottic airway obstruction.

5) Bleeding disorder.

Complications

1) Device malpositioning,

2) Airway obstruction by cuff infolding

3) Oropharyngeal trauma

4) Sore throat

5) Dysphagia

6) Dysphonia

Insertion

The standard insertion technique recommended by Dr. Brain involves full deflation of the cuff before insertion. This method proved varying degree of successful insertion on the first attempt ranging from 67%-90% in children. Sniffing position maintained during insertion. Non-inserting hand used to stabilize the occiput. The insertion of a LMA, whether it classic or otherwise, is successful only if the child is adequately anaesthetized, either breathing spontaneously or paralyzed and ventilated. The most common causes of failure to effectively ventilate with an LMA are inadequate depth of anaesthesia and wrong size too small a size produces a large leak while too large an LMA will not go beyond the posterior pharynx.

Insertion methods

The following three methods were used for insertion of LMA-Proseal

1. Digital method,

2. Introducer-guided insertion,

3. Gum elastic bougie-guided insertion.

Introducer guided insertion

The tip of the metal introducer is inserted into the strap situated at the top of the cuff. The airway and drainage tubes are folded around the introducer blade and into matching slots on either side of the introducer. Lubricant should be placed on the posterior tip. The tip is then pressed against the hard palate and manoeuvered to spread the lubricant along the hard palate. If the palate is high, a slightly lateral approach may be needed. The cuff is then slide inward, keeping pressure against the hard palate.

As the LMA-ProSeal is inserted, the introducer is kept close to the chin. The cuff should be observed to make certain that it has not folded over. The introducer is swung inward in a smooth circular movement. The jaw can be pulled downward by an assistant or pushed downward with the middle finger until the cuff has passed the teeth. The LMA-ProSeal is advanced until resistance is felt. The nondominant hand should be used to stabilize the airway tube as the introducer is removed by

following the curvature backward out of the mouth, taking care to avoid damage to the teeth. The bite block should be at the teeth [44] level.

Digital Method

The digital method for insertion is similar to the introducer method except that the tip of the index finger is placed near the locator strap, at the junction of the cuff and the two tubes. As the index finger passes into the mouth, the finger joint is extended and the LMA-ProSeal is pushed backward toward the other hand that gives counter pressure to maintain the sniffing position .Depending on patient and user finger size, the finger may need to be inserted to its fullest extent before resistance is encountered. The non-dominant hand should be used to stabilize the LMA as the finger is withdrawn.

Guided Method

With this technique, a lubricated stylet, bougie, fiberoptic endoscope, suction catheter, lightwand, or gastric tube is first placed through the drain tube .The patient end of the device is then inserted into the esophagus under laryngoscopic or fiberscopic guidance. The bougie should be pointing posteriorly, opposite to when it is used for intubation. The LMA-ProSeal is then advanced into place over the device. This method avoids folding the tip backward. It is more successful and less

traumatic than using the introducer tool or digital methods. This method has been used for patients with known difficult airways.

Cuff Inflation

After the LMA-ProSeal has been inserted, the cuff should be inflated with adequate air to attain a cuff pressure of up to 60 cm H_2O. During insertion and cuff inflation, the front of the neck should be observed for the upward movement of the cricoid cartilage. It indicates that the LMA mask has correctly placed. The cuff volume required for the LMA-ProSeal to create an effective airway seal is lower than for the LMA-Classic. In fact, an adequate seal can be obtained in most patients with no air in the cuff. However, at least 25% of the maximum recommended cuff volume should be inflated, to create an effective seal with G.I.Tract. [45]

Tests after Insertion

A small amount (1 to 2 mL) of water-based gel or a soap bubble should be placed on the end of the drainage tube that protrudes from the mouth and positive pressure applied to the airway tube. [46,47] If the LMA-Proseal is properly placed, there should be a slight up/down movement of the lubricant/ soap. If there is no movement or the bolus is ejected, the mask may not be correctly placed.

Tests for drainage tube air leak and patency

Air leak

Air leak up the drainage tube during positive pressure ventilation demonstrates that the gastrointestinal and respiratory tracts are not isolated from one another.

Large-volume air leaks can be detected readily by listening over the drainage tube or feeling the air with a hand, but small-volume air leaks are detected best by placing a water-based lubricant or a soap bubble over the end of the drainage tube.

Drainage tube patency and testing

Testing of drainage tube patency is mandatory for safe use of the LMA-Proseal. There are four tests of drainage tube patency:

1. Passage of a gastric tube
2. Passage of a fiberoptic scope
3. Inserting a lighted stylet through the drainage tube. (if the tip is folded the stylet will encounter resistance at a distance of 1 to 2 cm from the tip of the drain tube)
4. and the suprasternal notch tap test [48]

The first two are self-explanatory, and neither one needs to be invasive. The suprasternal notch tap test involves tapping the suprasternal notch or cricoid cartilage (that should lie immediately anterior to the distal cuff that contains the drainage tube) and observing simultaneous movement of a soap bubble at the tip of the drain tube but false positive and false-negative results can occur. [49]

Gastric tube insertion

Gastric tube insertion has the following advantages,

(1) It allows emptying the air or fluid from the stomach

(2) Used to assess the patency of the drainage tube[50]

(3) It acts as a guide to LMA -ProSeal reinsertion in case of accidental displacement occurs.

The disadvantages are

(1) There is risk of tracheal placement

(2) There is risk of trauma, the worst-case scenario being oesophageal perforation.

(3) The presence of the gastric tube may trigger regurgitation by interfering with oesophageal sphincter function

(4) The gastric tube blocks the drainage tube so that gas and fluid cannot escape from the oesophagus.

Main indication of gastric tube insertion

To empty the gas or fluid from the stomach that are present at the starting or that accumulate during procedure

The signs of correct placement of Laryngeal Mask Airway[51]

1. LMA (airway tube) coming out 1 cm on inflation of cuff (classic)

2. Good chest rise with manual ventilation

3. End tidal carbon dioxide (EtCO2) showing square wave.

4. No audible leak with peak airway pressure of 20 cm H2O. A leak below 20 cm H2O was considered a malposition with PLMA.[52]

5. Gel or soap bubble displacement test for PLMA (placing 1-2 ml of water based gel on the proximal end of the drain tube and positive pressure applied to the airway tube produce upward and downward movement of the gel.

6. Direct visualisation with fibre optic bronchoscope.

7. DT can be use to confirm the correct position [53]

8. Bilateral air entry on auscultation by stethoscope

9) Correlation between chest wall and bag movement

10) No visible cuff in oral cavity

The most commonly practiced methods are the EtCO2 and visual inspection of chest rise.

Sterilisation

The reusable LMA should be cleaned with warm water and dilute sodium bicarbonate solution (8%-10%).Steam autoclaving is the preferred method for sterilisation of LMA-Proseal. Immediately prior to steam autoclaving, the red plug is opened and cuff should be deflated. (pre –vaccum and wrapped) Autoclaving should be carried out within a standard steam sterilisation cycle of 134°C (+3°/-0°) for 3 minutes. Higher temperature can cause damage to the tube. A pipe cleaner type brush should be inserted through the distal aperture to clean the shaft. Ethylene oxide sterilization can also be used.

There may be a chance for residual air accumulation in the dorsal cuff. As much as possible air should be removed from cuff before autoclaving. Residual air tends to expand in the heat, causes damage to the cuff, pilot balloon, or valve.

I-GEL

I-GEL

I-Gel is a novel supraglottic airway management device (Intersurgical Ltd., Wokingham, UK) introduced clinically in 2007, and paediatric sized I-Gel were introduced clinically in 2010. It is made of thermoplastic elastomer, (Styrene Ethylene Butadiene Styrene) which is soft gel like and transparent. I-Gel is a disposable supraglottic airway device and it does not contain latex.

One special feature of this supraglottic device is a cuff, which is non inflatable in nature. [28] This feature facilitates easy insertion, and minimize tissue trauma and provides greater stability after insertion. Due to its thermo adaptability, I- Gel form an effective seal with pharyngeal and laryngeal structures and seal tend to improve with time. It is categorized as an uncuffed peri-laryngeal sealer according to Miller's classification .[54]

Parts of I-Gel

1. Non inflatable soft gel like cuff

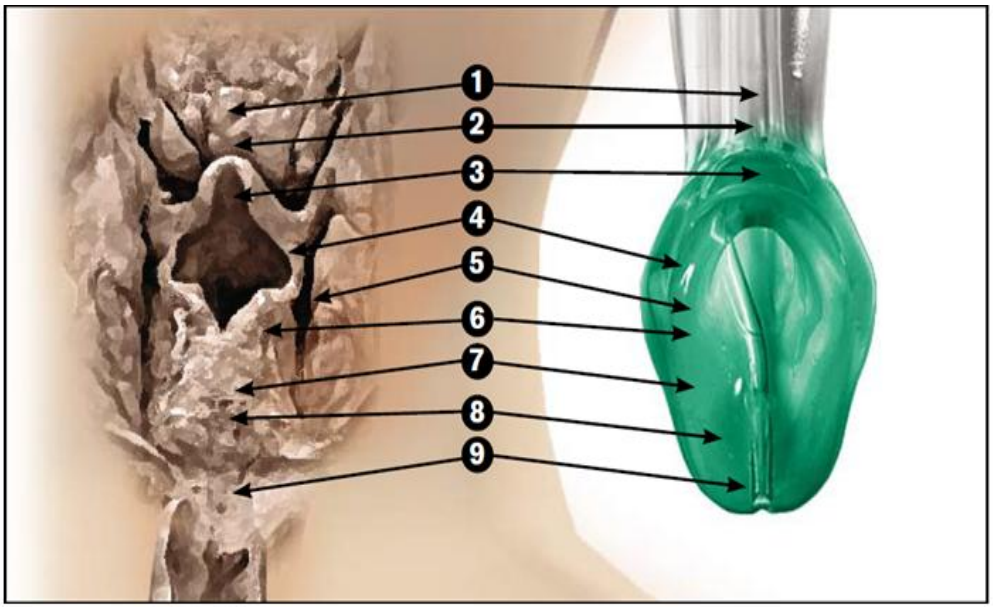
2. Oesophageal drain tube

3. Buccal cavity stabilizer

4. Epiglottic blocker

5.Airway tube with universal Fifteen millimeter adaptor

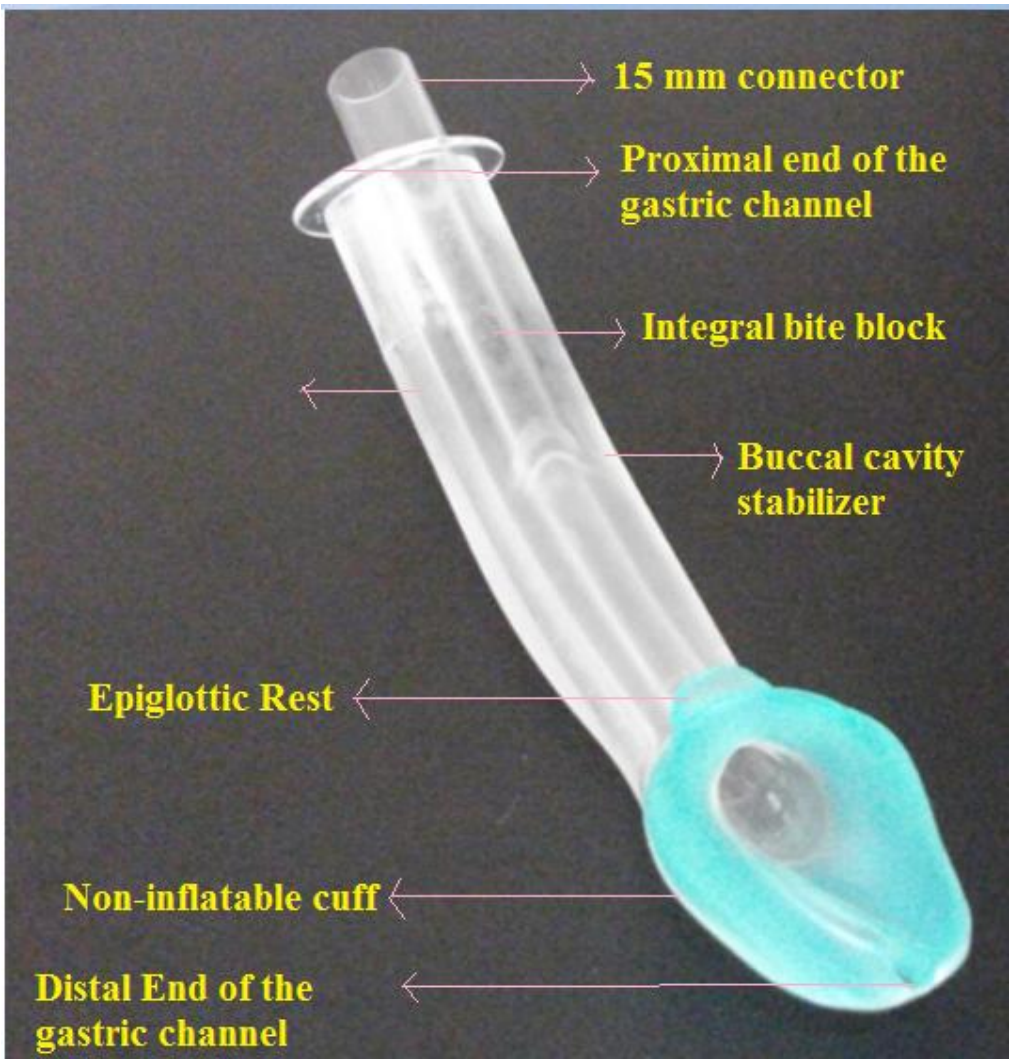
View of I-Gel in relation to the perilaryngeal structures



1. Tongue
2. Base of the tongue
3. Epiglottis
4. Aryepiglotticus
5. Pyriform fossa
6. Posterior cartilage
7. Thyroid cartilage
8. Cricoid cartilage
9. Oesophageal opening

The softness, shape, and contour of the cuff accurately mirrors the perilaryngeal structures to attain the perfect seal.

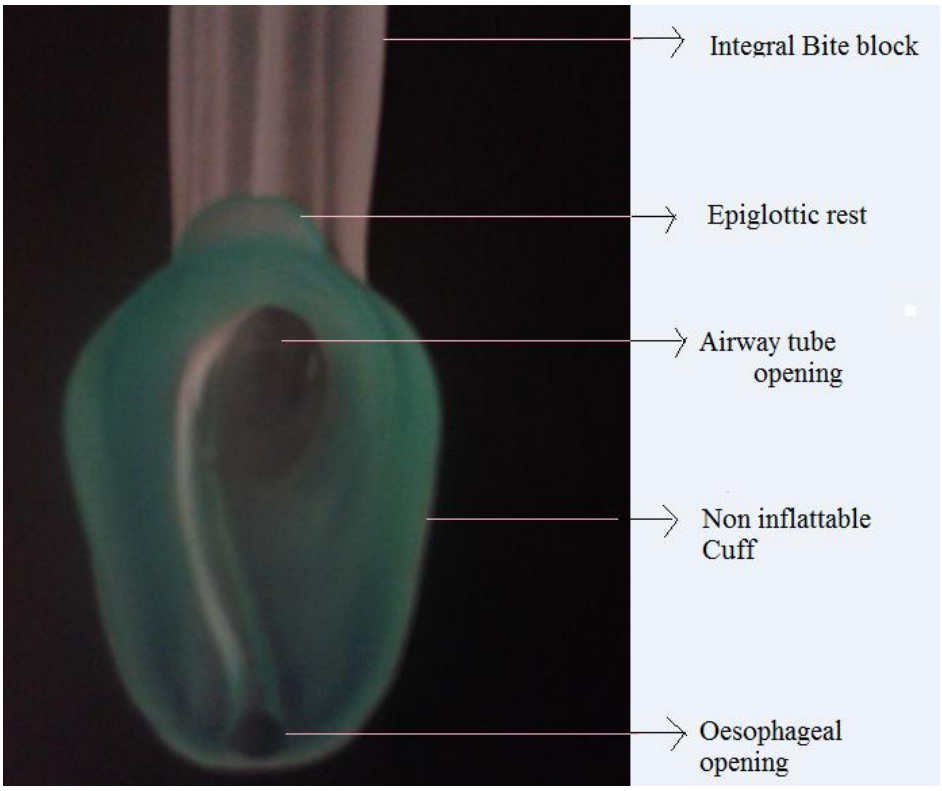
Components of I-Gel



Non inflatable soft gel like cuff

I-Gel has a novel non-inflatable soft gel like cuff, which accommodates perfectly over the pharyngeal and laryngeal framework. The softness, shape, and contour of the cuff accurately mirrors the perilaryngeal structures to attain a perfect seal. The tip of the cuff lies in the proximal oesophageal opening, isolating the upper oesophageal

opening from the inlet of larynx. The shape of the outer side of the cuff ascertains that the blood flow to the perilaryngeal structure is maintained and helps to minimize the possibility of vascular and nerve compression.



Oesophageal drain tube

Oesophageal drain tube has proximal and distal opening. Proximal opening is situated lateral to the airway tube in the flat connector. It runs through the device and ends in the distal tip of the non-inflatable mask. Since the distal tip of the cuff is designed in a way to provide the perfect fit into the oesophageal opening, the distal opening of the gastric tube

allows passage for feeding tube to empty the gastric contents and deflate the gas from the stomach.

Appropriate Size selection of the gastric tube and endotracheal tube.

Size of the I-Gel	Maximum gastric tube size (French)	Largest size (internal diameter) of the endo tracheal tube
1	NA	3.0 millimetre
1.5	10F	4.0 millimetre
2	12F	5.0 millimetre
2.5	12F	5.0 millimetre
3	12F	6.0 millimetre
4	12F	7.0 millimetre
5	14F	8.0 millimetre

Epiglottic blocker

The cuff portion of the I-Gel has epiglottic ridgeline, which prevent the down folding of the epiglottis and protects the distal airway tube opening. Since the epiglottic ridgeline at the proximal portion of the cuff rests at the base of the tongue, it stabilizes the device from moving upward and prevents the tip of the cuff from moving out of the proximal oesophageal opening.

Buccal cavity stabilizer

The stem of the I-Gel has an inbuilt bite block, which is elliptical in cross section. It is slightly curved to match the oesophageal anatomy. This feature provides stability and minimizes the axial rotation of the device, thereby reducing the risk of displacement or leak, when the child is placed in the lateral decubitus position.

Airway tube with universal fifteen-millimetre adaptor

1. The proximal connector provides connection to the patient end of the anaesthetic circuit system, which has a standard 15 mm universal adaptor.

2. Distal portion of the connector serve as an integral bite block.

3. Junction between the distal tip and body of the connector is 'V' shaped, which reduces the possibility of the airway tube occlusion.

4. There is horizontal black line in the stem of the I-Gel, which is used as a guide to depth of insertion.

5. The size of the device and recommended range of weight are marked on the proximal end of the stem in black colour.

Size selection

Various sizes of the I-Gel available for paediatric age group are 1, 1.5, 2 and 2.5.

Size of the I-Gel	Patient size	Patient weight guidance
1	Neonate	2 to 5 kg
1.5	Infant	5 to 12 kg
2	Small paediatric	10 to 25 kg
2.5	Large paediatric	25 to 35 kg
3	Small adult group	30 to 60 kg
4	Medium adult group	50 to 90 kg
5	Large adult group	Above 90 kg

Indications

1. Routine elective short surgical procedures requiring general anaesthesia

2. In failed intubation or difficult intubation situations, it has been used as a conduit for enotracheal intubation.

3. In difficult or failed intubation conditions used as a rescue device.

4. Used in outside operating room like radiology, Magnetic Resonance Imaging, diagnostic and short therapeutic procedures.

5. Cardiopulmonary resuscitation

6. Situations where inconvenient or difficult to hold the face mask

Contraindications

1. Full stomach patients posted for elective and emergency surgical procedures requiring general anaesthesia.

2. Less than 1.5 cm mouth opening.

3. Conditions which require high peak airway pressure, exceeding 40 cm H_2O.

4. Supraglottic pathology like cyst, abscess and hematoma.

5. Patients with low lung compliance or high resistance.

6. Situations associated with an increased risk of aspiration like hiatus hernia, oesophageal reflux disease, and previous gastric surgery.

Technique of insertion

I-Gel is lubricated on the non laryngeal surface and grasped along the bite block and the device is positioned in a fashion so that the outer portion of the cuff is facing towards patients chin. Patient's head should be maintained in the sniffing position. Then the chin is pressed gently down with the finger and the soft gel like tip of the cuff is introduced into the oral cavity in the direction towards the hard palate, then it is slide downward and backwards until a definitive resistance encountered.

Anaesthetic circuit is connected to the universal 15 mm adaptor. Proper positioning is confirmed by bilateral chest movement, $EtCO_2$ tracing, and auscultation of bilateral breath sounds by stethoscope.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Pennat JH, White PF, [55] 1993, in a review article described the laryngeal mask airway, its history and development of the LMA. The development of the LMA began in 1981 at the Royal London Hospital, Whitechapel, in the East End of London. Dr Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet. Although the LMA was developed as an artificial airway for routine general anaesthesia, it has a role in supporting airways that are difficult to manage and as an aid to blind and fibreoptic intubation an both elective and emergency surgeries. The LMA was first used in a failed intubation in 1983. Benumof suggests that the low risk/ benefit ratio associated with the LMA means that it may be a suitable alternative before trans tracheal jet ventilation is attempted. Tunstall believes it has a role in the difficult obstetric intubation when spontaneous ventilation has resumed. They summarized that LMA is a useful airway device for most adult and paediatric patients. It is a suitable alternative to the facemask and to tracheal intubation in a wide variety of clinical situations.

M. Lopez-Gil, J.Brimacombe and A. I. J. Brain et all 1999[56]conducted a study in a newer protypical LMA (pLMA) in 50 ASA I–II paediatric patients, weighing 10–45 kg, for whom the LMA was considered suitable. Mean age and weight were 75 (range 13–144) months and 23 (SD 11, range 10–45) kg, respectively. The male: female ratio was 35:15. Fifteen patients breathed spontaneously and 35 patients underwent mechanical ventilation. Duration of surgery was 40 (SD 10, range 11–60) min in patients breathing spontaneously and 74 (30, 25–140) min in the mechanically ventilated group. They found that all pLMA insertions were graded as easy and an adequate airway was achieved in all patients. The size No. 2 was used initially in 30 of 50 and the size No. 2.5 in 20 of 50 patients. In 46 of 50 patients, the vocal cords were seen fibre optically and airwayl leak pressure was 40 cm H2O in 49 of 50 patients. There was no incidence of gastric insufflations. Passage of the fibre optic scope into the oesophagus was possible in all patients. On removal, blood stained device was detected in three patients. There were no episodes of desaturation below 95%. They concluded that the pLMA is a easy to insert device, it facilitates high airway pressure ventilation and provides protection against gastric insufflations.

Mellisa wheeler MD 2006 [16] conducted a study to evaluate the clinical performance of a LMA-ProSeal in 120 paediatric surgical patients aged four months to thirteen years. The following datas were collected. Number of attempts taken for insertion, success and failure rate for device placement, airway seal pressure, desaturation below 95 %, possible complications like intraoperative bronchospasm, pulmonary aspiration, incidence of trauma, blood staining of the device. Induction was achieved with propofol and sevoflurane, none of the patient receive muscle relaxant. First attempt success was achieved in 94% of patients. First attempt was failed in 6% of the patients. Overall success rate for sump tube placement was 100%. None of the patient required device removal during surgery. There was no incidence of bronchospasm, desaturation below 95%, laryngospasm, or pulmonary aspiration. Blood staining of the device noted in 3% of the patients.55percentage of the patients received positive pressure ventilation, and 45%of the patients were allowed to breathe spontaneously. They concluded that, airway seal pressure achieved with Proseal LMA was high, it also got a gastric channel for aspiration of gas and fluid from stomach, pLMA might be a suitable alternative to endotracheal intubation for surgical procedures requiring positive pressure ventilation in paediatric patients.

Kannujia A, Saraswant N, Srivastava U, Mishra A, Saxena S [12] in 2009, conducted a prospective study to evaluate the clinical performance of the I-Gel in 50 ASA PS I-III patients, to ascertain the ease of insertion, time taken for insertion of the device, airway seal pressure and stability of the device during patient head and neck movement. Induction was achieved in supine position. All patients were premedicated with fentanyl 1to 1.5 µg per kilogram, midazolam 0.02mg per kilogram preoxygenation was done with 100% oxygen.

Induction was achieved with propofol 2to 2.5 mg per kilogram. Facemask ventilation done with nitrous oxide and oxygen in 2:1 ratio and halothane 1to 2%. Correct placement of the device was confirmed by bilateral chest movement, capnography, and oxygen saturation. First attempt success rate was 90%; 10% of the patients required second attempt for insertion and median insertion time was 11 seconds. Overall success rate for device placement was 100%. They concluded that I-gel is an easy to insert supraglottic airway device with high first attempt success rate and required short insertion time. It is useful device for patients requiring surgical procedures of 30-60 minutes duration in spontaneously breathing patients.

Franksen B, Renner J, Hanns R, Scholz J, Doerges V, Bein B et all [57], in 2009 conducted a study to compare the performance of the newer supraglottic airway device I-Gel and LMA unique in 80 patients undergoing minor gynaecological procedures. Parameters observed are, percentage of oxygen saturation, $EtCO_2$, peak airway pressure, time taken for insertion of the device. Postoperative complications like sore throat, dysphagia, dysphonia and hoarseness were noted. Time of insertion was comparable between two groups. Insertion was successful in all cases in I-Gel group and one failure in LMA-Unique group. Mean airway pressure in two groups were comparable.

I-Gel group showed significantly high airway leak pressure with a mean leak

Pressure of 29 cm H_2O compared with LMA -Unique group that showed mean leak pressure of 18 cmH2O. Both groups were comparable in terms of postoperative complications. They concluded that that the I-Gel may be advantageous with respect to significantly higher airway leak pressures.

Keller C, Brimacombe JR, Keller K, Morris R, 1999,[58] conducted a study to compare four different tests for assessing airway sealing pressure with the supraglottic airway device. They studied 80

paralysed, anaesthetized adult patients. Four different airway sealing pressure tests were conducted on each patient by two observers. Test 1 involved detection of an audible sound by listening over the mouth. Test 2 was detection of exhaled carbon dioxide by directing a gas sampling line for the capnography inside the mouth. Test 3 was observation of the steady value airway pressure in the aneroid pressure Manometer dial, while occluding the expiratory valve of the circle system. Test 4 was detection of an audible noise, lateral to the thyroid cartilage in the neck by auscultation using a stethoscope. Manometric stability test showed higher mean airway sealing pressure and good inter observer variability. They concluded that all four tests were excellent, but the Manometric stability test may be more appropriate for researchers comparing airway-sealing pressures.

Beringer RM, , Kelly F, Nolan J, Hardy R, Cook TM, **Simpson T, White MC et all 2011**[59] conducted a study in paediatric size I-gel in one hundred and twenty paediatric patients under general anaesthesia. In this study, time taken for insertion of the device, successful device placement at first attempt, second and third attempt success rate, fibre optic laryngeal imaging scores were compared. First attempt success rate was 92%. Eight patients (7%) required second attempt. One patient required third attempt for device insertion and device insertion was failed

in one child. Better fibre optic view of the vocal cards seen in 87 percentages of the patients. Median insertion time for I-Gel was 14 seconds and oropharyngeal leak pressure was 20 cmH_2O. No significant complications were noted. They concluded that I-Gel can be safely used in paediatric patients for both spontaneous and controlled positive pressure ventilation.

Orhan Tokgöz, Adnan Tüfek ,Serbülent Gökhan Beyaz, Feyzi Çelik, İlker Öngüç Aycan, Abdulmenap Güzel et all 2012 [60] conducted a study to evaluate the clinical performance of the supraglottic airway device I-Gel with LMA-ProSeal in 185 paediatric patients posted for elective surgery requiring general anaesthesia .Patients were randomly divided into two groups. I-Gel group (n = 95) and p-LMA group (n = 90). They compared, Airway leakage pressure, insertion time, fibre optic laryngeal image scores, ease of insertion and possible complications between in these groups. The airway leakage pressure was significantly high in I-Gel group (28 cmH_2O) compared to p-LMA group. Insertion time was shorter in I-Gel Group (19 ± 4seconds) than p-LMA Group (28 ± 5 second). Overall success rate was 95% for I-Gel Group and 94% for p-LMA Group-P. I-Gel provided better fibre optic view score (93%) compared to p-LMA (68%). Ease of insertion was

comparable between two groups. They concluded that I-gel is a safe alternative supraglottic airway device for use in paediatric patients.

Rakhee Goyal, Ravindra Nath Shukla & Gaurav Kumar 2011[61] et all Conducted a prospective randomized control study in 120 paediatric patients. In this study size 2 I-Gel compared with LMA-Proseal and LMA classic in an anaesthetized spontaneously ventilated patients. Patients were randomly divided into three groups. Oropharyngeal leak pressure, hemodynamic response, and postoperative complications were compared. Age, gender, type, and duration of surgery were comparable in all three groups. Success rate at first attempt for I-Gel was 95%; 90 percentages for both LMA-Proseal and LMA classic group. Oropharyngeal leak pressure was significantly high in I-Gel group (26 cm H_2O) compared to other two groups. (23cmH2O for LMA- Proseal and 22 cmH_2O for LMA classic). Hemodynamic responses were comparable between three groups. No incidence of clinically significant postoperative complications observed among three groups. They concluded that size 2 provided high oropharyngeal seal pressure compared with LMA-Proseal and LMA classic. I-Gel may be used as a safe alternative for other LMA in spontaneously breathing paediatric patients.

Z.I. Arslan, C.Balc , D.A.Oyusu, M.Yilmaz, N.Gurbuz, Ilce et all 2012 [62]

Conducted a study in 60 paediatric patients to compare the clinical performance of size 2 LMA-Proseal and LMA supreme in spontaneously ventilating children undergoing elective lower abdominal surgeries. In this study oropharyngeal leak pressure, incidence of gastric insufflations, trauma, postoperative complications, and ease of insertion of the devices compared between two groups. Mean oropharyngeal leak pressure for LMA-Proseal was significantly high (23 cmH2O) compared to LMA supreme. No incidence o desaturation or gastric insufflations noted between two groups. Ease of insertion, ventilator pattern, hemodynamic responses, and postoperative complications were comparable between two groups. They concluded that both LMA-Proseal and LMA supreme can be safely used in paediatric patients undergoing elective lower abdominal procedures.

Lee JR, Kim MS, Kim JT, Byon HJ, Park YH, Kim HS, Kim CS. 2012 [63]et all conducted a prospective randomized control trial in 99 healthy paediatric age group patients to compare the supraglottic airway devices I-Gel and LMA classic. Following parameters were observed, insertion time, airway seal pressure, ease of insertion, fibre optic view

and complications. Median insertion time was shorter with (17 seconds) I -Gel group compared with median insertion time of 21.0 seconds for LMA classic. Better fibre optic view of the glottis was found in 74% of the I-gel group compared to 43% in LMA classic group. Oropharyngeal seal pressure was comparable between two groups. They concluded that I-gel provided better glottic view, short insertion time, and similar airway leak pressure compared with classic LMA.

Fukuhara A, Okutani R, Oda Y.et all 2012 [64] compared (EPub ahead of print) the insertion performance of the paediatric size I-Gel supraglottic airway device with that of the ProSeal laryngeal mask airway (pLMA) in anesthetized children in a prospective, randomized, controlled manner. They included 134 children, aged 3 months to 15 years, posted for elective surgery requiring general anaesthesia. Oropharyngeal leak pressure was taken as a primary outcome variable. Other parameters observed are, ease of insertion, required time for insertion, fibre optic view, and first-attempt and overall success rates. There were no differences in the ease of insertion, insertion time, or leak pressure between the devices. Significantly better fibre optic view was obtained with the i-gel than with the proseal LMA .The view was significantly better with the sizes 2, 2.5, and 3 i-gel than with the size 1.5 i-gel , and the view was significantly better with the sizes 2.5 and 3 pLMA than with

the size 1.5 pLMA. The first-attempt success rates were 94% in the I-gel and 97 % in the proseal LMA groups. The overall success rates for insertion of the devices were 100 % in both groups. No children developed side effects requiring treatment with either device. They concluded that insertion of both paediatric sized I-gel and pLMA were successful in children. Compared to proseal LMA, I-gel provided better fibre optic view.

METHODOLOGY

METHODOLOGY

Study design

Our study was a single blinded, randomized comparative study conducted in Government Stanley medical college hospital, Chennai during the period of October 2011 to September 2012.

Study setting and population

After obtaining the approval from the institutional ethical committee of the Stanley Medical College, a pilot study was done to define the study population and decide on inclusion and exclusion criteria. A target population of 100 patients was decided. The parents were explained about the purpose of the study, the procedure, and the intended study methods. An informed consent was obtained.

Criteria for selection

INCLUSION CRITERIA

1. ASA PS I and ASA PS II
2. Child of age 2 to 8 years
3. Patients of either sex
4. Weight of 10 to 25 kgs

5. Mouth opening of more than 3 cm
6. Elective surgeries of duration up to 60 minutes, such as

Herniotomy, Circumcision, Orchidopexy, Vesicolithotomy, Hydrocele.

EXCLUSION CRITERIA

1. Restricted mouth opening
2. Altered airway anatomy
3. Congenital heart disease
4. Emergency surgeries
5. Risk of aspiration
6. Bleeding disorders

Relative contraindication would be a child with an uncontrolled respiratory tract infection.

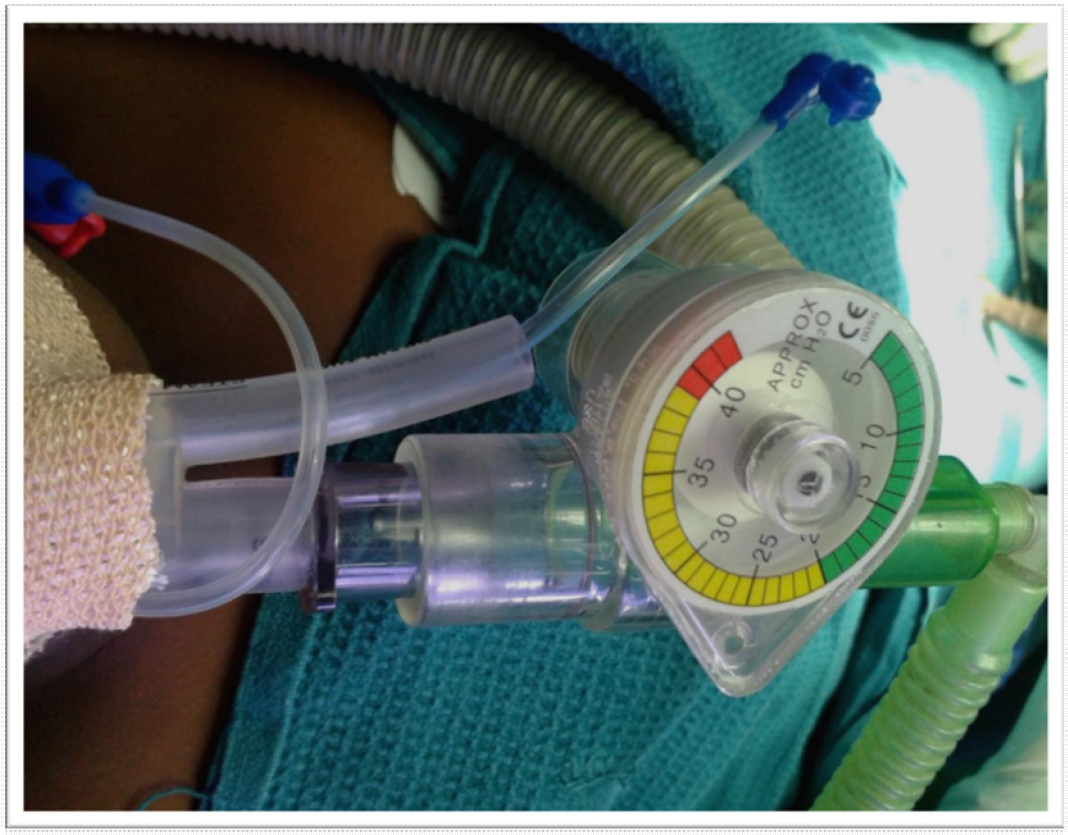
The selected children were randomized into one of two groups labelled as I and P by allotting lots with alphabets I and P. Children with lot I were assigned to group I. Those with lot P were assigned to group P. Each group was allotted with 50 children.

All children were fasted six hours pre-operatively for solids and 2 hours for clear fluids. The patients were brought into the operation theatre

and intravenous access obtained with appropriate size venous cannula. Intravenous fluid Ringer's lactate was started. Standard monitors like Pulse Oximeter, Automated Non-invasive Blood Pressure, ECG, Precardial stethoscope were connected and baseline values were recorded. All patients were premedicated with Inj. Atropine 20 µg / kg I.V, Inj.Midazolam 0.02 mg / kg I.V, Inj.Fentanyl 2 µg/kg I.V, and Inj.Ondansetron 0.1 mg/kg I.V , 5 min prior to induction of anaesthesia. Preoxygenation was done with 100% oxygen for 3 minutes. Induction was achieved with Inj.Propofol 3 mg/kg I.V mixed with Inj. Lignocaine 0.5 mg/kg. Facemask ventilation was done with 2% to 3% Sevoflurane and oxygen until optimal conditions for supraglottic device insertion were attained.

We considered, jaw muscle relaxation, denoted by easy upward and downward movement of the lower jaw**,** absence of eyelash reflex and no reaction to pressure employed over the both angles of the mandible**,** to indicate the depth of anaesthesia for insertion of the device. All the supra glottic airway device insertions were done by the same anaesthesiologist. Standard insertion technique recommended by the manufacturer was followed. After insertion, adequate airway was assessed from, bilateral symmetrical movement of the chest, normal thoracoabdominal movements, square waveform on capnograph with no audible

Size 2 LMA-Proseal with Gastric Tube



oropharyngeal leak and stable oxygen saturation. After confirming the correct placement, the device was secured over the maxilla. An appropriate size gastric tube was introduced through the drain tube. Correct placement of the gastric tube into the stomach was confirmed by insufflation of air heard on auscultation over the epigastrium or aspiration of gastric contents**.** Anaesthesia was maintained with Sevoflurane 3% in a mixture of 66% N2O and 33% oxygen. All patients were allowed to breathe spontaneously using paediatric circuit (Jackson Ree's modification of Ayre's T-piece). The anaesthetic gas flow was terminated at the end of the operation and patients were ventilated with 100% O2. After spontaneous eye opening supraglottic airway device was removed. Supraglottic airway device was inspected for blood staining. The patients were reviewed by the anaesthesiologist at PACU before sending the patient to the postoperative ward .Children were observed for 24 hrs after postoperatively.

Group P

LMA-Proseal size 2 & 2.5 were used for group P patients, in accordance with patient's weight and manufacturer's instruction. The Digital method (by using index finger) was used to insert the LMA-Proseal. Before insertion, the cuff was completely deflated and dorsal

Aneroid Cuff Pressure Manometer (TRACOE,REF720)

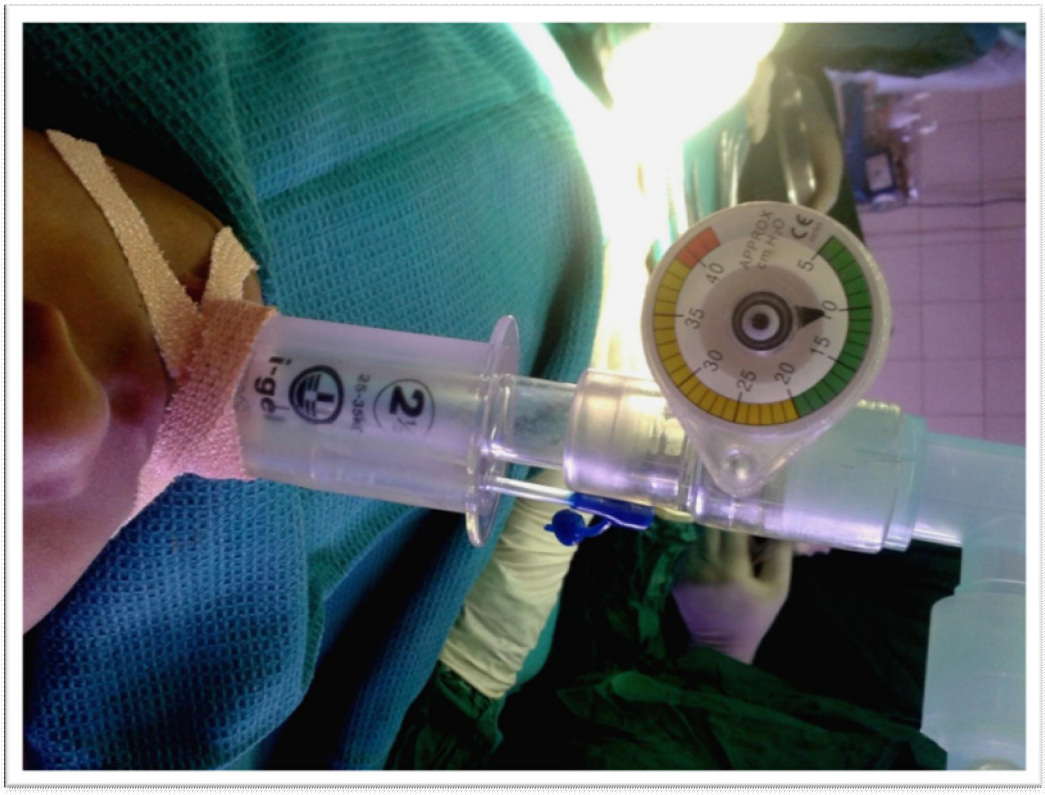
And Airway Pressure Monitor

surface of the device was lubricated with 2% lignocaine jelly. The child's head was stabilized in the sniffing position. The tip of the index finger was placed near the locator strap, at the junction of the cuff and the two tubes. As the index finger passes into the mouth, the finger joint was extended and the LMA-ProSeal was pushed backward toward the other hand that gives counter pressure to maintain the sniffing position .Depending on the patient, the finger was inserted to its fullest extent before (until the) resistance was encountered. The non-dominant hand was used to stabilize the LMA-Proseal as the finger is withdrawn. The cuff was inflated with up to 10 ml of air for size 2 LMA-Proseal and upto14 ml of air for size 2.5 LMA- Proseal. Cuff pressure was measured using an aneroid manometer (TRACOE, REF 720). Intra Cuff pressure was maintained throughout the surgery at 60cm H_2O. A gastric tube was passed through the drainage tube of the LMA-Proseal. 10F and 12F gastric tubes were selected for size 2 and size 2.5 LMA-Proseal respectively.

Group I

I -Gel size 1.5, 2 & 2.5 were used for group I patients, in accordance with patient's weight and manufacturer's instruction. Non-laryngeal surface of the I-Gel was lubricated with 2% lignocaine jelly and

Size 2.5 I-Gel with Gastric tube



it was grasped along the integral bite block. The device was positioned in a fashion so that the outer portion of the cuff is facing towards patients chin. Sniffing position was maintained during insertion. Non-inserting hand was used to stabilize the occiput. Then the chin was pressed gently down with the finger and the soft gel like tip of the cuff is introduced into the oral cavity in the direction towards the hard palate, then slide downward and backwards until a definitive resistance encountered. A gastric tube was passed through the drainage tube of the I-Gel device. Number 10 F gastric tube was selected for size 1.5 I-Gel, and 12F gastric tube was selected for size 2 and 2.5 I-Gel.

The following Para-meters were observed.

1. Airway seal pressure:

Test 1 (auscultation method)

Minimal airway pressure at which an audible noise detected, lateral to the thyroid cartilage in the neck by auscultation using a stethoscope.

Test 2 (Manometer stability)

An aneroid manometer was attached at the proximal end of supraglottic airway device in the paediatric Jackson Rees circuit and fresh gas flow set at 3L/m. The open tail end of the reservoir bag was pinched

with fingers to avoid gas leak and the reading at which there was no further increase in the manometer needle was noted. This denotes the airway pressure at which the leak was in equilibrium with the fresh gas flow. Circuit pressure was not allowed at any stage to rise beyond 40 cm H2O and oxygen saturation measured with finger probe oxymeter was not permitted to fall below 95%. We took average of three positive fluctuations in airway pressure in spontaneously breathing patients.

2. Ease of insertion

During insertion, the number and type of airway manipulations like gentle advancement, slight withdrawal of the device without removal and head extension with jaw thrust , required to maintain airway patency during case was recorded.

It was graded as “easy” if the device insertion was successful without any manipulation, or using only one manipulation.

It was graded as “difficult” if the device insertion requires more than one manipulation.

3. Insertion time

The time from removal of face mask to the confirmation of airway patency with supraglottic airway device in place by auscultation.

4. Number of attempts

Number of attempts taken for insertion was noted as first attempt/ second attempt/ third attempt. “Failure” of supraglottic airway device was identified as three unsuccessful insertion attempts.

5. Ease of insertion of gastric tube

The gastric tube insertion was termed “easy” if it was passed in the first attempt and termed “difficult” if it was passed in the second attempt and was termed “failure” if it could not be passed in two attempts.

Complications

Complications occurring during insertion, maintenance, and removal like, desaturation less the 95%, laryngospasm, aspiration of gastric contents, incidence of blood staining of the device, mucosal/ lip trauma, and postoperative airway complications like, hoarseness and cough were noted for each child.

Statistical Analysis

The data collected were scored and analyzed by using SPSS (Statistical Package for Social Science) Ver 16.01 statistical software. Continuous variables were presented as means with Standard deviation (sd) and categorical variables were presented as frequency and

percentages. “Student t-test” was used for testing the significance of all the variables (Mean & sd) in both the groups. “Chi-square test” was used to compare the proportions. All the statistical results were considered significant at P value < 0.05. All values were rounded off to a maximum of two decimals.

STATISTICAL ANALYSIS, OBSERVATION AND RESULTS

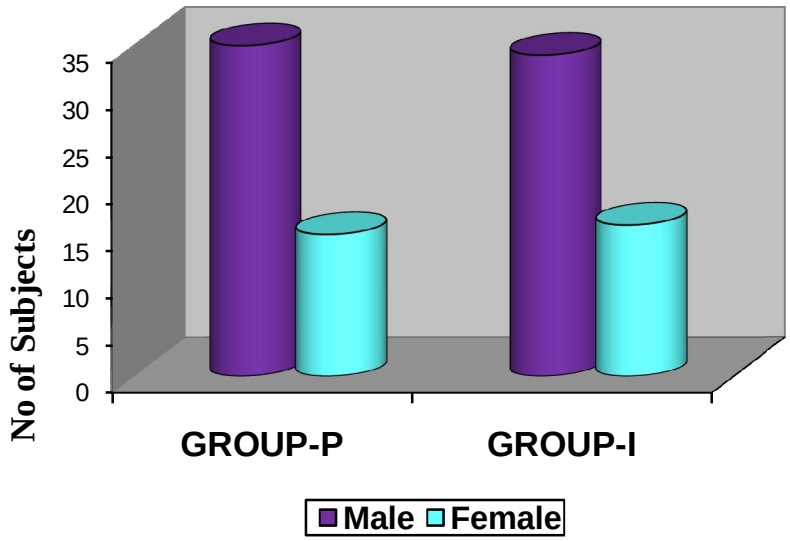
OBSERVATION AND RESULTS

Table-1

Gender distribution among group P and group I.

Sex	GROUP-P N=50		GROUP-I N=50		Total N=100	
	N	%	N	%	N	%
Male	36	72.00	34	68.00	70	70
Female	14	28.00	16	32.00	30	30
Chi-square value	**0.19**					
Df	**1**					
p-value	**0.66 (Not Significant)**					

Figure:1. Gender Distribution



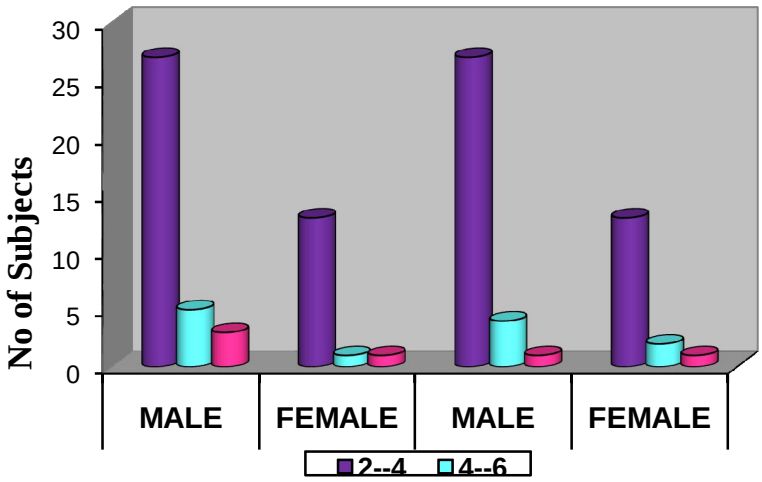
Among the 50 children in Group P 36 were boys, 14 were girls .In Group I, 34 were boys and 16 were girls. Both groups were comparable in terms of gender distribution.

Table-2.

Age Distribution among Group P and Group I (in years)

AGE (Yrs)	GROUP-P (N=50)		GROUP-I (N=50)		Total (N=100)	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
2-4	27	13	29	13	56	26
4 -6	5	1	4	2	9	3
6-8	4	0	1	1	5	1
Mean (sd)	**3.58 (1.62)**		**3.42(1.24)**		**3.50 (1.44)**	
T-value	**0.56**					
Df	**98**					
p-value	**0.58 (Not Significant)**					

Fig: 2. Age Distribution



In group P children, the minimum age is 2 yrs and maximum age is 8 yrs with a mean age of 3.58 yrs ± 1.62. In group I children, the minimum age is 2yrs and the maximum age is 8yrs. with mean age of

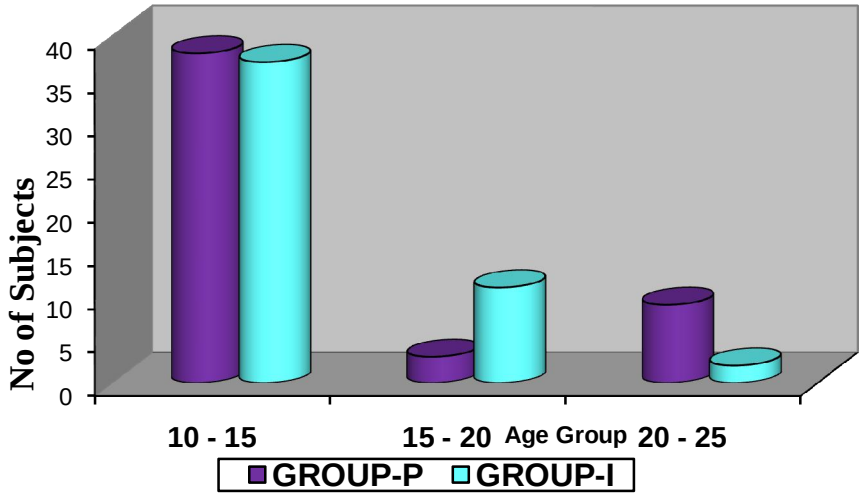
3.42 yrs±1.24. In group P there were 40 children between 2 to 4 years of age, 6 children between 4 to 6 years of age, 4 children between 6 to 8 years of age, while in group I there were 42 children between 2 to 4 years of age, 6 children between 4 to 6 years of age and 2 children between 6 to 8 years of age. Both the groups were comparable in terms of age, the average being similar around 3.5 years in both groups, with no statistical significance (p 0.58).

Table-3.

Comparison of Weight between two groups (in kilogram)

	GROUP-P	GROUP-I
Mean	14.30	13.82
Sd	4.17	3.65
t-Value	**0.61**	
Df	**98**	
p-value	**0.54 (Not Significant)**	

Figure: 3. Weight Distribution



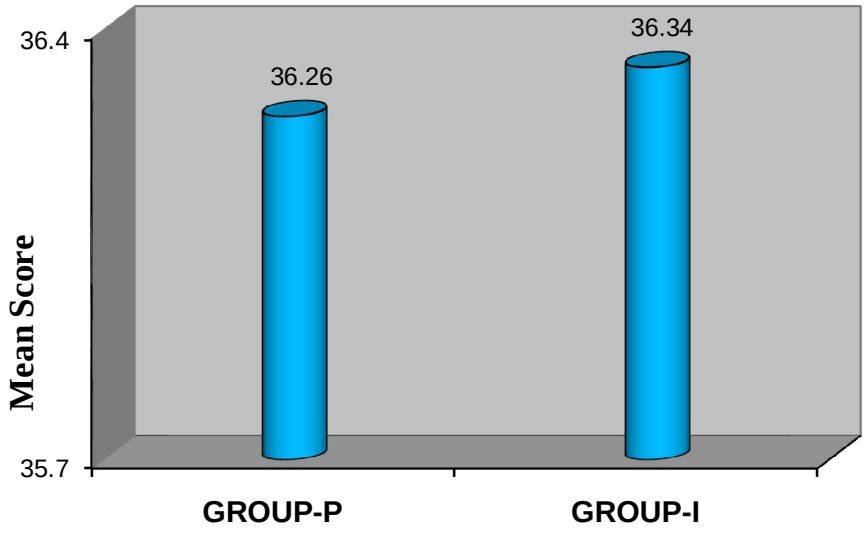
In group P children, the minimum weight is 10 kg and maximum weight is 25 kg with a mean weight of 14.30 ± 4.17 kg. In group I children, the minimum weight is 10 kg and the maximum weight is 25 kg with mean weight of 13.82 ± 3.65kg. No significant difference between two groups was found in terms of weight distribution the average being 14.06 kg. The difference in mean weight is statistically not significant.

Table-4

Comparison of duration of surgery between two groups. (In minutes)

	GROUP-P	GROUP-I
Mean	36.26	36.34
Sd	7.43	9.01
t-Value	**0.05**	
Df	**98**	
p-value	**0.96 (Not Significant)**	

Figure :4. Duration of Surgery

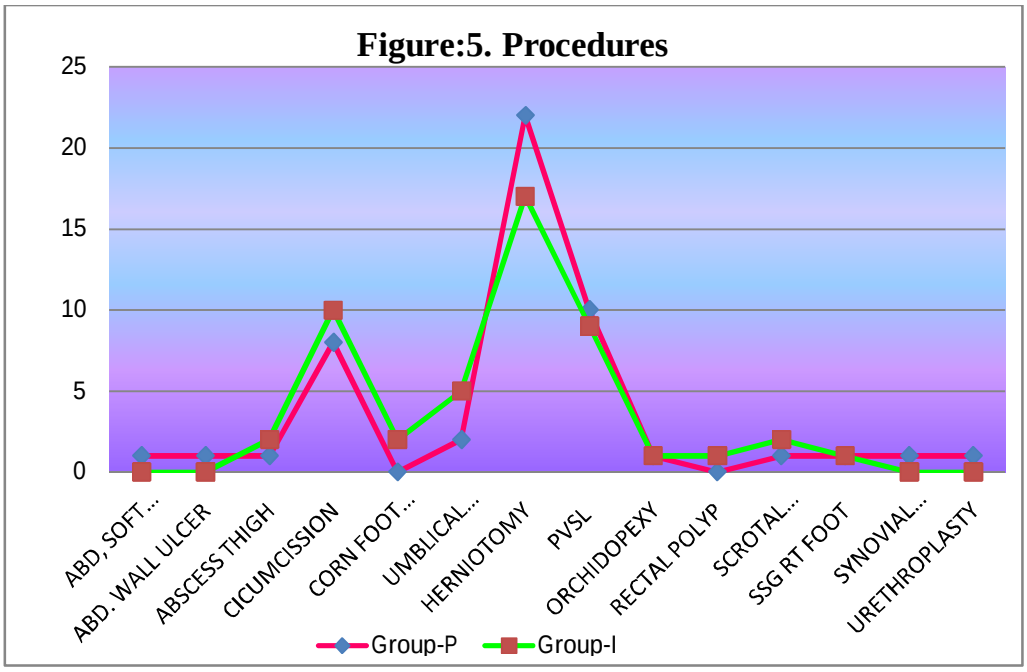


The shortest duration of surgery in group P is 20 minutes and the longest duration of surgery is 54 minutes. The mean duration of surgery is 36.26 ± 7.43minutes. The shortest duration of surgery in group I is 22 minutes and longest duration of surgery is 56 minutes. The mean duration of surgery is 36.34 ± 9.01 minutes. The mean being comparable between the two groups.

Table-5

Comparison of Type of surgery between two groups.

PROCEDURE	GROUP-P		GROUP-I		Total	
	N	%	N	%	N	%
ABD, SOFT TISSUE	1	2	0	0	1	1
ABD. WALL ULCER	1	2	0	0	1	1
ABSCESS THIGH	1	2	2	4	3	3
CICUMCISSION	8	16	10	20	18	18
CORN FOOT EXCISION	0	0	2	4	2	2
UMBLICAL HERNIA REPAIR	2	4	5	10	7	7
HERNIOTOMY	22	44	17	34	39	39
PVSL	10	20	9	18	19	19
ORCHIDOPEXY	1	2	1	2	2	2
RECTAL POLYP	0	0	1	2	1	1
SCROTAL EXPLORATION	1	2	2	4	3	3
SSG RT FOOT	1	2	1	2	2	2
SINOVIAL SWELLING BIOPSY	1	2	0	0	1	1
URETHROPLASTY	1	2	0	0	1	1
TOTAL	**50**	**100**	**50**	**100**	**100**	**100**
Chi-square value	**9.87**					
Df	**13**					
p-value	**0.71 (Not Significant)**					



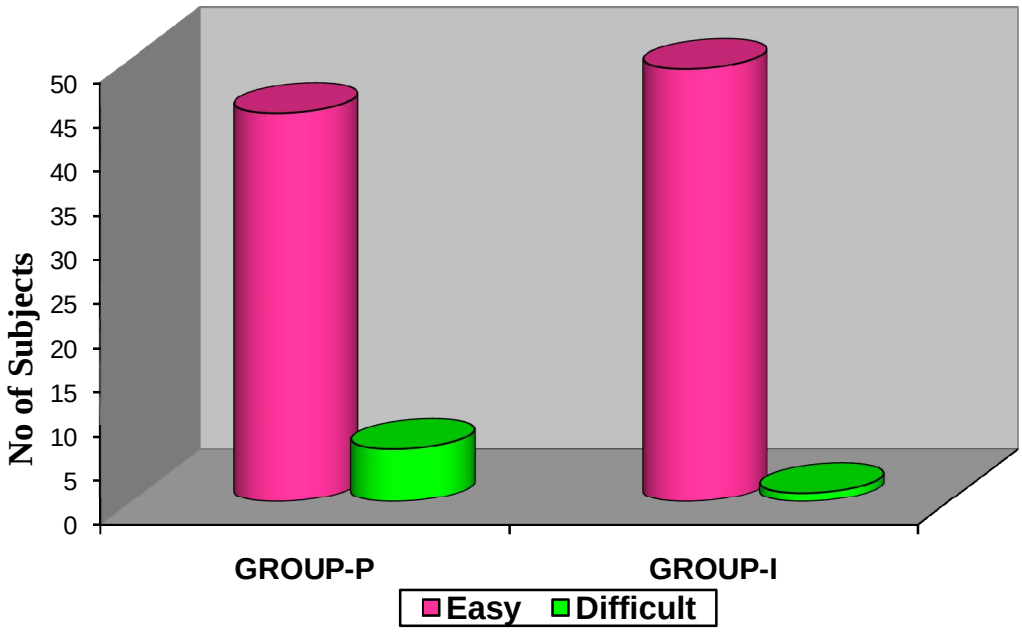
The maximum type of surgery done was herniotomy followed by circumcision. The distribution of type of surgeries is comparable in both the groups.

Table-6

Comparison of Ease of insertion between two groups.

	GROUP-P		GROUP-I		Total	
	N	**%**	**N**	**%**	**N**	**%**
Easy	44	88.00	49	98.00	93	93.00
Difficult	6	12.00	1	2.00	7	7.00
Chi-square	**3.84**					
Df	**1**					
p-value	**0.05 (Significant)**					

Figure: 6. Ease of Insertion



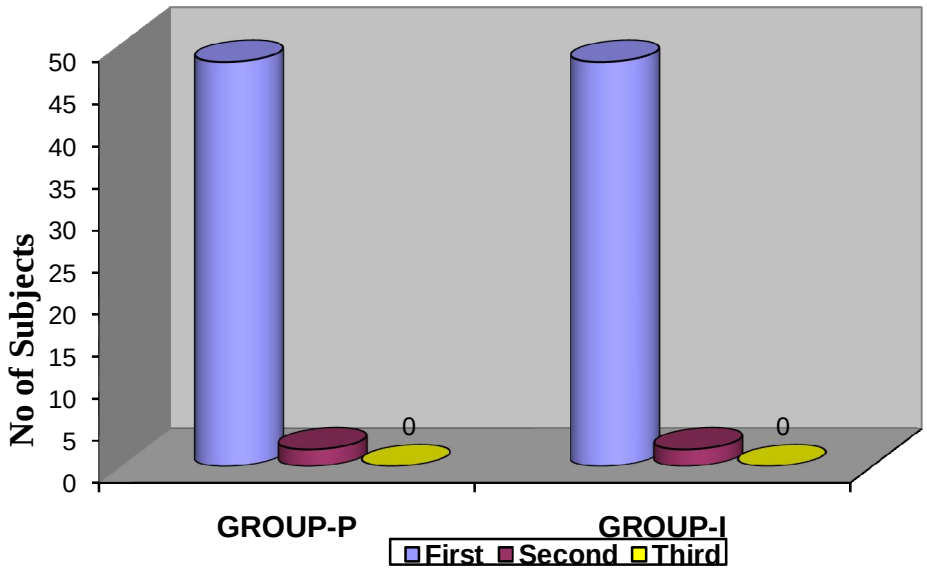
In Group P the insertion is easy in 88 %, where as in Group I it is 98%. In group P difficult insertion is 12%, in Group I difficult insertion is 2%. The difference between both Groups is statistically significant in term of ease of insertion. (p 0.05).

Table-7

Comparison of Number of attempts between two groups.

Attempts	GROUP-P		GROUP-I		Total	
	N	%	N	%	N	%
First	48	96.00	48	96.00	96	96.00
Second	2	4.00	2	4.00	4	4.00
Third	0	0	0	0	0	0
Chi-square	**0.001**					
Df	**1**					
p-value	**1.000 (Not Significant)**					

Figure:7. No of Attempts



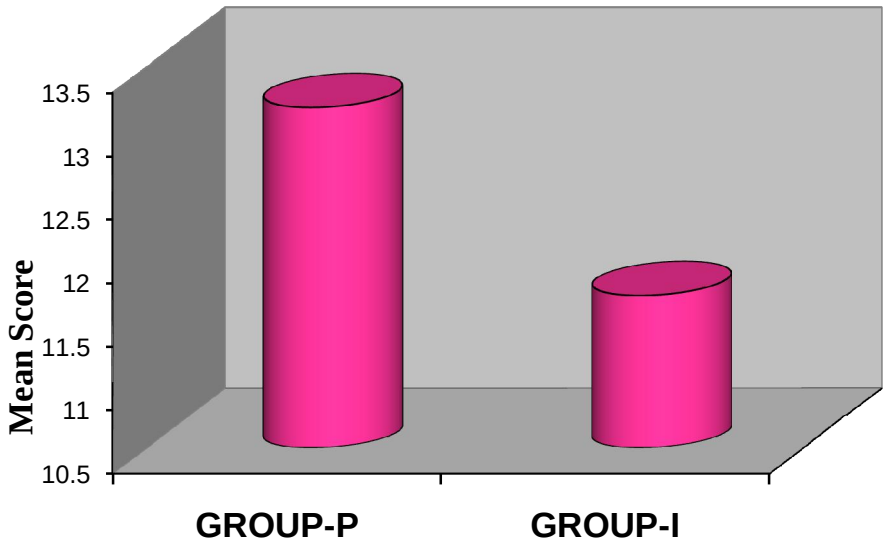
The first attempt success rate for both LMA-Proseal and I-Gel was 96.00%. The comparison doesn't show any statistically significant difference (p 1.000). The second attempt success rate is100% for both LMA-Proseal and I-Gel.

Table-8.

Comparison of insertion time between two groups (in seconds)

	GROUP-P	GROUP-I
Mean	13.50	11.70
Sd	2.65	2.27
t-Value	**3.65**	
Df	**98**	
p-value	**0.001(Significant)**	

Figure :8. Insertion Time



In group P the mean time taken for insertion is 13.50 ± 2.65 seconds. Whereas in group I mean time taken for insertion is 11.70 ± 2.27 seconds. In group-P the minimum time taken for insertion is 10 seconds

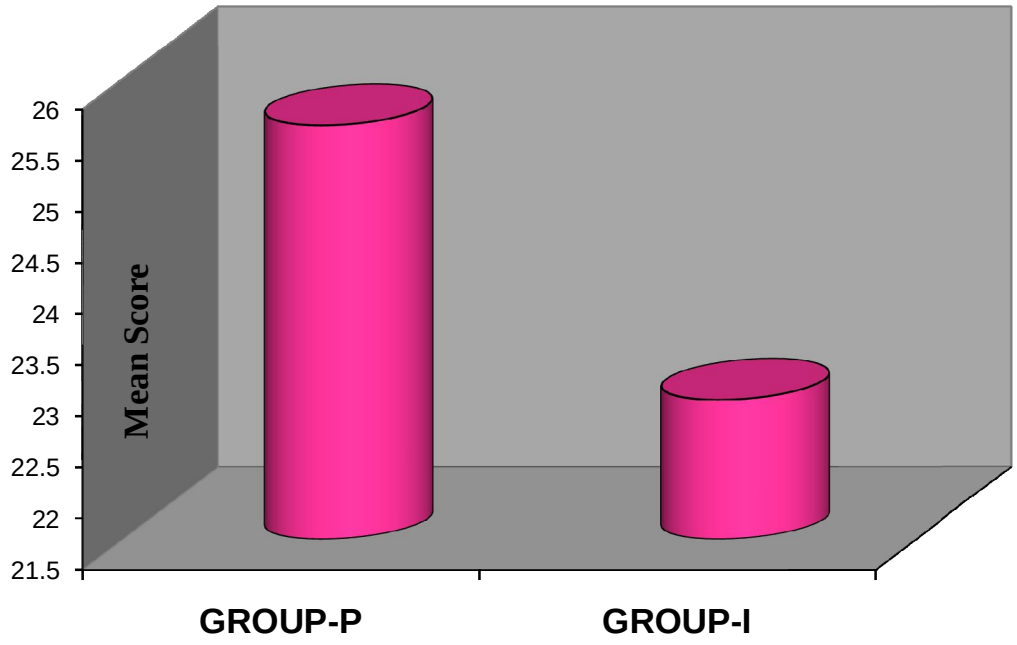
and maximum time taken for insertion is 25 seconds. In group-I the minimum time taken for insertion is 8 seconds and maximum time taken for insertion is 21seconds.The comparison of mean time of insertion for LMA-Proseal and I-Gel showed statistically significant difference (p0.001).

Table-9

Comparison of Airway seal pressure between two groups (cmH_2O)

	GROUP-P	GROUP-I
Mean	25.54	22.86
Sd	3.42	1.82
t-Value	**4.89**	
Df	**98**	
p-value	**0.0001 (Significant)**	

Figure:9. Airway Seal Pressure



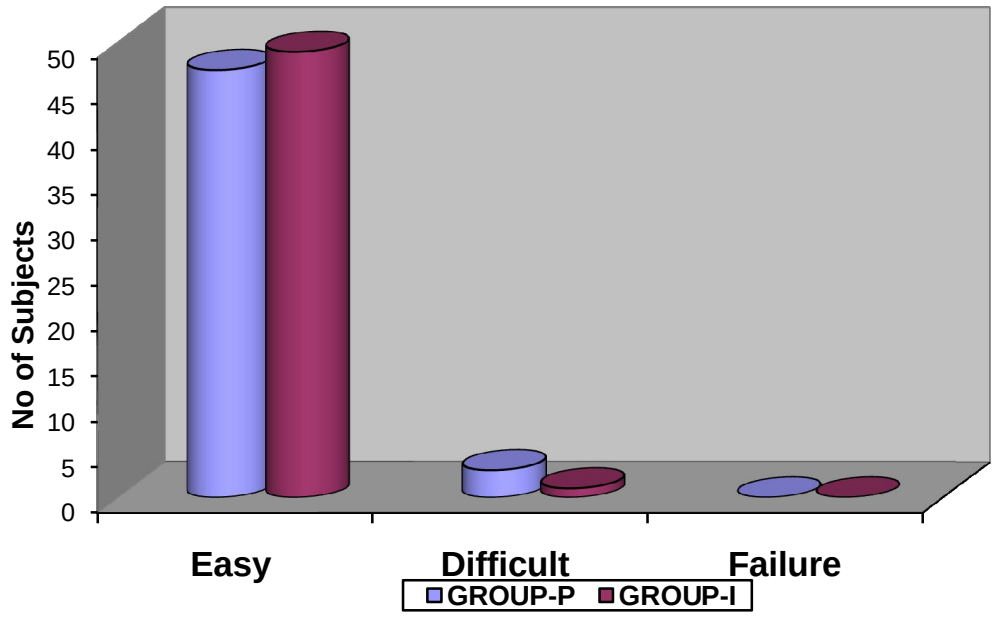
In Group P minimum seal pressure observed is 19 cmH_2O, maximum seal pressure is 32 cm H_2O.The mean seal pressure is 25.54 ± 3.42 cmH_2O. In Group I minimum seal pressure observed is 19 cmH_2O, maximum seal pressure is 26 cmH_2O and mean seal pressure is 22.86 ± 1.82 cmH_2O. Comparison of seal pressure between two groups showed statistically significant difference (P 0.0001).

Table-10

Comparison of Ease of Gastric Tube Placement between two groups.

	GROUP-P		GROUP-I		Total	
	N	**%**	**N**	**%**	**N**	**%**
Easy	47	94.00	49	98.00	96	96.00
Difficult	3	6.00	1	2.00	4	4.00
Failure	0	0	0	0	0	0
Chi-square	**1.04**					
Df	**1**					
p-value	**0.31 (Not Significant)**					

Figure: 10. Ease of Gastric Tube Placement



Gastric tube placement was easy in 94 % of group P, where as in Group I it was easy in 98%. It was difficult in 6% of group P, where as in

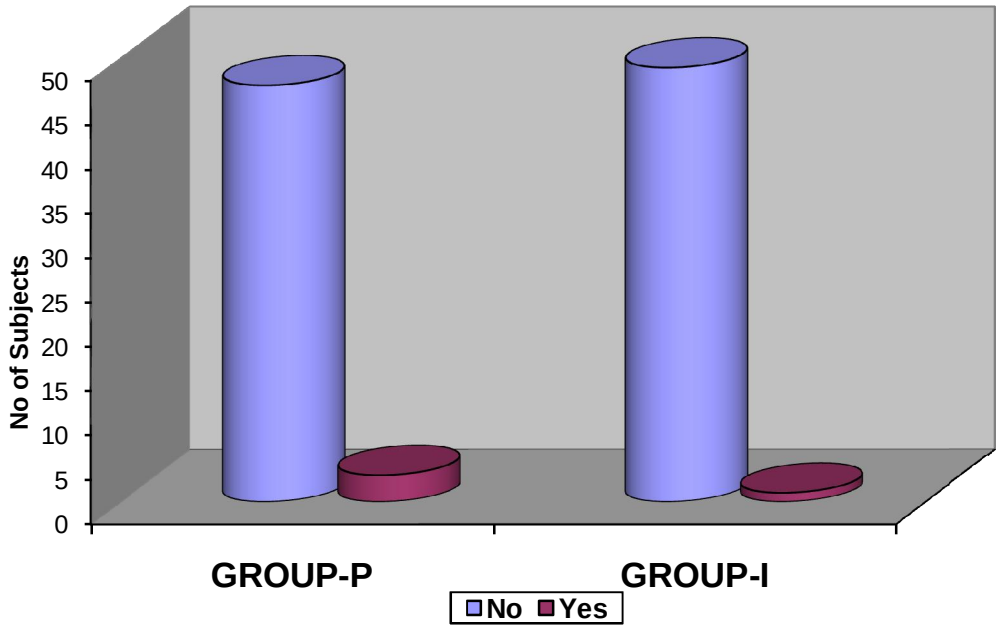
Group I it was difficult in 2%. Comparison of ease of gastric tube placement between two groups does not show any statistical significance. In the LMA-Proseal group, the gastric drainage tube could be inserted in the first attempt was only in forty seven cases, 3 cases were graded difficult in terms of insertion of the gastric tube. Out of the fifty cases, the gastric tube could be easily inserted in 49 cases in I-Gel group. Only one case was graded difficult in terms of insertion of the gastric drainage tube, which required a second attempt. Both groups were comparable in terms of ease of gastric tube placement.

Table-11.

Comparison of Blood staining of the device between two groups.

	GROUP-P		GROUP-I		Total	
	N	%	N	%	N	%
No	47	94.00	49	98.00	96	96.00
Yes	3	6.00	1	2.00	4	4.00
Chi-square	**1.04**					
Df	**1**					
p-value	**0.31 (Not Significant)**					

Figure :11. Blood Staining of the Device



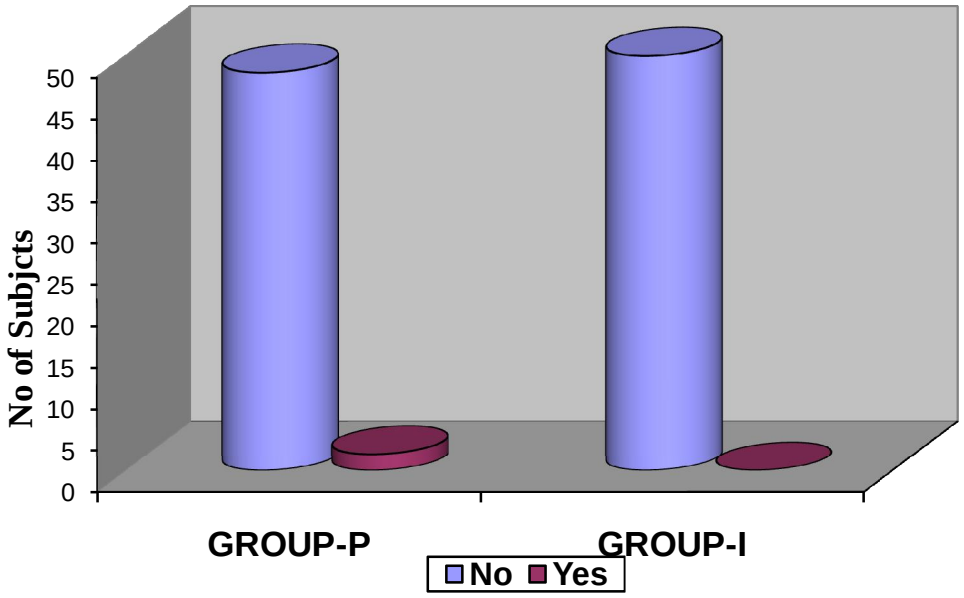
Incidence of blood staining of the device was 6% in Group P whereas 2% in group I. Comparison of blood staining of device as a complication in both groups does not show any statistical significance.

Table 12.

Comparison of Hoarseness after removal of the device between two groups.

	GROUP-P		GROUP-I		Total	
	N	%	N	%	N	%
No	48	96.00	50	100%	98	99.00
Yes	2	4.00	0	0.00	2	2.00
Chi-square	**2.04**					
Df	**1**					
p-value	**0.31 (Not Significant)**					

Figure: 12. Hoarsness



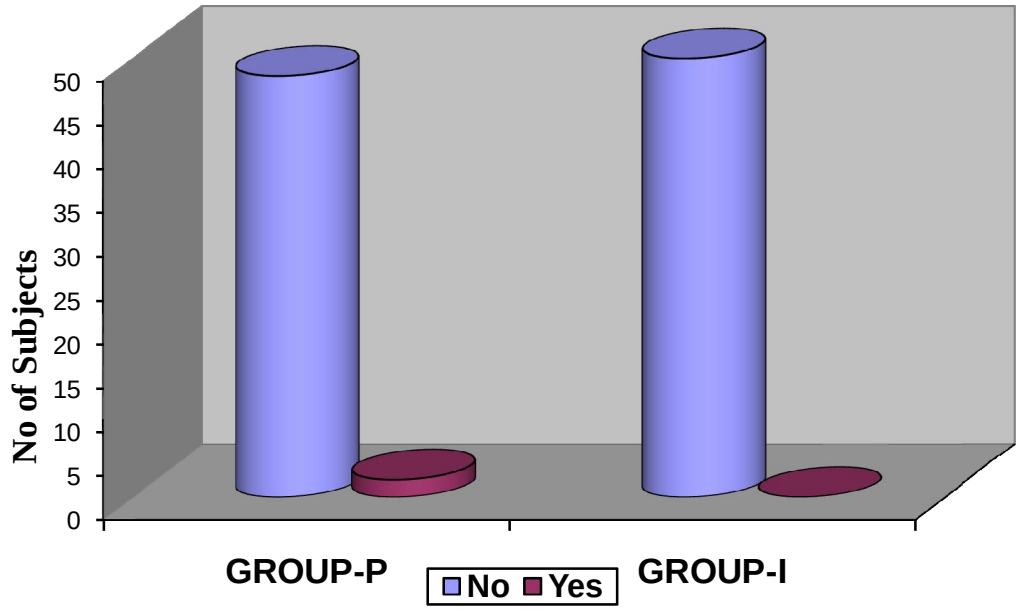
In group P two cases reported with hoarseness (4%). where as in group I, no cases developed hoarseness after removing the device. Comparison of hoarseness as a complication between two groups does not show any statistical significance.

Table 13

Comparison of Cough in the post operative period between two groups.

	GROUP-P		GROUP-I		Total	
	N	%	N	%	N	%
No	48	98.00	50	100%	98	98.00
Yes	2	4.00	0	0.00%	2	2.00
Chi-square	**2.04**					
Df	**1**					
p-value	**0.53 (Not Significant)**					

Figure:13.Cough



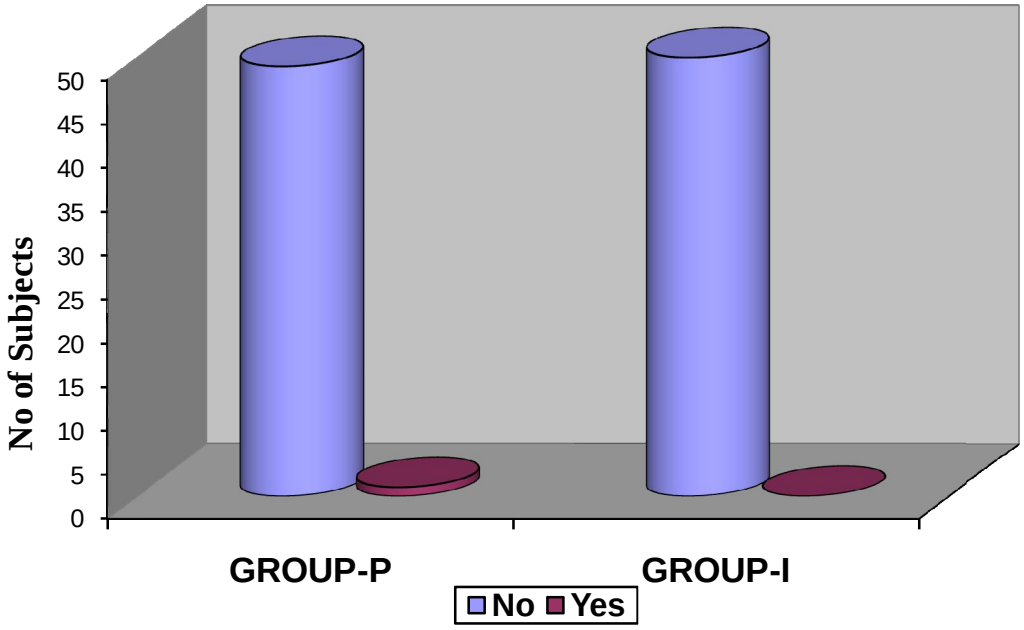
Two cases developed cough in the post operative period in group P (4%) and none of the cases in group I .Both groups were statistically not significant in terms of cough as a post operative complication.

Table-14

Comparison of Mucosal/lip trauma in two groups.

	GROUP-P		GROUP-I		Total	
	N	%	N	%	N	%
No	49	98.00	50	100%	99	99.00
Yes	1	2.00	0	0.00	1	1.00
Chi-square	**1.01**					
Df	**1**					
p-value	**0.32 (Not Significant)**					

Figure:14. Mucosal /lip Trauma



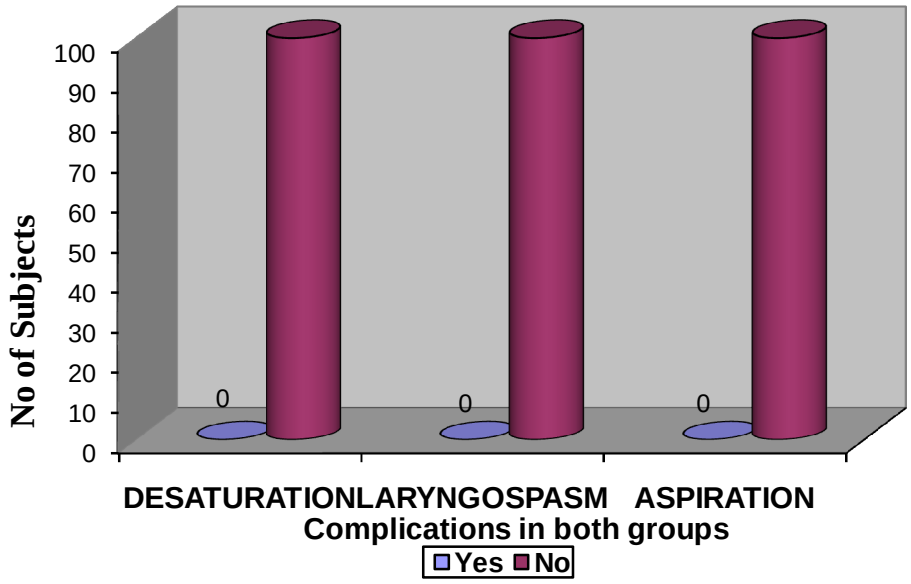
Lip trauma was noted in one case in group P (2%). There was no mucous / lip trauma in group I. Both groups does not show any statistical significance in terms of mucous/lip trauma as a complication.

Table 15

Other complications

Complications		GROUP-P		GROUP-I		Total	
		N	%	N	%	N	%
Desaturation	Yes	50	100	50	100	100	100
	No	0	0	0	0	0	0
Laryngospasm	Yes	50	100	50	100	100	100
	No	0	0	0	0	0	0
Aspiration	Yes	50	100	50	100	100	100
	No	0	0	0	0	0	0

Figure:15. Other Complications



There was no incidence of desaturation, laryngospasm, aspiration or noted among two groups.

DISCUSSION

DISCUSSION

Our study, comparing the supraglottic airway devices I-Gel with LMA-Proseal shows the mean age, average weight, sex ratio, duration of surgery and type of surgery were comparable between two groups. Our results presented that the I-Gel supraglottic airway device is advantageous over LMA-Proseal in terms of short insertion time, ease of insertion, ease of gatric tube placement and less incidence of complications in children; whereas LMA-Proseal has got advantage over the I-Gel in regards to high airway sealing pressure. I-Gel supraglottic airway device is as effective as LMA-Proseal in anaesthetized spontaneously breathing paediatric patients with mallampati class 1 and 2 airway with an acceptable airway sealing pressure.

Supraglottic airway devices are commonly used in *children between 2 to 6 years of age.* [65] In our institution, large numbers of paediatric patients in the age group of 2 to 8 years are admitted for surgery. Hence, we used these age group children in our study.

Since there is an increased risk of aspiration in full stomach paediatric patients, supraglottic airway devices are usually avoided for *emergency surgeries.*[40] Design of the cuff and the presence of gastric drain tube feature in both supraglottic airway devices, expected to reduce

the complications like pulmonary aspiration, regurgitation of gastric contents, and stomach insufflation, compared to LMA-classic.[44,20] However, I-Gel and LMA-Proseal should not be considered as an absolutely safe device, (aspiration may result if the tube is not correctly placed) in situations where there is a high risk and chances of regurgitation and aspiration.[66] Hence Emergency surgery patients were excluded from our study.

Size of the supraglottic airway devices and the maximum volume of air that can be used to inflate the cuff in our study were based on the manufacturer's recommendations.[38] We selected the size of the supraglottic airway device based on the patient's body weight.

Insertion of LMA needs adequate mouth opening for its successful placement. In restricted mouth opening patients, LMA insertion into the mouth is not possible.[67] Hence patients with restricted mouth opening (less than 2 cm) are excluded from the study population. There is higher incidence of airway obstruction in children with upper and lower respiratory tract infections, both intraoperatively and postoperatively.[3] Hence these children are also excluded from the study.

A pilot study with a *sample size* of 5 children in each group was done before the start of the study to decide on sample size. The mean

time of insertion and the standard deviation calculated from the study was used and the sample size calculated based on the formula given in monographers on statistics and applied probability. [68, 69]

Formula

$$n = \frac{[Z_{1-\alpha/2} + Z_{1-\beta}]^2 (2\sigma^2)}{(d)^2}$$

Where

$Z_{1-\alpha/2}$ = 1.96 (5% alpha level of significance)

$Z_{1-\beta=}$ 1.037 (80% power)

D = difference between two means

$\sigma = S_1+S_2 / 2$

From the pilot study the value of mean and standard deviation of insertion time (in seconds) of Group-1was (10.78 ± 3.30) and Group-II was (12.23 ± 3.50) calculated.

On entering the values,

$[Z_{1-\alpha/2} + Z_{1-\beta}]^2 = (1.96 +1.037)^2 = 8.98$

$\sigma = (s_1 +s_2) / 2$

$S = (3.30+3.50)/2 = 6.80/2 = 3.40$

$S^2 = (3.40)^2 = 11.56$

$2\sigma^2 = 11.56*2 = 23.12$

$d = (\text{Mean1} - \text{Mean2})$

$= (10.78-12.23) = -1.45$

$d^2 = 2.10$

$n = (8.98 * 23.12)/ 2.10$

$n = 207.62/2.10$

$n = 98.87\ (99)$

$n = 99$

From the above calculation *sample size* was decided as 100 (50 for each group).

To reduce the risk of pulmonary aspiration of gastric contents, infants and children are fasted before sedation and anesthesia.[70] In our study all children were fasted six hours pre-operatively for solids and 2 hours for clear fluids. We have used intravenous fluid (Ringer's lactate) according to 4-2-1 [71] formula for all children.

In children, *premedication* is required to minimize psychosocial stress and separation anxiety. [70] An ideal premedication agent should be readily acceptable, rapidly acting, with minimal side effects, helps in providing amnesia (anterograde). It should also provide prophylaxis against pulmonary aspiration of gastric contents, decrease airway secretions and facilitate the induction of anesthesia. The primary aim of premedication in children is anxiolysis.[73] Keeping above goals in mind, we have used Inj. Atropine, Inj.Midazolam, Inj.Fentanyl and Inj.Ondensetran as premedication agents. Midazolam is an effective drug in producing adequate sedation and anxiolysis in children. The main advantage of midazolam over other drugs is its rapid uptake and elimination. Midazolam as a premedication is given through oral, intramuscular, intravenous or intranasal routes.[70] Oral midazolam has high first pass metabolism and its oral bioavailability is only 15 – 27%, hence larger dose (0.25 to 0.75mg/kg) midazolam is needed orally. Intra venous midazolam (0.025 to 0.1 mg/kg) has rapid onset of action and high bioavailability. Midazolam has also been used via the nasal at a dose of 0.2 to 0.3 mg/kg or rectal route at a dose of 0.3 mg/kg but with their own disadvantages.[3] In our study we have used 0.05 mg /kg of intravenous midazolam and 2µg/kg of intravenous Inj.Fentanyl.

Various *induction techniques* are used for supraglottic device insertion each having its own advantages and disadvantages. Both the intravenous and inhalational techniques are widely used. [72] Intravenous induction is commonly done using either Thiopentone or Propofol.[73] Propofol is an ideal anaesthetic induction agent for supraglottic device insertion, because it profoundly reduces airway reflexes.[75] It is used at a dose of 2 to 5mg/kg.[76] In our study we used Inj.Propofol 3mg/kg mixed with 0.5 mg/kg of Inj.Lidocaine for all the cases. The sedative effect of both the propofol and midazolam are mediated by GABA-A receptors. The midazolam premedication reduces the dose of propofol and provides better condition for supraglottic device placement in children.[77] Addition of an opioid or intravenous lidocaine improves insertion conditions.

Sevoflurane has a rapid induction and recovery profile compared to halothane.[78] For this reason it is preferred over halothane. *Neuromuscular blocking drugs* are not needed if propofol is used as an induction agent. [74]

We maintained the patient's head in *sniffing position* for insertion of the supraglottic airway device. This is achieved by flexion at C6-C7 (neck flexion) and extension at occiput-C1. Sniffing position is ideal for supraglottic device insertion.[70] The neutral position may cause a small decrease in successful placement compared with the sniffing position.[79] In our study we used the following parameters to assess the *depth of*

anesthesia for insertion of the supraglottic airway devices. Jaw muscle relaxation, denoted by easy upward and downward movement of the lower jaw, [80] absence of eyelash reflex [61] and no reaction to pressure employed over the angles of the mandible[57]**.** After insertion, adequate airway was assessed from, bilateral symmetrical movement of the chest, normal thoracoabdominal movements, square waveform on capnograph with no audible oropharyngeal leak and stable oxygen saturation. [51] To achieve an adequate airway seal, the cuff pressure should be maintained at approximately 60 cm of H_2O**,** and to prevent oropharyngeal complications cuff pressure should not exceed the maximum pressure limit of 60 cm H_2O. [31]

Keller C [58] compared four different tests for assessing *airway sealing pressure* with the supraglottic airway device. He found that compared with the three other tests, manometric stability test demonstrated a higher mean airway sealing pressure. They concluded that all the four tests were excellent for clinical purposes but that the manometric stability test may be more appropriate for researchers comparing airway-sealing pressure.[58]

We have confirmed the *gastric tube* in the stomach by aspiration of gastric content from stomach or insufflation of air heard on auscultation over the epigastrium.[81]

We have used *SPSS software* [68,69] for statistical analysis. On evaluating a couple of the most used software for statistical analysis i.e Base SAS and SPSS, the following were the reasons for choosing SPSS over SAS

1. SPSS is easier to learn than other softwares, because it features a point and click interface 2. SPSS Documentation is much better and gives a better clarity on algorithms used for statistical procedures 3.It is comparatively less expensive than SAS 4. It has clear advantages because it is so much like the familiar Excel spreadsheet.

The overall success rate for supraglottic airway device insertion in our study was similar in both LMA-Proseal and I-Gel group with no statistical significance. I-Gel could be inserted successfully in all the cases. Our results are comparable with that of obtained by Ali Sarfraz Siddiqui[66] whose first attempt success rate for device insertion was 92%. Second attempt required in 8% of patients with an overall success rate of 100%. Similarly Lorenz G. Theiler et al[82] showed the first attempt success rate of 93% for device insertion in their study. Our study showed first attempt success rate of 96% and second attempt was required in 4% of the patients with overall success rate of 100%. In accordance with the results of KANNAUJIA A et al [12] whose first attempt success rate was high for I-Gel device, our study also showed high first attempt success rate for

I-Gel. In contrast to the results of Rakhee Goyal [61] whose first attempt success rate was 80% but second attempt success rate was 100% in the majority of patients, our study showed high first attempt rate. Choosing the appropriate size of the supra glottic airway device was important for achieving high first attempt success rate during insertion of the device. In our study we selected the supraglottic airway device size based on the weight of the patient according to manufacturer's recommendation. Another method to select the correct size laryngeal mask airway for children is to match the widest part of the mask to the width of the second to fourth fingers.[83] Since there was audible leak in one patient, size1.5 I-Gel was replaced with size 2 I-Gel. There is an overlap of the sizing guidelines for size1.5 and 2 for I gel (1.5 size for 5 to 12 kg weight group and size 2 for 10 to 25 kg) which is confusing for the users. Janakiraman et al [31] concluded that resizing the LMA improved the overall insertion success rate. In our study we found that the insertion of supraglottic devices like the LMA-Proseal and I-Gel does not produce any significant clinical effects, under adequate depth of anesthesia. Increasing the depth of anaesthesia is recommended if there is any incidence of coughing or breath holding during insertion.[84] Because of the length of the oropharyngeal and laryngeal arch is variable in children, the paediatric size I-Gel does not contain horizontal black line in the bite block.[28] It is

suggested that the paediatric size I-Gel should be inserted until definitive resistance is encountered. [28]

The LMA-Proseal in our study could be inserted successfully in the first attempt in 96% of the patients. 4% of the patients required second attempt and overall success rate was 100%. This result is in accordance with the results of Melissa Wheeler et al [16] whose first attempt success rate was 94% with second and third attempt the success rate was 100%. Wheeler M [16] and Goyal R et al[14] also found that the overall success rate of LMA-Proseal has been shown as 100%.

The mean insertion time and ease of insertion in our study was significantly less for I-Gel in comparison with the LMA-Proseal. In group P the mean time for insertion was 13.50 ± 2.65 seconds whereas, in group I mean time for insertion was 11.70 ± 2.27 seconds, In group I, ease of insertion was 98% and group P it was only 88%. Both ease of insertion and time taken for insertion of the supraglottic airway device was statistically significant between two groups.

In our study we found that I-Gel could be inserted easily in a short time and this was similar to the results of Kannujia A et al [12], whose study showed the mean insertion time for I-Gel supraglottic airway device was

11 seconds and they concluded that I-Gel is a simple and easy to insert supraglottic airway device.

Iswar Singh I et al [67] found that the mean insertion time of I-Gel was 8.5 ± 6.3 seconds and I-Gel insertion was easy in 29/30 patients, compared to Proseal LMA in which insertion was easy only 23/30patients and results were statistically significant.

Iswar singh [67] and Rakhee Goyall et al61 in their study found that placement of I-Gel was definitely easier than any other currently available supraglottic airway device which was comparable to our results.

I-Gel is an uncuffed peri- laryngeal sealer,[54] the insertion was easy and quick. It also provided a reliable airway. Brimacombe and colleagues[39] found that the difficulties in inserting LMA-Proseal were caused by larger cuff obstructing the digital intraoral positioning and actuation into the pharynx.

In contrast to the results of Lee JR et al,[63] and Franksen et al [57], who found that the mean time for insertion of I-Gel was17 seconds, Our study showed the mean insertion time of 11 seconds for I-Gel. This may be due to difference in criteria to measure the time for insertion. We calculated the time for insertion as the time from removal of face mask to confirmation of Supraglottic airway device by achieving sufficient

ventilation. But Lee JR et al [63] used time from mouth opening to inflation of LMA cuff for calculating time for insertion.

In our study, the mean airway seal pressure in the I-Gel (size 1.5, 2, 2.5) group was 22.6 ± 1.81 cmH2O and LMA-Proseal (size2, 2.5) Group was 25.54 cmH2O ±3.42 .This is in accordance with the results of Mellisa A Wheeler et al [16] who reported a mean leak pressure of 24.5cmH2O for number 2 & 2.5 size LMA-Proseal. Our results were comparable with that of Ali Sarfraz Siddiqui et al [66] whose average seal airway pressures for I Gel was 22.48 ± 2.07 cm H2O and in our study it was 22.6 ± 1.81cmH_2O.

In accordance with the results of I. Arslan, C. Balc et al, [62] who found that the seal pressure for size 2 LMA-Proseal was 24.6± 38 5.5 cmH_2O, our study showed that the mean airway pressure for LMA-Proseal (size2, 2.5) was 25.54± 3.41 cmH_2O.

Goyal R et al [14], Beringer RM et al [59], and H. Shimbori et al [85] found that the Oropharyngeal leak pressures were between 19-25 cmH2O for the same size LMA-Proseal (size 2) in spontaneously breathing children. Lardner et al also reported the same oropharyngeal leak pressures.

Lopez-gil et al [56] reported a higher oropharyngeal seal pressures in children receiving neuromuscular blockade with same size (size 2) LMA-Proseal (29cmH2O). In contrast to this, our study showed an oropharyngeal leak pressure of 25.54 ± 3.42 cmH2O for LMA-Proseal. In his study all the patients were paralyzed so they measured airway sealing pressure in a single occasion for each patient. In our study we allowed the patient in spontaneous ventilation, used two different sizes of LMA-Proseal, and took average of three positive fluctuations in airway seal pressure. This may be one of the reasons for the variation in airway sealing pressure.

Rakhee Goyal1et al [61] found high seal pressure for I-Gel group 26 ± 2.6 cmH2O in spontaneously breathing patient. Because of fluctuating airway pressure in the spontaneously breathing patients**,** it is ideal to take average of positive fluctuations in airway seal pressure [86] in spontaneously breathing patients. We took average of three positive fluctuations in airway seal pressure.

The I-Gel supraglottic airway device with its high airway leak pressure as observed by the manometer stability test in our study was 26.0 cm H2O. This was well within the normal limits for both spontaneous and controlled ventilation.

I-Gel provides adequate seal with perilaryngeal structure with non inflatable cuff. [26] The softness, shape, and contour of the non inflatable cuff accurately mirrors the perilaryngeal structures to attain a perfect seal. [26] The oropharyngeal seal tend to improve with time, due to warming of the thermoplastic cuff to body temperature.[28] The airway seal was better with the LMA-Proseal with its high airway seal pressure of 32 cm H_2O compared to I-Gel (26 cm H2O) which was statistically significant. The higher oropharyngeal seal pressure for the LMA-Proseal is most likely due to the deeper bowl and modified cuff design. [48] The modified design of the LMA-Proseal provides very good sealing effect for positive pressure ventilation.[52]

In our study, gastric tube could be inserted in all the cases in the I-Gel group and it was graded easy in 98% of the patients; in LMA-Proseal group, gastric tube could be inserted in all the cases and it was graded easy in 94% with no statistical difference between the groups. This is in consistence with the results of a study conducted by Amr M. Helmy[87], whose success rate of gastric tube insertion in I-Gel group was high.

H. Francksen [57] reported that the insertion of gastric tube in I-Gel in the first attempts was 90% and overall successes rate was 100%. Our study results are in consistence with this result.

Z. I. Arslan et al[62] and Lopez gil et al [56] found that the success rate of gastric tube placement in Proseal was 100%. Our study also shows similar results.

There were no reported cases of desaturation (SPO_2<95%), laryngospasm, and aspiration in either of two groups in our study. In our study, blood staining of the device was found in three cases in LMA-Proseal group and one case in I-Gel group which was statistically not significant.

Amr M Helmyet al [87] reported blood stained device only in 2 cases and they found that airway trauma was minimal with I-Gel. Our study result is also in consistence with this. Rakhee Goyal1et al[61] found that the incidence of complications both in LMA-Proseal and I-Gel groups are low. Iswar Singh I et al[67] found that the incidence of blood staining of the device in the Proseal LMA group was high (6/30) compared to I-Gel group (1/30). Our study showed the similar results.

In our study, post operative hoarseness and cough was noted in two cases in the LMA-Proseal group and no incidence of hoarseness or cough in I-Gel group which was statistically not significant. The bulky, inflatable cuffs of the LMA-Proseal may cause complications like mucosal injury, hoarseness, airway obstruction and gastric insufflation.

There was one case of lip trauma in LMA-Proseal group which could be due to second attempt insertion.

In our study, supraglottic insertion was done in all cases, none of the patients required abandonment of supraglottic airway device. We could not elicit the postoperative sore throat because of the young age group of the children.

One of the limitations of our study is that blinding has not been possible for recording supraglottic device insertion time and number of insertion attempts, as the insertion technique could not be masked. However, to minimize the bias, in our study we recorded the supraglottic airway device insertion time and number of attempts taken for insertion by an observer not involved in the study.

Second limitation of our study is absence of fiber optic confirmation of the airway patency. Clinical assessment of the correct placement is considered normal clinical practice for supraglottic airway device insertion in children [57]

Third limitation of our study is, we studied only in low risk (ASA PS I-II) patients with normal airways.

SUMMARY

SUMMARY

The aim of this study is to compare the clinical performance of I-Gel and LMA- Proseal in anaesthetized, spontaneously breathing, paediatric age group patients posted for elective, below umbilical surgical procedures. This a prospective single blind randomized comparative study.

After obtaining Institutional Ethical committee approval, hundred paediatric patients of ASA physical status I and II of either sex were included in the study. Patients were randomly assigned into two groups, Group P: LMA-Proseal (n=50) and Group I: I-Gel (n=50). The technique of anaesthesia was standardised in both the groups. The following parameters were compared.

1. Ease of insertion

2. Success rate to place at first attempt

3. Number of insertion attempts

4. Time taken for device insertion

5. Airway seal pressure

6. Ease of gastric tube placement

7. Occurrence of complications like bronchospasm, aspiration, cough, hoarseness, blood staining of the device, mucosal/ lip trauma.

Both groups were comparable in demographic characteristics. The mean insertion time for I-Gel was significantly less than LMA-Proseal (p0.001). The oropharyngeal seal pressure of I-Gel was significantly less when compared with LMA-Proseal (p0.0001). There was no statistical difference between the two groups in regards with number of attempts required for the placement of the supraglottic airway device and ease of insertion of gastric tube. Complications like cough, hoarseness, blood stained device were high in LMA-Proseal group. I-Gel aids easy and rapid insertion with an acceptable airway seal pressure. However, effective airway seal pressure with LMA-Proseal is better than I-Gel.

CONCLUSION

CONCLUSION

Based on the results of our study, we conclude that I-Gel aids easy and rapid insertion with an acceptable airway seal pressure. I-Gel scores well than LMA- Proseal in terms of lesser insertion time and lesser incidence of postoperative complications due to its noninflattable cuff and facilitate effective gastric drainage. However, effective airway seal pressure with LMA-Proseal is better than I-Gel. Both devices can be safely used in anaesthetized spontaneously ventilating children for short surgical procedures.

ANNEXURES

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ROFORMA

Name : Serial No :

Age : Date :

Sex : I.P.NO :

Weight :

Group assigned :

Diagnosis :

ASA status :

Airway :

Type of Surgery :

Duration of surgery :

Comorbid conditions :

Informed consent : Yes/no

Fasting : Yes/no

MONITORS

ECG : Baseline heat Rate:

SpO2 : NIBP:

IV access :

Pre medication :

Inj.Atropine

Inj.Midazolam

Inj.Fentanyl

Inj.Ondensetran

Preoxygenation :

Induction :

Inj .propofol

Inj. Lidocaine

Sevoflurane

SUPRAGLOTTIC DEVICE

I-Gel / LMA-Proseal insertion :

Size :

Insertion time (seconds) :

No of attempts : First / second / Third / Multiple / failed

Ease of insertion : Easy/ Difficult

Ease off Gastric tube placement : Easy/ Difficult

Cuff pressure/ Airway seal pressure (cmH2O) :

Spontaneous/controlled ventilation :

Muscle relaxant used : Yes/No

COMPLICATIONS

Laryngospasm :

Aspiration :

Desaturation (SpO_2<95%) :

Mucous Lip trauma :

Intra op Hemodynamics

HR : SPO_2 :

NIBP : EtCO2 :

After Extubation

Blood staining of the device : Yes/No

Cough : Yes/No

Hoarseness : Yes/No

Post op follow up

	Post op hemodynamics			
	HR	BP	SPO_2	COMPLICATIONS
1Hr				
2Hrs				
6Hrs				
12Hrs				
24Hrs				

REMARKS: Anesthesiologist signature

Sl. No.	NAME	AGE	SEX	DATE	IP NO	Wt(KG	ASA	PROCEDURE	GROUP	SIZE	INSERTION TIME(SEC)	AIRWAY	ATTEMPTS
1	VISHWANATHAN	3	MALE	18-Oct-11	74041	10	ASA-1	CICUMCISION	P	SIZE-2	13	MPC-1	1
2	APARNA	4	FEMALE	18-Oct-11	74132	18	ASA-2	HERNIOTOMY Rt	I	SIZE-2	13	MPC-2	1
3	SUGUMAR	3	MALE	20-Oct-11	74140	10	ASA-1	HERNIOTOMY Lt	I	SIZE-1.5	12	MPC-2	1
4	SHASANTHI	3	FEMALE	20-Oct-11	74149	16	ASA-1	HERNIOTOMY.Rt	P	SIZE-2	25	MPC-1	1
5	MONIKA	3	FEMALE	20-Oct-11	74182	14	ASA-1	UMBICAL HERNIA REPAIR	I	SIZE-1.5	11	MPC-1	1
6	VIGNESH	8	MALE	20-Oct-11	74195	21	ASA-1	Rt PV SAC LIGATION	P	SIZE-2.5	13	MPC-1	1
7	SARAN	3	MALE	22-Oct-11	74199	19	ASA-2	SCROTAL EXPLORATION	I	SIZE-2	11	MPC-2	1
8	AATHAVAN	2Y3M	MALE	22-Oct-11	74200	13	ASA-1	CIRCUMCISSION	P	SIZE-2	14	MPC-2	1
9	SAMUEL	4	MALE	25-Oct-11	74236	18	ASA-1	Lt PV SAC LIGATION	I	SIZE-2	10	MPC-1	1
10	PRAVEEN	2	MALE	27-Oct-11	74259	10	ASA-2	HERNIOTOMY Rt	I	SIZE-1.5	12	MPC-1	1
11	SRINATH	2	MALE	27-Oct-11	74262	25	ASA-1	HERNIOTOMY Rt	P	SIZE-2	12	MPC-2	1
12	MOHMAD RASHEED	2	MALE	27-Oct-11	74263	13	ASA-1	HERNIOTOMY Rt	P	SIZE-2	16	MPC-2	1
13	ASWINI	3	FEMALE	29-Oct-11	74264	12	ASA-1	HERNIOTOMY Rt	I	SIZE-1.5	12	MPC-1	1
14	SURESH	5	MALE	29-Oct-11	74269	22	ASA-1	CIRCUMCISION	P	SIZE-2	14	MPC-1	1
15	VISHNUVARDHAN	3	MALE	8-Nov-11	74290	10	ASA-1	CIRCUMCISION	I	SIZE-1.5	10	MPC-1	1
16	DEVA	3Y5M	MALE	8-Nov-11	74296	10	ASA-2	Lt PV SAC LIGATION	I	SIZE-1.5	11	MPC-2	1
17	MARYVARSHA	4	FEMALE	12-Nov-11	74341	12	ASA-1	SWELLING	P	SIZE-2	15	MPC-1	2
18	BARATH	2	MALE	19-Nov-11	74480	11	ASA-1	Lt PV SAC LIGATION	I	SIZE-2	9	MPC-2	1
19	AKASH	4	MALE	29-Nov-11	74628	14	ASA-1	Lt PV SAC LIGATION	I	SIZE-2	14	MPC-1	1
20	TARUN PRANAV	3Y4M	MALE	29-Nov-11	74630	13	ASA-1	CIRCUMCISION	P	SIZE-2	12	MPC-1	1

Sl. No.	NAME	EASE OF INSERTION	SEAL PRESSURE (CmH2O)	DURATION OF SURGERY (MIN)	EASE OF GASTRIC TUBE PLACEMENT	SPONTANEOUS/ CONTROLED	DESATURATION	LARYNGOSPASM	ASPIRATION	BLOOD STAINING OF THE DEVICE	HOARSNESS	COUGH	MUCOSAL /LIP TRAUMA
1	VISHWANATHAN	EASY	29	22	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
2	APARNA	EASY	23	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
3	SUGUMAR	EASY	24	46	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
4	SHASANTHI	EASY	30	48	DIFFICULT	SPONT	NO	NO	NO	NO	NO	NO	NO
5	MONIKA	EASY	26	37	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
6	VIGNESH	EASY	26	46	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
7	SARAN	EASY	26	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
8	AATHAVAN	EASY	27	29	DIFFICULT	SPONT	NO	NO	NO	YES	NO	NO	NO
9	SAMUEL	EASY	23	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
10	PRAVEEN	EASY	22	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
11	SRINATH	EASY	29	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
12	MOHMAD RASHEED	DIFFICULT	27	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
13	ASWINI	EASY	22	37	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
14	SURESH	EASY	32	24	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
15	VISHNUVARDHAN	EASY	22	22	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
16	DEVA	EASY	25	42	EASY	SPONT	NO	NO	NO	YES	NO	NO	NO
17	MARYVARSHA	DIFFICULT	27	35	EASY	SPONT	NO	NO	NO	NO	YES	NO	YES
18	BARATH	EASY	23	46	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
19	AKASH	EASY	24	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
20	TARUN PRANAV	EASY	28	33	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO

Sl. No.	NAME	AGE	SEX	DATE	IP NO	Wt(KG)	ASA	PROCEDURE	GROUP	SIZE	INSERTION TIME (SEC)	AIRWAY	ATTEMPTS
21	KARTHIKA	2Y3M	FEMALE	29-Nov-11	74782	13	ASA-1	HERNIOTOMY Lt	I	SIZE-2	12	MPC-1	1
22	YUGENDRAN	4	MALE	14-Jan-12	74783	14	ASA-1	HERNIOTOMY Rt	P	SIZE-2	16	MPC-1	1
23	NITHISHA	2	FEMALE	14-Jan-12	74784	11	ASA-1	HERNIOTOMY.Rt	I	SIZE-1.5	20	MPC-1	2
24	SUDARSAN	2	MALE	14-Jan-12	74786	10	ASA-1	HERNIOTOMY Rt	P	SIZE-2	13	MPC-2	1
25	VETRIVEL	3	MALE	21-Jan-12	75780	14	ASA-1	RECTALPOLYP	I	SIZE-2	11	MPC-2	1
26	SUNIL	4	MALE	21-Jan-12	75559	13	ASA-1	UMBLICAL HERNIA	I	SIZE-2	11	MPC-1	1
27	KARTHIGA	3	FEMALE	28-Jan-12	39780	14	ASA-2	SYNOVIAL BIOPSY LEG	P	SIZE-2	14	MPC-2	1
28	KISHORE	2Y4M	MALE	28-Jan-12	75936	13	ASA-1	CIRCUMCISION	I	SIZE-2	10	MPC-2	1
29	PAUL DANIEL	4	MALE	28-Jan-12	75931	11	ASA-1	Lt PV SAC LIGATION	P	SIZE-2	14	MPC-1	1
30	AJITHA	3	FEMALE	31-Jan-12	77232	10	ASA-1	UMBLICAL HERNIA	I	SIZE-1.5	14	MPC-1	1
31	RAMANI	8	FEMALE	31-Jan-12	77365	22	ASA-1	ABD. WALL ULCER	P	SIZE-2.5	14	MPC-1	1
32	SHYAMALA	2Y6M	FEMALE	31-Jan-12	75932	13	ASA-1	HERNIOTOMY Lt	P	SIZE-2	13	MPC-1	1
33	MAHEETHA	2	FEMALE	31-Jan-12	77366	10	ASA-2	HERNIOTOMY Rt	I	SIZE-1.5	21	MPC-2	2
34	DILSAN	2Y4M	MALE	7-Apr-12	77536	13	ASA-1	CIRCUMCISION	P	SIZE-2	12	MPC-1	1
35	AJITHA	4	FEMALE	7-Apr-12	34222	15	ASA-1	SSG RT FOOT	P	SIZE-2	14	MPC-2	1
36	PRADEEP	6Y2M	MALE	7-Apr-12	77538	12	ASA-2	CIRCUMCISION	I	SIZE-2	12	MPC-1	1
37	PREETHA	8	FEMALE	14-Apr-12	28103	25	ASA-1	CORN FOOT EXCISION	I	SIZE-2.5	11	MPC-1	1
38	KARTHIK	3	MALE	14-Apr-12	78310	10	ASA-1	Lt PV SAC LIGATION	P	SIZE-2	19	MPC-2	1
39	ISWARYA	5	FEMALE	14-Apr-12	2607/12	17	ASA-1	SSG RT FOOT	I	SIZE-2	11	MPC-1	1
40	GIRIKESH	3	MALE	14-Apr-12	78324	14	ASA-1	SCROTAL EXPLORATION	P	SIZE-2	12	MPC-1	1

Sl. No.	NAME	EASE OF INSERTION	SEAL PRESSURE (CmH2O)	DURATION OF SURGERY (MIN)	EASE OF GASTRIC TUBE PLACEMENT	SPONTANEOUS/ CONTROLED	DESATURATION	LARYNGOSPASM	ASPIRATION	BLOOD STAINING OF THE DEVICE	HOARSNESS	COUGH	MUCOSAL/ LIP TRAUMA
21	KARTHIKA	EASY	24	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
22	YUGENDRAN	EASY	29	50	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
23	NITHISHA	DIFFICULT	20	38	DIFFICULT	SPONT	NO	NO	NO	NO	NO	NO	NO
24	SUDARSAN	EASY	22	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
25	VETRIVEL	EASY	21	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
26	SUNIL	EASY	24	56	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
27	KARTHIGA	EASY	31	32	EASY	SPONT	NO	NO	NO	YES	NO	NO	NO
28	KISHORE	EASY	25	22	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
29	PAUL DANIEL	EASY	23	42	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
30	AJITHA	EASY	25	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
31	RAMANI	EASY	30	41	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
32	SHYAMALA	EASY	27	30	EASY	SPONT	NO	NO	NO	NO	NO	YES	NO
33	MAHEETHA	EASY	23	32	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
34	DILSAN	EASY	29	27	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
35	AJITHA	EASY	25	50	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
36	PRADEEP	EASY	24	23	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
37	PREETHA	EASY	20	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
38	KARTHIK	DIFFICULT	23	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
39	ISWARYA	EASY	21	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
40	GIRIKESH	EASY	28	35	EASY	SPONT	NO	NO	NO	NO	NO	YES	NO

Sl. No.	NAME	AGE	SEX	DATE	IP NO	Wt(KG)	ASA	PROCEDURE	GROUP	SIZE	INSERTION TIME (SEC)	AIRWAY	ATTEMPTS
41	GOWTHAMI	3	FEMALE	14-Apr-12	74627	12	ASA-1	UMBLICAL HERNIA	I	SIZE-2	11	MPC-1	1
42	NARESH KUMAR	5	MALE	17-Apr-12	78314	21	ASA-1	HERNIOTOMY. Rt	P	SIZE-2.5	13	MPC-1	1
43	SAKTHI KALA	2	FEMALE	17-Apr-12	78380	10	ASA-1	HERNIOTOMY Rt	P	SIZE-2	11	MPC-2	1
44	DANUSH	4	MALE	17-Apr-12	78383	11	ASA-1	Rt PV SAC LIGATION	P	SIZE-2	12	MPC-1	1
45	JAIKARTHI	2	MALE	17-Apr-12	79096	10	ASA-1	CICUMCISION	I	SIZE-1.5	13	MPC-1	1
46	MUTHU	4	MALE	21-Apr-12	78386	13	ASA-1	Lt PV SAC LIGATION	P	SIZE-2	12	MPC-2	1
47	JOSEPHIN	2	FEMALE	24-Apr-12	78712	10	ASA-1	UMBLICAL HERNIA	P	SIZE-2	15	MPC-1	1
48	NAREN	6	MALE	24-Apr-12	79223	23	ASA-1	ORCHIDOPEXY Lt	I	SIZE-2.5	12	MPC-1	1
49	ASWIN	2	MALE	28-Apr-12	78823	12	ASA-1	Rt PV SAC LIGATION	P	SIZE-2	12	MPC-1	1
50	SHYAM	3	MALE	28-Apr-12	78827	14	ASA-1	SCROTAL EXPLORATION	I	SIZE-2	9	MPC-1	1
51	MOHAMED IRFAN	2	MALE	28-Apr-12	78839	11	ASA-1	CIRCUMCISION	P	SIZE-2	14	MPC-2	1
52	THIRUMALAI	3	MALE	28-Apr-12	78876	12	ASA-1	CIRCUMCISION	I	SIZE-1.5	10	MPC-2	1
53	VASUNDARA	3	FEMALE	12-May-12	78851	13	ASA-1	HERNIOTOMY. Rt	P	SIZE-2	12	MPC-1	1
54	RAHUL	3	MALE	12-May-12	79098	14	ASA-1	THIGH ABSCESS Lt	I	SIZE-2	10	MPC-1	1
55	NIVETHA	4	FEMALE	12-May-12	79100	16	ASA-1	THIGH ABSCESS Lt	I	SIZE-2	12	MPC-1	1
56	NAVEEN	2	MALE	12-May-12	78752	10	ASA-1	HERNIOTOMY.Rt	P	SIZE-2	14	MPC-2	1
57	THIRUMALAI	2Y6M	MALE	5-Jun-12	79222	12	ASA-2	Rt PV SAC LIGATION	P	SIZE-2	13	MPC-2	1
58	KEERTHANA	4	FEMALE	5-Jun-12	79102	19	ASA-1	HERNIOTOMY Rt	I	SIZE-2	13	MPC-1	1
59	VETRIVEL	2	MALE	28-Jun-12	79226	11	ASA-1	Rt .PV SAC LIGATION	I	SIZE-1.5	11	MPC-2	1
60	JEEWANATHAN	4	MALE	28-Jun-12	80116	14	ASA-2	Lt. PV SAC LIGATION	I	SIZE-2	14	MPC-1	1

Sl. No.	NAME	EASE OF INSERTION	SEAL PRESSURE (CmH2O)	DURATION OF SURGERY (MIN)	EASE OF GASTRIC TUBE PLACEMENT	SPONTANEOUS/ CONTROLED	DESATURATION	LARYNGOSPASM	ASPIRATION	BLOOD STAINING OF THE DEVICE	HOARSNESS	COUGH	MUCOSAL /LIP TRAUMA
41	GOWTHAMI	EASY	20	37	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
42	NARESH KUMAR	EASY	21	32	EASY	SPONT	NO	NO	NO	NO	YES	NO	NO
43	SAKTHI KALA	DIFFICULT	22	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
44	DANUSH	EASY	29	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
45	JAIKARTHI	EASY	22	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
46	MUTHU	EASY	20	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
47	JOSEPHIN	DIFFICULT	20	39	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
48	NAREN	EASY	26	48	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
49	ASWIN	EASY	23	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
50	SHYAM	EASY	24	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
51	MOHAMED IRFAN	EASY	25	20	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
52	THIRUMALAI	EASY	25	23	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
53	VASUNDARA	EASY	28	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
54	RAHUL	EASY	23	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
55	NIVETHA	EASY	21	29	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
56	NAVEEN	EASY	27	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
57	THIRUMALAI	EASY	32	34	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
58	KEERTHANA	EASY	22	42	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
59	VETRIVEL	EASY	24	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
60	JEEWANATHAN	EASY	19	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO

Sl. No.	NAME	AGE	SEX	DATE	IP NO	Wt(KG)	ASA	PROCEDURE	GROUP	SIZE	INSERTION TIME (SEC)	AIRWAY	ATTEMPTS
61	ANDHAN	4	MALE	3-Jul-12	80117	16	1	Lt PV SAC LIGATION	P	SIZE-2	14	MPC-1	1
62	ABDUL HASIM	7	MALE	5-Jul-12	80614	14	1	HERNIOTOMY.Lt	P	SIZE-2	12	MPC-2	1
63	JOSUAH	3Y5M	MALE	5-Jul-12	81518	15	1	HERNIOTOMY.Lt	I	SIZE-2	10	MPC-1	1
64	GUNASEKAR	3Y4M	MALE	5-Jul-12	81517	16	2	CIRCUMCISION	I	SIZE-2	8	MPC-1	1
65	PRADISH	4	MALE	7-Jul-12	81738	12	1	CIRCUMCISION	I	SIZE-1.5	10	MPC-2	1
66	SUNDARAM	4	MALE	7-Jul-12	81741	11	1	HERNIOTOY Lt	P	SIZE-2	15	MPC-1	1
67	SUDHAN	5	MALE	7-Jul-12	80113	20	2	CIRCUMCISION	I	SIZE-2	12	MPC-2	1
68	SAKTHIVEL	4	MALE	10-Jul-12	81652	10	1	CICUMCISION	I	SIZE-1.5	12	MPC-2	1
69	PUVIYARASU	8	MALE	10-Jul-12	81752	22	1	ORCHIDOPEXY.Lt	P	SIZE-2.5	14	MPC-1	1
70	LOGESH	3	MALE	12-Jul-12	81868	13	1	UMB. HERNIA REPAIR	I	SIZE-1.5	12	MPC-1	1
71	PRASAD	2	MALE	12-Jul-12	81866	10	1	HERNIOTOMY. Lt	P	SIZE-2	12	MPC-1	1
72	RAGUL	2	MALE	12-Jul-12	81867	11	1	CIRCUCISION	P	SIZE-2	10	MPC-2	1
73	PRAVEENKUMAR	5	MALE	12-Jul-12	81872	14	1	CIRCUMCISION	I	SIZE-1.5	12	MPC-1	1
74	VINISH	2	MALE	14-Jul-12	81928	11	1	HERNIOTOY.Rt	I	SIZE-1.5	13	MPC-1	1
75	MONISHA	3Y6M	FEMALE	14-Jul-12	81937	10	1	HERNIOTOY.Lt	P	SIZE-2	11	MPC-2	1
76	RITHIESH	3	MALE	17-Jul-12	81999	15	1	HERNIOTOY.Rt	I	SIZE-2	12	MPC-1	1
77	MADESHWARI	2	FEMALE	17-Jul-12	81953	10	2	ABSCESS THIGH	P	SIZE-2	12	MPC-1	1
78	HEMASHRI	5	FEMALE	17-Jul-12	81870	20	1	HERNIOTOY.Rt	I	SIZE-2.5	11	MPC-1	1
79	HEMA	3	FEMALE	17-Jul-12	81879	15	1	HERNIOTOMY.Rt	P	SIZE-2	19	MPC-2	1
80	NARESH	2	MALE	19-Jul-12	82003	10	1	HERNIOTOY.Rt	I	SIZE-1.5	10	MPC-1	1

Sl. No.	NAME	EASE OF INSERTION	SEAL PRESSURE(CmH2O)	DURATION OF SURGERY (MIN)	EASE OF GASTRIC TUBE PLACEMENT	SPONTANEOUS/ CONTROLED	DESATURATION	LARYNGOSPASM	ASPIRATION	BLOOD STAINING OF THE DEVICE	HOARSNESS	COUGH	MUCOSAL/LIP TRAUMA	DENTAL TRAUMA
61	ANDHAN	EASY	19	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
62	ABDUL HASIM	EASY	22	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
63	JOSUAH	EASY	23	34	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
64	GUNASEKAR	EASY	23	22	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
65	PRADISH	EASY	23	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
66	SUNDARAM	EASY	27	36	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
67	SUDHAN	EASY	22	26	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
68	SAKTHIVEL	EASY	24	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
69	PUVIYARASU	EASY	26	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
70	LOGESH	EASY	20	50	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
71	PRASAD	EASY	23	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
72	RAGUL	EASY	22	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
73	PRAVEENKUMAR	EASY	21	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
74	VINISH	EASY	23	48	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
75	MONISHA	EASY	21	35	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
76	RITHIESH	EASY	21	46	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
77	MADESHWARI	EASY	27	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
78	HEMASHRI	EASY	23	46	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
79	HEMA	EASY	25	45	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO
80	NARESH	EASY	23	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO	NO

Sl. No.	NAME	AGE	SEX	DATE	IP NO	Wt(KG)	ASA	PROCEDURE	GROUP	SIZE	INSERTION TIME (SEC)	AIRWAY	ATTEMPTS
81	LIYASATH NISHA	3Y6M	FEMALE	21-Jul-12	81936	16	1	CORNFOOT EXCISION	I	SIZE-1.5	12	MPC-1	1
82	SELVAM	3	MALE	21-Jul-12	82052	12	1	Lt.PV SAC LIGATION	I	SIZE-2	14	MPC-1	1
83	RAGUL	2	MALE	24-Jul-12	82005	12	1	URETHROPLASTY	P	SIZE-2	12	MPC-1	1
84	MARIMUTHU	5	MALE	24-Jul-12	82008	15	1	HERNIOTOMY.Lt	P	SIZE-2	12	MPC-1	1
85	KAMALESH	3	MALE	24-Jul-12	82009	13	1	HERNIOTOMY.Rt	P	SIZE-2	11	MPC-2	1
86	SANJAY	4Y3M	MALE	24-Jul-12	82065	19	1	Lt.PV SAC LIGATION	I	SIZE-2.5	12	MPC-2	1
87	ANBUSELVAM	2	MALE	26-Jul-12	82132	14	1	Lt.TV SAC LIGATION	P	SIZE-2	12	MPC-1	1
88	ROHINI	2	FEMALE	26-Jul-12	82058	10	1	HERNIOTOMY.Lt	I	SIZE-1.5	9	MPC-1	1
89	ELIZHARASAN	3	MALE	28-Jul-12	82060	12	1	CIRCUMCISSION	P	SIZE-2	14	MPC-1	1
90	YOGARAJAN	3	MALE	31-Jul-12	82134	22	1	HERNIOTOMY .Lt	P	SIZE-2.5	12	MPC-1	1
91	AVINESH	2Y6M	MALE	31-Jul-12	82142	11	1	Rt.PV SAC LIGATION	I	SIZE-1.5	11	MPC-2	1
92	CHINNA MANI	4	FEMALE	31-Jul-12	82149	23	1	HERNIOTOMY.Rt	P	SIZE-2.5	18	MPC-1	2
93	ARUNKUMAR	2	MALE	31-Jul-12	82132	10	1	HERNIOTOMY. Lt	I	SIZE-2	10	MPC-2	1
94	YOUNISH	5	MALE	18-Aug-12	82216	15	1	HERNIOTOMY.Rt	P	SIZE-2	16	MPC-1	1
95	BABU	4	MALE	18-Aug-12	82206	15	1	Lt.PV SAC LIGATION	P	SIZE-2	13	MPC-1	1
96	PREMA	4	FEMALE	25-Aug-12	82213	13	1	HERNIOTOMY. Rt	I	SIZE-2	11	MPC-2	1
97	ABINESH	3	MALE	25-Aug-12	82209	15	1	HERNIOTOMY.Lt	I	SIZE-2	11	MPC-1	1
98	SRI KRISHNI	5	FEMALE	22-Sep-12	82283	22	1	UMBLICAL HERNIA	P	SIZE-2.5	10	MPC-1	1
99	SANTHOSH KUMAR	4	MALE	22-Sep-12	82278	13	1	HERNIOTOMY.Rt	P	SIZE-2	12	MPC-2	1
100	VISHOTH	6	MALE	22-Sep-12	82291	16	1	HERNIOTOMY.Lt	P	SIZE-2	11	MPC-1	1

Sl. No.	NAME	EASE OF INSERTION	SEAL PRESSURE (CmH2O)	DURATION OF SURGERY (MIN)	EASE OF GASTRIC TUBE PLACEMENT	SPONTANEOUS/ CONTROLED	DESATURATION	LARYNGOSPASM	ASPIRATION	BLOOD STAINING OF THE DEVICE	HOARSNESS	COUGH	MUCOSAL/ LIP TRAUMA
81	LIYASATH NISHA	EASY	24	25	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
82	SELVAM	EASY	20	42	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
83	RAGUL	EASY	24	49	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
84	MARIMUTHU	EASY	21	39	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
85	KAMALESH	EASY	21	30	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
86	SANJAY	EASY	24	34	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
87	ANBUSELVAM	EASY	28	39	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
88	ROHINI	EASY	20	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
89	ELIZHARASAN	EASY	21	24	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
90	YOGARAJAN	EASY	29	36	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
91	AVINESH	EASY	22	40	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
92	CHINNA MANI	DIFFICULT	22	37	EASY	SPONT	NO	NO	NO	YES	NO	NO	NO
93	ARUNKUMAR	EASY	26	36	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
94	YOUNISH	EASY	27	40	DIFFICULT	SPONT	NO	NO	NO	NO	NO	NO	NO
95	BABU	EASY	25	37	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
96	PREMA	EASY	25	41	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
97	ABINESH	EASY	23	42	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
98	SRI KRISHNI	EASY	26	54	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
99	SANTHOSH KUMAR	EASY	24	47	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO
100	VISHOTH	EASY	28	31	EASY	SPONT	NO	NO	NO	NO	NO	NO	NO

nehahspj f t y; jhs;

mWit rpfpr;irapd; nghJ LMA-Proseal kwWk; I-Gel tHpahf FHe;ij fSf;F kaf;f kUe;J bfhLf;Fk; Kiwfis xggpLk; Ma;t[

nehahspfSf;fhd j f t y;

Muha;r;rpad;nehf;fKk; Mjha';fSk/

c';fs; cwtpdiu <LgLj;j jpl;lkplggl;Lss; ,e;j kUj;Jt Muha;r;rp Ma;thd J. mWit rpfpr;irapd; nghJ LMA-Proseal myyJ I-Gel vd;Dk; Supraglottic Airway Device tHpahf kaf;f kUe;J bfhLf;Fk; Kiwfis xggpLk; Ma;thFk/

bghJthf ,j;ji fa Kiwapy; kaf;f kUe;J bfhLggjw;F nehahspad; tha; tHpahf LMA-Proseal kwWk; I-Gel brYj;jggl;L Rthr FHha;f;Fs; kaf;f kUe;J brYj;Jk; tz;zk; bghUj;jggLk/

tHf;fkhf FHe;ij fSf;F kaf;f kUe;J bfhLggjw;F FHe;ij apd; Rthr FHhapy; (Trachea) rWoa{g; (Endotracheal Tube) brYj;jggl;L kaf;f kUe;J bfhLf;fggLk/ ,jdhy; FHe;ij fSf;F ,Uky; bjhz;il typ. Rthr FHhapy; fhak; VwgLjy; Bronchospasm nghdw gyntW gf;f tpistf[s; Vwgl thaggf[cs;sJ/

Mdhy; ,e;j g[jpa Supraglottic Airway Device. LMA-Proseal kwWk; I-Gel cgfuzk; tHpahf kaf;f kUe;J bfhLf;Fk; nghJ ,j;ji fa gf;f tpistf[s; kpftk; FiwthFk/ nkYk; Rygkhd Kiwak; Tl/ ,e;j Ma;tpy; LMA-Proseal kwWk; I-Gel cgfuz';fs; tHpahf kaf;f kUe;J bfhLggjd; epiwfs; Fiwfs; vd;d vdgJk; vJ Rygkhd kwWk; ghJ fhgghd Kiw vdgJk; xggpLggLk/

Ma;tf[Kiw: ,e;j Ma;tpy; g'nfw;Fk; c';fs; cwtpdh; (FHe;ij) mWit rpfpr;irf;F jahh; braggLthh/ mWit rpfpr;irf;F Kd; rpy moggil ,uj;j Ma;tf[s; (Blood Test) nkwbfhss; sggLk; mWit rpfpr;irf;F Kd;4 Kjy;6 kzpneuk; tiuve;j Mfhuk; mUe;jhky; ,Uf;f ntz;Lk/ mWit rpfpr;ir mdW mth; mWit mu';fpw;F vLj;J bryygglthh/ m';F mtUf;F LMA-Proseal

kwWk; l-Gel tha; tHpahf brYj;jggl;L Rthrf; FHha; tHpahf kaf;f kUe;J bryYk; tz;zk; bghUj;jggl;L kaf;f kUe;J bfhLf;fggLk/

mWit rpfpr;irf;F gpd; c';fs; FHe;ij kaf;fj;jpYUe;J btspna bfhz;L tuggl;L gpd; (Recovery Room) kaf;f kUe;J bjspt[miwapy; itj;J fz;fhzpf;fggl;L. gpd;ngh!;l;Mg;(Post Op) thhpy; fz;fhzpf;fggLthh/

Ma;tpy; cz;lhf Toa ,lh;fs;

midj;J kaf;f kUe;J KiwfSld; ,UggJ nghynt ,e;j Kiwapyk; rpy vjphghuhj ,lh;fs; Vwglyhk/

Ma;tpy; c';fs; chpikfs;

c';fs; kUj;Jt gjpntLfs; kpftk; me;ju';fkhf itj;Jf; bfhs;sggLk/ ,e;j Ma;tpd; Kot[fs; mwptpay; gj;jphpf;iffspy; gpuRhpf;fggl yhk/ Mdhy;bga iu btspapLtJ Kyk; c';fs; cwtpdh;milahsk; fhl;lggl khl;lhh;fs/ ,e;j Ma;tpy; c';fs; cwtpdhpd; g'pnfwg[jd;dpr;irahdJ kwWk; fhuz';fs; vijak[k; Twhknyna ePh;fs; ,e;j Ma;tpypUe;J ve;j xU neuj;jpYk; tpyfpf; bfhs;syhk/ vggo ,Ue;jhYk; c';fs; cwtpdUf;F jFe;j kaf;f kUe;J bfhLj;J mWit rpfpr;ir braggLk/ ,e;j Ma;tpy; Vnj Dk; gf;f tpist[fs; Vwgl;lhy; c';fs; cwtpdUf;F KG rpfpr;ir kUj;Jt FGtpduhy;mspf;fggLk/

ehs; nehahspd; ifbahggk/

,lJ bgUtpuy;nuif

(kUj;Jtuhy;goj;J fhl;lggl;lJ)

Ra xgg[j y;go t k;

Ma;t[b ra;aggLk; j i ygg[

mW i t r‹f‹r;i ra‹d;ngh J LMA-Proseal **kw‰Wk;** I-Gel **tH‹ahf FHe;i j f S f;F ka f;f kUe;J b fhL f;Fk; K i wf i s xgg‹Lk; Ma;t[**

Muha;r;r‹ e‹i ya k;	:	muR !;lhd;y‹ kU j;J t k i d b r d;i d -600001
g';F bgWk;nehahs‹d;v z ;	:	
t a J	:	
bgw‰nwhh;bgah; t‹yhr k;	:	bgw‰nwhh; , j i d ( ) Fw‹f;f t[k;: gh y‹d k;: M z ;/bg z ;

nkny Fw‹gg‹l;Ls;s kU j;J t Ma;t‹d; t‹tu';f s; v d f;F t‹s f;fggl;l J/ v d;D i l a re‰nj f ';f i s n f l;f t[k; m j w;fhd j F e;j t‹s f;f ';f i s bgw t[k; thaggs‹f;fggl;l J/ ☐

ehd; v d; FHe;i j i a (k f d‹/k f s) , t;tha;t‹y; j d;d‹i rahf jhd; g'‰nfw;f i t f;f‹nwd; ve;j f hu z j;j‹dhnyh ve;j f l;l j;j‹Yk; ve;j r l;l r‹f;fYf;Fk; c lg lhk y; v d; FHe;i j i a (k f d‹/k f s) , t;tha;t‹y; , Ue;J b fhs;s yhk; v d‰W mw‹e;J b fhz‰nl d‹/ ☐

, e;j Ma;t[rk‰ke;j khfnth. , i j rhh‰e;j nkYk; Ma;t[nkw‰b fhs;Sk; ngh J k; , e;j Ma;t‹y; g';F bgWk; kU j;J th; v d; FHe;i j a‹D i l a kU j;J t mw‹f;i f f i s ghhgg j w;F v d;m Dk j‹ n j i ta‹y;i y v d mw‹e;J b fhs;f‹nwd‹/ v d;k f d‹/k f i s Ma;t‹y; , Ue;J t‹y f‹f;b fhz ;lhYk; , J bgh Ue;J k;v d mw‹f‹nwd‹/ ☐

, e;j Ma;t‹d; K.y k; f‹i l f;Fk; j f t y;f i sa[k; gh‰nrh j i d K o t[f i sa[k; kw‰Wk; r‹f‹r;i r b j hl hghd j f t y;f i sa[k; kU j;J th; nkw‰b fhs;Sk; Ma;t‹y; ga dgL j;j‹f; b fhs;s t[k; m i j g‹uRh‹f;f t[k; v d;K Gk d J l d;r k‰k j‹f;f‹nwd‹/ ☐

, e;j Ma;t‹y; v d; FHe;i j i a (k f d‹/k f s) <LgL j;j KGk d J l d; xgg[f; b fhs;f‹nwd‹/ , e;j ka f;f kUe;J f s; kw‰Wk; ka f;f K i wa‹d hy; Vwgl f;T oa g‹d; t‹i s t[f s; kw‰Wk; v j‹hghuh j t‹i s t[f s;gww‹v d f;F t‹s f;f khf b j h‹t‹f;fggl;l J/ ☐

, e;j Ma;tpy; vd; FHe;i j f;F mWit rpfpr;ir apd; nghJ LMA-Proseal kw;Wk; I-Gel Proseal Supraglottic Airway Device tHpahf kaf;f kUe;J brYj;jggLk; vdg i j mwpe;J mjw;F KGkd Jld; rk;kjpf;fpnwd/

, e;j Ma;tpy; vd; FHe;i j apd; eyd; fUjpna g'n fw;fpnwd/

bgwpnwhhpd; i f bahggk;////////////////////////////// , lk;/////////////////nj jp////////

f l;i l tpuy; nu i f (, e;j go tk; fhl;lggl;L gpe;J i f nu i f msp f;fpnwd)

Ma;thshpd; i f bahggk;/ ////////////////////////////// , lk;/////////////////nj jp////////

Ma;thshpd; bgah;//

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Comparisson of performance of supraglotic airway devices I-Gel and LMA ProsealTM in Paediatric elective surgeries

Principal Investigator : Dr.R.Punidhavardhani

Designation : PG in M.D (Anaesthesiology)

Department : Department of Anaesthesiology
Government Stanley Medical College,
Chennai-1

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 12.10.2011 at the Modernized Seminar Hall, Stanley Medical College, Chennai-1 at 2PM

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

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

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

MEMBER SECRETARY, 3/11/11
IEC, SMC, CHENNAI