

**A STUDY OF COMPARISON OF SUPRAGLOTTIC AIRWAY  
DEVICES I-GEL AND ILMA (INTUBATING LARYNGEAL  
MASK AIRWAY) FOR EASE OF INSERTION AND AS  
CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION**

**A PROSPECTIVE COMPARATIVE STUDY**

*Dissertation submitted to*

**THE TAMILNADU**

**Dr.M.G.R MEDICAL UNIVERSITY**

*In partial fulfilment of the requirement*

*for the award of the degree*

**M.D {ANAESTHESIOLOGY}**

**Branch -X**



**GOVERNMENT KILPAUK MEDICAL COLLEGE**

**KILPAUK, CHENNAI, TAMILNADU**

**APRIL 2017**

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## **BONAFIDE CERTIFICATE**

This is to certify that the dissertation entitled “**THE COMPARISON OF SUPRAGLOTTIC AIRWAY DEVICES I-GEL AND ILMA{ INTUBATING LARYNGEAL MASK AIRWAY} FOR EASE OF INSERTION AND AS CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION** ” is the bonafide original work of **Dr. AMALA SAVIO A** in partial fulfilment for the award of degree Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr.MGR Medical University, Chennai at Kilpauk Medical College and Hospital during the academic year 2015-2017

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## **CERTIFICATE BY THE GUIDE**

This is to certify that the dissertation entitled “**THE COMPARISON OF SUPRAGLOTTIC AIRWAY DEVICES I-GEL AND ILMA {INTUBATING LARYNGEAL MASK AIRWAY}FOR EASE OF INSERTION AND AS CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION** ” is the bonafide original work of **Dr. AMALA SAVIO A** in partial fulfilment for the award of degree doctor of medicine in Anaesthesiology by the Tamilnadu Dr.MGR Medical University, Chennai at Kilpauk Medical College and Hospital during the academic year 2015-2017

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## **DECLARATION**

I, Dr AMALA SAVIO A solemnly declare that this dissertation entitled “COMPARISON OF SUPRAGLOTTIC AIRWAY DEVICES I-GEL AND ILMA{INTUBATING LARYNGEAL MASK AIRWAY} FOR EASE OF INSERTION AND AS CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION - A PROSPECTIVE COMPARATIVE STUDY” was prepared by me at Government Kilpauk Medical College and Hospital, Chennai, under the guidance and supervision of **Dr. A .CHANDRASEKARAN MD.**, Professor, Department of Anaesthesiology, Government Kilpauk Medical College and Hospital, Chennai.

This dissertation is submitted to **The Tamil nadu Dr. M.G.R. Medical University, Chennai** in partial fulfillment of the University regulations for the award of the degree of **M.D. (Anaesthesiology)** in the examinations to be held in April 2017. This study was conducted in Government Kilpauk Medical College and Hospital, Chennai-10 . I have not submitted this dissertation to any university previously for the award of any degree or diploma .

Place: Chennai  
Date:

**(Dr.AMALA SAVIO A )**

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### INTRODUCTION

The prime responsibility and aim of any anaesthesiologist is the maintenance of airway with anesthesia induction. From the time endotracheal intubation was introduced, undue problems have occurred due to failed ventilation and tracheal intubation. Supraglottic airway devices (SAD) are helpful in patients with difficult airways and in emergency situations and in cardiopulmonary resuscitations. The large majority of general anaesthetics are in recent days delivered with supraglottic airway devices which have become an unavoidable resource in difficult airway algorithm. Some supraglottic airway devices are used for blind or fiberoptic guided intubation in the airway management. They can be efficiently used as rescue airway devices in patients with difficult airway and their use has increased in anaesthesia practice and emergency services.

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### INTRODUCTION

The prime responsibility and aim of any anaesthesiologist is the maintenance of airway with anesthesia induction. From the time endotracheal intubation was introduced, undue problems have occurred due to failed ventilation and tracheal intubation. Supraglottic airway devices (SAD) are helpful in patients with difficult airways and in emergency situations and in cardiopulmonary resuscitations. The large majority of general anaesthetics are in recent days delivered with supraglottic airway devices which have become a unavoidable resource in difficult airway algorithm. Some supraglottic airway devices are used for blind or fiberoptic guided intubation in the airway management. They can be efficiently used as rescue airway devices in patients with difficult airway and their use has increased in anaesthesia practice and emergency services.



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## **INTRODUCTION**

The prime responsibility and aim of any anaesthesiologist is the maintenance of airway .From the time endotracheal intubation was introduced, undue problems have occurred due to failed ventilation and tracheal intubation. Many studies have proved that airway mismanagement occurs in most cases due to lack of proper expertise and equipments. Supraglottic airway devices { SAD } are one such equipments which are helpful in patients with difficult airways and in emergency situations and in cardiopulmonary resuscitations<sup>1</sup>. The large majority of general anaesthetics are in recent days delivered with supraglottic airway devices which have become a unavoidable resource in difficult airway algorithm .Some supraglottic airway devices are used for blind or fiberoptic bronchoscopy {FOB} guided intubation in the airway management . They can be efficiently used as rescue airway devices in patients with difficult airway and their use has increased in anaesthesia practice and emergency medical services<sup>29</sup> .

## **AIM OF THE STUDY**

To compare supraglottic airway devices , I-GEL and INTUBATING LMA { ILMA } for ease of insertion and as a conduit for blind endotracheal intubation.

## **OBJECTIVES OF THE STUDY**

- 1} To study the effectiveness of Supraglottic airway devices I-GEL And ILMA {INTUBATING LARYNGEAL MASK AIRWAY} in emergency airway management<sup>9</sup>]
- 2} To evaluate the feasibility for blind endotracheal intubation using I-GEL and ILMA {INTUBATING LARYNGEAL MASK AIRWAY} as conduits in difficult intubation conditions

## **SUPRAGLOTTIC AIRWAY DEVICES**

Supraglottic airway devices comprises a important source of airway equipments that promote oxygenation and ventilation without the need for endotracheal intubation .The word “supraglottic” means above the glottis and it covers the larynx . These products are also called as “extraglottic “ devices by some authors<sup>13</sup>.

Supraglottic airway devices are intermediate between the face mask and endotracheal tube{ ETT} in terms of anatomical position , size , invasiveness , technique and skills in insertion etc .These devices function outside the trachea but helps in providing a airtight airway<sup>2</sup>

# **HISTORY AND EVOLUTION OF SUPRAGLOTTIC**

## **AIRWAY DEVICES**

Dr. Archie Brain developed LARYNGEAL MASK AIRWAY { LMA } in 1982 at Royal London hospital as a modification of the Goldman dental mask. He invented and developed the LMA classic by modifying Goldman nasal mask which he fused with an obliquely cut endotracheal tube (ETT). The device was developed to attenuate the need for ETT placement and thereby reduce airway morbidity due to tracheal intubation. Many prototypes of laryngeal mask airway {LMA} were tested subsequently by Brain. He also tested the device on his own by using local anaesthesia and also published many papers and conducted many studies<sup>3</sup>

Dr Chandy verghese was another scientist who was eager in these devices and he invented many scientific aspects and technical skills related to the insertion of these devices in the patient's airway eg. Chandy's maneuver

The LMA Classic soon received wide recognition over time and received a standard applause from the anaesthesia community all over the world. After some three years of use in anaesthesia practice, the LMA classic was used by over one third of anaesthesia providers bypassing facemask ventilation and ETT for airway management especially in elective short surgical procedures<sup>12</sup>. The reasons for this observation are, that the supraglottic airway devices and the LMA Classic in particular are

- 1} VERSATILE
- 2} USED IN VARIOUS PATIENT POSITIONS
- 3} REQUIRE LESS SKILLS
- 4} PATIENT SATISFACTION
- 5} LOW FAILURE and
- 6} LESS INCIDENCES OF POSTOPERATIVE SORE THROAT AND DYSPHAGIA

SAD'S were generally classified as, first-generation SADs and second generation SADs devices .First generation devices were developed during the period of propofol and with evolution of time devices with new designs, functions and sizes were developed to counter the complications and failure rates with first generation devices . This search for improved SADs resulted in the invention of several new innovative supraglottic airway devices {second generation SADs}<sup>3</sup>. Some of the innovative functions applied in second generation devices are

- 1} Inbuilt suction tube or drainage tube eg PROSEAL LMA , I-GEL
- 2} More applicable positive pressure ventilation
- 3} Disposability eg .I-GEL
- 4} Integrated bite block eg .I-GEL
- 5} As conduit for endotracheal intubation eg ILMA

The second generation devices has seen a rapid rise in clinical practice in last decade. Although first generation devices were the most used in clinical studies and trials , second generation devices are being mostly used in developed countries , as they provide excellent advantages over the LMA Classic and similar devices. After the LMA classic became available in 1989 many additional devices were added to the LMA equipment family to satisfy specific patient needs and a number of other devices were developed with new innovations , designs and functions . There are a large number of supraglottic airway devices some of which appears similar to LMA family and others that work under a different concept.

# **CLASSIFICATION**

## **BASED ON THE NUMBER OF LUMEN-**

### **1. Single Lumen Devices:-**

- LMA-Classic
- LMA- Unique
- LMA-Flexible
- ILMA
- C-trach
- Soft seal
- Laryngeal Airway Device(LAD)
- Ambu Laryngeal Mask
- Pharyngeal airway express(PAX)
- Cobra Perilaryngeal Airway(CPLA)
- Laryngeal Tube(LT)
- Cuffed oropharyngeal airway
- Stream Lined Liner of the Pharyngeal Airway(SLIPA)
- Glottic Aperture Seal Device.

### **2. Double Lumen Devices:-**

- Proseal LMA
- Combitube
- Laryngeal Tube Suction(LTS)
- Airway Management Device(AMD)



### **3. Triple Lumen Devices:-**

- Elisha Airway Device(EAD)

## **BASED ON SEALING MECHANISM**

### **1. Cuffed perilaryngeal sealer**

#### **Non-directional non esophageal Sealers**

- Classic LMA
- Flexible LMA
- LMA unique

#### **Directional Non-esophageal sealing**

- Fastrach LMA
- ALMA.

#### **Directional esophageal sealing**

- Proseal LMA
- Supreme LMA

### **2. Cuffed pharyngeal sealer**

#### **Without esophageal sealing**

- COPA
- PAX

#### **With esophageal sealing**

- Combitube
- Laryngeal tube

### **3. Cuff less preshaped sealer: -**

#### **With esophageal sealing-**

- Baska mask
- I-gel

#### **Without esophageal sealing-**

- SLIPA {streamlined liner of the pharynx airway}
- AirQ-SP.

## **BASED ON GENERATION**

### **FIRST GENERATION**

#### **FEATURES**

- Simple airway device
- Low pressure pharyngeal seal
- May or may not protect from aspiration
- Have no specific design to lessen the risk
- Eg ; Classic Lma, Flexible Lma, Laryngeal tube, Cobra perilaryngeal airway

### **SECOND GENERATION**

#### **FEATURES**

- It is specially designed for safety.
- They provide high pressure pharyngeal seal and reduce the risk of aspiration.
- They may be more efficacious in ventilation

Examples include Proseal LMA, Supreme LMA, Laryngeal tube suction 2, Laryngeal tube suction D , I-gel and SLIPA .

## **INDICATIONS**

- 1} Recommended as rescue airways in cannot ventilate cannot intubate scenarios
- 2} Procedures in outside the operating room procedures like radiotherapy and MRI and also in diagnostic and short therapeutic procedures
- 3} Head and neck surgeries
- 4} Bronchoscopy and laser surgery of trachea

## **CONTRAINDICATIONS**

- 1} Small oral aperture
  - 2} Any oropharyngeal or hypopharyngeal mass
  - 3} Esophageal pathology
  - 4} Full stomach patients
  - 5} In patients with poor lung compliance
-

## **ADVANTAGES OF SAD**

- Increased speed and ease of placement
- Less requirement of technical expertise
- Improved hemodynamic stability
- Minimal intraocular and intracranial pressure changes during insertion
- Increased airway tolerance
- Low frequency of coughing during emergence

## **DISADVANTAGES**

- Inadequate positive pressure ventilation
- More chances of aspiration of gastric content
- Sore throat
- Vascular compression and nerve damage

## COMPLICATIONS OF SUPRAGLOTTIC AIRWAY DEVICES

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Complications related to supraglottic airway devices are bound to happen and they became apparent years after their introduction and use in clinical practice . Some of the complications are

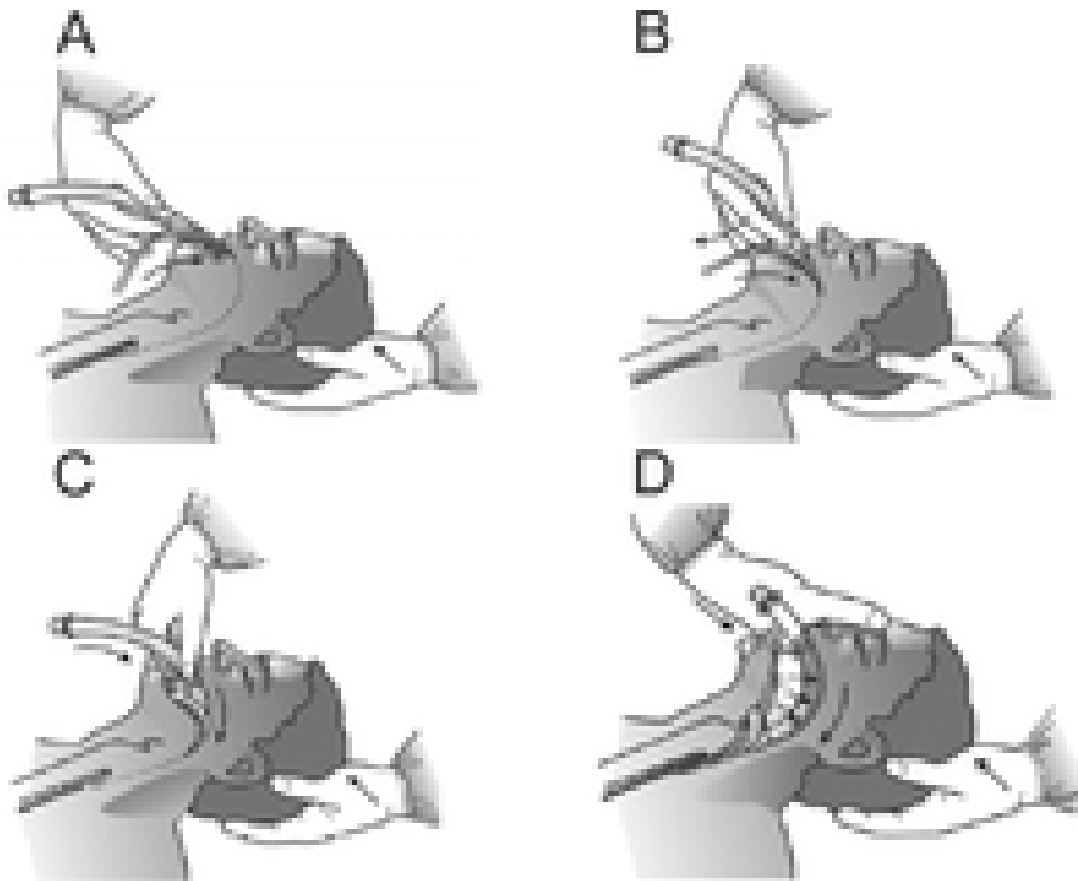
- 1} FAILURE IN VENTILATION AND OXYGENATION
- 2 } AIRWAY TRAUMA LIKE TONGUE CONGESTION AND EDEMA
- 3 } ASPIRATION OF GASTRIC CONTENTS
- 4} COMPRESSION INJURIES TO PHARYNGEAL NERVES AND LINGUAL, HYPOGLOSSAL, AND RECURRENT LARYNGEAL NERVE

## TECHNIQUES AND PRECAUTIONS FOR SUCCESSFUL USE OF SUPRAGLOTTIC AIRWAY DEVICES

The following Techniques and precautions will help improve success with use of SADs.

- 1} Selection of correct patient for correct procedure eg; fasted patients with normal lung compliance
- 2} Selection of correct size for correct patient {large cuffed SADs tend to function better with positive pressure ventilation<sup>4</sup>
- 3} Correct Patient position for correct device ie, most of the devices require morning sniffing position except combitube and ILMA which require neutral head position
- 4 } Correct insertion technique
- 5} Correct fixation technique
- 6 } Confirmation of correct placement ventilation and oxygenation by means of clinical assessment , auscultation and capnography .
- 7} Try to use limited tidal volume by controlling the endtidal carbondioxide concentration.

- 8} Do not use the gastric port if oesophageal trauma ,oesophageal varices , upper GI bleed or any coagulopathy is suspected.
  
- 9} To use safe removal technique{ try to expel the device smoothly and when the patient is in deep plane or fully conscious and awake }



### TECHNIQUES OF LMA INSERTION – CLASSICAL METHOD<sup>2</sup>

- A** – position the patient in slight head extension and neck flexion and hold LMA in one hand and support the head with other hand
- B** – Hold the device like a pencil with the index finger in the junction between cuff and shaft and move against hard palate
- C** – Proceed the device against the posterior pharyngeal wall till a resistance is felt



**D** – Move further till your index finger is inside the mouth of the patient and hold the shaft of the device with other hand simultaneously taking out the index finger

Confirm the position of the device by

1 } Clinical judgement

2 } Auscultation and capnography

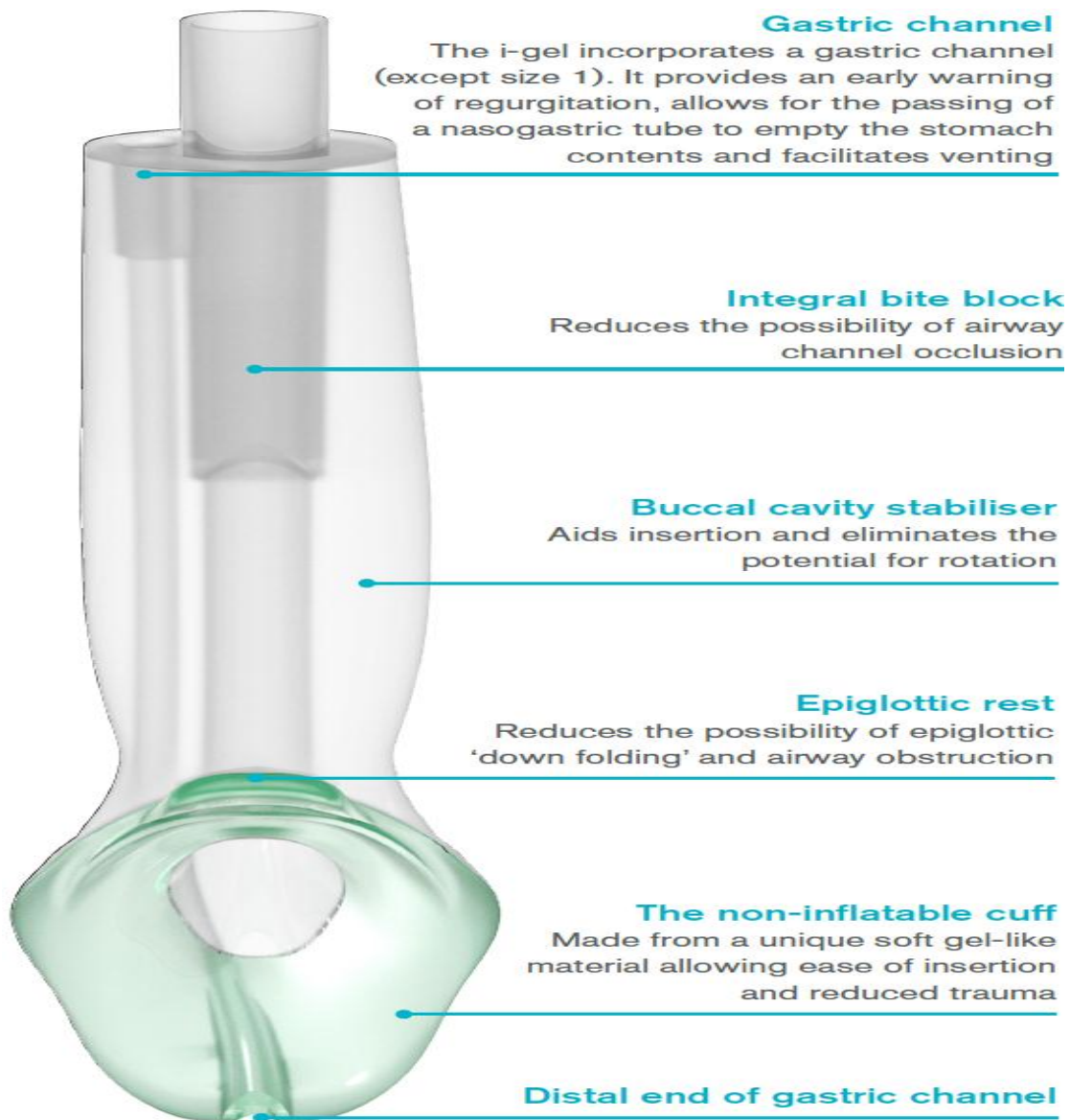
### **OTHER METHODS OF INSERTION**

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- Partial inflation method
- 180 degree rotation method
- Laryngoscopy aided method
- Stylet aided method
- Insertion from the side of the mouth opening

## **I- GEL**

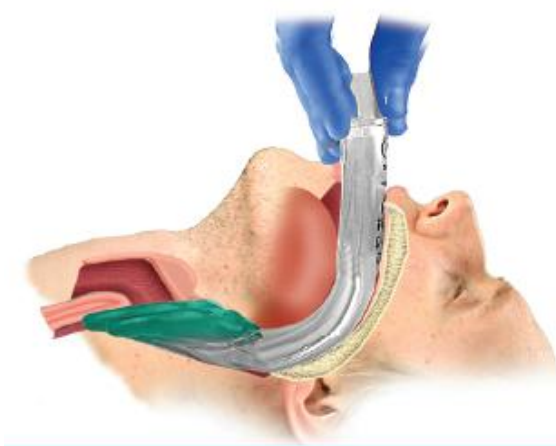
Second generation Supraglottic airway device designed by Muhammed Nasir a UK based anaesthesiologist . It is developed and marketed by Intersurgicals Ltd a UK based company . It is made of a thermoplastic elastomer and the mask is made of a soft polymer. The device lack a inflatable cuff. The device is designed to precisely fit into the laryngeal and perilaryngeal structures. The device provide a greater seal pressure and increased speed of insertion and does not require inflation. It is Cuffless designed for single use . The mask is made of a soft polymer and the shape is like that of a inflated LMA posteriorly and fits the perilaryngeal structures anteriorly . Other parts of I-GEL include a narrow bore oesophageal drain tube ,a wide bore airway tube and a Integral bite block . The size varies from size 1 to size 5 ie from neonates to large adults . It contains an epiglottic rest at the anterior part of the cuff which reduces the possibility of epiglottis ‘down folding’ and airway obstruction<sup>14</sup>



## METHOD OF INSERTION



Remove the i-gel from the protective cradle. Grasp the lubricated i-gel firmly along the integral bite block. Position the device so that the **i-gel** cuff outlet is facing towards the chin of the patient. The patient should be in the 'sniffing the morning air' position with head extended and neck flexed. The chin should be gently pressed down before proceeding. Introduce the leading soft tip into the mouth of the patient in a direction towards the hard palate.



Glide the device downwards and backwards along the hard palate with a continuous but gentle push until a **definitive resistance** is felt .










The tip of the airway should be located into the upper oesophageal opening (a) and the cuff should be located against the laryngeal framework (b). The incisors should be resting on the integral bite-block (c).



If there is early resistance during insertion a 'jaw thrust' (above) or 'Insertion with Deep Rotation' (right) is recommended.

## SIZES OF I-GEL

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

- The I-GEL Mask is made of a thermoplastic elastomer (SEBS-Styrene Ethylene Butadiene Styrene) which is very flexible and the material has a feel of human tissue. The heat of the body activates the gel component of the polymer and fits the hypopharynx that helps the device to rest and also helps in covering the perilaryngeal structures<sup>14</sup>.

### **Advantages:-**

- Easy to insert { Because it does not have cuff }
- Reduced incidence of postoperative dysphagia and sore throat { Because of truncated tip }<sup>17</sup>
- Good emergency rescue device
- Used as conduit for intubation {Because of wide lumen }<sup>16</sup>
- Less chances of gastric aspiration {Because of presence of gastric channel}

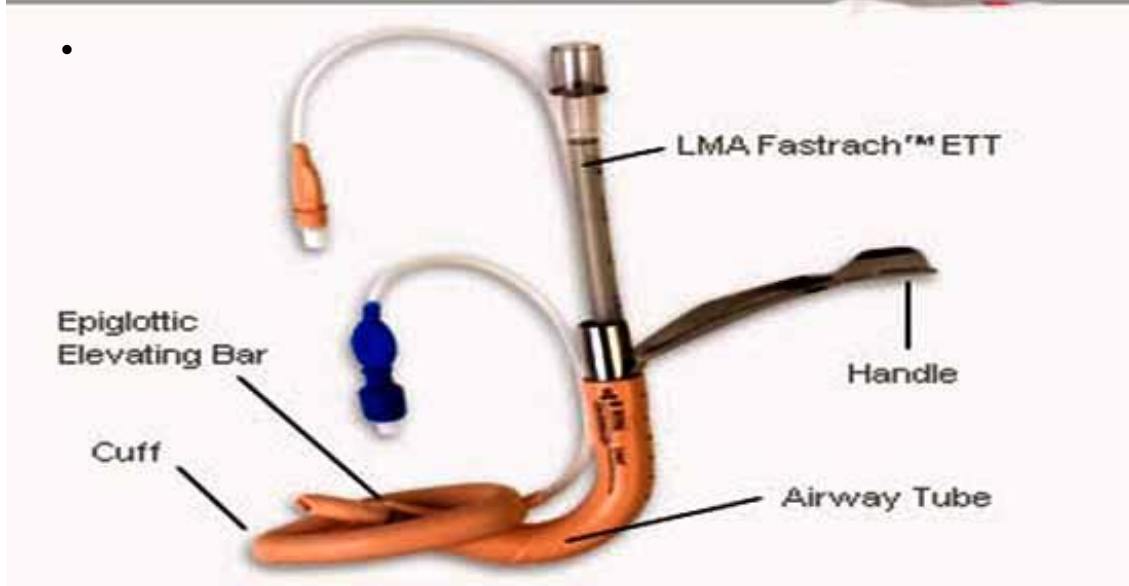
## **INTUBATING LMA (ILMA)**

Dr. Brain in 1997 developed the Intubating LMA (ILMA), also known as LMA FOSTRACH stemming from the success of LMA classic<sup>11</sup>. It was designed to allow for endotracheal intubation<sup>15</sup>. LMA FOSTRACH consists of a large internal diameter to allow ETT, a rigid airway tube, an epiglottic elevating bar, and a tracheal tube guiding ramp. The Intubating LMA is not intended for intubation with paediatric endotracheal tubes<sup>27</sup>.

### **CHARACTERISTICS ; It is**

- A modification of the C-LMA.
- Has a rigid (stainless steel) anatomically curved, short & wide bore shaft that follows the curve of the hard palate and the posterior pharyngeal wall<sup>30</sup>
- An epiglottic elevator bar at the mask aperture
- Armoured flexible ET tube with a longitudinal and a horizontal black line - coincides with the epiglottic elevating bar<sup>28</sup>.
- A stabilizer rod of 25cm
- Seal pressure is 60 cmH<sub>2</sub>O

## The Intubating LMA™ Airway



## ILMA AND ETT SIZE<sup>8</sup>





Body weight	ILMA size	Air volume	Tracheal Tube
30-50kg	3	20ml	7mm
50-70kg	4	30ml	7.5mm
70-100kg	5	40ml	8mm

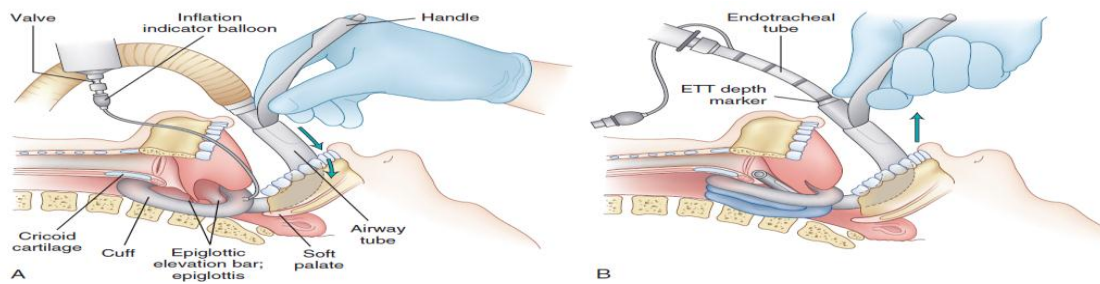
### **INSERTION TECHNIQUE**

- Position: Neutral
- Hold rigid handle parallel to patient's chest.
- Glide the mask along the palate till the straight part of the rigid tube is parallel to the chin.
- Rotate the rigid handle directing towards patient's nose till it can not be advanced.
- Inflate the cuff & check ventilation.
- Introduce ETT with black line facing rigid handle till 15 cm mark.
- Now grip ILMA handle firmly and lift it forward by few millimeters without levering.

- Advance the tube using clinical judgment.
- Inflate the cuff and check for tracheal intubation.
- After confirmation of tracheal intubation deflate the ILMA cuff.
- Remove ETT connector
- Insert the stabilizing rod in the ETT to keep it in place.
- Remove the ILMA gently over the stabilizing rod until it is clear of the oral cavity.
- Stabilize the ETT to prevent accidental extubation.
- Remove ILMA and the stabilizing rod.
- Reconnect ETT connector and the breathing circuit and confirm the position again

## **CHANDY S MANEUVER<sup>2</sup>**

- They increases the seal pressure and aligns the axes of trachea and FETT.
- First step : Rotating ILMA in coronal & sagittal plane in an attempt to find least resistant ventilation position.
- Second step : is to grasp the handle and use it to draw LMA forward 2-5 mm in a lifting action without levering teeth.



## **ADVANTAGES**

- It is useful in cannot ventilate and cannot intubate scenarios.
- It allows fast insertion into correct position without moving head and neck.
- It can be used alone or can be used as a guide to intubation.
- It facilitates ventilation between intubating LMA and ETT insertion.
- It is used as a conduit for fiberoptic intubation in the presence of airway pathology or any mass in the oral cavity <sup>6</sup>

## **DISADVANTAGES**

It is more likely to dislodge in head and neck manipulation.

It is unsuitable for MRI.

It is difficult in insertion with limited mouth opening. On removal of ILMA tracheal tube can be displaced downwards.

## REVIEW OF LITERATURE

**1. Halwagi et al 2012 and Sastre et al in 2012** demonstrated 100% success rate for I-GEL and ILMA as ventilatory devices.<sup>1</sup> They conducted study in 100 subjects .In this study a higher success rate was achieved in blind tracheal intubation with ILMA group compared to I-GEL group .Intubation was successfully done in 77.5% cases in first attempt and remainder needed second attempt by using some maneuvers. In the present study, the conclusion was that the time needed for successful lung ventilation and blind tracheal intubation was shorter in ILMA group than I-GEL group which was statistically significant ( $p < 0.05$ )<sup>5</sup>

**2. Kleine- Brueggeney et al 2011** studied the ease of insertion and blind endotracheal intubation in I-GEL and ILMA<sup>7</sup> . The total study subjects were 80 patients He observed that ease of insertion of SAD , blind endotracheal intubation using I-GEL and ILMA , laryngeal grading using supraglottic airway devices I-GEL and ILMA according to fiberoptic view <sup>5</sup>. It was concluded that blind intubation using ILMA was better than I-GEL since the p value derived was also significant  $< 0.0001$  using unpaired t test .

Laryngeal grading according to fiberoptic view was also better in I-gel group and ease of insertion was better in I-GEL group<sup>9</sup> . The difference in laryngeal grading in both the groups could be due to presence of the epiglottic bar in the ILMA which may cause poorer fibrescopic view and intubation

through the device . The I-GEL airway has its epiglottic blocker on the outer surface of the bowl, and the fibrescopic view of larynx is usually straight and unobstructed[7]. In I-gel group, in the cases in which blind tracheal intubation failed (9 patients) even after maneuvers, needed stylet for intubation with Macintosh laryngoscope. The laryngeal grading in most of these patients (7 patients) were grade II according to Cormack Lehane grading system<sup>4</sup>.

**3. Keijer et al 2009** observed the incidence of sore throat , dysphagia in I-GEL and ILMA studying in 100 patients . He observed that the incidence of sore throat was lesser in I-gel group as compared to ILMA group<sup>5</sup> In the present study ,the incidence of dysphagia, hoarseness , lip trauma , dental trauma was absent in both the groups<sup>1</sup>.

**4. Theiler et al (2011)** studied “visualized blind intubation” through the I-gel and the LMA Fastrach in patient presenting with at least one criterion for difficult intubation. The study was carried out in 100 patients . Their results demonstrated a substantially poor success rate (15%) with I-gel as compared with the LMA Fastrach (69%)<sup>5</sup> .The success rate of tracheal intubation on the first attempt with the LMA Fastrach, as reported in earlier randomized controlled trials, varies between 48% to 87% <sup>22</sup> . Results of the present study have shown comparable success rate for tracheal intubation with PVC ETTs through both the types of SADs<sup>1</sup> .

**5. Sameer Kapoor et al and Dharma Das Gupta et al 2014** conducted study in 100 patients, comparing the ease of insertion of ILMA and I-GEL and blind endotracheal intubation using ILMA and I-GEL, they observed an overall success rate of insertion of supraglottic devices in both the groups was 100% which was similar to various previously conducted studies. In this study, first-attempt success rate for blind tracheal intubation was comparable in both the groups and overall success rate was higher in LMA FOSTRACH group as compared to I-GEL group<sup>1</sup>. In I-GEL group the success rate improved with external laryngeal manipulation<sup>18</sup>. In group ILMA, ETT was inserted with reverse orientation as this method resulted in higher success rate. It optimises the ETT with the angle of trachea resulting in better first-attempt success rate of ETT insertion{10}. They observed that 90° counter-clock rotation and external laryngeal maneuver {ELM} resulted in substantially superior results in case of I-GEL. The incidence of postoperative complications was comparable in both the groups. In this study dysphonia was more in ILMA group<sup>5</sup>.

**6. Priyamvada Gupta, et al Dharam Das Jethava, et al Durga Jethava et al in 2008** evaluated the success rate of blind tracheal intubation through two different SADs I-gel and LMA Fastrach. The complications if any were also studied: A total of 100 patients undergoing elective surgery under general anaesthesia were randomised in two groups comprising of 50 patients each to tracheal intubation using either i-gel (I group) or LMA Fastrach (F group). The Results showed that there was no difference in the incidence of

adequate ventilation with either of the SAD{1}. The success rate of tracheal intubation in first attempt was 66% in Group I and 74% in Group F, while overall success rate of tracheal intubation was 82% in Group I when compared to 96% in Group F. Time taken for successful tracheal intubation through LMA Fastrach was lesser (20.96 s) when compared to i-gel (24.04 s)<sup>10</sup>. Complication rates were statistically similar in both the groups. They concluded that I-gel is a better device for rescue ventilation due to its quick insertion but an inferior intubating device in comparison to LMA Fastrach<sup>5</sup>.

**7. Theodora et al in 2013** Investigated whether nursing staff can successfully use the I-gel and the Intubating laryngeal mask airway (ILMA) {LMA FOSTRACH } during cardiopulmonary resuscitation. Forty five nurses inserted the I-gel and the ILMA in a mannequin with continuous and without chest compressions. Mean intubation times for the ILMA and I-gel without chest compressions were  $20.60 \pm 3.27$  and  $18.40 \pm 3.26$  s, respectively ( $p < 0.0005$ ). ILMA proved more successful than the I-gel regardless of compressions. Continuation of compressions caused a prolongation in intubation times for both the I-gel ( $p < 0.0005$ ) and the ILMA ( $p < 0.0005$ ). In this mannequin study, it was concluded that nursing staff can successfully intubate using the I-gel and the ILMA as conduits with comparable success rates, regardless of whether chest compressions given or not given

**8} Jatin Lal et al in 2015** evaluated I-gel to be used as an effective ventilatory device and as a conduit for endotracheal intubation. After informed consent, 50 ASA I-II adults with normal airways undergoing elective surgery under general anaesthesia requiring intubation were allocated to undergo blind tracheal intubation using i-gel<sup>25</sup>.

I-gel insertion was successful in all 50 (100%) patients [46 (92%) in 1<sup>st</sup>, 3 (6%) in 2<sup>nd</sup> and 1(2%) in 3<sup>rd</sup> attempt]. The mean duration of insertion of i-gel was  $18.20 \pm 2.32$  seconds. The mean airway seal pressure was  $26.78 \pm 4.10$  cm H<sub>2</sub>O. Overall successful rate of intubation through i-gel was 78% [34(68%) in 1<sup>st</sup>, 3(6%) in 2<sup>nd</sup> and 2(4%) in 3<sup>rd</sup> attempt]. The mean time for intubation using i-gel was  $23.28 \pm 8.22$  seconds. They concluded that I-gel provides effective ventilation with acceptable airway seal pressures and can serve as alternative conduit for blind endotracheal intubation<sup>24</sup>.

**9} Uppal et al 'Fletcher et al and Kinsella et al in 2008** assessed the ability of I-gel to provide pressure-controlled ventilation (PCV) during anaesthesia. It was assessed by measuring the gas leaks and comparing these values with that of the tracheal tube<sup>17</sup>.

Twenty-five patients, ASA I–II, were recruited to the study. Patients received a standard anaesthetic technique followed by an initial placement of the i-gel. The lungs were then ventilated at three different pressures (15, 20, 25 cm H<sub>2</sub>O) using PCV. There was no significant difference between the leak fractions



of the i-gel and the tracheal tube at 15 and 20 cm H<sub>2</sub>O PCV. At 25 cm H<sub>2</sub>O, the median difference in leak fraction was 0.02 ( $P=0.014$ ) and the median difference in leak volume was 26.5 ml ( $P=0.006$ ). There was no evidence of gastric insufflations with any of the pressures used during PCV.

**10} Michalek et al, W. Donaldson et al ,Graham et al 2014** studied the comparison of I-GEL and ILMA as a conduit for blind tracheal intubation in three different airway mannequins<sup>5</sup>. A prospective study with 25 participants evaluated the success rate of blind intubation (using a gum-elastic bougie, an Aintree intubating catheter (AIC) and designated tracheal tube) and fibroscope-guided tracheal intubation (through the intubating laryngeal mask airway and the I-GEL supraglottic airway) on three different airway mannequins<sup>6</sup>. Twenty five anaesthetists performed three intubations with each method on each of three mannequins. The success rate of FOB guided technique was significantly higher than blind attempts with both devices<sup>19</sup>. All blind techniques were significantly more successful in the ILMA group compared to the I-gel<sup>20</sup>

**11} Brain AI et al Verghese et al, Addy et al in 1997** assessed the efficacy of the intubating laryngeal mask airway (ILMA), as a ventilatory device and blind intubation guide. Out of 149 of 150 (99.3%) patients, in 75 (50%) patients no resistance was encountered and the trachea was intubated at the first attempt, 28 (19%) patients required one adjusting manoeuvre and 46 (31%) patients required 2-4 adjusting manoeuvres before intubation was successful. There were 13 patients with potential or known airway problems. The lungs of

all of these patients were ventilated easily and the trachea intubated using the ILMA. In 10 of 13 (77%) of these patients, no resistance was encountered and the trachea was intubated at the first attempt; three of 13 (23%) patients required one adjusting manoeuvre. Tracheal intubation required significantly fewer adjusting manoeuvres in patients with a predicted or known difficult airway ( $P < 0.05$ ). They concluded that the ILMA appeared on initial assessment to be an effective ventilatory device and intubation guide for routine and difficult airway patients not at risk of gastric aspiration<sup>10</sup>.

**12} Dimitriou v et al , Voyagis gs et al 1999** evaluated the efficacy of a newly developed prototype illuminated flexible catheter to facilitate tracheal intubation through the intubating laryngeal mask and compared this light-guided technique with the conventional blind tracheal intubation through the intubating laryngeal mask. . The success rate for the blind and light-guided technique was 91% and 100%, respectively ( $P = 0.003$ ). They concluded that the use of an illuminated flexible catheter carries advantages either in optimizing the intubating laryngeal mask position in the laryngopharynx or in achieving a quick and safe light-guided advancement from laryngopharynx into the trachea<sup>6</sup> .

**13} Young et al 2003** Indicated that intubating laryngeal-mask airway (ILMA) may be an ideal device for airway control in the rural trauma patient. The ILMA is an advanced laryngeal-mask airway designed to allow oxygenation of the unconscious patient as well as blind tracheal intubation with an endotracheal tube. ILMA has been found to be reliable and successful when

other techniques fail, such as fiberoptic intubation and direct laryngoscopy. The ILMA has also been reported to cause less hemodynamic change and less injury to the teeth and lips than direct laryngoscopy. Further, the ILMA was found to be easier and faster to use with a higher success rate than either the combitube or endotracheal tube for unskilled healthcare providers. Limitations and complications of the ILMA may include aspiration, esophageal intubation, damage to the larynx or other tissues during blind passage of a tracheal tube, and edema of the epiglottis.

## **MATERIALS AND METHODOLOGY**

### **TYPE OF STUDY**

A prospective, Comparative study

### **PLACE OF STUDY**

Government Kilpauk Medical College and Hospital

### **SAMPLE SIZE**

The formula for calculating sample size is given as

$N = \{Z_{1\alpha/2} \cdot \sigma/E\}^2$  Where

N = sample size

Sigma = population standard deviation

E = margin of error

Z = the value for the given confidence interval

Confidence level is estimated at 95%

Standard deviation 3.79

Z value of 1.96

Margin of error is estimated at +/-1

Power of study 80 percent

The sample size calculated was 56. In my study 60 subjects were taken

60 adult patients satisfying the inclusion criteria was enrolled in the study.

## **INCLUSION CRITERIA**

- 1) Adult patients undergoing elective surgery requiring general anaesthesia.
- 2) ASA physical status 1 – 2
- 3) Patients with age >18 years and <60 years
- 4) Patients with height:150-180cm
- 5) Patients who have given valid informed consent
- 6) Patients with MPC I & II

## **EXCLUSION CRITERIA**

- 1) Patients not satisfying inclusion criteria.
- 2) Patients requiring techniques such as rapid sequence induction.
- 3) Patients with oral pathology with distorted anatomy.
- 4) Patients with Trismus/TMJ pathology/ MPC III & IV
- 5) Pregnant, Gastroesophageal reflux disease & hiatus hernia patients
- 6) Patients who are unconscious or severely ill.
- 7) Morbidly obese patients.
- 8) Patients with neck swelling/thyroid.
- 9) Patients with post burns contracture neck.

## **MATERIALS :**

- 1) Anaesthesia machine
- 2) Supraglottic airway devices ILMA & I-GEL size 3 & 4
- 3) ET Tube of size 7 & 7.5 mm ID
- 4) Laryngoscope with different blade sizes

The following were kept ready.

- Anesthesia machine and circuits { checked }
- Endotracheal tubes → Cuffed Portex tubes of appropriate size
- Endotracheal tube of one size less { which was used as a modified stabilizer rod for I-GEL since I-GEL is not provided with a standard stabilizer rod }
- Macintosh laryngoscope → with appropriate and large sized blade.
- Oral and Nasopharyngeal airway
- Functioning suction apparatus
- Monitors → ECG monitor and Pulse oximeter, NIBP ,ETCO2 with capnograph
- Laryngeal mask airway of appropriate size
- Stabilizer rod for ILMA device
- Emergency drugs tray

## **METHODOLOGY**

This Study was conducted on 60 patients undergoing elective surgery under general anaesthesia, after getting approval from Institutional ethics committee. Written informed consent was obtained from all patients. After premedication with Ranitidine 50 mg and Metoclopramide 10 mg intravenously 30 minutes before induction, patient was shifted to the operation theatre. In the operation theatre, after establishing an intravenous route, Ringer lactate solution was started. Standard monitors were connected eg } NIBP ,ECG ,ETCO<sub>2</sub> ,SPO<sub>2</sub> . All patients received intravenous Glycopyrrolate 0.2mg, Fentanyl 2microgram/kg and Midazolam 0.03mg/kg, 10 minutes before induction of anaesthesia. . All the patients was preoxygenated with 100% oxygen for 3 minutes. Induction was done with appropriate inducing agents and Muscle relaxation was facilitated with appropriate Nondepolarising Muscle relaxants and mask ventilation was continued for 3 minutes with mixture of Oxygen, and Nitrous oxide. Depending on body weight the following sizes of the SADs (I-GEL/ILMA) and endotracheal tube (ETT) were chosen with little change in manufacturer's recommendations

Size of SAD	Patients bodyweight in kilograms	ETT Internal diameter size
I-GEL		
Size 3 {three }	30-50 kg	7.0mm
Size 4 {four }	50-90kg	7.5mm
ILMA Size 3 {three}	30-50kg	7.0mm
Size 4{four}	50-70kg	7.5mm
Size 5 {five}	>70kg	7.5mm

Conventional PVC (Polyvinylchloride) endotracheal tube ( Portex ) is used for blind endotracheal intubation. Both SADs and ETT are lubricated with 2% Lignocaine jelly prior to use. The I-gel supraglottic airway device was inserted in extended neck position {classical method }, while the ILMA was inserted in neutral neck position. Duration of successful SAD insertion is defined as the time elapsed from the insertion of SAD between the dental arches until the confirmation of successful ventilation determined by chest wall movement, auscultation of breath sounds, capnography and absence of oropharyngeal leak with peak airway pressure of  $> 20$  cm of H<sub>2</sub>O<sup>1</sup>. The time will be measured with the help of a stopwatch. The number of attempts required for SAD insertion were recorded. A failed attempt is defined as removal of the device from the mouth before it is reinserted .If the device is not successfully inserted in third attempt this is recorded as failure of SAD insertion.



Following this, blind tracheal intubation is to be attempted through SAD. Duration of successful blind tracheal intubation through SAD is defined as the time elapsed from passing the ETT through SAD until the confirmation of successful ventilation, which is determined by chest rise, auscultation of breath sounds and capnography. In I-GEL group, SAD was removed using one size smaller tracheal tube. {In case of I-GEL since it is not provided with the stabilizer rod } In ILMA group ETT was removed using the stabilizer rod provided along with the ILMA set .

When resistance is felt during ETT Insertion in I-GEL group following maneuvers can be used

1. ETT was rotated 90 degree counterclockwise and then inserted
2. Cricoid pressure<sup>26</sup>

IN ILMA group ETT , was inserted with

1. Reverse orientation,
2. Inserted with conventional technique and then rotated through 180 degree once it crosses the proximal opening in LMA <sup>1</sup>

In both the study groups, maximum three attempts at device insertion and maximum three attempts at tracheal intubation were allowed. If tracheal intubation through the device is unsuccessful, it was performed by direct laryngoscopy or the procedure was completed with the SAD in place depending on the implications and need of the surgical procedure

## **PARAMETERS ANALYSED**

### **EASE OF INSERTION BASED ON SUBJECTIVE SCORE**

Easy	-	score 1
Satisfactory	-	score 2
Diifficult	-	score 3

### **NUMBER OF ATTEMPTS FOR SAD INSERTION AND BLIND TRACHEAL INTUBATION**

Maximum of three attempts each for SAD insertion and ETT insertion were done .More than three attempts taken, was considered failure.

### **DURATION FOR INSERTION OF SAD AND BLIND TRACHEAL INTUBATION**

Calculated from the time duration that elapsed from passage of SAD through the dental arches and ETT through the SAD to the confirmation of successful ventilation confirmed clinically and by Endtidal carbondioxide concentration monitoring.

### **THE PRESENCE OR ABSENCE OF POSTOPERATIVE DYSPHAGIA, SORETHROAT ,HOARSENESS OF VOICE etc**

Was enquired at the end of the procedure.

All patients were observed in the recovery room for half an hour postoperatively and shifted to postoperative ward for further care .

All recorded data were collected and statistical analysis were done.

## **OBSERVATION AND RESULTS –STATISTICAL ANALYSIS**

This prospective non randomized, double arm, single blinded, Comparative study was done to evaluate the efficacy of supraglottic airway devices I-GEL and ILMA as emergency ventilatory devices and their ability as conduit for blind intubation<sup>10</sup> .

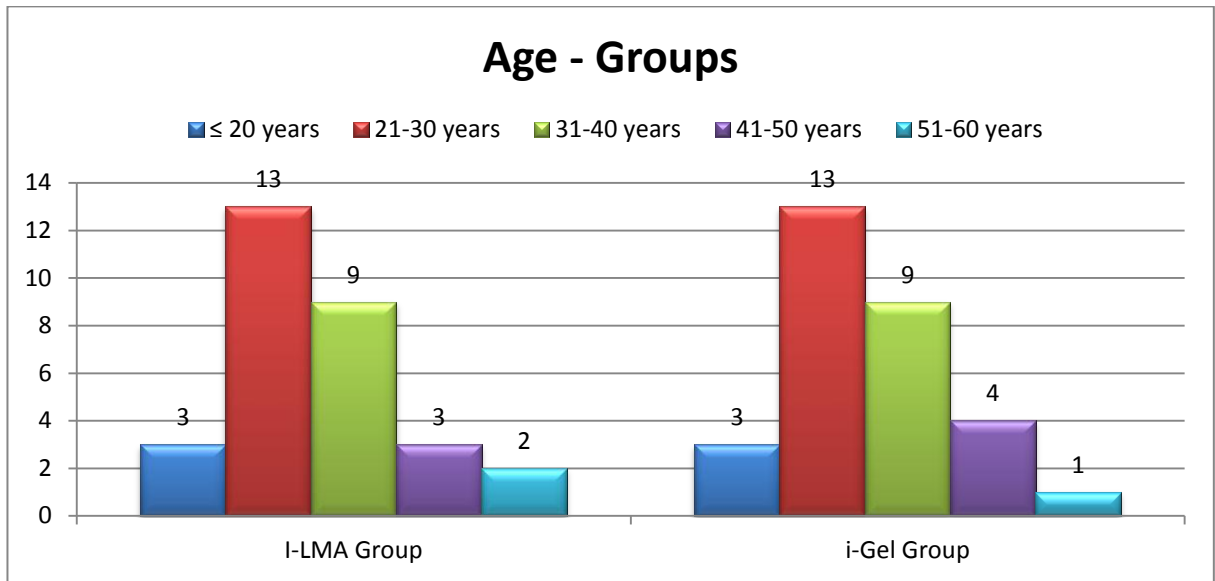
All data were collected and tabulated

### **GROUPS**

<b>Groups</b>	<b>Intervention</b>	<b>Number</b>
<b>ILMA Group</b>	ILMA ( 30 ) inserted after 3 min ventilation followed by blind ETT intubation	30
<b>I-GEL Group</b>	I GEL (30) inserted after 3 min ventilation followed by blind ETT intubation	30

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test.. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as  $P < 0.05$ . The data was analysed using SPSS version 16 and Microsoft Excel 2007<sup>10</sup> .

## AGE

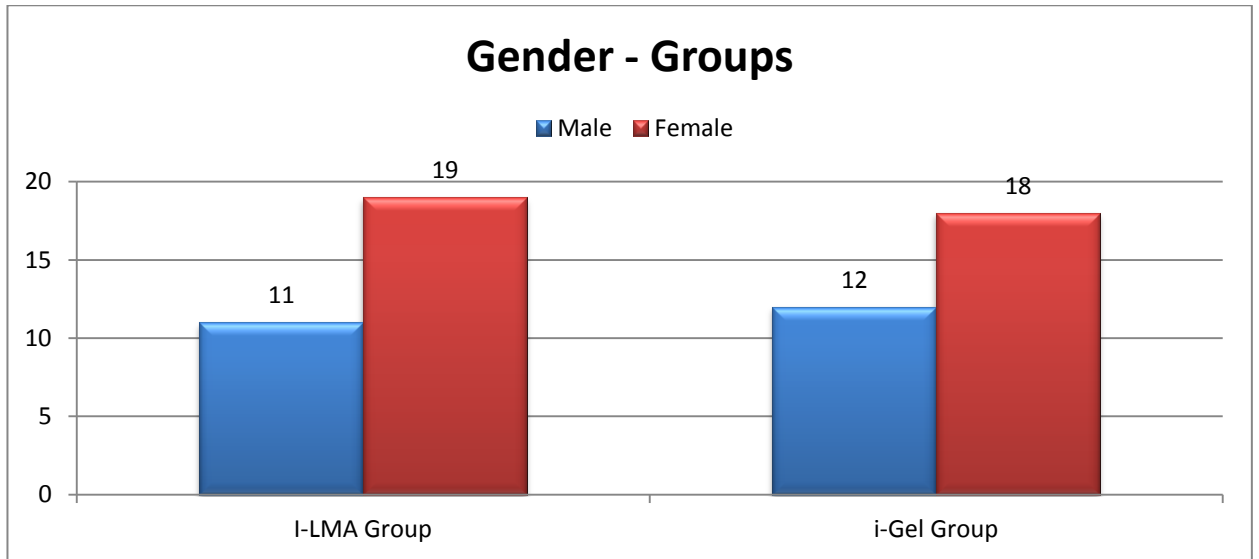


Age - Groups	ILMA Group	%	I-GEL Group	%
≤ 20 years	3	10.00	3	10.00
21-30 years	13	43.33	13	43.33
31-40 years	9	30.00	9	30.00
41-50 years	3	10.00	4	13.33
51-60 years	2	6.67	1	3.33
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Age Distribution	ILMA Group	I-GEL Group
<b>Mean</b>	30.50	30.60
<b>SD</b>	9.92	8.59
<b>P value Unpaired t Test</b>	0.9669	

Majority of the ILMA group patients belonged to 21-30 years age class interval (n=13, 43.33%) with a mean age of 30.50 years. In the I-GEL group patients, majority belonged to 21-30 years class interval (n=13, 43.33%) with a mean age of 30.60 years. The association between the intervention groups and age distribution is considered to be not statistically significant since  $p > 0.05$  as per unpaired t test.

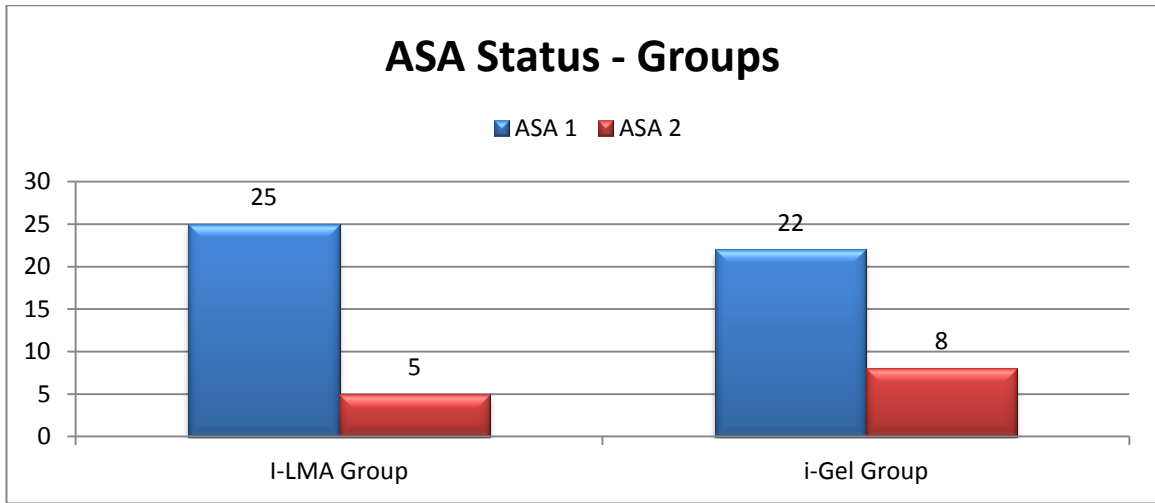
## GENDER



Gender - Groups	ILMA Group	%	I-GEL Group	%
Male	11	36.67	12	40.00
Female	19	63.33	18	60.00
Total	30	100	30	100
P value Chi Square Test			0.7906	

Majority of the ILMA group patients belonged to female gender (n=19, 63.33%). In the I-GEL group patients, majority too belonged to female gender (n=18, 60.00%). The association between the intervention groups and gender status is considered to be not statistically significant since  $p > 0.05$  as per chi squared test.

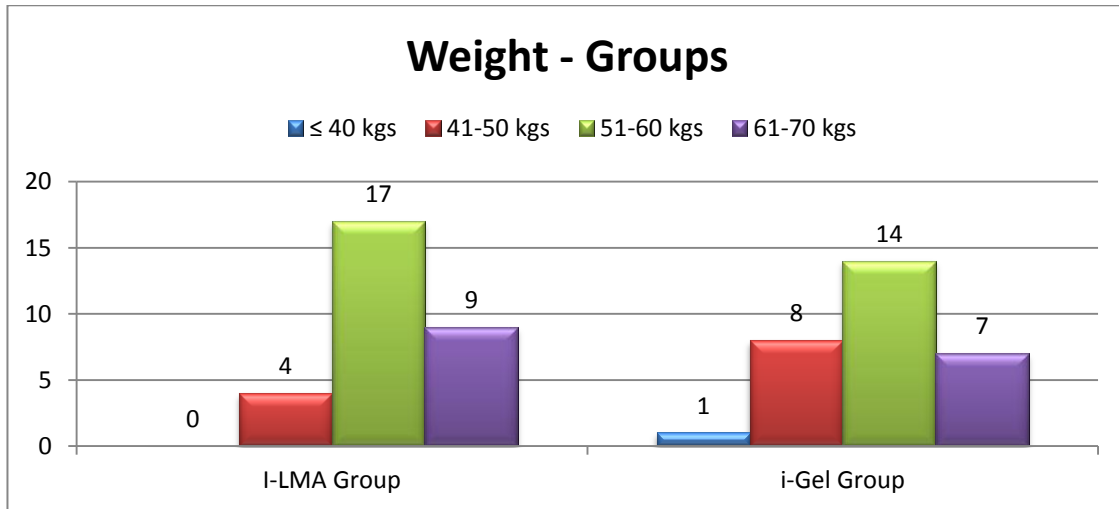
## ASA



ASA Status - Groups	ILMA Group	%	I-GEL Group	%
ASA 1	25	83.33	22	73.33
ASA 2	5	16.67	8	26.67
<b>Total</b>	30	100	30	100
<b>P value</b>			0.3472	
<b>Chi Square Test</b>				

Majority of the I-LMA group patients belonged to ASA 1 (n=25, 83.33%). In the i-Gel group patients, majority too belonged to ASA 1 (n=22, 73.33%). The association between the intervention groups and ASA status is considered to be not statistically significant since  $p > 0.05$  as per chi square test.

## WEIGHT

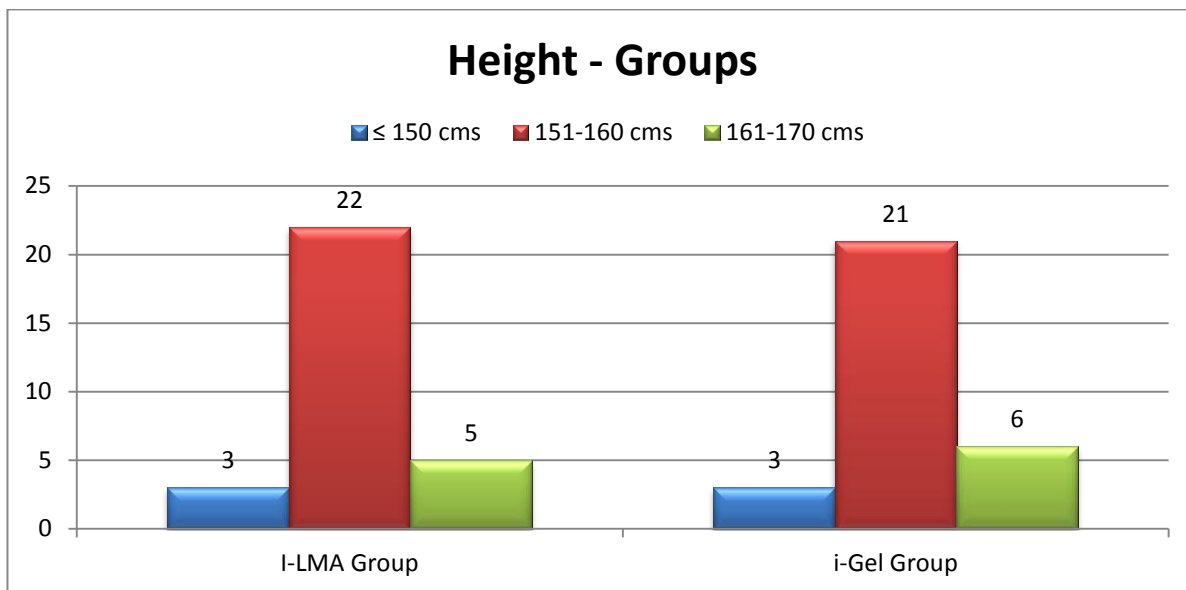


Weight - Groups	ILMA Group	%	I-GEL Group	%
≤ 40 kgs	0	0.00	1	3.33
41-50 kgs	4	13.33	8	26.67
51-60 kgs	17	56.67	14	46.67
61-70 kgs	9	30.00	7	23.33
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Weight Distribution	ILMA Group	I-GEL Group
Mean	57.10	54.13
SD	6.54	7.41
<b>P value Unpaired t Test</b>	<b>0.1055</b>	

Majority of the ILMA group patients belonged to 51-60 kgs weight class interval (n=17, 56.67%) with a mean weight of 57.10 kgs. In the I-GEL group patients, majority belonged to 51-60 kgs weight class interval (n=14, 46.67%) with a mean weight of 54.13 kgs. The association between the intervention groups and weight distribution is considered to be not statistically significant since  $p > 0.05$  as per unpaired t test.

## HEIGHT



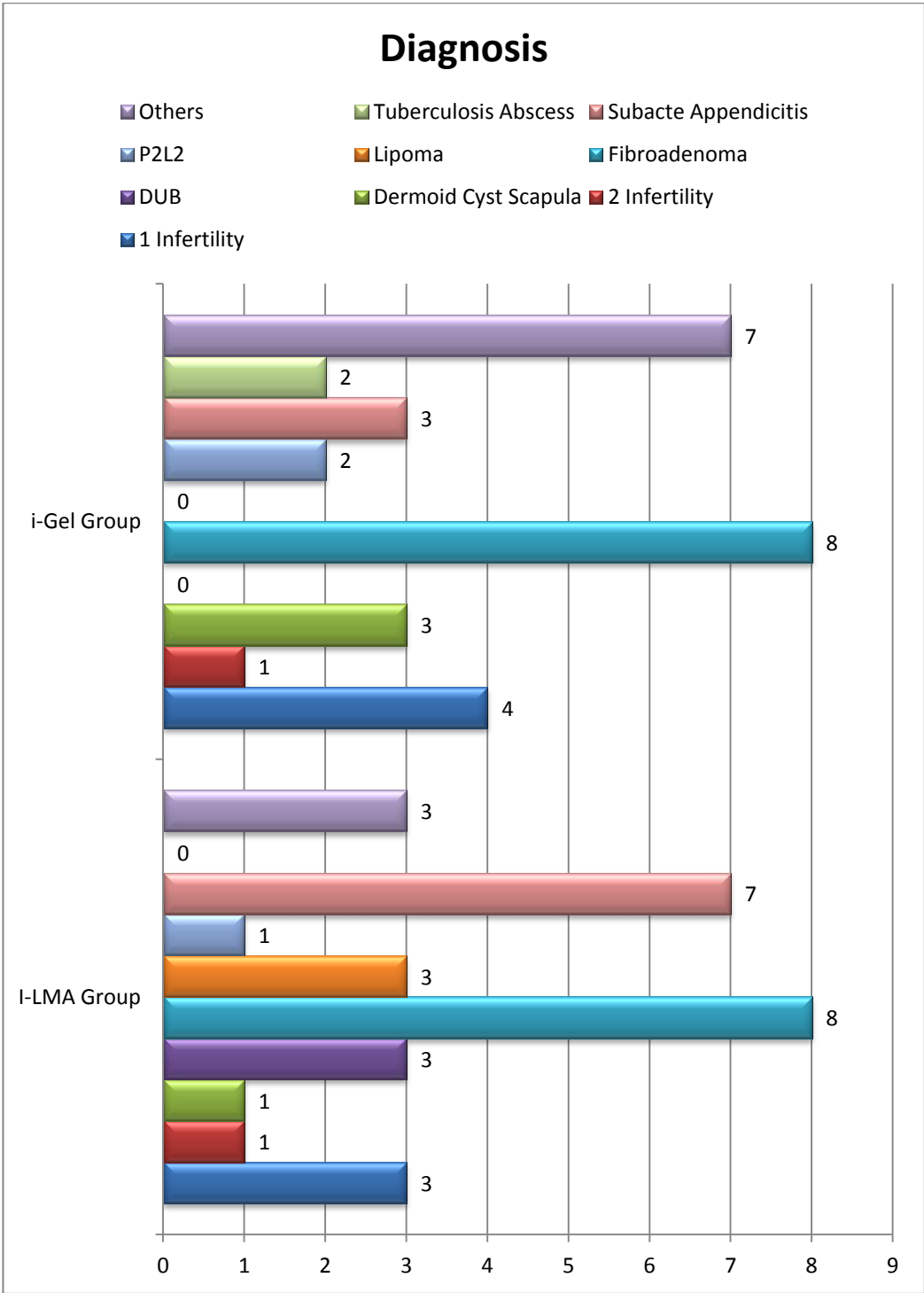
Height - Groups	ILMA Group	%	I-GEL Group	%
≤ 150 cms	3	10.00	3	10.00
151-160 cms	22	73.33	21	70.00
161-170 cms	5	16.67	6	20.00
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Height Distribution	ILMA Group	I-GEL Group
<b>Mean</b>	156.73	156.77
<b>SD</b>	4.79	5.29
<b>P value Unpaired t Test</b>	0.9797	

Majority of the ILMA group patients belonged to 151-160 cms height class interval (n=22, 73.33%) with a mean height of 156.73 cms. In the I-GEL group patients, majority belonged to 151-160 cms height class interval (n=21, 70.00%) with a mean height of 156.73 cms. The association between the intervention groups and height distribution is considered to be not statistically significant since  $p > 0.05$  as per unpaired t test.

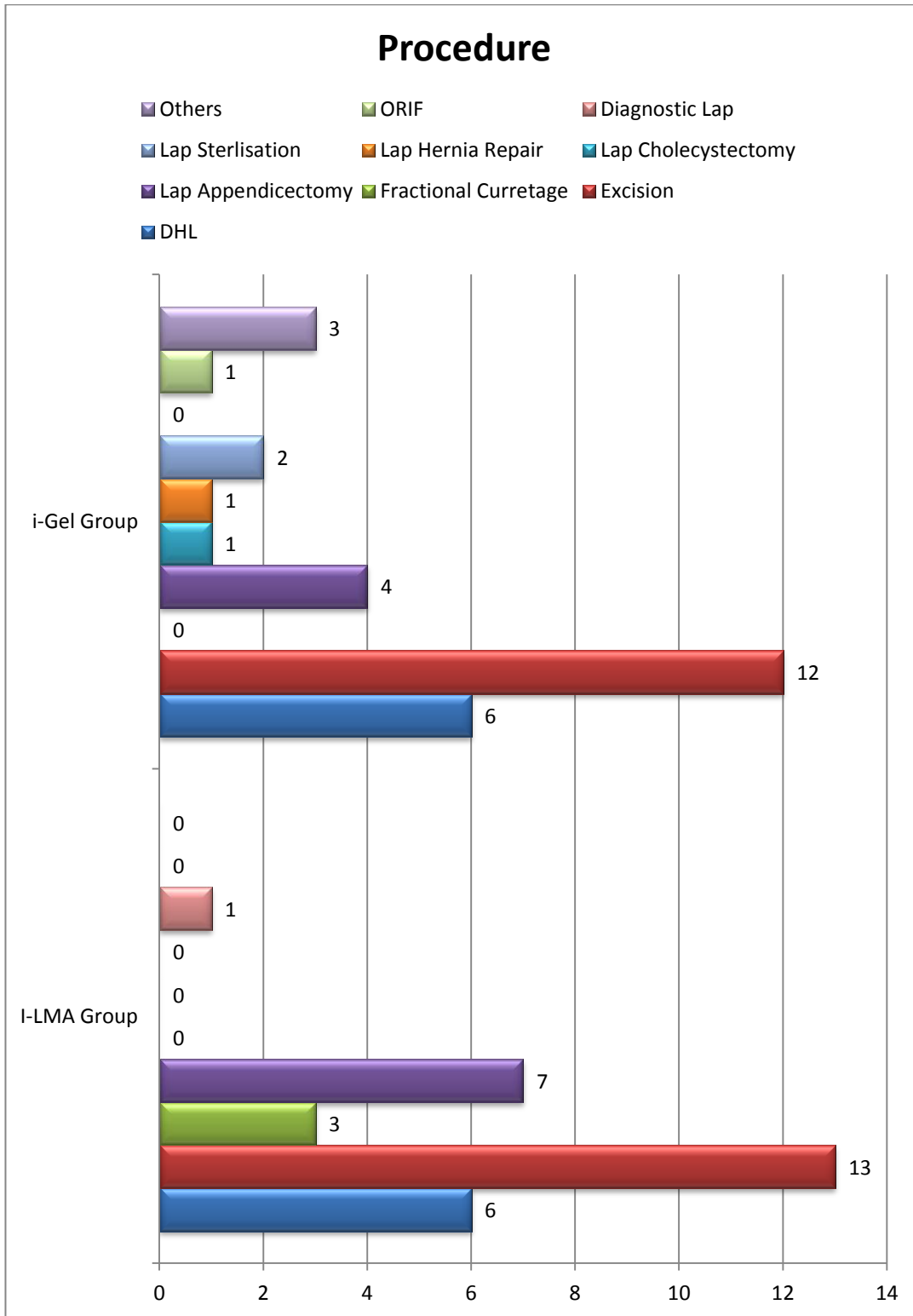


# DIAGNOSIS



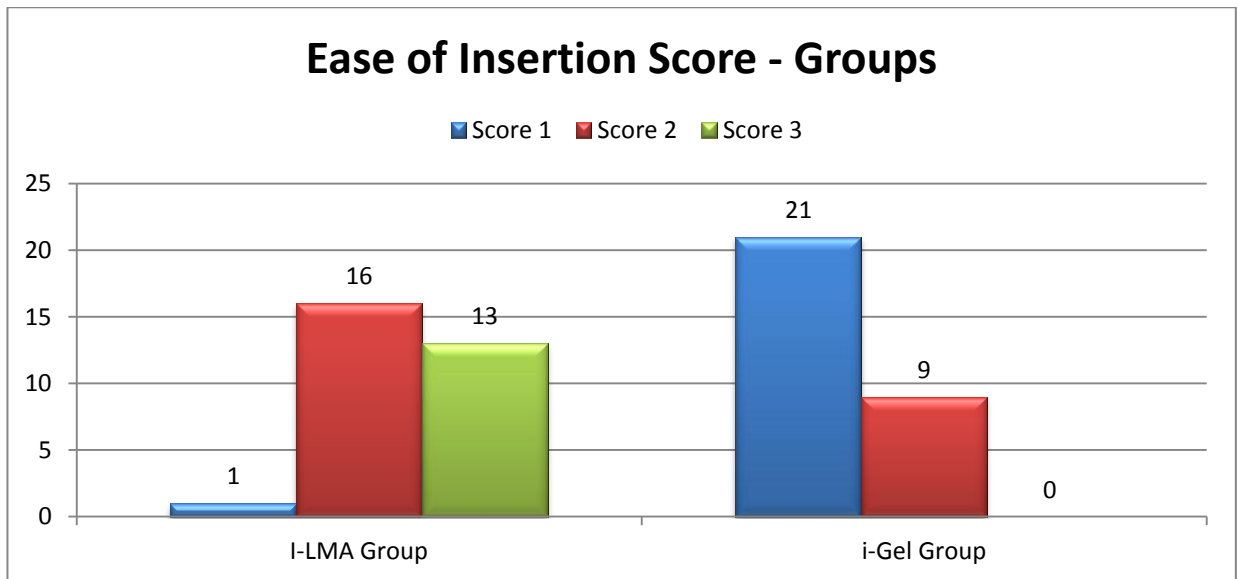
<b>Diagnosis</b>	<b>ILMA Group</b>	<b>%</b>	<b>I-GEL Group</b>	<b>%</b>
<b>1 Infertility</b>	3	10.00	4	13.33
<b>2 Infertility</b>	1	3.33	1	3.33
<b>Dermoid Cyst Scapula</b>	1	3.33	3	10.00
<b>DUB</b>	3	10.00	0	0.00
<b>Fibroadenoma</b>	8	26.67	8	26.67
<b>Lipoma</b>	3	10.00	0	0.00
<b>P2L2</b>	1	3.33	2	6.67
<b>Subacute Appendicitis</b>	7	23.33	3	10.00
<b>Tuberculosis Abscess</b>	0	0.00	2	6.67
<b>Others</b>	3	10.00	7	23.33
<b>Total</b>	30	100	30	100

# PROCEDURE



<b>Procedure</b>	<b>ILMA Group</b>	<b>%</b>	<b>I-GEL Group</b>	<b>%</b>
<b>DHL</b>	6	20.00	6	20.00
<b>Excision</b>	13	43.33	12	40.00
<b>Fractional Curettage</b>	3	10.00	0	0.00
<b>Lap Appendicectomy</b>	7	23.33	4	13.33
<b>Lap Cholecystectomy</b>	0	0.00	1	3.33
<b>Lap Hernia Repair</b>	0	0.00	1	3.33
<b>Lap Sterlization</b>	0	0.00	2	6.67
<b>Diagnostic Lap</b>	1	3.33	0	0.00
<b>ORIF</b>	0	0.00	1	3.33
<b>Others</b>	0	0.00	3	10.00
<b>Total</b>	30	100	30	100

## EASE OF INSERTION SCORE



Ease of Insertion Score - Groups	ILMA Group	%	I-GEL Group	%
Score 1	1	3.33	21	70.00
Score 2	16	53.33	9	30.00
Score 3	13	43.33	0	0.00
Total	30	100	30	100
P value Fishers Exact Test	<b>&lt;0.0001</b>			

By conventional criteria the association between the intervention groups and ease of insertion score is considered to be statistically significant since  $p < 0.05$ .

## **Results**

Majority of the ILMA group patients had ease of insertion score 2 (n=16, 53.33%). In the i-Gel group patients, majority had ease of insertion score 1 (n=21, 70.00%). The decreased incidence of ease of insertion score 1(easy) in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of  $<0.0001$  as per fishers exact test.

## **Discussion**

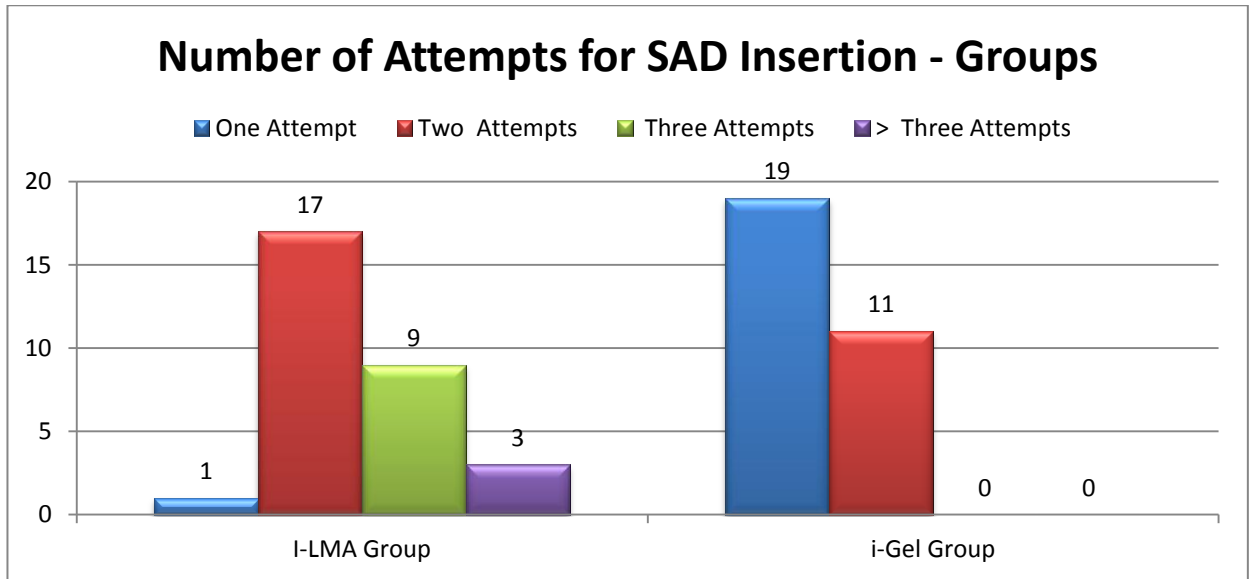
The incidence of ease of insertion score 1(easy) was meaningfully less in ILMA group compared to the I-GEL group by percentage difference of 66.67 percentage points ( 95% decrease). This difference is true and significant and has not occurred by chance.

## **Inference**

In this study the ease of insertion score was significantly and consistently lower in I-GEL group compared to the ILMA group when used for ease of insertion and as conduit for blind end tracheal intubation.

In other words I-GEL was 21 times more easier to insert compared to ILMA based on statistically significant ease of insertion score.

## NUMBER OF ATTEMPTS FOR SAD INSERTION



Number of Attempts for SAD Insertion - Groups	ILMA Group	%	I-GEL Group	%
<b>One Attempt</b>	1	3.33	19	63.33
<b>Two Attempts</b>	17	56.67	11	36.67
<b>Three Attempts</b>	9	30.00	0	0.00
<b>&gt; Three Attempts</b>	3	10.00	0	0.00
<b>Total</b>	30	100	30	100
<b>P value Fishers Exact Test</b>			<b>&lt;0.0001</b>	

By conventional criteria the association between the intervention groups and number of attempts for SAD insertion is considered to be statistically significant since  $p < 0.05$ .

## **Results**

Majority of the ILMA group patients had 2 attempts for SAD insertion (n=17, 56.67%). In the I-GEL group patients, majority had 1 attempts for SAD insertion (n=19, 63.33%). The increased number of attempts for SAD insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of  $<0.0001$  as per Fishers exact test.

## **Discussion**

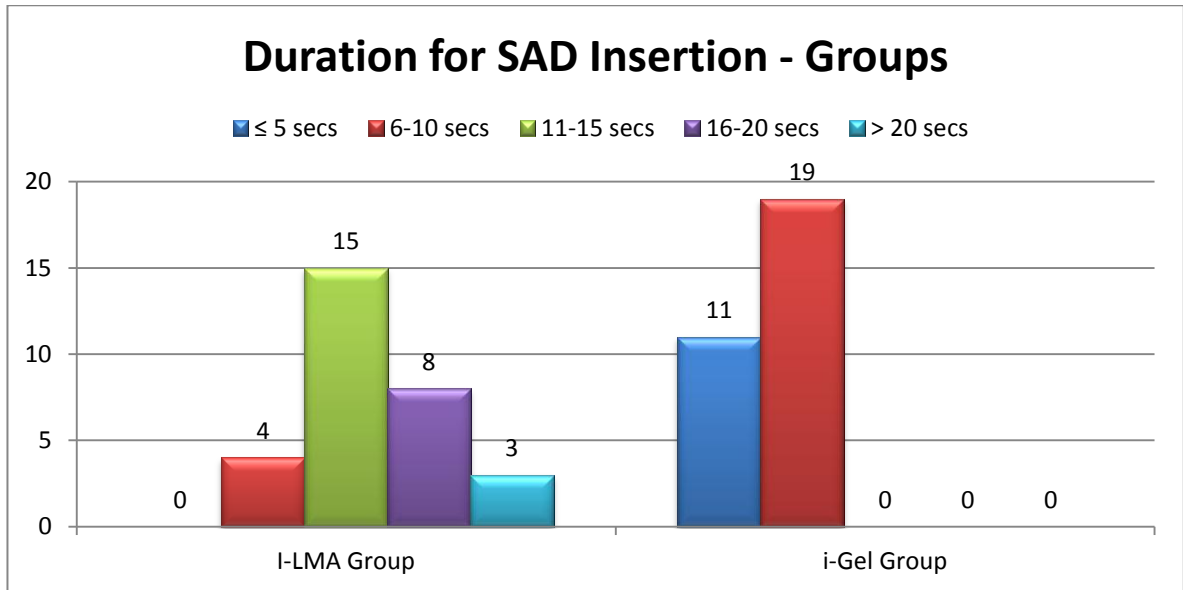
The incidence of SAD insertion on first attempt was meaningfully less in ILMA group compared to the I-GEL group by percentage difference of 60.00 percentage points ( 95% decrease). This difference is true and significant and has not occurred by chance.

## **Inference**

In this study the SAD insertion on first attempt was significantly and consistently higher in I-GEL group compared to the ILMA group when used for ease of insertion .In other words I-GEL had 19 times more successful insertion on first attempt success rate compared to ILMA based on statistically significant number of attempts for SAD insertion status.



## DURATION FOR SAD INSERTION



Duration for SAD Insertion - Groups	ILMA Group	%	I-GEL Group	%
≤ 5 secs	0	0.00	11	36.67
6-10 secs	4	13.33	19	63.33
11-15 secs	15	50.00	0	0.00
16-20 secs	8	26.67	0	0.00
> 20 secs	3	10.00	0	0.00
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Duration for SAD Insertion	ILMA Group	I-GEL Group
Mean	14.90	6.70
SD	4.52	2.17
<b>P value</b> <b>Unpaired t Test</b>		<b>&lt;0.0001</b>

By conventional criteria the association between the intervention groups and duration for SAD insertion is considered to be statistically significant since  $p < 0.05$ .

## **Results**

Majority of the ILMA group patients had 11-15 secs as duration for SGAD insertion (n=15, 50.00%) with a mean of 14.90 secs . In the I-GEL group patients, majority had 6-10 secs as duration for SGAD insertion (n=19, 63.33%) with a mean of 6.70 secs. The increased mean duration for SGAD insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of  $<0.0001$  as per unpaired t test.

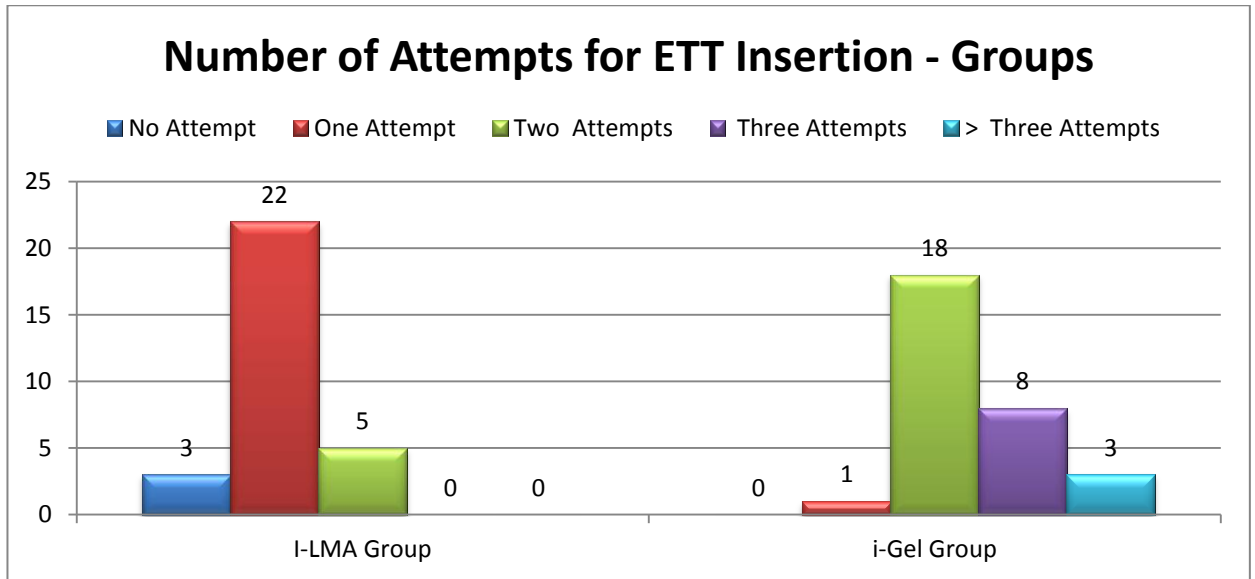
## **Discussion**

The mean duration for SGAD insertion was meaningfully more in ILMA group compared to the I-GEL group by mean difference of 8.20 secs ( 55% increase). This difference is true and significant and has not occurred by chance.

## **Inference**

In this study the mean duration for SGAD insertion was significantly and consistently lower in I-GEL group compared to the I-LMA group when used for ease of insertion .In other words ILMA needed 2.2 more time duration for SAD insertion compared to I-GEL based on statistically significant duration for SAD insertion distribution.

## NUMBER OF ATTEMPTS FOR ETT INSERTION



Number of Attempts for ETT Insertion - Groups	ILMA Group	%	I-GEL Group	%
No Attempt	3	10.00	0	0.00
One Attempt	22	73.33	1	3.33
Two Attempts	5	16.67	18	60.00
Three Attempts	0	0.00	8	26.67
> Three Attempts	0	0.00	3	10.00
<b>Total</b>	30	100	30	100
<b>P value</b>			<b>&lt;0.0001</b>	
<b>Fishers Exact Test</b>				

By conventional criteria the association between the intervention groups and number of attempts for ETT insertion is considered to be statistically significant since  $p < 0.05$ .

## **Results**

Majority of the ILMA group patients had 1 attempt for ETT insertion (n=22, 73.33%). In the I-GEL group patients, majority had 2 attempts for ETT insertion (n=18, 60.00%). The decreased number of attempts for ETT insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of  $<0.0001$  as per fishers exact test.

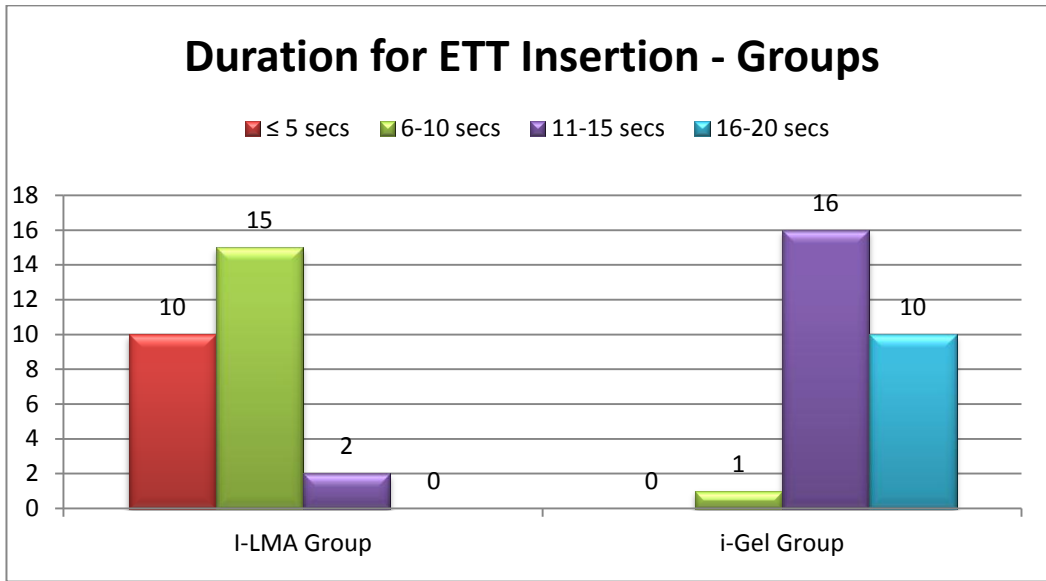
## **Discussion**

The incidence of ETT insertion on first attempt was meaningfully more in I-LMA group compared to the I-GEL group by percentage difference of 70.00 percentage points ( 95% increase). This difference is true and significant and has not occurred by chance.

## **Inference**

In this study the ETT insertion on first attempt was significantly and consistently lower in I-GEL group compared to the ILMA group when used as conduit for blind end tracheal intubation. In other words ILMA had 22 times more SAD insertion on first attempt success rate compared to I-GEL based on statistically significant number of attempts for ETT insertion status.

## DURATION FOR ETT INSERTION



Duration for ETT Insertion - Groups	ILMA Group	%	I-GEL Group	%
No Attempt	3	10.00	0	0.00
≤ 5 sec	10	33.33	0	0.00
6-10 sec	15	50.00	1	3.33
11-15 secs	2	6.67	16	53.33
16-20 sec	0	0.00	10	33.33
> 20 sec	0	0.00	3	10.00
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Duration for ETT Insertion	ILMA Group	I-GEL Group
Mean	5.90	12.90
SD	3.08	5.10
P value		<0.0001
Unpaired t Test		

By conventional criteria the association between the intervention groups and duration for ETT insertion is considered to be statistically significant since  $p < 0.05$ .

## **Results**

Majority of the ILMA group patients had 6-10 secs as duration for ETT insertion (n=15, 50.00%) with a mean of 5.90 secs . In the I-GEL group patients, majority had 11-15 secs as duration for ETT insertion (n=16, 53.33%) with a mean of 12.90 secs. The decreased mean duration for ETT insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of  $<0.0001$  as per unpaired t test.

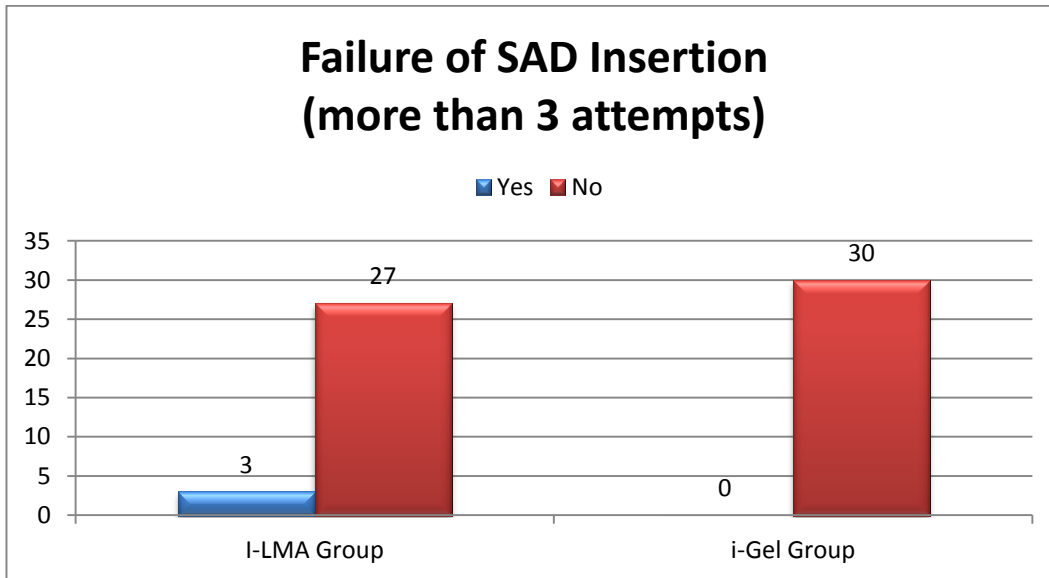
## **Discussion**

The mean duration for ETT insertion was meaningfully less in ILMA group compared to the I-GEL group by mean difference of 7.00 secs ( 54% decrease). This difference is true and significant and has not occurred by chance.

## **Inference**

In this study the mean duration for ETT insertion was significantly and consistently higher in I-GEL group compared to the ILMA group when used as conduit for blind end tracheal intubation. In other words I-GEL needed 2.19 more time duration for ETT insertion compared to ILMA based on statistically significant duration for ETT insertion distribution.

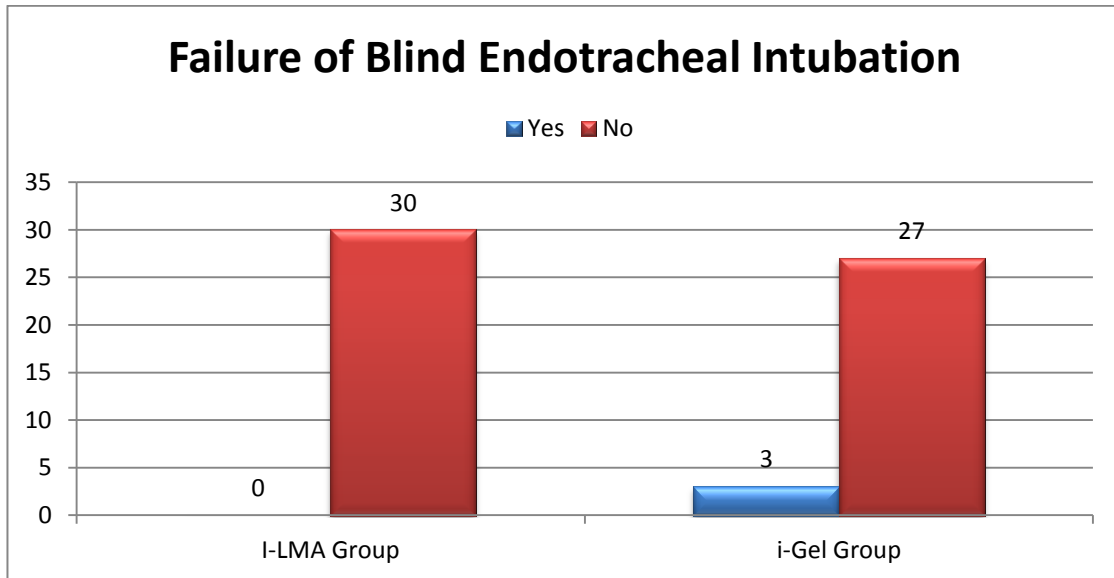
## Failure of SAD Insertion (more than 3 attempts)



Failure of SAD Insertion (more than 3 attempts)	ILMA Group	%	I-GEL Group	%
Yes	3	10.00	0	0.00
No	27	90.00	30	100.00
Total	30	100	30	100
P value			0.1186	
Fishers Exact Test				

Majority of the ILMA group patients belonged to failure of SAD less than three attempts status (n=27, 90.00%). In the I-GEL group patients, majority too belonged to failure of SAD less than three attempts status (n=30, 100.00%). The association between the intervention groups and Failure of SAD Insertion (more than 3 attempts) status is considered to be not statistically significant since  $p > 0.05$  as per chi squared test.

## Failure of Blind Endotracheal Intubation

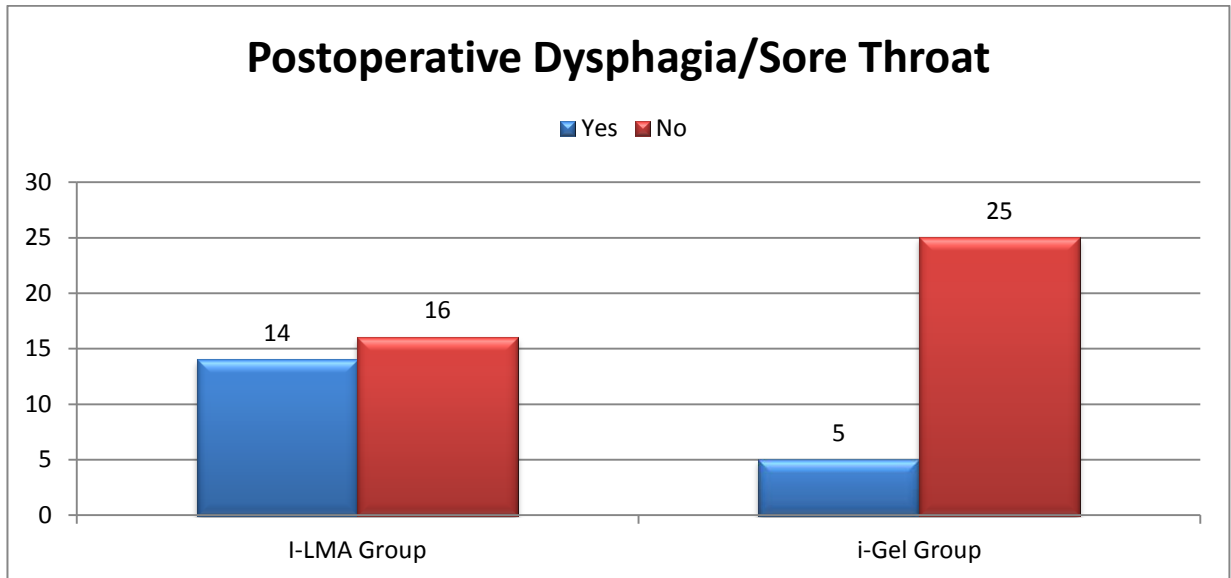


Failure of Blind Endotracheal Intubation	ILMA Group	%	I-GEL Group	%
Yes	0	0.00	3	10.00
No	30	100.00	27	90.00
<b>Total</b>	30	100	30	100
<b>P value</b>			0.1186	
<b>Fishers Exact Test</b>				

Majority of the ILMA group patients belonged to no failure of blind endotracheal intubation status (n=30, 100.00%). In the I-GEL group patients, majority too belonged to no failure of blind endotracheal intubation status (n=27, 90.00%). The association between the intervention groups and no failure of blind endotracheal intubation status is considered to be not statistically significant since  $p > 0.05$  as Fishers exact test.



## Postoperative Dysphagia/Sore Throat



Postoperative Dysphagia/Sore Throat	ILMA Group	%	I-GEL Group	%
Yes	14	46.67	5	16.67
No	16	53.33	25	83.33
<b>Total</b>	30	100	30	100
<b>P value</b>			<b>0.0125</b>	
<b>Fishers Exact Test</b>				

By conventional criteria the association between the intervention groups and postoperative dysphagia/sore throat status is considered to be statistically significant since  $p < 0.05$ .

## **Results**

Majority of the ILMA group patients had no postoperative dysphagia/sore throat (n=16, 53.33%). In the I-GEL group patients, majority had no postoperative dysphagia/sore throat (n=25, 83.33%). The increased incidence of postoperative dysphagia/sore throat in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of 0.0125 as per Fishers exact test.

## **Discussion**

The incidence of postoperative dysphagia/sore throat was meaningfully more in ILMA group compared to the I-GEL group by percentage difference of 30.00 percentage points ( 64% increase). This difference is true and significant and has not occurred by chance.

## **Inference**

In this study the incidence of postoperative dysphagia/sore throat was significantly and consistently lower in I-GEL group compared to the ILMA group when used for ease of insertion and as conduit for blind endo tracheal intubation.

In other words ILMA had 2.80 times more SGAD incidence of postoperative dysphagia/sore throat compared to I-GEL based on statistically significant postoperative dysphagia/sore throat status.

## **DISCUSSION**

Expertise in Airway management is a critical skill in the safe administration of anaesthesia<sup>6</sup>. For managing a difficult airway some of the pre requisites are

- 1} proper airway assessment
- 2} Meticulous selection of proper patient and proper preoperative optimization
- 3} Selection of well trained and experienced personnel in airway management
- 4} Equipments and devices for safe airway management .

The major factor in anaesthesia related morbidity is related to difficult mask ventilation and difficult intubation . Difficult tracheal intubation { successful intubation requiring more than 3 attempts or taking longer than 10 min } occurs in one to four percent of the population<sup>6</sup> .

Over the past few years there have been much focus on devices to decrease the problem of difficult airway and ventilation . The utmost problem is inability to oxygenate, ventilate or the combination of these factors . Over the past two decades there have been a search for equipment and devices for attenuating the problem of difficult oxygenation and ventilation<sup>6</sup> .

Supraglottic airway devices are one such innovation discovered and are helpful in difficult airways and in emergency life threatening situations .The use of supraglottic airway devices as a means of rescue in patients who are difficult to intubate or ventilate has increased in the field of anaesthesiology and emergency medicine.

These devices require

- 1} Less technical skills
- 2} Associated with less increase in intracranial pressure /intraocular pressure /intra gastric pressure
- 3} Has good device tolerance

Many studies were done to evaluate the efficacy of supraglottic airway devices as emergency rescue airway devices and also as conduit for blind or fiberoptic guided endotracheal intubation.

The present study was done to compare the supraglottic airway devices I-GEL and ILMA for ease of insertion to assess their ability to function as emergency rescue airway devices and also as a conduit devices for tracheal intubation in difficult intubation conditions

## **Demographic Data**

The demographic variables were similar in both groups and there were no statistically significant changes { $p > 0.05$  }

## **OTHER DATAS**

### **Supraglottic Airway Device {Sad }Ease Of Insertion And Number Of Attempts**

In the study conducted by Bhandari et al and Halwagi et al they demonstrated 100 percent success rate for both I-GEL and ILMA insertion, either in first or second attempt . With first attempt of SAD insertion, the successful ventilation rate was 95% In I-GEL group and in ILMA group it was 90% .It was 100 % in both the groups in the second attempt<sup>8</sup>

In this study, 70% of patients {21 patients } in I-GEL group got a score of 1 compared to 3.33% {1 patient} in ILMA group . 9 patients {30% } in I-GEL group got a score of 2 while 21 patients {53.3% } in ILMA group got the same score . score of 3 was given to 13 patients {43.3% } in ILMA Group while in I-GEL group no patients found to be difficult .Regarding the number of attempts in ILMA group only one patient {3.33% }was able insert in one attempt as compared to 19 patients {63.33% } in I-GEL group . 17 patients {56.67% } in ILMA group and 11 patients {36.67% } in I-GEL group were inserted in the second attempt . 9 patients {30 % } in ILMA group needed third attempt where as I-GEL group dint needed the third attempt . 3 patients {10 % } in ILMA

group needed more than three attempts .From these recordings and analysis it can be concluded that I-GEL was a better device for emergency rescue ventilation device when compared to ILMA since the data analysed using Fischers exact test and the p value derived was significant  $< 0.0001$  , in both criterias ie, ease of insertion and number of attempts<sup>8</sup>

### **Duration of insertion of supraglottic airway device:**

In the study conducted by Bhandari et al they concluded that the time for successful ventilation with I-GEL was 20.92 seconds and 31.75 seconds in ILMA group { $p < 0.001$  }. In my study only 4 patients 13.33 % needed less than 10 seconds for insertion while all other patients needed more than 10 seconds. In I-GEL group all patients {100 % } were inserted in less than 10 seconds. Thus it can be concluded from the above data and analysis I GEL was the better device for emergency rescue ventilation since the p value derived using unpaired t test was significant  $p < 0.0001$  .

### **Blind Endotracheal Intubation**

In the study conducted by Bhandari et al ,first attempt success rate for blind tracheal intubation was comparable in both the groups and overall success rate in second attempt was higher in i-gel group as compared to ILMA group, unlike the results of Halwagi et al (2012) and Sastre et al (2012) who noticed higher success rate of blind tracheal intubation with ILMA. Bhandari et al observed that time for successful intubation through I-GEL was 20.41 seconds and 30.68 seconds in ILMA group .

In my study 22 patients were intubated using ILMA in first attempt compared to only one patient in I-GEL . 5 patients in ILMA group needed second attempt and 18 patients in I-GEL group needed the same .8 patients in I-GEL group needed third attempt but that was not the case in ILMA group . 3 patients in ILMA group were not attempted intubation since the insertion of SAD took more than three attempts in these patients .In I-GEL group intubation failed in three patients . The p value derived using fishers exact test was significant  $< 0.0001$  . Also regarding the duration for intubation, 28 patients in ILMA group were intubated in less than 10 seconds only 2 patients needed more than 10 seconds . In I-GEL group only 4 patients were intubated in less than 10 seconds were as 23 patients needed more than 10 seconds . In 3 patients in I-GEL group intubation attempt failed . Thus it can be concluded that blind intubation using ILMA was better than I-GEL since the p value derived was also significant  $<0.0001$  using unpaired t test .

### **Failure Of Sad Insertion {More Than 3 Attempts}**

In the study by Bhandari et al, they demonstrated 100% success rate both for I-GEL and ILMA and there were no failures in each group .

In my study regarding SAD insertion only 3 patients in ILMA group needed more than 3 attempts and they were not attempted insertion and was considered as failure . In I-GEL group all 30 patients were inserted , either in the first or second attempt and thus no failures were recorded .Since the majority

in each group had successful SAD insertion, it can be concluded that the association between the intervention groups and Failure of SAD Insertion (more than 3 attempts) status is considered to be not statistically significant since  $p > 0.05$  as per chi squared test.

### **Failure Of Blind Endotracheal tube Intubation**

In the study by Bhandari et al and Halwagi et al both demonstrated a 100 % success rate for blind endotracheal intubation in either groups ie I-GEL and ILMA . This was done either in the first or second attempt using cricoid pressure in case of I-GEL and reverse orientation of the tube in case of ILMA .

In my study majority of the patients in either group I-GEL and ILMA were intubated except in case if I-GEL group where there was 3 failures , because these patients needed more than three attempts and also duration went past 20 seconds. .Since majority of the patients in both I-GEL and ILMA group were blindly intubated using SAD, it can be concluded that the association between the intervention groups and failure of blind endotracheal intubation status is considered to be not statistically significant since  $p > 0.05$  as per fishers exact test.

### **Postoperative Sore Throat ,Dysphagia , Hoarseness**

In the study by Bhandari et al there were no incidence of sore throat or dysphagia in either groups{1} . in study conducted by Keijer et al incidence of



sore throat was more in ILMA group . Sameer et al concluded that ILMA group had more incidence of dysphonia .

In my study 14 patients in ILMA group complained of sore throat , dysphagia etc whereas only 5 patients in I-GEL group complained so and the p value derived was significant  $p < 0.0125$  . By conventional criteria the association between the intervention groups and postoperative dysphagia/sore throat status is considered to be statistically significant since  $p < 0.05$  using Fishers exact test and it can be concluded ILMA has more chances of postoperative sorethroat and dysphagia.

## CONCLUSION

It can be safely concluded from above study results that I-GEL is a better emergency ventilatory device comparable to the study by Kleine-Brueggeney et al and ILMA as better conduit for blind endotracheal intubation comparable to the study by Halwagi et al and Sastre et al but unlike Bhandari et al<sup>5</sup>

## **SUMMARY AND CONCLUSION**

**TITLE :** A Prospective Comparative study of supraglottic airway devices I-GEL and ILMA for ease of insertion and as a conduit for blind endotracheal intubation<sup>9</sup> .

**KEYWORDS :** Supraglottic airway devices , I-GEL , ILMA , ease of insertion , blind endotracheal intubation .

**AIM :** This study is done to evaluate the efficacy of supraglottic airway devices I-GEL and ILMA as emergency ventilatory devices by comparing ease of insertion and as conduits for blind endotracheal intubation which can be used in difficult intubating conditions .

**METHODS :** 60 patients posted for surgical procedures under general anaesthesia. Patients fulfilling inclusion criteria were included in the study and were enrolled and analysed. Patients induced with appropriate Induction agents and Non depolarizing muscle relaxants and ventilated for 3 min prior to SAD insertion and again ventilated for one minute prior to blind ETT intubation

**Group A – ILMA ( 30 )** inserted after 3 min ventilation followed by blind ETT intubation

**Group B – I GEL (30)** inserted after 3 min ventilation followed by blind ETT intubation

Variables such as ease of insertion ,number of attempts and duration of insertion of SADS , number of attempts and duration of blind ETT insertion and postoperative sorethroat , dysphagia etc were compared.

The collected data were statistically analysed and tabulated .

## **RESULTS:**

The statistical analysis tools used in this study for the comparison of demographic variables , ease of insertion , number of attempts and duration of insertion of SAD , number of attempts and duration for ETT insertion ,failure and postoperative sorethroat and dysphagia were chi square test and fishers exact test . The p value derived for ease of insertion , number of attempts ,and duration of insertion of SGADS I-GEL and ILMA were  $p < 0.001$  favouring I-GEL . Likewise the p value derived for number of attempts and duration for ETT insertion through I-GEL and ILMA were  $p < 0.0001$  favouring ILMA . The p value derived for incidence of postoperative sore throat and dysphagia was  $p < 0.0125$  ,favouring I-GEL . It was concluded that from above results that I-GEL is a better device for emergency rescue ventilation because of its ease of insertion and lesser incidence of postoperative sore throat and dysphagia as compared to ILMA whereas ILMA is a better device for blind endotracheal intubation compared to I-GEL

## **CONCLUSION**

It can be safely concluded that I-GEL is easier to insert and a better airway device for emergency rescue ventilation compared to ILMA and ILMA is a better conduit for blind endotracheal intubation than I-GEL .

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## ANNEXURES

### **ETHICAL COMMITTEE APPROVAL CERTIFICATE**

**INSTITUTIONAL ETHICAL COMMITTEE**  
**GOVT. KILPAUK MEDICAL COLLEGE,**  
**CHENNAI-10**  
**Protocol ID, No. 16/2016 Dt: 23.01.2016**  
**CERTIFICATE OF APPROVAL**

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "Comparison of supraglottic airway devices, intubating LMA (LMA Fastrach) and F-GEL for ease of insertion and as conduit for blind endotracheal intubation" - For Project Work submitted by Dr.A Anand Savio, PG Student of MD (Anaesthesia), Govt. Kilpauk Medical College, Chennai-10.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

  
HEENA  
Govt. Kilpauk Medical College,  
Chennai - 10

## PROFORMA

### “COMPARISON OF SUPRAGLOTTIC AIRWAY DEVICES I-GEL AND ILMA FOR EASE OF INSERTION AND AS CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION”

Name: Age/Gender: IP Number:

Height: cm Weight: kg BMI:

Date of surgery:

ASA Physical status: Co morbidity: Drug history

**Group A** – ILMA ( 30 ) inserted after 3 min ventilation followed by blind ETT intubation

**Group B** – I GEL (30) inserted after 3 min ventilation followed by blind ETT intubation

#### ASSESSMENT CRITERIA (following parameters will be assessed)

S.NO:	CRITERIAS	GROUP A	GROUP B
1.	Ease of insertion of SAD based on subjective score Easy – score 1 Satisfactory – score 2 Difficult – score 3		
2.	Number of attempts for SAD insertion		
3.	Duration for SAD insertion		
4.	No: of attempts for ETT insertion		
5.	Duration of ETT insertion		
6.	Postoperative dysphagia, hoarseness of voice, sorethroat		

## PATIENT CONSENT FORM

Study Detail : **COMPARISON OF SUPRAGLOTTIC AIRWAY DEVICES, [ILMA] INTUBATING LMA AND I-GEL FOR EASE OF INSERTION AND AS CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION.**

Study centre : GOVT. KILPAUK MEDICAL COLLEGE HOSPITAL

Patients Name :

Patients Age :

Identification Number :

Patient may check these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving reason, without my legal rights being affected.

I Understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access.

However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well – being or any unexpected or unusual symptoms.

I hereby consent to participate in this study.

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests.

Signature/thumb Impression : Place

Patients Name and address : Date

Signature of investigator : Place

Study investigator's Name : Date

## சுய ஒப்புதல் படிவம்

### ஆய்வு செய்யப்படும் தலைப்பு

கீழ்பாக்கம் அரசு மருத்துவமனையில் அறுவை சிகிச்சை செய்துகொள்ளபோகும் நோயாளிகளுக்கு சுப்ராகிளாட்டி முச்சுகுழாய் சா தனங்களான ஐ ஜெல் ஐயும் இன்டுபேட்டிங் எல்எம்ஏ ஐயும் எந்த அளவு முச்சுகுழாயில் செலுத்த ஏதுவாக உள்ளது என்பதையும் அதன்வழியாக என்டோட்ரக்கியல்டியுப் செலுத்தவும் எவ்வாறு வசதியாக உள்ளது என்பதையும் அறுவைக்குபின் தொண்டை கரகரப்பு மற்றும் முழுங்குவதற்கு சிரமம் இருக்கிறதா ஆகியவற்றையும் ஒப்பிட்டு ஆய்வு

ஆராய்ச்சி நிலையம்: மயக்கவியல் மருத்துவத் துறை,

கீழ்ப்பாக்கம் மருத்துவக்கல்லூரி அரசு மருத்துவமனை, சென்னை

பங்கு பெறுபவரின் பெயர்:

உறவு முறை:

பங்கு பெறுபவரின் எண்:

பங்கு பெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களைக் கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.



நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.



இந்த ஆய்வு சம்மந்தமாகவும், மேலும் இது சார்ந்தஆய்வு மேற்கொள்ளும்போதும், இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்துகொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.



இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும், அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.



இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்துகொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறாக நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.



இந்த ஆய்வில் சுப்ராகிளாட்டி முச்சுகுழாய்   
சாதனங்களான ஐ ஜெல் ஐயும் இன்டுபேட்டிங் எல்எம்ஏ  
ஐயும் எந்த அளவு முச்சுகுழாயில் செலுத்த ஏதுவாக  
உள்ளது என்பதையும் அதன்வழியாக என்டோட்  
ரக்கியல்டியுப் செலுத்தவும் எவ்வாறு வசதியாக உள்ளது  
என்பதையும் அறுவைக்குபின் தொண்டை கரகரப்பு  
மற்றும் முழுங்குவதற்கு சிரமம் இருக்கிறதா  
ஆகியவற்றையும் ஒப்பிட்டு ஆய்வு குறித்து ஆராய்ச்சி  
செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் .....

இடம் ..... தேதி .....

கட்டைவிரல் ரேகை:

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

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ஆய்வாளரின் கையொப்பம் .....

இடம் ..... தேதி .....

ஆய்வாளரின் பெயர் .....



## INFORMATION TO PARTICIPANTS

Investigator :- Dr. A.AMALA SAVIO

Name of the participant :-

Title : **COMPARISON OF SUPRAGLOTTIC AIRWAY DEVICES, INTUBATING LMA [ILMA] AND I-GEL FOR EASE OF INSERTION AND AS CONDUIT FOR BLIND ENDOTRACHEAL INTUBATION**

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria.

### **What is the purpose of this research?**

In this study ease of insertion of supraglottic airway devices intubating LMA and I-GEL and their use as conduit for endotracheal intubation will be compared as they are useful in such situation for rescue ventilation when tracheal intubation fails

**Discomforts and risks:** Postop sore throat, cough, hoarseness of voice as a result of intubation can occur. But they can be managed effectively

### **Confidentiality:**

Patients who participated in the study and their details will be maintained confidentially and at any cost, those details will not be let out

### **Right to withdraw :**

Patients will not be forced to complete the study. At any cost, in such circumstances the treatment will not be compromised.

Date :

Signature of the investigator: -

Place :

Signature/Thumb impression

## MASTER CHARTS

## **KEY TO MASTER CHART**

ETT	:	ENDOTRACHEAL TUBE
SAD	:	SUPRAGLOTTIC AIRWAY DEVICE
LAP	:	LAPROSCOPIC
DUB	:	DYSFUNCTIONAL UTERINE BLEEDING
DHL	:	DIAGNOSTIC HYSTERO LAPROSCOPY
ORIF	:	OPEN REDUCTION AND INTERNAL FIXATION

## **ABBREVIATIONS**

ASA	-	American society of anaesthesiologists
ETCO2	-	Endtidal carbondioxide
ETT	-	Endotracheal tube
ILMA	-	Intubating laryngeal mask airway
NDMR	-	Non-depolarising muscle relaxants
SAD	-	Supraglottic airway device



**ILMA SUPRAGLOTTIC AIRWAY DEVICES (SAD)**

S.NO	NAME	AGE	SEX	ASA STATUS	weight IN KGS	HEIGHT IN CM	DIAGNOSIS	PROCEDURE	ANAESTHESIA	EASE OF INSERTION SUBJECTIVE SCORE	NO OF ATTEMPTS FOR SAD INSERTION	DURATION OF SAD IN SEC	NO OF ATTEMPTS ETT INSERTION	DURATION FOR ETT INSERTION (SEC)	FAILURE - SAD INSERTION YES / NO	POST OF DYSPHAGIA, SORETHROAT
1	sridevi	20	f	1	53	156	FIBROADENOMA	EXCISION	GA	2	2	12	1	4	NO	PRESENT
2	NAGARANI	34	F	2	60	152	1 INFERTILITY	DHL	GA	3	3	14	1	3	NO	PRESENT
3	JYOTHI	32	F	1	54	160	2 INFERTILITY	DHL	GA	2	2	9	1	5	NO	NIL
4	NAGAJOTHI	28	F	1	54	158	TUBERCULOUS ABSCESS	DHL	GA	3	>3	>20			YES	PRESENT
5	SEVATHA	38	F	1	62	150	1 INFERTILITY	DHL	GA	2	2	10	1	5	NO	PRESENT
6	BHAVANI	24	F	2	61	156	1 INFERTILITY	DHL	GA	3	3	15	1	4	NO	PRESENT
7	MADASAMY	33	M	1	70	164	SEROMA LEFT EAR	EXCISION	GA	3	3	18	1	5	NO	PRESENT
8	PALANIAMMAL	48	F	2	68	160	DUB	FRACTIONAL CURETTAGE	GA	2	2	14	1	4	NO	NIL
9	DEIVANAI	22	F	1	45	152	FIBROADENOMA	EXCISION	GA	2	2	12	1	5	NO	PRESENT
10	ARJUN	32	M	1	56	160	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	3	>3	>20			YES	PRESENT
11	LAKSHMI	43	F	1	58	156	DUB	FRACTIONAL CURETTAGE	GA	2	2	9	2	12	NO	PRESENT
12	SATHYA	23	F	1	54	153	FIBROADENOMA	EXCISION	GA	2	2	12	1	5	NO	NIL
13	UDHYABALU	55	M	1	65	166	LIPOMA NECK	EXCISION	GA	3	2	14	1	5	NO	NIL
14	BANUPRIYA	24	F	1	55	154	FIBROADENOMA	EXCISION	GA	2	2	12	1	6	NO	PRESENT
15	KARTHIK	20	M	1	56	158	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	1	1	6	1	6	NO	NIL
16	SAMSON	18	M	1	60	156	DERMOID CYST SCAPULA	EXCISION	GA	3	3	18	1	6	NO	PRESENT
17	SATHYAVAN	26	M	1	64	162	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	2	2	13	1	6	NO	NIL
18	DURAIRAJ	34	M	1	54	154	LIPOMA BACK	EXCISION	GA	3	3	18	2	10	NO	PRESENT
19	SELVARANI	22	F	1	61	160	FIBROADENOMA	EXCISION	GA	2	2	14	1	8	NO	NIL
20	GEETA	32	F	1	56	161	P2L2	DHL	GA	3	3	17	2	10	NO	PRESENT
21	MANI	26	M	1	58	166	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	2	2	14	2	10	NO	NIL
22	HEMALATHA	33	F	2	45	148	TUBERCULOUS ABSCESS	DIAGNOSTIC LAP	GA	2	2	12	1	13	NO	NIL
23	RADHIKA	23	F	1	45	152	FIBROADENOMA	EXCISION	GA	2	2	14	1	6	NO	PRESENT
24	ANANDRAJ	44	M	1	62	160	LIPOMA FACE	EXCISION	GA	3	>3	>20			YES	PRESENT
25	SIVARAJ	26	F	1	56	156	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	2	2	12	1	7	NO	NIL
26	SANGEETHA	22	F	1	45	152	FIBROADENOMA	EXCISION	GA	3	3	16	1	6	NO	PRESENT
27	RAJMOHAN	32	M	1	60	154	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	2	2	15	1	7	NO	NIL
28	SEETHALAXMI	24	F	1	54	148	FIBROADENOMA	EXCISION	GA	3	3	18	2	6	NO	PRESENT
29	MARIASELVAM	54	F	2	66	158	DUB	FRACTIONAL CURETTAGE	GA	3	3	18	1	7	NO	NIL
30	VEERASAMY	23	M	1	56	160	SUBACUTE APPENDICITIS	LAP APPENDICECTOMY	GA	2	2	16	1	6	NO	NIL