INTRODUCTION

Maintenance of airway is an integral part of general anaesthesia and is a vital aspect for providing adequate oxygenation and ventilation. Over the years general anaesthesia has undergone many advances. Management of the airway has come a long way since the development of endotracheal intubation to the present day usage of the supraglottic airway devices and other airway adjuncts[1].

Although tracheal intubation is the gold standard method for maintaining patent airway during anaesthesia yet it is associated with complications such as soft tissue trauma, dental injury, haemodynamic instability, oesophageal intubation, hypoxia and sore throat, as it requires laryngoscopy and manipulation of the vocal cords[2]. These complications are very common during endotracheal intubation especially in paediatric patients due to their unique airway features [2].

Laryngeal mask airway (LMA) is a suitable alternative to the facemask or to the tracheal intubation in a wide variety of clinical situations as it fits between facemask and endotracheal tube in terms of anatomical position and degree of invasiveness[3].

LMA has been well established in adult patients for more than a decade and is often used for management of unanticipated difficult intubation[2]. It is a key device at several places in American Society of Anaesthesiologist (ASA) algorithm for difficult airway[4].

Since then the classic LMA (cLMA) has revolutionized paediatric anaesthetic practice. It is widely used in routine anaesthesia for children and has also greatly

aided the management of children with difficult airway[5]. It has the largest safety evidence base and is the benchmark by which other devices should be evaluated[6]. Because of its ease of insertion and reduced trauma, LMA device has replaced ETT in many procedures[5].

The cLMA consists of an inflatable silicone mask and a connecting tube. It is inserted blindly into the pharynx, forming a low-pressure seal around the laryngeal inlet and permits gentle positive pressure ventilation (PPV).

Nevertheless, use of cLMA is limited due to various complications especially in paediatric patients. Seal achieved by cLMA provides less protection against pulmonary aspiration. The low pulmonary compliance requires peak inspiratory pressure greater than 20 cm H_2O which leads to gas leakage and gastric distention. It often functions poorly during intermittent positive pressure ventilation (IPPV). The cuff of the device is inflated to create seal which has potential to cause tissue distortion, venous compression and nerve injury[5].

The i-gel (Intersurgical Ltd, Wokingham, Berkshire, UK) is a recent novel supraglottic airway device designed to fit the peri-pharyngeal and hypolaryngeal structures without use of an inflatable cuff. It is made of a thermoplastic elastomer with a soft durometer which provides a seal in patients with wide range of anatomical variation. The i-gel is a single-use supraglottic airway device, which became available in CE marked paediatric sizes in March 2009 and was officially launched for use in January 2010[7].

The i-gel supraglottic device is known for easier insertion. The cuff is ‘anatomically shaped’ and the stem is elliptical in cross section to minimize axial

rotation which provides greater stability. It contains both airway and drainage tubes and an integral bite block. It is associated with minimal tissue compression and hence has established itself as one of the ideal supraglottic device in adults[7].

These advantages of the i-gel supraglottic airway could be ideal for its use in paediatric patients. There is lack of high quality data to evaluate the efficacy of supraglottic devices. The best evidence requires a randomized clinical trial comparing a new device against an established alternative, to detect clinically relevant differences in important outcomes[7].

Airway complications are more likely with use of smaller LMA devices namely size 1 and 1.5 and also, there are fewer studies in literature comparing efficacy of size 2 i-gel and cLMA[8, 9, 10].

Hence, we designed this study to compare the clinical efficacy of size 2 i-gel supraglottic airway and classic LMA to evaluate ease of insertion, airway sealing pressure, duration of insertion and complications in paediatric patients undergoing surgeries under general anaesthesia at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

AIMS & OBJECTIVES

The aims and objectives of the study were to compare the supraglottic airway devices, i-gel (size 2) and classic LMA (size 2) for

1. Ease of insertion,
2. Airway sealing pressure,
3. Duration of insertion
4. Any complications.

In paediatric patients posted for elective surgeries under general anaesthesia.

"ONE YEAR RANDOMIZED CLINICAL TRIAL TO COMPARE EFFICACY OF I-GEL SUPRAGLOTTIC AIRWAY AND CLASSIC LARYNGEAL MASK AIRWAY FOR EASE OF INSERTION IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA"

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ENDORSEMENT BY THE HOD/PRINCIPAL/ HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled "**ONE YEAR RANDOMIZED CLINICAL TRIAL TO COMPARE EFFICACY OF I-GEL SUPRAGLOTTIC AIRWAY AND CLASSIC LARYNGEAL MASK AIRWAY FOR EASE OF INSERTION IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA"** is a bonafide research work done by **REG NO. BA0111005.**

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LIST OF ABBREVIATIONS USED

ASA	-American Society of Anaesthesiologist
BP	-Blood Pressure
cLMA	-Classic laryngeal mask airway
cm	-Centimeter
CNS	-Central nervous system
CO_2	-Carbon dioxide
CVS	-Cardiovascular system
$etCO_2$	-End tidal carbon dioxide
ETT	-Endotracheal tube
FG	-French guage
GIT	-Gastrointestinal tract
H_2O	-Water
Hb	-Haemoglobin
i-gel	-Intersurgical
i.m	-Intramuscular
Inj.	-Injection
IPPV	-Intermittent positive pressure ventilation
IV	-Intravenous
Kgs	-Kilograms
LMA	-Laryngeal mask airway
Mcg	-Micrograms
Mg	-Milligrams
Min	-Minute
mL	-Millilitre

OGT	-Orogastric tube
OSP	-Oropharyngeal sealing pressure
PCV	-Pressure controlled ventilation
PLMA	-ProSeal laryngeal mask airway
PPV	-Positive pressure ventilation
PR	-Pulse rate
RR	-Respiratory rate
SAD	-Supraglottic airway device
Sec	-Seconds
SPO_2	-Saturation percentage of oxygen
URTI	-Upper respiratory tract infection

ABSTRACT

Introduction: Management of the airway has come a long way since the development of endotracheal intubation to the present day usage of supraglottic airway devices. The classic LMA (cLMA) has revolutionized paediatric anaesthetic practice. The i-gel is a recent novel supraglottic airway device designed to fit the pharyngeal, laryngeal and perilaryngeal structures without use of an inflatable cuff. Hence, we designed this study to compare the clinical efficacy of i-gel (size 2) and classic LMA (size 2) for ease of insertion, airway sealing pressure, duration of insertion and complications in paediatric patients posted for elective surgeries under general anaesthesia.

Methodology: The present randomized clinical trial was conducted in 80 ASA I and II paediatric patients aged between 1-6 years, weighing 10 to 20 Kgs posted for surgeries under general anaesthesia in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. Patients were allocated into two equal groups, Group A. classic LMA (n=40) and Group B. i-gel (n=40). All the data collected were analysed. The demographic data, duration of insertion and airway seal pressure were analysed using unpaired‘t’ test. Sex and complications were compared using chi square test. Ease of insertion was analysed using fisher exact test.

RESULTS: In our study, insertion was very easy in 26 patients in group cLMA and 31 patients in group i-gel, easy in 13 patients in group cLMA and 9 patients in group i-gel. Difficult insertion was seen in 1 patient in group cLMA. These differences are not statistically significant (p=0.323). The mean duration of insertion was 20.85$\pm$3.26 sec in group cLMA and 20.17$\pm$2.43 sec in group i-gel,

which is not significant (p=0.298). The mean airway sealing pressure was 21.52±1.43 in group cLMA and 27.1±1.19 in group i-gel which is statistically significant **(**p<0.001**).** No significant complications were noted in both groups.

CONCLUSIONS: The i-gel (size 2) is easier to insert, provides a higher airway sealing pressure compared to cLMA and hence can be safely used in paediatric patients.

KEYWORDS: i-gel supraglottic airway, classic LMA, paediatric

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF PHOTOGRAPHS

REVIEW OF LITERATURE

Airway management during general anaesthesia has been dominated by the face mask and tracheal intubation. When a facemask is used, gap between base of tongue and glottis is not bypassed. This may cause obstruction during anaesthesia when tone of the upper airway muscles decrease and there is loss of patent airway. Tracheal intubation secures airway and bypasses this problem compared to ventilation by face masks[11]. But, tracheal intubation requires use of laryngoscope and muscle relaxation for direct vision, which is associated with various complications such as accidental extubation, tissue damage, endobronchial intubation, post intubation stridor and tube blockage[1]. These complications are more frequent in paediatric patients[12].

Supraglottic airway devices (SAD) are widely used as an alternative to tracheal intubation for surgeries requiring general anaesthesia. SADs are indicated for securing and maintaining airway for general anaesthesia in patients during spontaneous or controlled ventilation. They offer many advantages namely, rapid access to airway, do not require laryngoscope or neuromuscular blocking agents for insertion and are tolerated in lighter planes of anaesthesia[9]. Additional benefit is its use as rescue device and fibreoptic conduit when intubation is difficult or unsuccessful[13].

The laryngeal mask airway (LMA) is now the most widely used supraglottic airway device in anaesthesia.It was designed by Archie Brain in 1981 and came into clinical practice in 1988. It is designed to be inserted blindly into the pharynx and it forms a seal around the laryngeal inlet. Classic LMA is considered as the benchmark against which all other SADs must be judged[9].

Since its inception, cLMA has revolutionized paediatric anaesthetic practice. It is widely used in routine anaesthesia for children and has also greatly aided the management of children with difficult airway[11].

The LMA has undergone various modifications to suit different airway situations. First generation devices such as cLMA, flexible LMA and LMA-Unique are simply 'airway tubes' whereas, second generation devices such as LMA ProSeal, LMA Supreme and i-gel airway incorporates specific design features to improve safety by protecting against regurgitation and aspiration[9].

Jamil SN et al in a study, compared use of LMA with endotracheal intubation in children. They studied 100 ASA I and II children weighing 10-20 kg for efficacy of LMA in children during PPV, its haemodynamic changes and postoperative complications compared to endotracheal intubation. LMA was placed in first attempt in 94% cases, 4% required second attempt and 2% required third attempt. PPV was effective in 98% of the patients. The haemodynamic response to LMA insertion was much less and minimal changes in pulse rate and blood pressure upon insertion was noted as no laryngoscopy was required. So, they concluded that the LMA is a suitable alternative to endotracheal intubation for elective surgical procedures in paediatric patients as it provides a satisfactory airway for PPV in paediatric patients[5].

Nevertheless, use of cLMA in paediatric patients is associated with many complications. Airway seal of cLMA does not protect the airway against risk of aspiration especially during PPV and can lead to gas leakage and gastric distension. Also, cuff of the device has potential risk of tissue distortion, venous compression and nerve injury[6].

The i-gel is a relatively new supraglottic airway device which creates non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures which avoids compression trauma that can occur due to supraglottic airway devices with inflatable cuff. It became available in CE marked paediatric sizes in March 2009 and was officially launched for use in January 2010[7].

In an observational evaluation of i-gel in 50 paediatric patients, **Beylacq L et al** studied ease in inserting i-gel, seal pressure, gastric leak, any complications, ease in inserting gastric tube and ventilatory parameters during PPV. All devices were inserted at the first attempt and the mean seal pressure was 25 cm H_2O. These results were similar to other studies concerning laryngeal mask airway in terms of leak pressure and complications rate. They concluded that i-gel has good insertion success rate and very few complications and seems to be an efficient and safe device for paediatric airway management.[14].

In a similar evaluation of paediatric i-gel airway during anaesthesia in 120 children weighing between 5 and 35 Kgs, **Beringer RM et al** studied proportion of children in whom the i-gel could be inserted without complications, to establish clear airway and enabling spontaneous and controlled ventilation. They reported that insertion and subsequent ventilation was successful on the first attempt in 110 children (92%), the second attempt in eight children (7%) and the third attempt in one child. Median insertion time was 14-16 sec and following successful insertion, all 119 children (100%) had adequate chest movement and stable oxygen saturations. So, they concluded that i-gel was inserted without complications, establishing a clear airway for spontaneous and controlled ventilation in 113 children and proved to be an effective supraglottic airway device for use in children[7].

In a randomized trial comparing the i-gel with the LMA classic in children undergoing general anaesthesia, **Lee JR et al** concluded that the insertion time for the i-gel was significantly shorter than that for the LMA classic although ease of insertion did not differ between the two groups and both devices were inserted without any difficulty (grade I) in 78% and 76% of children respectively. The i-gel provided a better view of the glottis compared with cLMA, good fibreoptic view (grade I and II) of glottis was obtained in 74% of the i-gel group and 43% of cLMA group, $p < 0.001$. Also, it is associated with few complications in children.The median oropharyngeal leak pressure was 20 cm H_2O, similar with both devices.This study demonstrates that i-gel is an effective device for use in children[15].

In a similar study comparing i-gel with classic LMA in anaesthetized paralysed children undergoing elective surgery, **Das B et al** concluded that haemodynamic parameters, ease of insertion and postoperative complications were comparable between the i-gel and cLMA groups, but airway sealing pressure was 26.1 ± 2.4 and 22.64 ± 2.2 cm H_2O for i-gel and cLMA groups respectively, $p<0.05$ which was significantly higher in the i-gel group. Hence, size 2 i-gel is equally safe, efficient and cost effective in children compared to other prototypical paediatric supraglottic airway devices with added advantage of gastric channel. So, i-gel can be used in children in both elective surgeries and procedures outside operating room[16].

In study to compare three supraglottic devices, size 2 i-gel with cLMA and PLMA of same size in 90 children weighing 10-20 Kgs, posted for elective surgeries in anaesthetised paralysed children, **Das B et al** concluded that size 2 i-gel is comparable to PLMA and cLMA of same size in terms of haemodynamic parameters, ease of insertion and postoperative complications. OSP was significantly higher in i-

gel group (27.1±1.69 cm H_2O) compared to PLMA and cLMA groups,respectively (22.73±1.44, 23.63±1.35). Hence, size 2 i-gel is equally safe, efficient and cost effective in children compared with other paediatric supraglottic airway devices[17].

In an another study, **Jagannathan N et al** compared i-gel and laryngeal mask airway supreme in 170 children,aged 3 months to 11 years and 5-50 Kgs in weight for airway leak pressure, ease and time of insertion, insertion success rate, fibreoptic grade of view, ease of gastric tube placement, number of airway manipulations, quality of airway during maintenance and complications, concluded that the median airway leak pressure for i-gel was higher than LMA supreme (20 cm H_2O vs 17 cm H_2O, p= 0.001) in infants and children but there was no difference in the time for device insertion, fibreoptic grade of view, quality of airway and complications. Hence, i-gel can be a useful alternative to the LMA supreme in children[18].

A study comparing efficacies of i-gel and LMA ProSeal for airway management in paediatric patients by **Torgoz O et al** to compare airway leakage pressure, insertion time, fibreoptic laryngeal image scores, ease of insertion and possible complications between these groups. They concluded that i-gel group showed significantly higher airway leakage pressures compared to ProSeal group (28±5 vs 20±4 cm H_2O, $p<0.01$). The overall insertion success rate was 95% for i-gel group and 94% for ProSeal group but there was no statistically significant differences with regard to ease of insertion, p=0.97. Hence, i-gel is an effective and safe alternative supraglottic airway device for use in children[2].

In a study, **Uppal V et al** compared i-gel with cuffed tracheal tube for gas leaks during pressure-controlled ventilation. They concluded that there was no statistically significant difference between the leak fractions of the i-gel and the

tracheal tube at 15 and 20 cm H_2O PCV. So, i-gel can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures[19].

In a study to compare postoperative throat and neck complaints after use of the i-gel versus the traditional laryngeal mask, **Sardi et al** studied 121 patients with general anaesthesia administration and measured postoperative sore throat, cervical pain and dysphonia, number of attempts and pressure in airway tract. They concluded that the i-gel laryngeal mask demonstrated to be a safe issue, with low incidence of morbidity to administered general anaesthesia and good profile to decrease important complications like the postoperative odynophagia and cervical pain[20].

Hence, with obvious benefits of i-gel observed in the literature an attempt is made to compare clinical efficacy of the devices, size 2 i-gel with similar size cLMA to evaluate ease of insertion, airway sealing pressure, duration of insertion and any complications in paediatric patients posted for elective surgeries under general anaesthesia.

METHODOLOGY

The present study titled **"One year randomized clinical trial to compare efficacy of i-gel supraglottic airway and classic laryngeal mask airway for ease of insertion in paediatric patients undergoing general anaesthesia**" was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2012 to December 2012.

A total of 80 ASA I and II paediatric patients, aged 1 to 6 years and weighing 10 to 20 Kgs posted for elective surgeries under general anaesthesia were included in the study.

Inclusion criteria

- ASA grade I and II
- Body weight between 10 to 20 Kgs
- Elective surgeries of less than 1 hour duration under general anaesthesia in supine position.

Exclusion Criteria

- Known or predicted difficult airway
- Any pathology of the neck, upper respiratory tract or upper gastrointestinal tract
- Surgeries requiring trendenlenburg's position
- History of lung diseases
- Potentially full stomach patients.

Sample size

Sample size was calculated using the results of previous similar studies and substituting the values in below stated formula:

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

Taking the level of significance at 5% (α=0.05) and power of the test as 80% (β=0.2), $\overline{x_1}$= 6.6 and $\overline{x_2}$ = 0.1, Zα=1.96 and Zβ=0.84, sample size of 40 was obtained in each group.

After obtaining the approval from the hospital ethical committee, patients were allocated in a randomized manner by opening a computer generated 'sealed envelope' method into two groups of 40 each, Group A. classic LMA (size 2) and Group B. i-gel (size 2).

Procedure

An informed and written consent was obtained from the parents of all the patients during pre-anaesthetic check up one day prior to the surgery. A meticulous history and a thorough clinical examination including airway assessment were carried out and following investigations were done.

1. Complete blood count
2. Routine urine examination
3. Blood urea and serum creatinine
4. Chest X-ray, if necessary

All the patients were pre-medicated with i.m. ketamine (5mg/kg) and glycopyrrolate (0.01mg/kg) before shifting the patient to operating room.

In the operating room, a standard anaesthesia protocol was followed. Routine monitoring was done with electrocardiograph, non-invasive blood pressure, pulse oximetry (SPO_2) and end tidal CO_2 ($etCO_2$). The head and neck of the patient was placed in the sniffing position with the occiput rested on a firm pillow 5 cm in height.

The airway device to be used was prepared for insertion and its dorsal surface lubricated with a clear, water based gel, with the cuff completely deflated in case of classic LMA. Size 2 device was used for both the cLMA and i-gel.

An intravenous (IV) access was established. All the patients were preoxygenated with 100% oxygen for 3 minutes. Anaesthesia was induced with midazolam 0.05 mg/kg, fentanyl 2 mcg/kg, propofol 2 mg/kg and additional boluses of 1-2mg/kg, if required. After cessation of spontaneous respiration, patient's lungs were ventilated with 100% oxygen using a face mask until sufficient depth of anaesthesia, indicated by easy up and down movement of the lower jaw and no reaction to pressure applied to both angles of mandible. Then, the airway devices i-gel (size 2.0) or cLMA (size 2.0), were inserted in strict accordance with the manufacturer's recommendations by senior anaesthesiologist with more than 3 years of experience of LMA usage.

The insertion technique for LMA Classic and i-gel supraglottic airway included neck flexion, head extension, full deflation of the cuff, in case of classic LMA and the use of the index finger to press the device into and advance it around

the palatopharyngeal curve. A slight lateral approach was used if resistance was felt in the oropharynx.

Successful placement of the device was assessed by adequate chest expansion, absence of audible leak and lack of gastric insufflation (by epigastric auscultation) and square wave capnography.

Failed insertion was defined by any of the following criteria.

1. Failed passage into the pharynx
2. Malposition (air leaks)
3. Ineffective ventilation (maximum expired tidal volume <6 ml kg-1 or/and etCO_2>60 cm of H_2O).
4. More than 3 attempts

If the device could not be successfully inserted as defined above, the patient's trachea was intubated conventionally and was excluded from the study.

The ease of insertion was defined as:

- Very easy- airway manipulation not required
- Easy - jaw thrust by assistant
- Difficult- jaw thrust and deep rotation or second attempt used for proper insertion

The duration of insertion was defined as the time between picking up the prepared i-gel supraglottic airway or LMA classic and successful placement was obtained.

Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 liter min-1, and noting the airway pressure in the anaesthetic breathing system at equilibrium (maximum allowed was 40 cm H_2O) using manometer.

For LMA classic, the intra cuff pressure was set at 60 cm H_2O to obtain an effective airway seal for positive pressure ventilation. Anaesthesia was maintained with 50:50 oxygen-nitrous oxide mixture and sevoflurane (1%) on spontaneous respiration.

The presence/absence of oropharyngeal air leaks (detected by audible leak over the mouth), gastric air leaks (detected by auscultating over the epigastrium) were noted. Any adverse events like laryngospasm, bronchospasm, and hypoxia were recorded.

Data about ease of insertion, airway sealing pressure, duration of insertion and any complications during insertion were noted and recorded.

At the end of the surgery, anaesthetic agents were discontinued and the devices were removed after the child was awake and the return of the protective airway reflexes. Any adverse events like hypoxia, laryngospasm, bronchospasm and any occult/visible blood on the device were noted.

Statistical Analysis: All the data collected were analysed. The demographic data, duration of insertion and airway seal pressure are analysed using unpaired‘t’ test. Sex and complications are compared using chi square test. The ease of insertion is analysed using fisher exact test. Data are mean and standard deviation unless otherwise specified. Significance is taken as p value <0.05.

BASIC SCIENCES

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

MOUTH: The roof of the mouth is formed of anterior 2/3 hard palate and posterior 1/3 soft palate. Adequate mouth opening is essential for SAD placement. Hard palate is shaped such that food is directed into oropharynx with soft palate shielding the nasopharynx. SAD may be difficult to pass into oropharynx if angle of approach between the hard palate and posterior oropharyngeal wall is less than 90 degrees.

OROPHARYNX: SAD passes through the oropharynx to enter the laryngopharynx. It lies directly posterior to the oral cavity and it extends from below the soft palate to the upper border of the epiglottis.The posterior wall consists of the prevertebral fascia and the bodies of the second and third cervical vertebrae. The lateral walls contain the paired tonsillar fossae which are formed by the palatoglossal and palatopharyngeal folds and contain the palatine tonsils. If the palatine tonsils are grossly enlarged it may impede the passage of SAD into the oropharynx. Medial to the tonsillar fauces lies the base of the tongue. The tongue base is anterior to the laryngeal inlet and attaches to the epiglottis by the paired lateral glossoepiglottic folds and by the single median glossoepiglottic fold. Glossoepiglottic folds bind two spaces, the epiglottis and the valleculae.

LARYNGOPHARYNX AND HYPOPHARYNX: It extends inferiorly from the upper edge of the epiglottis to the inferior edge of the cricoid cartilage and communicates with the oropharynx, the laryngeal inlet and the oesophagus. A small pyriform fossa

lies on each side of the laryngeal inlet, bounded medially by the aryepiglottic folds and laterally by the thyroid cartilage and thyrohyoid membrane.

NEUROVASCULAR CONSIDERATIONS: There is risk of compression of several nerves and blood vessels within the tissues of the oropharynx due to malposition or over inflation of the cuff of laryngeal mask[22]. Lingual artery at the base of the tongue, the glossopharyngeal nerve between the superior and middle constrictor muscles, recurrent laryngeal nerve deep to the border of the inferior constrictors and the lingual nerve below the inferior border of the superior constrictor against the periosteum of the mandible posterior to the third molar are the most common structures at risk of cuff related complications.

PHYSIOLOGICAL IMPLICATIONS[23]:

CARDIOVASCULAR SYSTEM: Insertion of the SAD is associated with only 0-20% rise in blood pressure and heart rate in paediatric patients. SAD can be inserted in the lighter planes of anaesthesia.

RESPIRATORY SYSTEM: Airway complications such as laryngospasm, bronchospasm, trauma and sore throat are less frequent with supraglottic airway than with endotracheal intubation. The SAD causes minimal triggering of the lung defences as there is no airway manipulation[22]. It has been seen that paediatric patients with URTIs have improved oxygen saturation compared with endotracheal intubation.

INTRACRANIAL PRESSURE: Use of SAD as a conduit to endotracheal intubation in patients undergoing neurosurgery, had a minimal effect on the intracranial pressure during insertion.

GASTROINTESTINAL SYSTEM:

THE SWALLOWING REFLEX: Insertion of the SAD in lighter planes of anaesthesia triggers variety of protective and digestive reflexes including coughing, gagging, retching, swallowing and hypersalivation. With increasing depth of anaesthesia, these reflexes are suppressed to a varying degree. Impact of SAD tip with the glottis results in coughing, but it may also occur due to irritation of the glottic opening by the secretions as supraglottic airway is inserted.

SAD insertion is successful as a blind technique as it utilizes normal existing physiological mechanism of swallowing to follow natural curve and the direction of the upper airway with inserting finger to guide LMA in the oral cavity. However, swallowing reflex is suppressed for insertion and tolerance of the LMA in the oral cavity.

OESOPHAGUS: The insertion and presence of mask in the pharynx involve various upper gastrointestinal tract reflexes. The pharynx contains mechanoreceptors and chemoreceptors, which play important role in triggering the primary peristaltic wave of deglutition. However, inappropriate stimulation of these trigger zones may produce a less coordinated response such as secondary peristalsis which lacks coordination of primary peristalsis and can result in relaxation of lower oesophageal sphincter without immediate restoration of the tone of the sphincter.

PHARYNGEAL MUCOSA: The inflated cuff causes compression of the pharyngeal mucosa and tissue trauma. No major pharyngeal trauma has been associated with supraglottic airway insertion and airway complications are less as compared to the endotracheal intubation[24].

A very rare complication mentioned in literature is the theoretical risk of ischemia of the pharyngeal mucosa produced by the pressure of the mask over it. This can be avoided by keeping cuff pressure values under 44 mm Hg, which is the perfusion pressure of the capillaries of pharynx.

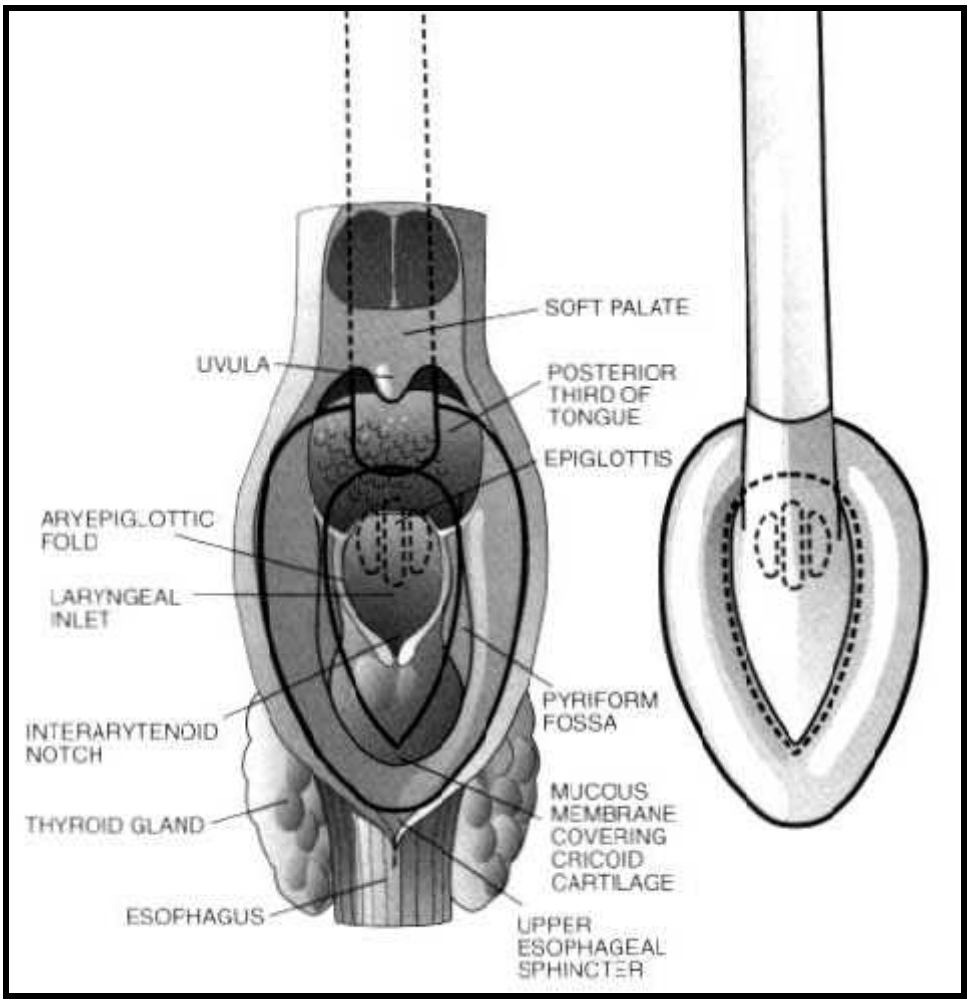


***Figure 1**: Schematic representation of position of **LMA** in hypopharynx*

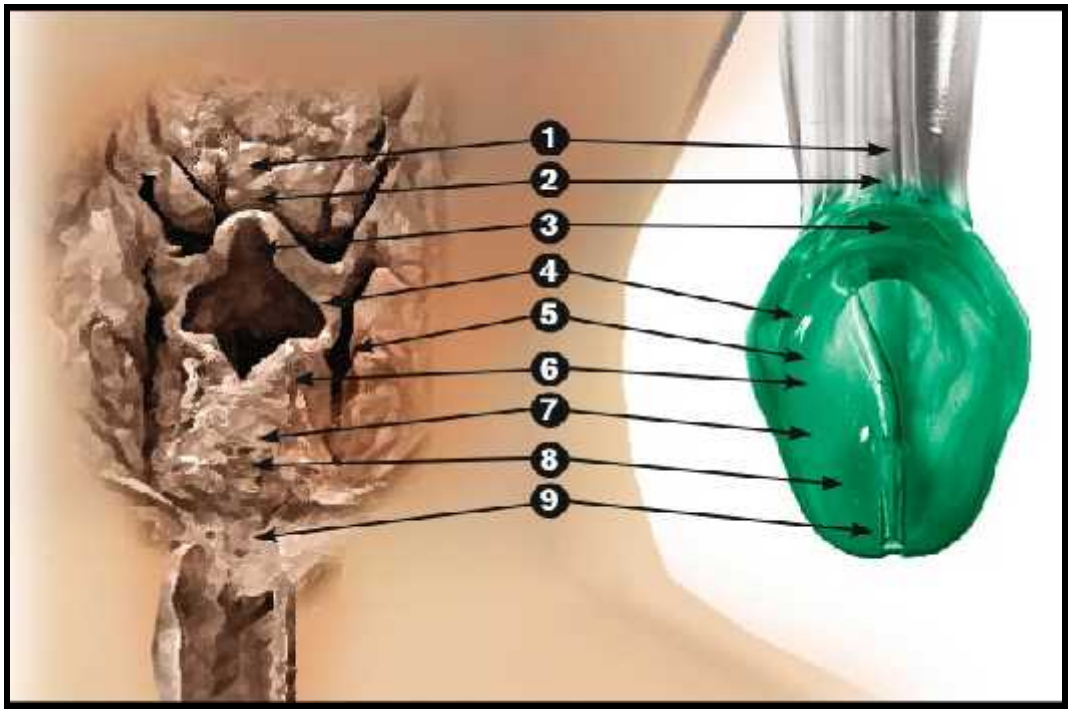


Figure 2: *View of the* **i-gel** *cuff in relation to the laryngeal framework*

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

I-GEL AIRWAY[25]:

The i-gel (Intersurgical Ltd, Wokingham, Berkshire, UK) is novel and innovative single use supraglottic airway management device designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures whilst avoiding the compression trauma that can occur with inflatable supraglottic airway devices.

CHARACTERISTICS OF I-GEL AIRWAY DESIGN ARE:

- It is made of thermoplastic elastomer, which is soft, gel-like and transparent to create a non-inflatable anatomical seal over laryngeal framework providing a reliable perilaryngeal seal.
- An anatomical device, which achieves a mirrored impression of the pharyngeal, laryngeal and perilaryngeal structures.
- It causes minimal compression or displacement trauma to the tissues and structures in the vicinity.
- It is latex free, sterile, single patient use device
- The buccal cavity stabiliser has a widened, elliptical, symmetrical and laterally flattened cross sectional shape, providing good vertical stability and axial strength upon insertion.
- It has an integrated gastric channel that can provide an early indication of regurgitation, facilitates venting of gas from the stomach and allows for the passing of a nasogastric tube to empty the stomach contents.
- It has an artificial epiglottis and a protective ridge which helps to prevent the epiglottis from down folding or obstructing the distal opening of the airway

I-GEL AIRWAY SELECTION GUIDELINES

TABLE 1: Following are the guidelines for selections of sizes of i-gel airway

SIZE	PATIENT WEIGHT (Kgs)	MAXIMUM SIZE ENDOTRACHEAL TUBE (mm)	MAXIMUM SIZE OROGASTRIC TUBE (FG)
1	2-5	3.0	N/A
1.5	5-12	4.0	10
2	10-25	5.0	12
2.5	25-35	5.0	12
3	30-60	6.0	12
4	50-90	7.0	12
5	>90	8.0	14

PRE-INSERTION PREPARATION

- Wear gloves
- Open i-gel package and take out protective cradle containing the device
- Remove i-gel and transfer it to the palm of the same hand that is holding the protective cradle, supporting the device between the thumb and index finger. Place water based lubricant onto middle of the smooth surface of the cradle in preparation for lubrication.
- Grasp the i-gel with free hand along the integral bite block and lubricate the back, front and the sides of the cuff with a thin layer of lubricant. Avoid touching the cuff of the device with your hands.
- Place the i-gel back into the cradle in preparation for insertion.
- The cradle is not an introducer and must never be inserted into the patient's mouth.

INSERTION TECHNIQUE

- Grasp the lubricated i-gel firmly along the integral bite block. Position the device so that the i-gel cuff outlet is facing towards the chin of the patient.
- Patient should be in sniffing position with head extended and neck flexed. The chin should be gently pressed down before proceeding to insert the i-gel.
- Introduce the leading soft tip into the mouth of the patient in a direction towards the hard palate.
- Glide the device downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt.

- It is not necessary to insert fingers or thumbs into the patient's mouth during the process of inserting the device.
- If there is early resistance during insertion a 'jaw thrust', 'insertion with deep rotation' or 'triple maneuver' is recommended.
- At this point the tip of the airway should be located into the upper oesophageal opening and the cuff should be located against the laryngeal framework. The incisors should be resting on the integral bite-block.
- The i-gel should be taped down from 'maxilla to maxilla'.

PRECAUTIONS AND STEPS TO FACILITATE VENTILATION

- Optimal depth of anaesthesia must be achieved prior to attempting insertion (i.e. absence of eyelash reflex, easy up and down movement of the lower jaw, no reaction to pressure applied to both angles of the mandible)
- After insertion, connect to anaesthesia circuit and check for leaks from the drain tube and airway tube
- Excessive air leak during manual ventilation is primarily due to sub-optimal depth of anaesthesia or sub-optimal depth of i-gel insertion.
- Verify position of the bite block
- Do not allow peak airway pressure of ventilation to exceed 40 cm H_2O.
- Do not leave the device in situ for more than 4 hours.
- After insertion, i-gel should be taped down from maxilla-to-maxilla.

INDICATIONS:

- For securing and maintaining a patent airway in routine and emergency anaesthetics for operations for fasted patients during spontaneous or intermittent positive pressure ventilation (IPPV).
- The i-gel may also be beneficial in establishing patent airway during resuscitation of the unconscious patient in pre-hospital or intra-hospital setting and advanced life support techniques.

OTHER POTENTIAL APPLICATIONS:

- Use by the ambulance crew in difficult or unexpectedly difficult intubations in a pre-hospital setting in order to quickly establish and maintain a clear airway.
- Securing a clear airway in difficult or unexpectedly difficult intubations in airway management of a patient in the operating theatre.
- In a known difficult or unexpectedly difficult intubation, for intubating the patient, by passing an endotracheal tube (ETT) through the device under fibre-optic guidance.
- In a difficult or unexpectedly difficult intubation, to pass a gum-elastic bougie blindly, but gently, through the device whilst in-situ, into the trachea and to rail-road the ETT over it.
- In the Intensive Care patient, for weaning a certain category of the population, in whom an endotracheal tube is not well tolerated.
- In difficult mouth opening situations, i-gel can also be inserted under direct vision with the help of a laryngoscope.

CONTRAINDICATIONS:

- Full stomach patients for routine and emergency anaesthetic procedures
- Patients with an ASA or Mallampati score of III or above
- Trismus, limited mouth opening, pharyngo-perilaryngeal abscess, trauma or mass.
- Inadequate levels of anaesthesia which may lead to coughing, bucking, excessive salivation, retching, laryngospasm or breath holding thus complicating the anaesthetic outcome.
- Procedures requiring device in situ for more than 4 hours.
- Patients with any condition which may increase the risk of a full stomach e.g. hiatus hernia, sepsis, morbid obesity, pregnancy or a history of upper gastro-intestinal surgery etc.
- As with all supraglottic airway devices, particular care should be taken with patients who have fragile and vulnerable dental work, in accordance with recognized airway management practices and techniques.

***Figure 3**: i-gel supraglottic airway*

CLASSIC LMA[26]:

The Classic LMA was introduced by Dr. Archie brain in the United Kingdom, which became available in 1989. The classic LMA has a well-established role in the management of patients with normal and difficult to manage airways. Although originally developed for airway management of routine cases with spontaneous ventilation, it is now listed in ASA difficult airway algorithm in 5 different places as an airway (ventilatory device) or a conduit for endotracheal intubation.

CHARACTERISTICS OF CLASSIC LMA DESIGN ARE[27]:

- Classic LMA is made of medical grade silicone and is latex free.
- It has 3 main components of the classic LMA: an airway tube, mask and mask inflation line.
- The airway tube (shaft) is curved and connected to an elliptical spoon shaped mask at a 30 degree.
- An inflatable cuff surrounds the inner rim of the mask
- An inflation tube and self-sealing pilot balloon are attached to the proximal wider end of the mask.
- Two flexible vertical bars where the tube enters the mask prevents the tube from being obstructed by the epiglottis.
- It is to be discarded after 40 autoclaving.

CLASSIC LMA SELECTION GUIDELINES

TABLE 2: Following are the guidelines for selections of sizes of cLMA

SIZE	PATIENT WEIGHT (Kgs)	MAXIMUM INFLATION VOLUME (ml)	MAXIMUM SIZE OROGASTRIC TUBE (ID in mm)	LARGEST FIBRESCOPE THAT CAN FIT INTO TRACHEAL TUBE (OD in mm)
1	Up to 5	4	3.5	2.7
1.5	5-10	7	4.0	3.0
2	10-20	10	4.5	3.5
2.5	20-30	14	5.0	4.0
3	30-50	20	6.0 cuffed	5.0
4	50-70	30	6.0 cuffed	5.0
5	70-100	40	7.0 cuffed	5.0
6	Over 100	40	7.0 cuffed	5.0

INSERTION METHODS

Classic LMA may be inserted using anyone of the following techniques

1. Standard index finger insertion technique
2. 180-degree technique
3. Partial inflation technique
4. Thumb insertion technique

STANDARD INDEX FINGER INSERTION TECHNIQUE

Classic LMA is inserted using standard technique in midline or slightly diagonal approach with cuff fully deflated. The head should be in sniffing position and non-inserting hand should be used to stabilize the occiput. The tube portion is grasped as if it were a pen, with the index finger pressing on the point where the tube joins the mask. With the aperture facing forward, the tip of the cuff is placed against the inner surface of the upper incisors or gums. As the LMA is advanced, the mask portion is pressed against the hard palate by using the index finger. By withdrawing the other fingers as index finger is advanced and slightly pronating the forearm, it is possible to insert the mask fully into position with a single movement.

180 DEGREE TECHNIQUE

LMA is inserted with laryngeal aperture pointing cephalad and rotate it 180 degrees as it enters the hypopharynx. A distinct pop may be felt by the introducing hand.

PARTIAL INFLATION TECHNIQUE

LMA is inserted with partially or fully inflated cuff. Although this technique may offer some advantages for an inexperienced user, the device may be frequently malpositioned.

THUMB INSERTION TECHNIQUE

The thumb insertion technique is suitable for patients where access to the head from behind is difficult or impossible. Insertion is similar to the standard technique except that the LMA is held with the position occupied by the index finger in that

technique. As the thumb nears the mouth, the fingers are stretched forward over the patients face. The thumb is advanced to its fullest extent. Before removing the thumb, the tube is pushed into its final position by using the other hand.

ANATOMY:

The cuff is pressed against several structures in sequence – the hard palate, the soft palate, the naso/oropharyngeal and then the hypopharyngeal portion of the posterior pharyngeal wall. The ideal final anatomic position occupied by the classic LMA is as follows: The distal cuff sits in the hypopharynx at the junction of the upper oesophagus and respiratory tracts, where it forms a circumferential low pressure seal around the glottis. Superiorly, the upper part of the mask lies under the base of the tongue, allowing the epiglottis to rest within the bowl of the mask at an angle probably determined by the extent to which passage of the mask has deflected it down-wards. When inflated, it lies with the tip resting against the upper esophageal sphincter, the sides facing the pyriform fossae with the upper surface behind the base of the tongue and the epiglottis pointing upwards. The aperture of a properly positioned LMA aligns itself anatomically with the laryngeal inlet. The tip of the LMA cuff lies at a variable depth behind the cricoid cartilage; and the posterior surface immediately anterior to the C2 to C7 cervical vertebrae. The laryngeal inlet can be tipped anteriorly by the inflated LMA cuff when cricoid pressure is applied; this may explain why blind intubation via the LMA is more difficult with cricoid pressure applied.

SIGNS OF CORRECT LMA PLACEMENT:

- Slight outward movement of the tube upon LMA inflation.
- The presence of a smooth oval swelling in the neck around thyroid and cricoid area.
- No cuff visible in oral cavity.
- Expansion of chest wall on bag compression

MEASURES TO DECREASE THE ASPIRATION WHILE USING cLMA:

- Avoid using the device in patients who are full stomach or have factors predisposing to regurgitation
- Insert LMA only when adequate depth of anaesthesia is reached
- Keep the cuff inflated until the patient is awake
- Avoid lubricating anterior surface of the mask, since it can be aspirated.

INDICATIONS:

- Elective short surgical procedures under general anaesthesia excluding head and neck surgery
- Rescue airway in “cannot intubate, can ventilate” and “cannot intubate, cannot ventilate” scenario if the problem is supraglottic in nature, since successful use of the LMA does not require the constellation of factors required for direct laryngoscopy and tracheal intubation.
- In 1996 it entered the American Society of Anaesthesiologists’ difficult airway algorithm in five different places, both as a ventilatory device (airway) and a conduit for endotracheal intubation.
- Cardiopulmonary resuscitation

- cLMA acts as a conduit to facilitate flexible fibreoptic bronchoscopy for diagnostic or interventional purposes and aid tracheal intubation in paediatric patients. Tracheal intubation via a LMA should be carried out with the aid of a fibreoptic scope because blind techniques may fail if the epiglottis is down folded over the laryngeal aperture, as occurs commonly in children.

CONTRAINDICATIONS:

- Mouth opening less than 1.5 cm
- Poor lung compliance
- Airway pressure more than 20 cm of H_2O
- Full stomach patients

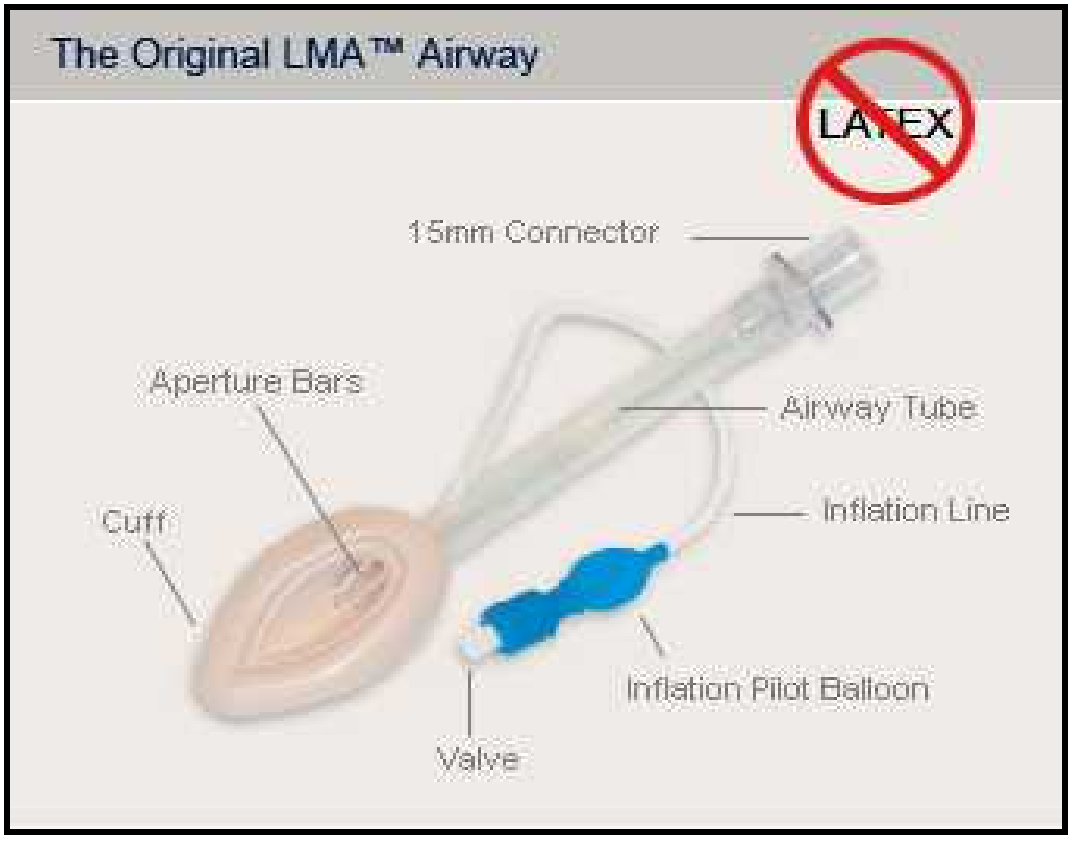
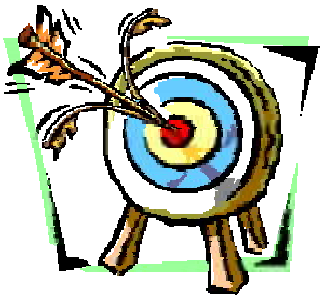


Figure 4: *Classic LMA*

Introduction



Objectives

Review of Literature

Basic Sciences

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure-I

Annexure-II

Annexure-III

Annexure-IV

RESULTS

The objectives of the present study were to compare i-gel (size 2) and classic LMA (size 2) for ease of insertion, airway sealing pressure, duration of insertion and any complications in paediatric patients undergoing general anaesthesia.

The study was conducted in the Department of Anaesthesiology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2012 to December 2012.

A total of 80 ASA I and II paediatric patients aged 1 to 6 years, weighing between 10 to 20 Kgs posted for elective surgeries under general anaesthesia were included in our study. Patients were allocated in a randomized manner by a computer generated ‘sealed envelope’ method into two groups of 40 each:

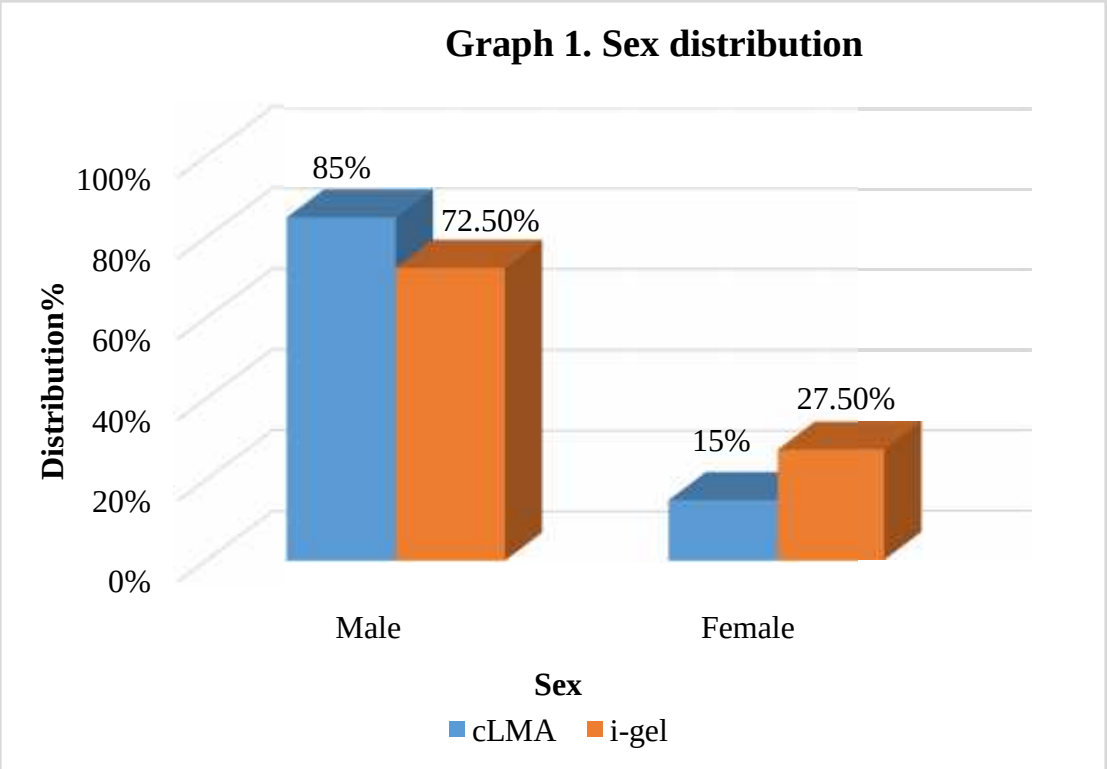
Group A. Classic LMA (size 2)

Group B. i-gel (size 2)

The data obtained were analysed and the final results and observations are tabulated below.

Table 3. Sex distribution

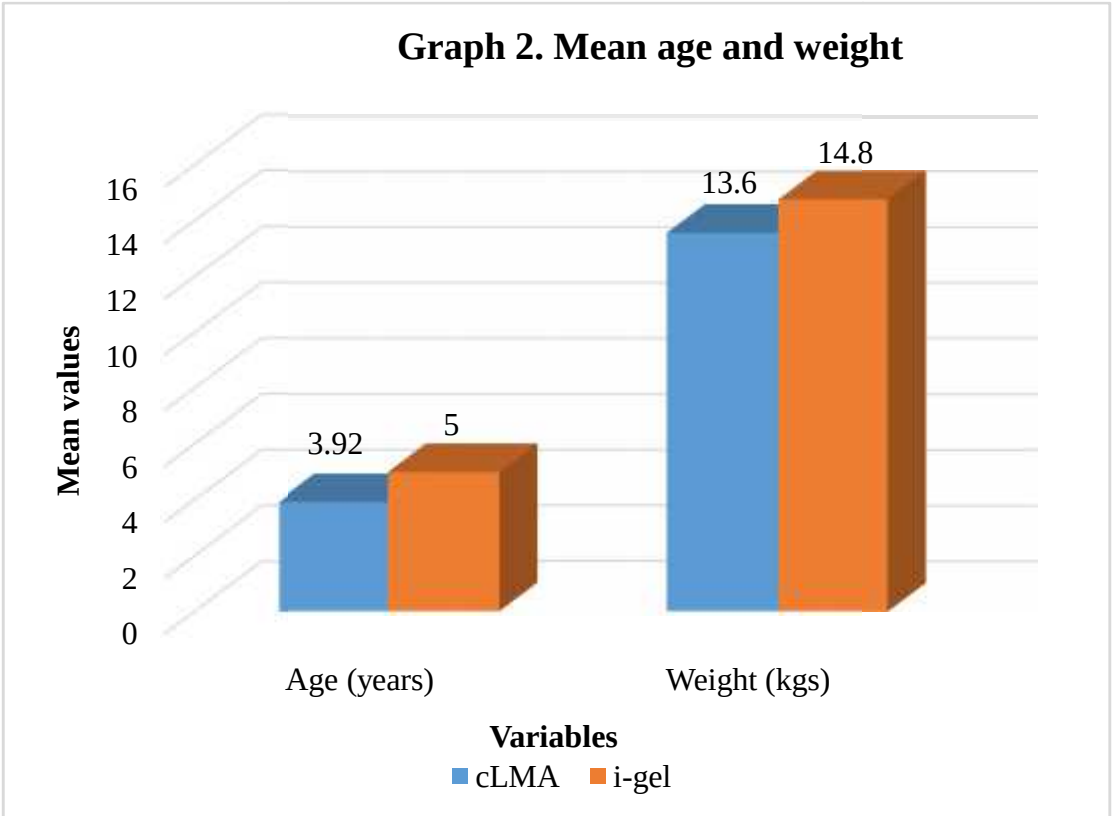
SEX	Group A (n=40)		Group B (n=40)	
	Number	Percent	Number	Percent
Male	34	85%	29	72.5%
Female	6	15%	11	27.5%
Total	40	100%	40	100%



In our study, there were 34 males, 6 females in cLMA group and 29 males, 11 females in i-gel group which is not statistically significant (p=0.132).

Table 4. Age and weight

Parameters	Group A. (n=40)	Group B. (n=40)	$t_{>8}$	p value
	Mean ± standard Deviation	Mean ± standard deviation		
Age (years)	3.92±2.40	5±2.72	1.871	0.065
Weight (Kgs)	13.6±2.84	14.8±2.89	1.986	0.051

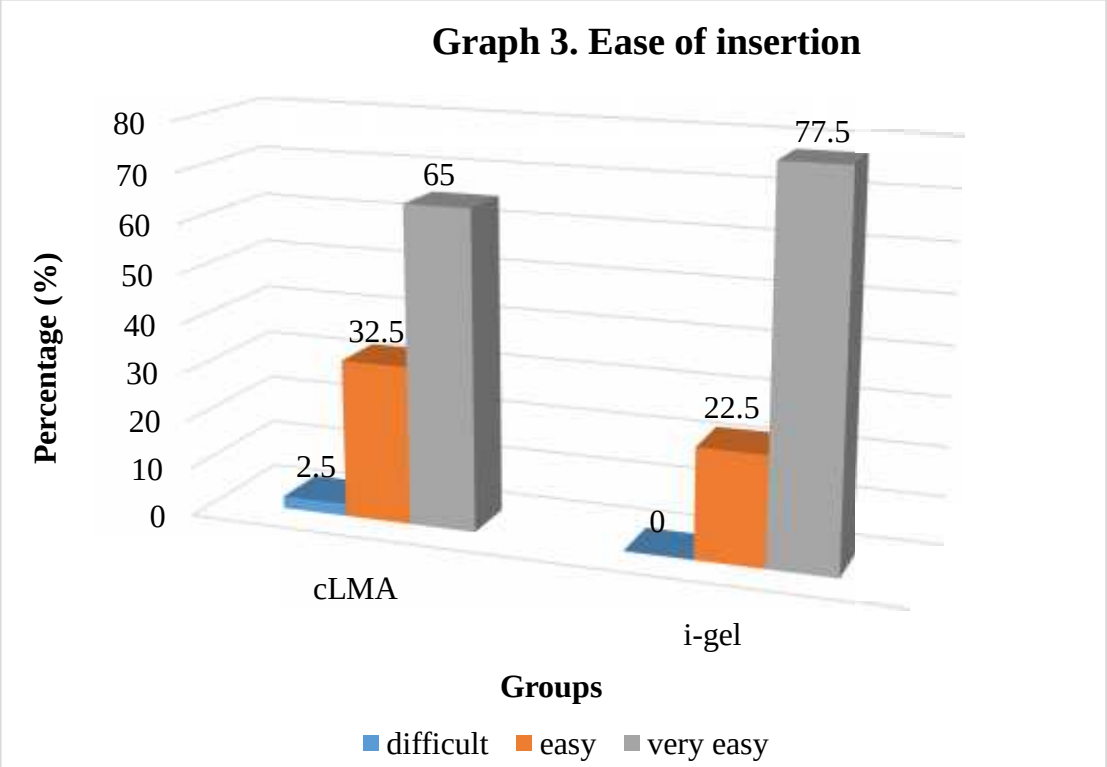


The mean age was 3.92±2.40 in group cLMA and 5±2.72 years in group i-gel (p= 0.065). There is no statistically significant difference between the two groups. Both groups arecomparable with respect to age.

The mean weight was 13.6±2.84 Kgs in group cLMA and 14.8±2.89 Kgs in group i-gel which is not statistically significant (p=0.051). Both groups were comparable with respect to weight.

Table 5. Ease of insertion

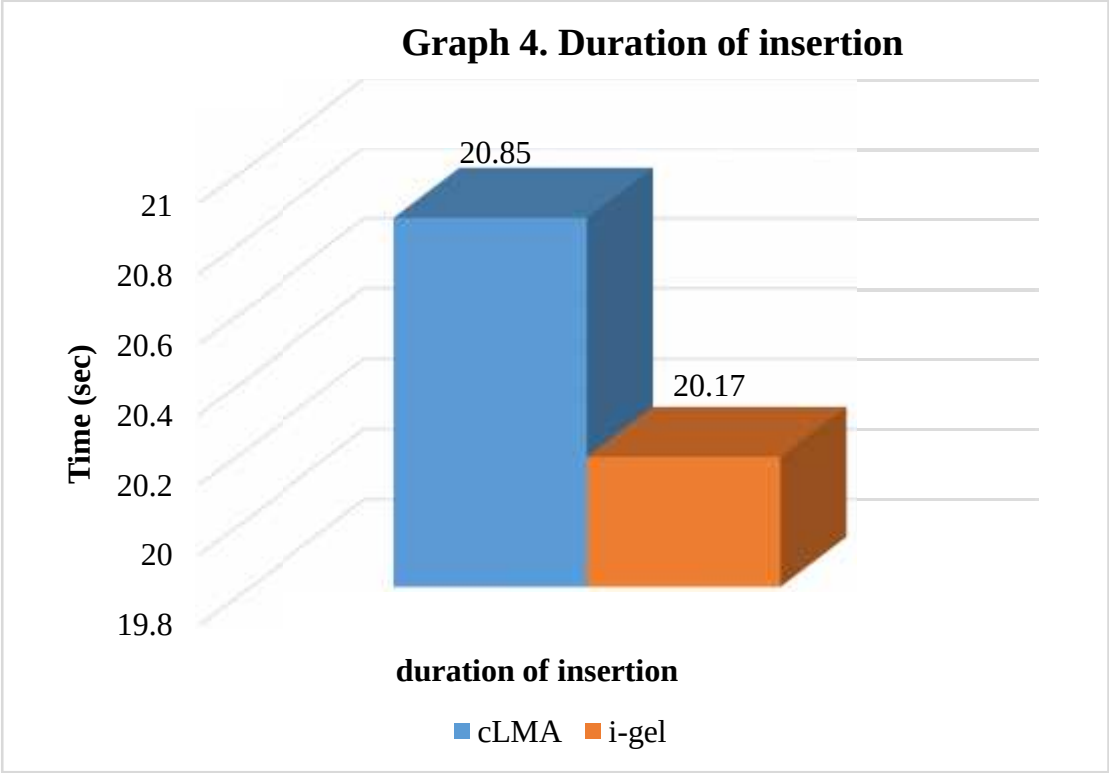
Groups	Difficult (%)	Easy (%)	Very easy (%)	Total
Group A.	1 (2.5)	13 (32.5)	26 (65)	40
Group B.	0	9 (22.5)	31 (77.5)	40



In our study, insertion was very easy in 26 patients in group cLMA and 31 patients in group i-gel and easy in 13 patients in group cLMA and 9 patients in group i-gel. Difficult insertion was seen in 1 patient in group cLMA. This difference is not statistically significant. (p=0.323).

Table 6. Duration of insertion

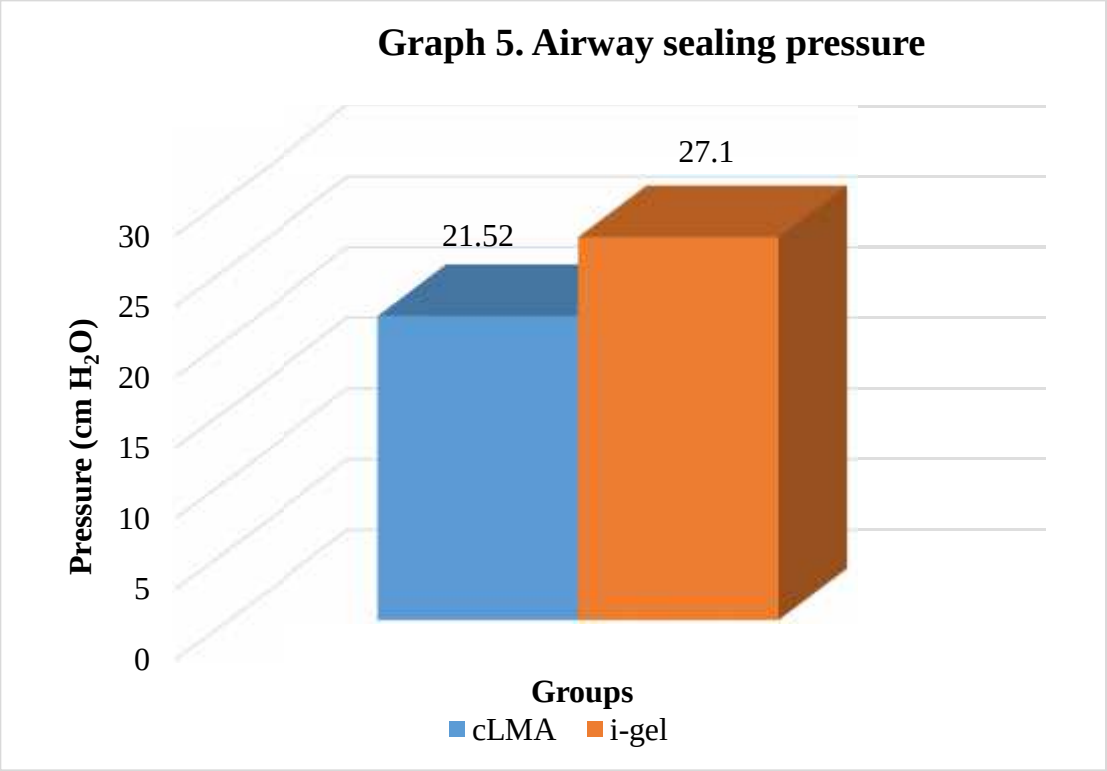
Groups	Duration of insertion (Sec)	p-value	$t_{>8}$
Group A.	20.85±3.26	0.298	1.048
Group B.	20.17±2.43		



In our study, the mean duration of insertion was 20.85±3.26 sec in group cLMA and 20.17±2.43 sec in group i-gel. This difference is not statistically significant (p=0.298, $t_{>8}$ = 1.048)

Table 7. Airway sealing pressure

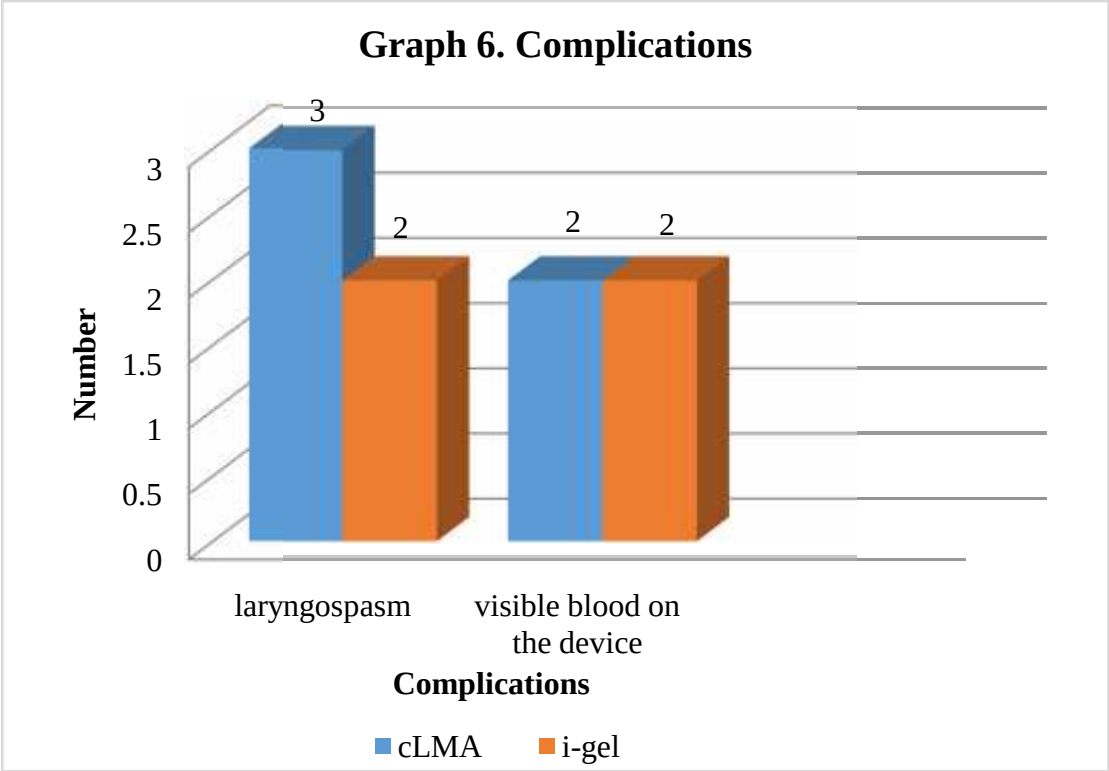
Groups	Airway sealing pressure (cm H_2O)	p-value	$t_{>8}$
Group A.	21.52±1.43	p<0.001	18.911
Group B.	27.1±1.19		



The mean airway sealing pressure was 21.52±1.43 in group cLMA and 27.1±1.19 in group i-gel. The airway sealing pressure was more in i-gel group which is statistically significant (p<0.001, $t_{>8}$ =18.911).

Table 8. Complications

Complications	Group A. (n=40)	Group B. (n=40)	p value
Laryngospasm	3	2	p=1
Bronchospasm	0	0	-
Hypoxia	0	0	-
Visible blood on the device	2	2	p=1



In our study, laryngospasm was noted in 3 patients in group cLMA and 2 patients in i-gel group, visible blood on the device was noted in 2 patients each in both the groups which is statistically insignificant. No bronchospasm, hypoxia or any other complications were noted in patients of either group.

DISCUSSION

Supraglottic airway devices are placed outside the larynx forming a seal around it. Laryngeal masks represent a subset of these devices. Once used solely to replace the facemask with spontaneous ventilation, laryngeal masks are now often used as substitutes for the tracheal tube and to deliver PPV[11].

Laryngeal masks have evolved since Dr. Archie Brain's prototype of the early 1980s. The original laryngeal mask, the laryngeal mask airway (LMA) has been studied extensively in children. It allows adequate oxygenation and ventilation in children under general anaesthesia and is the ideal rescue device for failed facemask ventilation. It serves as an ideal conduit for fiber-optic tracheal intubation and even, facilitates neonatal resuscitation[11].

Technical difficulties with laryngeal masks increase with decreasing age. Airway problems are more likely such as poor sealing, movement and dislodgement of the mask, compression of glottic structures, reflex activation of the airway and gastric insufflation[11].

The i-gel is a recent novel second generation supraglottic airway device that consists of a noninflatable laryngeal mask made from a gel-like thermoplastic elastomer and an anatomically shaped cuff which is easier to insert[25]. Safety of the i-gel as a supraglottic airway device in adults is established in various studies[28,29].

Thus, this study was designed to compare the clinical efficacy of i-gel airway (size 2) and classic LMA (size 2) to evaluate ease of insertion, airway sealing

pressure, duration of insertion and any complications in paediatric patients undergoing elective surgeries under general anaesthesia.

A total of 80 ASA I and II paediatric patients aged 1-6 years weighing 10-20 Kgs posted for elective surgery under general anaesthesia divided into two groups of 40 each, were enrolled in our study.

In our study, there were 34 male and 6 female patients, 29 male and 11 female patients in cLMA, i-gel groups respectively. The mean age was 3.92±2.40 years in group cLMA and 5±2.72 years in group i-gel. The mean weight was 13.6±2.84 Kgs in group cLMA and 14.8±2.89 kgs in group i-gel. Both groups are comparable with respect to sex, weight and age.

The supraglottic airway devices (SAD's) provide ease of placement and hands free maintenance, along with a relatively secure airway. Insertion of an SAD's may be less stimulating to sympathetic nervous system then laryngoscopy and tracheal intubation and is also better tolerated at lighter levels of anaesthesia, potentially decreasing side effects and hospital stay[30].

In our study, insertion was very easy in 26 patients in group cLMA and 31 patients in group i-gel whereas insertion was easy in 13 patients in group cLMA and 9 patients in group i-gel. Difficult insertion was seen in 1 patient only in group cLMA, which is not statistically significant (p=0.323).

The results of our study are similar to a study by **Das et al**, comparing i-gel supraglottic device with classic laryngeal mask airway in 60 anesthetized paralyzed children undergoing elective surgery with no failures in insertion of the airway observed in any group. Ease of insertion was similar in the i-gel and cLMA group[16].

Similarly, in a study, **Beylacq et al** observed that the i-gel, a single use supraglottic airway device in children was inserted at the first attempt and the results are similar to our study[14].

The i-gel is easier to insert as the large diameter cylindrical airway tube contained within buccal cavity stabiliser is anatomically widened and concave to eliminates the potential for rotation and provides vertical strength for insertion[31]**.**

In our study, the mean duration of insertion was less with group i-gel (20.17±2.43 sec) than group cLMA (20.85±3.26 sec), but is not statistically significant (p=0.298).

Similar results were seen in a study comparing the i-gel with the LMA classic in children by **Lee J-R et al**, with shorter insertion times for the i-gel compared with the LMA classic[15]. In another study by **Tokgok et al**, comparing efficacies of i-gel and LMA ProSeal for airway management in paediatric patients, insertion time was shorter for i-gel group than LMA ProSeal group (19±4 sec vs. 28±5 sec, p=0.01)[2].

The lesser duration of insertion required for i-gel may be due to less flexible stem of i-gel which facilitates insertion and also the presence of a noninflatable cuff.

Owing to the moderate pharyngeal seal provided by the supraglottic airway devices, controlled ventilation may not always possible and there is a risk of pulmonary aspiration of regurgitant matter. Aspiration requires regurgitant fluid to reach the laryngeal inlet and it depends on the seal the SAD makes with oesophagus (oesophageal seal) combined with seal with pharynx (pharyngeal seal), which will determine the likelihood of spill into the larynx[6].

In our study the mean airway sealing pressure was 21.52±1.43 cm H_2O in group cLMA and 27.1±1.19 cm H_2O in group i-gel. The difference in airway sealing pressure noted is statistically significant ($p<0.001$).

Similar results were observed in the study by **Das et al**, comparing three supraglottic devices of size 2 i-gel, PLMA and cLMA in anaesthetised paralyzed children undergoing elective surgery. The mean airway sealing pressure between PLMA and cLMA was comparable, but there was a statistically significant difference between the i-gel and the other groups. It was 27±1.69, 22.73±1.44, 23.63±1.35 cm H_2O for the i-gel, PLMA and cLMA groups respectively[17].

Another study by **Jagannathan N et al**, comparing the i-gel and laryngeal mask airway supreme in children observed that the median airway leak pressure for the i-gel was higher than LMA supreme, 20 cm H_2O vs 17 cm H_2O respectively[18].

In a study by **Das et al**, size 2 i-gel was compared with cLMA of the same size in anaesthetized, paralyzed children. They found that the oropharyngeal leak pressure was 26.1±2.4 and 22.64±2.2 cm H_2O for i-gel and cLMA groups, respectively and OSP was significantly higher in the i-gel group[16].

Results of these studies in paediatric patients are comparable to the results of our study.

The higher airway sealing pressure created by i-gel maybe due to the soft, noninflatable cuff which fits snugly onto the perilaryngeal framework, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, perithyroid, peri-cricoid, posterior cartilages and spaces. So, each structure receives an impression fit, thus supporting the seal by enveloping the laryngeal inlet.

In our study, laryngospasm was noted in only 3 patients in group cLMA and 2 patients in i-gel group which is statistically insignificant. The visible blood on the devices was noted in 2 patients each in both the groups which is statistically insignificant. Bronchospasm, hypoxia and no other complication were noted in patients of either group.

In a study by **Sardi et al** who compared throat and neck complaints after use of the i-gel versus the traditional laryngeal mask observed less odynophagia, cervical pain and airway pressures with i-gel than the conventional LMA[20].

Similarly, in a cohort evaluation of the i-gel airway in 120 children by **Beringer RM et al**, observed fewer complications during insertion: one developed laryngospasm, one developed stridor and one child moved. Hence, i-gel SAD is a safe alternative in paediatric patients undergoing general anaesthesia[7].

The i-gel airway is associated with fewer airway complications. This may be due to gel filled cuff which is less traumatic to the airway. However, both i-gel and cLMA were associated with less complications during insertion and removal of the device in our study.

Thus, the results of these various studies comparing the efficacy of the i-gel with already established devices such as cLMA, PLMA etc. in paediatric patients are comparable to the results of our study with respect to higher airway sealing pressure in i-gel group. No significant difference was found in duration of insertion, ease of insertion between the groups. Minimal complications are observed in both the groups.

LIMITATIONS

The present study has few limitations.

Size 2 of both the devices were compared. Hence, results may not be applicable to other sizes. Patients with normal airway were included in the study. Hence, use of i-gel should be studied in patients with difficult airway. The i-gel needs to be compared with other newer paediatric SADs available such as PLMA and Ambu AuraOnce.

CONCLUSION

The results of the present study show that i-gel (size 2) is easier to insert, provides higher airway sealing pressure with fewer complications when compared to the cLMA (size 2) and hence, can be a suitable alternative to cLMA in paediatric patients.

SUMMARY

The present study titled "**One year randomized clinical trial to compare efficacy of i-gel supraglottic airway and classic laryngeal mask airway for ease of insertion in paediatric patients undergoing general anaesthesia"** was aimed to compare the clinical efficacy of size 2 i-gel supraglottic airway and size 2 classic LMA to evaluate ease of insertion, airway sealing pressure, duration of insertion and complications in paediatric patients posted for elective surgeries under general anaesthesia**.**

The study was conducted in 80 ASA I and II patients, aged 1 to 6 years and weighing between 10 to 20 Kgs posted for elective surgery under general anaesthesia in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2012 to December 2012. After obtaining the approval from the hospital ethical committee, patients were allocated in a randomized manner by a computer generated 'sealed envelope' method into two groups of 40 each, Group A- Classic LMA (size 2) and Group B- i-gel (size 2).

In our study, demographic data was comparable in both the groups. Insertion was very easy in 26 patients in group cLMA and 31 patients in group i-gel, easy in 13 patients in group cLMA and 9 patients in group i-gel. Difficult insertion was seen in 1 patient in group cLMA. The mean duration of insertion was 20.85$\pm$3.26 sec in group cLMA and 20.17$\pm$2.43 sec in group i-gel. These differences are not statistically significant (p=0.323). The mean airway sealing pressure was 21.52$\pm$1.43 cm H_2O in

group cLMA and 27.1±1.19 cm H_2O in group i-gel which is statistically significant ($p < 0.001$). No significant complications were noted in both the groups.

To conclude, i-gel (size 2) is easier to insert, provides a higher sealing pressure with similar duration of insertion with no significant complications compared to cLMA (size 2) and hence, can be safely used in children.

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ANNEXURE-I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr./Mrs./Miss. _____we are requesting you to enroll your child in a study titled **"One year randomized clinical trial to compare efficacy of i-gel supraglottic airway and classical laryngeal mask airway for ease of insertion in paediatric patients undergoing general anaesthesia" at KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELGAUM** conducted by J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Sir/Madam we request you to enroll your child to participate in our study as he/she is eligible for participating in the study. During the study you will be asked some questions regarding your child's present complaint and you are requested to answer to the best of your knowledge.

Your child's participation in research is voluntary. Based on your consent if you decide not to participate, you are free to withdraw at any time.

The purpose of research is to compare efficacy of i-gel supraglottic airway and classical laryngeal mask airway for ease of insertion in paediatric patients undergoing general anaesthesia.

Procedure Involved:

If you agree to enroll your child in my study, I will ask your child's present, past and family history. Then your child will be clinically examined in detail and routine investigations like Haemoglobin will be done. After giving general anaesthesia with Sevoflurane, the supraglottic airway device to be inserted will be chosen as per randomization.

Risks and Benefits:

The benefit of taking part in this study are that these newer advanced airway devices combines the best features of all the previous laryngeal mask airways in one device. They can be used as an effective alternative to endotracheal tubes which carry an inherent risk of patient trauma, from vocal cord damage to pharyngeal soft tissue injury. There are no observable risks associated with this study.

Voluntary Participation / Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll your child in this study. Your decision will not change present or future health care services offered to your child at KLES hospital, Belgaum.

Alternatives:

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

Privacy and Confidentiality:

The only people to know that your child is a research subject are members of the research team. No information about your child or information provided by you during the research will be disclosed to other without your written permission except:

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

Authorization to Publish Results:

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

Financial Incentives for participation:

No financial incentives are being offered to the enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law.

Questions:

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact, Department of Anaesthesiology, KLES Hospital and MRC.

If you have any queries about your rights as a study subject, you may call Dr. Prakash V. Patil Professor, Department of Pathology, Chairman, J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Ph. 9880219404 at J.N. Medical College, Belgaum.

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

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

Subject Name : _____

Left Thumb Print of Mother/Father:

Signature: _____ Date:

Witness Name : _____ Signature: _____Date :

Investigators Name: _____ Signature: _____Date :

Place : _____

ANNEXURE IV – MASTER CHART

Cm	-	Centimeter
F	-	Female
H_2O	-	Water
I and D	-	Incision and Drainage
Kgs	-	Kilograms
M	-	Male
PBC	-	Post burn contracture
Sec	-	Seconds

ANNEXURE-II

PROFORMA

"ONE YEAR RANDOMIZED CLINICAL TRIAL TO COMPARE EFFICACY OF I-GEL SUPRAGLOTTIC AIRWAY AND CLASSIC LARYNGEAL MASK AIRWAY FOR EASE OF INSERTION IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA" AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELGAUM.

Patient's name: Age:

I.P no.: Sex:

Weight: Address:

Anaesthesiologist:

Preoperative diagnosis:

Name of the operation:

PRE-ANAESTHETIC EVALUATION

History in brief:

Chief complaints:

Past history:

Personal history:

Drug therapy:

Previous anaesthetic experience:

General physical examination:

Height: Weight:

Pallor / Edema / Icterus / Cyanosis / Clubbing / Lymphadenopathy

P.R.: R.R.:

B.P.: Temperature:

Musculoskeletal system examination:

Teeth: Jaw movements:

Airway assessment: Spine:

Systemic examination:

CVS: RS:

CNS: GIT:

Investigations

Hb%: Urine routine:

S. Creatinine: Blood urea:

Chest X-ray, if necessary:

ASA Grade:

Inclusion criteria

1. ASA grade I and II
2. Body weight between 10 to 20 kg
3. Elective surgeries of less than 1 hour duration under general anaesthesia in supine position

Exclusion criteria

1. Known or predicted difficult airway
2. Any pathology of neck, upper respiratory tract or upper GIT
3. Tredenlenburg's position
4. History of lung diseases
5. Potentially full stomach patients

Methods

After obtaining the approval from the hospital ethical committee, patients were allocated in a randomized manner by opening a computer generated 'sealed envelope' method into two groups of 40 each, Group A. classic LMA (size 2) and Group B. i-gel (size 2).

A total of 80 ASA I and II paediatric patients, aged 1 to 6 years and weighing 10 to 20 Kgs, posted for elective surgeries under general anaesthesia were included in the study.

All the patients were pre-medicated with i.m. ketamine (5mg/kg) and glycopyrrolate (0.01mg/kg) before shifting the patient to operating room.

In the operating room, a standard anaesthesia protocol was followed. Routine monitoring was done with electrocardiograph, non-invasive blood pressure, pulse oximetry (SPO_2) and $etCO_2$. The head and neck of the patient was placed in the sniffing position with the occiput rested on a firm pillow 5 cm in height.

The airway device to be used was prepared for insertion and its dorsal surface lubricated with a clear, water based gel, with the cuff completely deflated in case of cLMA. Size 2 device was used for both the cLMA and i-gel.

An intravenous (IV) access was established. All the patients were preoxygenated with 100% oxygen for 3 minutes. Anaesthesia was induced with midazolam 0.05 mg/kg, fentanyl 2 µg/kg, propofol 2mg/kg and additional bolus of 1-2mg/kg of propofol, if required. After cessation of spontaneous respiration, patient's lungs were ventilated with 100% oxygen using a face mask until sufficient depth of anaesthesia, indicated by easy up and down movement of the lower jaw and no reaction to pressure applied to both angles of mandible. Then, the airway devices i-gel (size 2.0) or cLMA (size 2.0), were inserted in strict accordance with the manufacturer's recommendations by senior anaesthesiologist with more than 3 years of experience of LMA usage.

The insertion technique for cLMA and i-gel supraglottic airway included neck flexion, head extension, full deflation of the cuff, in case of classic LMA and the use of the index finger to press the device into and advance it around the palatopharyngeal curve. A slight lateral approach was used if resistance was felt in the oropharynx.

Successful placement of the device was assessed by adequate chest expansion, absence of audible leak and lack of gastric insufflations (by epigastric auscultation) and square wave capnography.

Failed insertion was defined by any of the following criteria.

1. Failed passage into the pharynx
2. Malposition (air leaks)
3. Ineffective ventilation (maximum expired tidal volume <6 ml kg-1 or/and etCO_2>60 cm of H_2O).
4. More than 3 attempts

If the device could not be successfully inserted as defined above, the patient's trachea was intubated conventionally and was excluded from the study.

The ease of insertion was defined as:

- Very easy- airway manipulation not required
- Easy - jaw thrust by assistant
- Difficult- jaw thrust and deep rotation or second attempt used for proper insertion

The duration of insertion was defined as the time between picking up the prepared i-gel supraglottic airway or LMA classic and successful placement was obtained.

Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 liter min-1, and noting the airway pressure in the anaesthetic breathing system at equilibrium (maximum allowed was 40 cm H_2O) using manometer.

For cLMA, the intra cuff pressure was set at 60 cm H_2O to obtain an effective airway seal for PPV. Anaesthesia was maintained with 50:50 oxygen-nitrous oxide mixture and sevoflurane (1%) on spontaneous respiration.

The presence/absence of oropharyngeal air leaks (detected by audible leak over the mouth), gastric air leaks (detected by auscultating over the epigastrium) were noted. Any adverse events like laryngospasm, bronchospasm, and hypoxia were recorded.

Data about ease of insertion, airway sealing pressure, duration of insertion and any complications during insertion were noted and recorded.

At the end of the surgery, anaesthetic agents were discontinued and the devices were removed after the child was awake and the return of the protective airway

reflexes. Any adverse events like hypoxia, laryngospasm, bronchospasm and any occult/visible blood on the device were noted.

Statistical Analysis:All the data collected were analysed. The demographic data, duration of insertion and airway seal pressure were analysed using unpaired‘t’ test. Sex and complications were compared using chi square test. The ease of insertion was analysed using fisher exact test. Data are mean and standard deviation unless otherwise specified. Significance is taken as p value <0.05.

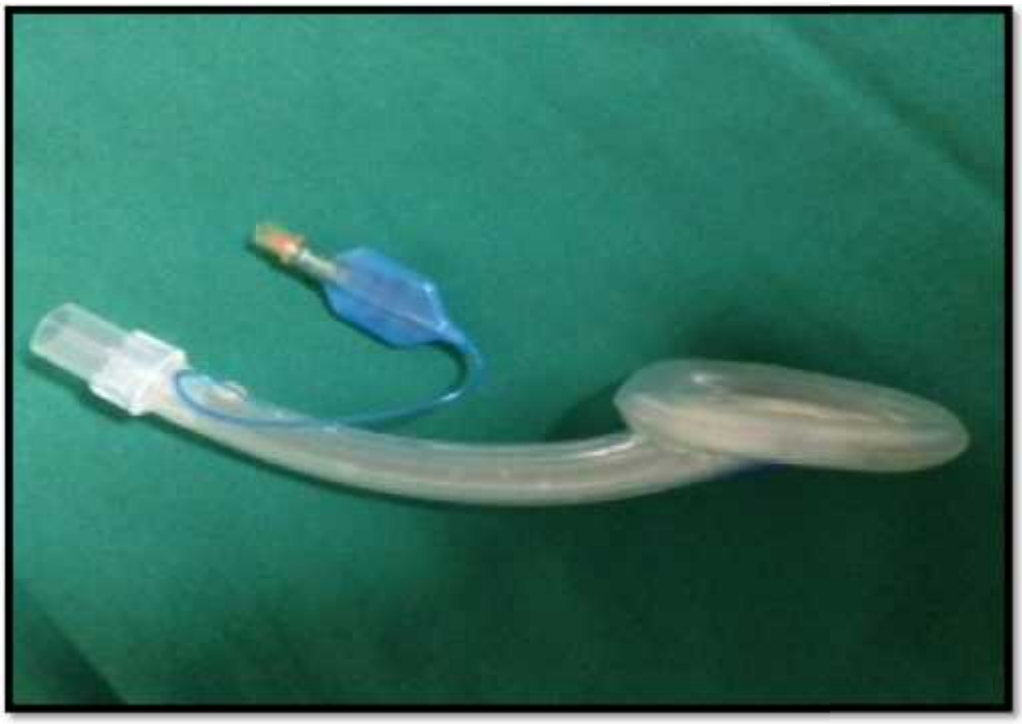
Observations:

EASE OF INSERTION		
Very easy	Easy	Difficult

Duration of insertion (sec)	
Airway sealing pressure (cm of H_2O)	

Complications (if any)	

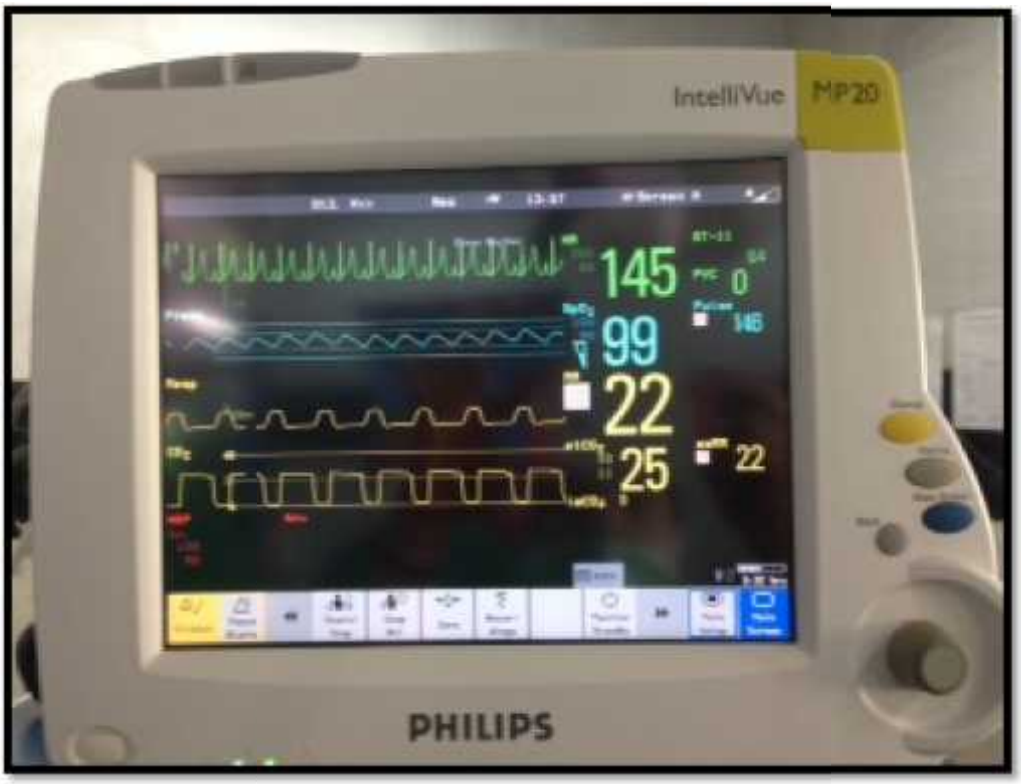
ANNEXURE III – PHOTOGRAPHS



Photograph 1: Classic LMA

Photograph 2: i-gel supraglottic airway

Photograph 3: Anaesthesia work station



Photograph 4: Monitor

S.No	IP.NO.	SEX	WEIGHT(Kg)	PROCEDURE	EASE OF INSERTION	DURATION OF INSERTION (seconds)	AIRWAY SEALING PRESSURE (cm H_2O)	COMPLICATIONS (GROUP B)			
								LARYNG0-SPASM	BRONCH0-SPASM	HYPO-XIA	VISIBLE BLOOD ON THE DEVICE
1	490880	F	16	plaster application	very easy	16	28				
2	492444	F	12	cystoscopy	easy	21	26				
3	492697	M	12	hydrocele repair	very easy	17	27				
4	487416	F	15	debridement	very easy	16	27	YES			
5	455944	M	12	polypectomy	easy	23	25				
6	454627	M	16	circumcision	very easy	18	29				YES
7	454544	M	11	hernia repair	very easy	15	28				
8	456537	M	12	circumcision	very easy	19	28				
9	498172	F	13	tongue tie release	very easy	21	27				
10	494118	M	12	hydrocele repair	very easy	19	26				
11	490880	F	16	debridement	very easy	20	28				
12	494118	F	20	debridement	very easy	19	25				
13	510106	M	20	ganglion excision	easy	23	26				YES
14	510610	M	13	circumcision	very easy	21	28				
15	599392	M	20	circumcision	very easy	22	27				
16	492090	F	16	ulcer debridement	easy	27	28				
17	489276	M	17	plaster application	very easy	19	27				
18	485358	M	14	PBC release	easy	21	26				
19	490100	F	10	plaster application	very easy	20	27				
20	485131	M	12	appendicetomy	very easy	21	26				
21	479108	M	14	closed reduction	very easy	22	25				

S.No	IP.NO.	SEX	WEIGHT(Kg)	PROCEDURE	EASE OF INSERTION	DURATION OF INSERTION (seconds)	AIRWAY SEALING PRESSURE (cm H_2O)	COMPLICATIONS (GROUP B)			
								LARYNG0-SPASM	BRONCH0-SPASM	HYPO-XIA	VISIBLE BLOOD ON THE DEVICE
22	471763	M	20	hernia repair	very easy	21	28	YES			
23	469260	M	17	circumcision	very easy	19	26				
24	468587	M	14	hernia repair	very easy	21	27				
25	473290	M	13	circumcision	very easy	20	29				
26	462750	M	16	hernia repair	very easy	21	25				
27	489945	M	12	closed reduction	easy	23	26				
28	485257	F	14	PBC release	very easy	19	27				
29	460103	M	16	orchiopexy	very easy	16	28				
30	470705	M	16	hernia repair	very easy	17	29				
31	470604	M	14	polydactyly release	very easy	21	27				
32	468411	M	17	hernia repair	very easy	18	28				
33	468541	M	15	lipoma excision	very easy	20	27				
34	468852	M	14	circumcision	very easy	22	26				
35	462315	M	17	hernia repair	very easy	20	29				
36	458341	M	16	hernia repair	very easy	21	28				
37	467870	F	20	PBC release	easy	23	27				
38	473696	F	10	cystoscopy	easy	24	26				
39	456532	M	19	circumcision	easy	22	29				
40	478970	M	11	cyst excision	very easy	19	28				

S.No	IP.NO.	SEX	WEIGHT (kg)	PROCEDURE	EASE OF INSERTION	DURATION OF INSERTION (seconds)	AIRWAY SEALING PRESSURE (cm H_2O)	COMPLICATIONS (GROUP A)			
								LARYNG0-SPASM	BRONCH0-SPASM	HYPO-XIA	VISIBLE BLOOD ON THE DEVICE
1	466366	M	11	hernia repair	very easy	21	22				
2	474657	F	13	lymph node biopsy	very easy	24	21				
3	468935	F	14	lipoma excision	very easy	26	20				
4	497182	M	16	lymph node biopsy	easy	25	21				
5	493955	M	15	open reduction	very easy	23	20				
6	493084	M	13	hernia repair	very easy	20	23				
7	494218	F	19	ulcer debridement	easy	23	22				
8	494412	M	18	cystoscopy	easy	26	21	YES			
9	494135	M	11	cystoscopy	very easy	19	22				
10	494167	M	10	orchiopexy	easy	24	19				
11	493047	F	14	hernia repair	very easy	18	23				
12	498213	M	13	hydrocele repair	very easy	20	24				
13	492216	M	14	fistula excision	very easy	19	21				
14	492132	M	10	lymph node biopsy	easy	25	19				YES
15	481328	M	19	cystoscopy	very easy	16	21				
16	481529	M	10	hernia repair	very easy	18	23				
17	490098	M	12	lipoma excision	very easy	15	24				
18	461875	M	13	I and D	easy	25	21				
19	458972	F	16	cystoscopy	very easy	19	22				
20	472497	M	11	stent removal	very easy	17	20				

S.No	IP.NO.	SEX	WEIGHT (kg)	PROCEDURE	EASE OF INSERTION	DURATION OF INSERTION (seconds)	AIRWAY SEALING PRESSURE (cm H_2O)	COMPLICATIONS (GROUP A)			
								LARYNG0-SPASM	BRONCH0-SPASM	HYPO-XIA	VISIBLE BLOOD ON THE DEVICE
21	470775	M	10	hernia repair	easy	22	21				
22	473293	M	20	closed reduction	very easy	20	24				YES
23	467825	M	11	hernia repair	very easy	22	23				
24	476072	M	10	hydrocele repair	easy	23	20				
25	466201	F	10	open reduction	very easy	18	22				
26	459586	M	15	cystoscopy	very easy	20	20				
27	457456	M	14	cystoscopy	easy	16	19	YES			
28	471196	M	13	hydrocele repair	very easy	15	21				
29	460105	M	12	hydrocele repair	difficult	27	20	YES			
30	471286	M	13	cystoscopy	very easy	20	23				
31	483162	M	12	hernia repair	very easy	19	22				
32	456110	M	11	circumcision	very easy	17	21				
33	476990	M	13	hernia repair	very easy	20	24				
34	499313	M	20	muscle biopsy	easy	23	21				
35	475971	M	17	hydrocele repair	easy	25	22				
36	503917	M	15	hernia repair	easy	24	21				
37	503930	M	14	hernia repair	very easy	20	22				
38	504960	M	12	circumcision	very easy	19	23				
39	505568	M	15	circumcision	easy	23	20				
40	504350	M	14	cystoscopy	very easy	18	23				