"A RANDOMIZED CLINICAL COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VERSUS I-GEL AIRWAY FOR EASE OF INSERTION AND HEMODYNAMIC STABILITY"

Submitted by

DR.PRATIBHA.S.D



Dissertation submitted to the B. L. D. E. U'S SHRI B. M. PATIL MEDICAL COLLEGE AND RESEARCH CENTER, BIJAPUR KARNATAKA

In partial fulfillment of the requirements for the degree of

MD

In

ANAESTHESIOLOGY

Under the guidance of

DR. VIDYA PATIL _{M.D.} PROFESSOR DEPARTMENT OF ANAESTHESIOLOGY

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2014

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I hereby declare that this dissertation entitled "A RANDOMIZED CLINICAL COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VERSUS I-GEL AIRWAY FOR EASE OF INSERTION AND HEMODYNAMIC STABILITY" is a bonafide and genuine research work carried out by me under the guidance of DR. VIDYA PATIL _{M.D.} Professor, Department of Anaesthesiology.

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LIST OF ABBREVIATIONS

BP	Blood Pressure
BT	Bleeding time
СТ	Clotting time
CNS	Central nervous system
CVS	Cardiovascular system
Gp	Group
Hrs	Hours
Min	Minutes
IM	Intramuscular
I.V.	Intravenous
kg	Kilogram
mg	Milligram
PR	Pulse rate
SD	Standard deviation
PLMA	Proseal LMA
LMA	laryngeal mask airway
RR	Respiratory rate
NIBP	Non invasive blood pressure
MAP	Mean arterial pressure
ETT	Endotracheal tube

ABSTRACT

INTRODUCTION:

One of the major responsibilities of an anesthesiologist is to provide adequate ventilation to the patient. Difficult airway has been responsible for as many as 30% of deaths attributable to anaesthesia.

The I-gel is the most recent development in supraglottic airway devices. The I-gel is a new single use non inflatable supraglottic airway device. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation.

The proseal laryngeal mask airway (PLMA), has improved features like, modified cuff to improve the seal around the glottis and a drain tube to provide a bypass channel for regurgitated gastric contents.

I-gel was found easy to insert and hemodynamically stable than PLMA.

AIM:

To compare clinically Proseal LMA versus I-gel airway for ease of insertion, pulse rate and blood pressure in both the groups.

Methodology:

A Randomized clinical trial was designed in which 126 patients of ASA-I and II undergoing elective surgeries under general anaesthesia in whom airway was secured with Proseal LMA/I-gel airway, for surgeries lasting for less than 2 hrs. They were randomly allocated into two groups.

Group-A, n=63-PLMA inserted

Group-B, n=63-I-gel inserted

The parameters observed were ease of insertion, duration of insertion, number of attempts, pulse rate, systolic B.P, diastolic B.P, MAP and complications.

Results :

I-gel was found to be a better alternative supraglottic airway device than PLMA with controlled ventilation, since it is easy to insert and produces less hemodynamic changes than PLMA.

Conclusion :

This study concludes that, I-gel is a better alternative supraglottic airway device than PLMA with controlled ventilation, since it is easy to insert and produces less hemodynamic changes than PLMA.

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INTRODUCTION

One of the major responsibilities of an anesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing functional respiration is the airway.

No anesthetic is safe unless diligent efforts are devoted to maintain an intact functional airway. Further, inability to maintain a patient's airway for more than few minutes results in brain damage or death. It has been established that inability to successfully manage difficult airway has been responsible for as many as 30% of deaths attributable to anaesthesia.

The approach of airway has evolved greatly in recent times since development of endotracheal intubation by Macewan in 1880 to present day use of modern devices.

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between facemask and tracheal tube. These devices are placed outside trachea but provide a hands free means of achieving a gas tight airway.

The first successful supraglottic airway device, described by Archie Brain "laryngeal mask airway" (LMA) classic became available in 1989. Later additional devices were added to LMA family to satisfy specific needs .The I-gel is the most recent development in supraglottic airway devices. It was developed by Dr. Mohammad Aslam Nasir in January 2007. The I-gel is a new single use non inflatable supraglottic airway device. It is composed of a soft gel like transparent, thermoplastic elastomer. It is designed to achieve a mirrored impression of the

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pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation.

The I-gel is a truly anatomical device. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work, mirroring the shape of the epiglottis, aryepiglottic folds, pyriform fossae, perithyroid, pericricoid, posterior cartilages and spaces. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation.

The proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in clinical practice in 2000, has improved features like modified cuff to improve the seal around the glottis and a drain tube to provide a bypass channel for regurgitated gastric contents, its seal being more effective than that of classic LMA . Laryngeal cuff of PLMA is made of softer silicon. It covers the posterior aspect of bowl of mask and presses the bowl forwards when inflated. Increased depth of bowl is designed to improve seal with the larynx from soft plastic with an anatomically preformed shape that line the pharynx. This shows positive pressure ventilation may be achieved without a cuff inflating mechanism that is required in other airway types such as laryngeal mask.

The I-gel and PLMA have added advantages like protection against aspiration and an added port for insertion of Ryle's tube for gastric emptying. The advantages make these airways superior to classic LMA.

OBJECTIVES OF STUDY

To compare clinically proseal LMA verses I-gel airway for :

- 1. Ease of insertion :
 - a. Number of attempts of insertion of each device.
 - b. Mean time for insertion (time taken to insert the device and confirmation by ventilation) of each device.
- 2. Pulse rate and blood pressure monitoring in both groups.

REVIEW OF LITERATURE

Today, anaesthetic and critical care practice clinicians in west continue to face difficulty in tracheal intubation in 1-3% cases and failed intubation in approximately 0.05-0.2% cases. Although we do not have any Indian data in this regard, the incidence may be presumed to be several folds higher given our limited resources and inadequate training in many of our medical institutions.

In view of the simplicity, easy availability and high success rate of laryngeal mask, all clinicians responsible for patients airway management should be well versed in versatility and multi faceted use during routine and difficult airway situations.

The prototype LMA came into existence in 1981 by visionary zeal of Dr. Archie I. J. Brain, a british anesthetist, at Royal London hospital, white cape, in the east end of London.

In 1982 Archie I. J. Brain¹ had done pilot study involving 23 patients. He concluded that laryngeal mask airway can be an aid to neuromuscular blockade in situations where the level of anesthesia should be sufficient to abolish gag reflex and relax jaw and is of particular value in maintaining difficult airway. Most recent development in supraglottic airway device is I-gel Berkshire, UK.

Now recently many modifications of classic laryngeal mask airway came into existence, one such modification is Proseal LMA. It was introduced in 2000 by Archie Brain with its improved safety features, namely a modified cuff to improve the seal around the glottis and a drain tube to provide a bypass channel for regurgitated gastric contents.

In 1989, P. M. Bodrick, N. R. Webster, and J. F. Nun studied 100 ASA grade I, II spontaneously breathing patients aged 16-65yrs, weighing 35-75kg using LMA in variety of general surgery, genitourinary surgery, gynecological surgery and orthopedic surgery². Total of 18 different anaesthetists none having experience in use of LMA were involved in the study. Anaesthesia was induced with inj. Thiopentone 6mg/kg in over 45 sec. and then airway secured with LMA, when adequate Jaw relaxation was confirmed. Anaesthesia was maintained with volatile anaesthetics in 70% N₂O and 30% O₂ Patients were allowed to breathe spontaneously. Clinically satisfactory airway was obtained in 98 patients without need to support jaw, extend the head or to handle the patient in anyway, LMA passed easily without introducer in 92 patients. Insertion was successful in first attempt in 80%, in second attempt in 70% of remaining 20 patients, in third attempt in 4 of the remainder and LMA was replaced with a Guedel oropharyngeal airway in other two patients and in other 10 patients, severe airway obstruction, coughing and laryngospasm occurred. 12 patients had a temporary sore throat in postoperative period; excellent airway patency was obtained in 98% patients.

In 1992, J. G. Wilson, D. fell S. Robinson & G. Smith studied 40 ASA grade I patients aged 26-38yrs, weighing 45-72kg undergoing elective gynecological surgery requiring neuromuscular block. They studied pressor response using LMA versus endotracheal tube³. Anaesthesia was induced with inj. Thiopentone 4.5mg/kg i.v. and maintained with 67% nitrous oxide and 1% enflurance in oxygen. Four minutes after induction either tracheal intubation by direct laryngoscope with no. 8 ETT or LMA insertion with no. 3 was performed. Heart rate increased after induction of anaesthesia and increased again after airway instrumentation. Mean heart rate remain elevated after instrumentation until 3 min in ET group but began to decrease after 1

min in LMA group. There was a significant difference between the groups at 2 min and 3 min after insertion. The maximum mean increase in systolic BP was 51.3% in ET group and 22.9% LMA group occurring at mean time of 38.8 sec and 44.2sec respectively. Diastolic BP increased significantly in ET group at 30 sec and 1 min. Changes in LMA group did not reach significance. Maximum mean increases in DBP at 30 sec were 53.20% in ET group and 27.7% in LMA group. An attenuated cardiovascular response to insertion of LMA was excluded if there were risk factors for gastroesphageal reflux. Both proseal LMA and SLIPA were easy to insert (100% success) and ventilate with respective mean maximum sealing pressure of 31(4.6) and 30(5.2) cm.

In 1993 D. G. Swan, S. A. Edwards, R. J. Chestnut studied 60 ASA grade I & II patients aged 18-50yrs weighing 42-115kg undergoing elective gynecological laparoscopic surgeries comparing LMA & ETT⁴. Anaesthesia was induced with inj propofol 2.5mg/kg and inj. Fentanyl 1mg/kg. Patients in ETT group were then given inj. Atracuriun 0.3mg/kg i.v. The LMA & ETT were inserted in usual way and patients were allowed to breathe spontaneously with ventilation being assisted to maintain normocapnia during the period of pneumoperitoneum. Anaesthesia was maintained with Enflurane (0.5-2%) with 67% nitrous oxide in oxygen. Laparoscopy was carried out using nitrous oxide as the insufflating gas. Patients with ETT group were reversed with Inj. Atropine 1.2mg and Inj. Neostigmine 2.3mg i.v. The LMA was removed in OT when patients were able to follow verbal commands. The LMA group had shorter duration of insertion and recovery times, but there was no significant difference in quality of surgical condition between two groups, the ETCO₂ was higher in patient with LMA. The tracheal tube group had significantly higher heart rate and systolic blood pressure at 5min after induction, but there were no

difference thereafter. There was a greater incidence of nausea in LMA group 4 hrs after operation and greater incidence of hoarseness and sore throat in tracheal tube at 4 hrs postoperatively. Use of the LMA to allow assisted spontaneous ventilation is a safe technique.

In 1994 J. H. Devitt, Richard wenstone, Alva G Noel and Michael P. O. Donnel studied 48 ASA gr- I & II patients, aged 20-65yrs, weighing 40-106 kg undergoing elective surgery with LMA with positive pressure ventilation⁵. After induction of anaesthesia controlled ventilation was used with four different peak pressure setting in each patient. Inspiratory and expiratory volumes, qualitative assessment of gastroesophageal insufflations and leak at neck were recorded. After data collection using LMA, trachea was intubated and measurements were repeated for tracheal tube ventilation. Leak fraction for ventilation with LMA was continuously greater than those measured with ET ventilation at similar ventilation pressure. Leak fraction with LMA ventilation increased with increasing pressure, whereas ET ventilation remains unchanged. The frequency of gastro esophageal insufflations ranged from 2.1% at ventilation pressure of 15cmH₂O.

In 1996 M. P. Drage, J. N. Unez, R. S. Vanghan, T. Asai studied 60ASA gr- I & II patients aged 18-65 yrs weighing 48-94 kg undergoing variety of elective surgery indicating Jaw thrust as clinical test to assess the adequate depth of anaesthesia for insertion of the LMA⁶. In one group insertion of LMA was attempted after loss of verbal contact (group-V) and in other group, after loss of motor response to Jaw thrust (group-I) LMA No. 4 was used in both men and women. Anaesthesia was induced by using inj. Fentanyl 1mcg/kg i.v. followed by Inj. Propofol 600mg/hr (95mg/min) and patients were asked to countdown numbers slowly. Anaesthesia was maintained with 1% isoflurane and 66% nitrous oxide in oxygen. The proportions of optimal condition

in group I were 87% compared with 13% in group V. The insertion of LMA was successful in all patients in group – I. Whereas it failed in 22 of 30(73%) patients in group V. Conditions were sub optimal in 4 patients of group I. The loss of motor response to jaw thrusting is a reliable clinical test to assess the adequate depth of anaesthesia for insertion of the LMA.

In 1997 P. P. Bupat and E. Verghese, studied 100ASA group I & II patients age 20-44yrs, weighing 95-100kg undergoing elective gynecological laparoscopies using LMA, for incidence of regurgitation⁷. Anaesthesia was induced with Inj. Fentanyl 1-1.5mcg/kg i.v. Inj. Propofol 2.5mg/kg and Inj. Atracurium 0.3mg/kg i.v. LMA was introduced when adequate jaw relaxation was achieved and cuff inflated. A fibreoptic laryngoscope was passed to confirm the postion of LMA to look for methylene blue staining, P^{H} electrode was introduced just above the vocal cord in the bowl of LMA, P^{H} was recorded every 6 sec. Anaesthesia was maintained with $N_2O +$ O_2 + isoflurane 0.5 to 1%. At the end of surgery LMA and P^H electrode were removed in recovery area when patients were awake. 95 insertions were successful at first attempt, 5 at second attempt. In 43 patients the FOB score was 1, in 51 patients 2, in 2 patients 3 and in 4 patients the score was 4. Upper oesophageal opening was seen in 4 patients 14 obese (BMI >30) and 6 morbidly obese (BMI >35) patients had uneventful anaesthesia. 14 patients had history of reflux and one patient had a hiatus hernia all remained asymptomatic during observation period of 3 weeks. Staining of larynx after induction and insertion of LMA did not occur in 99 patients. In one patient in whom the upper esophageal opening was visible, blue dye was seen immediately after induction. Postoperative fiberoscopy in this patient showed staining but not in remaining 99 patients. Airway leak prior to pneumoperitoneum was 8%

which increased to 23% during pneumoperitoneum. Incidence of regurgitation during laparoscopies with LMA and IPPV is extremely low.

In 2000, J Brimacombe, C. Keller and C. Hormann studied 40 ASA gr–I&II patients aged 21-60yrs weighing 50-110 kg comparing effectiveness of pressure support ventilation and continuous positive airway pressure using LMA No.5 for all patients for peripheral musculoskeletal surgery⁸. Anaesthesia was induced with Inj. Fentanyl 2 mcg/kg iv Inj. Propofol 3.5mg/kg and maintained with Inj. Propofol 6mg/kg / hour with oxygen and air in FiO₂ 30%. In group I patients underwent CPAP, PSV & CPAP in sequence. In group 2 patients underwent PSV, CPAP and PSV. In both groups PSV showed lower ETCO₂ (P<0.001) higher SPO₂ (P<0.001) and higher expired tidal volume (p<0.001) compared with CPAP. In both groups PSV had similar leak fraction, respiratory rate, MAP and heart rate compared with CPAP. Leak fraction was <1% and gastric distension did not occur. PSV provides more effective gas exchange than unassisted ventilation with CPAP during LMA anaesthesia while preserving leak fraction and haemodynamic homeostasis.

In 2001 Tae-Hyung Han, J. Brimacombe Eun-Jenlee and Hong senk yang studied 1067 ASA gr- I & II patients aged 19-40yrs weighing 34-84kg undergoing elective caesarian section using LMA⁹. A rapid sequence induction with Inj. Thiopentone 3-4mg/kg i.v. Inj. Suxamethonium 1.5mg/kg i.v. and single handed cricoid pressure by an assistant was done. Anaesthesia was maintained with N₂O + 50% O₂ and volatile agent enflurane 1-1.5% or isoflurane 0.5-1.5%, LMA No. 3 for patient <45kg, No. 4 for patient >45kg was introduced and cuff inflated. Cricoid pressure was maintained until delivery but was relaxed if insertion or ventilation was difficult. Patients were intubated if an effective airway was not obtained within 90 sec or SPO₂<94% or ETCO₂ <45mmhg. LMA was removed when patient obeys verbal

commands in OT. An effective airway was obtained in 99% patients, 98% at the first attempt and 1% at the second or third attempt. Air leakage or partial airway obstruction occured in 21% patients and 0.7% patients required intubation. Incidence of hypoxia (SPO₂ <90%) aspiration, regurgitation, laryngospasm, bronchospasm or gastric insufflations was not noted in any patients. Surgical conditions were satisfactory and APGAR scores were >7 after 5 min. LMA is effective and probably safe for elective and caesarian section in healthy selected patients when managed by experienced LMA users.

In 2003 Yuh-Yang, Kno-shin chen, Chien-chin chen, I-yin-cin, chan-Chien choa and Tzong lon wang studied role of capnography for LMA positioning¹⁰. Five patients who had experienced multiple trauma and airway compromise were involved in study. After maintaining cervical immobilization, the patients were preoxygenated under sellick maneuver. LMA was inserted carefully (awake intubation) and then tube placement was confirmed immediately after assessing first breath delivered by bag mask. Chest wall movement was observed for confirmation of LMA placement, secondary confirmation was done by pulse oximetry, a continuous capnography and chest radiography. In three cases the position of LMA could not be confirmed by primary method. The uncertainty was due to audible breathing sound and epigastric bubbling. Continuous ETCO2 reading revealed that 2 of three cases did not have proper positioning of LMA. Initial ETCO2 was 12 & 8mmHg and pulse oximetry demonstrated 93%&92%. After repositioning ETCO2 increased to 30 & 29mmHg whereas SPO2 was 95%&92%. Continuous display of the level of CO2 was done as it varies throughout the ventilation cycle. As the LMA covers both airway and partially the oesophagus, awake intubation itself makes dislodgement of LMA a high

possibility. Confirmation of LMA position by secondary means by capnography is very useful.

In 2005 Donald M. Miller, Luigi Camporata conducted a study to compare the efficacy of the proseal LMA and SLIPA with standard tracheal tube (TT) in 150 consecutive day care laparoscopic gynecologic surgical procedures requiring general anaesthesia¹¹. 150 patients were randomized into three groups. An identical general anaesthesia technique was used in all patients apart from addition of muscle relaxant and reversal agents in TT group. Patients were excluded if there were risk factors for gastro esophageal reflux. Both proseal LMA & SLIPA were easy to insert (100% success) and ventilate with respective mean maximum pressures of 31(4-6) and 30(5-2) cmH₂O, P= (0.4). With no muscle relaxants systolic pressures in SLIPA group was more stable in response to insertion than in TT group. With proseal LMA there was lower incidence of sore throat than with TT (30% V/s 57%), (P<0.05%) but there was lesser difference as compared with SLIPA (30% V/S 49%) (P > 0.05).

In 2005 Dr. Sanjib Das Adhikary Graec Korula conducted a pilot study in 30 patients to evaluate sanjivani airway mask (SAM) as supraglottic airway¹². They evaluated SAM for ease of insertion, haemodynamic stability and untoward events in anaesthesia Patients who were breathing spontaneously were compared with the results of another group of patients undergoing similar procedures using LMA. The SAM being disposable, inexpensive and preinflated device maintains the airway as LMA. Untoward events like trauma due to device, laryngospasm and cough were more in SAM group of patients. If proven by further multi centred trials SAM can be a replacement for the LMA particularly for biohazard patients coming for short surgical procedures.

In 2007 N. M. Wharton, B. Gibbison, D. A. Gabbott, G. M. Haslam, N. Machathta and T. M. Cook evaluated performance of I-gel supraglottic airway device in manikins and anaesthetized patients when used by novices medical students, non anaesthetist physicians and allowed health professionals, all unfamiliar with the I-gel¹³. 50 I-gel were placed in manikins, 80% (44/50) were placed on first attempt with median insertion time of 14 sec (range 7-45). I-gel were placed in 40 healthy anaesthetized patients. Success on first attempt was 82.5% (33/40) and on the second attempt 15% (6/40). After three attempts there were no failures. Median insertion time was 17.4sec (range 7-197). Median airway seal was 20 cmH₂O (13-40). One case of regurgitation and partial aspiration occurred.

In 2007 Parul Jindal, Aslam Rizvi J. P. Sharma have done a study to evaluate and compare the hemodynamic changes during insertion of supraglottic devices LMA, SLIPA or I-gel¹⁴. This prospective study was conducted on 75 patients of either sex, 20-70yrs, ASA gr-I & II scheduled to undergo elective surgical procedures under general anaesthesia. Exclusion criteria consisted of patients with ASA III, IV blood pressure \geq 150/100 mmHg, history of sore throat within the previous 10 days, full stomach, patients scheduled for head, neck surgery and patients with potential difficult airway (MP grade IV). 75 patients were divided into three groups (25each) to receive either one of the three supraglottic devices I-gel, SLIPA or LMA. Patients were induced with propofol 1.5to2.5mg/kg slowly and vecuronium 0.1mg/kg to facilitate intubation. All three supraglottic devices were introduced using standard techniques by a single anaesthesiologist who was noted to possess considerable experience in all the three techniques. Maintenance of anesthesia was done with 66% N₂O in oxygen, muscle relaxant vecuronium 0.015mg/kg and morphine 0.1mg/kg. episodes of hypoxia during intubation, serial heart rate, arterial pressure, SPO₂ were recorded. Number of intubation attempts was similar among all groups but intubation time was significantly longer in LMA group (7.68 \pm 6.9) while compared to I-gel (3.48 \pm 1.41) and SLIPA (5.16 \pm 0.68) .It was observed that I-gel produced less hemodynamic changes than SLIPA.

In 2008 Ishwar singh Monika Gupta, Mansi Tandon studied comparison of clinical performance of I-gel with PLMA in elective surgeries¹⁵. 60 ASA gr-I & II adult patients were randomly assigned into two groups. Group –I (n=30) for I-gel and group P(n=30) for PLMA. They assessed airway sealing pressure, ease of insertion, success rate of insertion, ease of gastric tube placement, airway trauma by postoperative blood staining of device, tongue, lip and dental trauma, regurgitation/aspiration and cost effectiveness. The success rate of first attempt of insertion and ease of gastric tube placement was more with group I (P >0.05). Blood staining of device of bornchospasm, laryngospasm, regurgitation, aspiration or hoarseness in either group.

In 2008 Puri G D, Hegde H V, Jayant A, Bhukal I studied haemodynamic and bispectral index response to insertion of SLIPA compared with LMA^{16.} 100 patients were randomized to receive either a classic LMA or SLIPA following induction with fentanyl and propofol titrated to a target BIS of 40 and compared heart rate, mean arterial pressure & BIS responses to insertion. Mean arterial pressure was significantly higher (p<0.05) with SLIPA at 1,2,3,4 & 5 mins. BIS increased significantly (p<0.05) at 1,2,3,4 and 5 mins following insertion of both devices but there was no significant difference between the groups. There was significantly (p=0.001) higher incidence of blood on device with SLIPA (20/50) V/S LMA 6/50.

Thus they concluded that insertion of SLIPA causes significantly higher blood pressure response but similar BIS response.

In 2008 Bimla Sharma, Minal Bhan, Aparna Sinha, Jayshree Sood and V. P. Kumra conducted a randomized prospective comparative study of PLMA versus tracheal tube in Laparoscopic cholecystectomy¹⁷. 60 adults aged 18-75yrs ASA physical status I & II patients were randomly allotted to two groups of 30 each using either PLMA or TT. In this study success rate of first attempt at insertion was higher for TT but not significant (p<0.05). Peak airway pressure (PAP) was higher in PLMA group (p<0.05) at intubation, 2 mins after intubation and at pneumoperitoneum, but were below oropharyngeal pressure. PLMA group was associated with better haemodynamic profile (p <0.05) than TT group. The placement of gastric tube was successful in all patients. There was no incidence of regurgitation or pulmonary aspiration in either group.

In 2009, a preliminary study was conducted for I-gel airway device by Ashish kannaujia, Aditya Kumar, Surekha Saxena¹⁸. This study was conducted on 50 consecutive patients of ASA I-II to determine the ease of insertion, time to achieve effective airway, oropharyngyeal pressure and airway stability on head and neck movement. Induction was done with propofol and I-gel inserted. An effective airway was confirmed by bilateral chest movement, square wave on capnograph and SPO₂ >95%. The success rate at first attempt was 90% with a median insertion time of 11sec (range 8-45). Five patients needed second attempt while none needed 3^{rd} attempt. The manipulations needed to achieve effective airway were increasing depth of insertion of I-gel in 4(8%) cases, jaw thrust or chin lift in 2(4%) cases. Oropharyngeal seal pressure was 20cm H₂O (16 to 40cmH₂O). Gastric tube placement

was done in 50% of cases. It was successful and easy in all cases. No adverse event was noted in the perioperative period.

ANATOMY OF LARYNX

The larynx¹⁹ is an air passage, a sphincter and an organ of phonation, and extends from the tongue to the trachea. It projects ventrally between the great vessels of the neck and is covered anteriorly by skin, fasciae and the hyoid depressor muscles. Above, it opens into the laryngopharynx and forms its anterior wall; below, it continues into the trachea (see Fig. 1). At rest, the larynx lies opposite the third to sixth cervical vertebrae in adult males.

SKELETON OF THE LARYNX

The skeletal framework of the larynx is formed by a series of cartilages interconnected by ligaments and fibrous membranes, and moved by a number of muscles. The hyoid bone is attached to the larynx: it is usually regarded as a separate structure with distinctive functional roles. The laryngeal cartilages are the single thyroid, cricoid and epiglottic cartilages .and the paired arytenoid, cuneiform, corniculate and tritiate cartilages(Fig.1)

Figure No 1 : Anterolateral view of the laryngeal cartilages and

ligaments.



The corniculate, cuneiform, tritiate and epiglottic cartilages and the apices of the arytenoid are composed of elastic fibrocartilage, with little tendency to calcify. The thyroid, cricoid and the greater part of the arytenoid cartilages consist of hyaline cartilage.

EPIGLOTTIS

The epiglottis is a thin leaf-like plate of elastic fibrocartilage which projects obliquely upwards behind the tongue and hyoid body, and in front of the laryngeal inlet. Its free end, which is broad and round, and occasionally notched in the midline, is directed upwards. Its attached part, or stalk (petiolus), is long and narrow and is connected by the elastic thyroepiglottic ligament to the back of the laryngeal prominence of the thyroid cartilage just below the thyroid notch. Its sides are attached to the arytenoid cartilages by aryepiglottic folds (which contain the aryepiglottic muscle). There is a depression, the vallecula, on each side of the median fold. The lower part of its anterior surface, behind the hyoid bone and thyrohyoid membrane, is connected to the upper border of the hyoid and separated from the thyrohyoid membrane by adipose tissue. This surface forms the oblique anterior wall of the laryngeal vestibule. The cartilage is posteriorly pitted by small mucous glands and is perforated by branches of the internal laryngeal nerve and fibrous tissue, which means that the posterior surface of the epiglottis is in continuity through these perforations with the pre-epiglottic space.

THYROID CARTILAGE

The thyroid cartilage is the largest of the laryngeal cartilage. It consists of two quadrilateral laminae with anterior borders that fuse along their inferior two-thirds at a median angle to form the subcutaneous laryngeal prominence (Adam's apple'). Posteriorly, the laminae diverge, and their posterior borders are prolonged as slender horns, the superior and inferior cornua.

The internal surface of the lamina is smooth. Above and behind, it is slightly concave and covered by mucosa. The thyroepiglottic ligament, the paired vestibular and vocal ligaments, the thyroarytenoid, thyroepiglottic and vocalis muscles, and the stalk of the epiglottis are all attached to the inner surface of the cartilage, in the angle between the laminae. The true vocal folds lie 6-9 mm below the median thyroid notch. The superior border of each lamina is concave behind and convex in front, and the thyrohyoid membrane is attached along this edge. The inferior border of each lamina is concave behind and nearly straight in front, and the two parts are separated by the inferior thyroid tubercle. Anteriorly, the thyroid cartilage is connected to the cricoid cartilage by the anterior (median) cricothyroid ligament, which is a thickened portion of the cricothyroid membrane.

CRICOID CARTILAGE

The cricoid cartilage is attached below to the trachea, and articulates with the thyroid cartilage and the two arytenoid cartilages by synovial joints. It forms a complete ring around the airway, the only laryngeal cartilage to do so . It is smaller, but thicker and stronger, than the thyroid cartilage, and has a narrow curved anterior arch, and a broad, flatter posterior lamina.

Cricoid lamina

The cricoid lamina is approximately quadrilateral in outline, and 2-3 cm in vertical dimension. It bears a posterior median vertical ridge that creates posterior

concavities on either side. The two fasciculi of the longitudinal layer of oesophageal muscle fibres (muscularis externa) are attached by a tendon to the upper part of the ridge. Posterior cricoarytenoid attaches to a shallow depression on either side of the ridge.

The superior border runs obliquely up and back and lateral cricoarytenoid. The posterosuperior aspect of the lamina presents a shallow median notch, on each side of which is a smooth, oval, convex facet, directed upwards and laterally, for articulation with the base of an arytenoid cartilage.

The internal surface of the cricoid cartilage is smooth and lined by mucosa.

ARYTENOID CARTILAGE

The paired arytenoid cartilages articulate with the lateral parts of the superior border of the cricoid lamina . Each is pyramidal, and has three surfaces, two processes, a base and an apex. The posterior surface, which is triangular, smooth and concave, is covered by transverse arytenoid. The anterolateral surface is convex and rough, and bears, near the apex of the cartilage. The medial surface is narrow, smooth and flat, and is covered by mucosa: its lower edge forms the lateral boundary of the intercartilaginous part of the rima glottidis. The base is concave, with a smooth surface for articulation with the lateral part of the upper border of the cricoid lamina.

CORNICULATE CARTILAGES

The corniculate cartilages are two conical nodules of elastic fibrocartilage which articulate with the apices of the arytenoid cartilages, prolonging them posteromedially. They lie in the posterior parts of the aryepiglottic mucosal folds, and are sometimes fused with the arytenoid cartilages.

CUNEIFORM CARTILAGES

The cuneiform cartilages are two small, elongated, club-like nodules of elastic fibrocartilage, one in each aryepiglottic fold, anterosuperior to the corniculate cartilages, and are visible as whitish elevations through the mucosa.

SOFT TISSUES

The skeletal framework of the larynx is joined to surrounding structures by extrinsic membranes. It is also interconnected by intrinsic ligaments and fibroelastic membranes, of which the thyrohyoid, quadrangular and cricothyroid membranes and the conus elasticus are the most significant. The thyrohyoid membrane is external to the larynx, whereas the paired quadrangular membranes, the cricothyroid membrane and the conus elasticus are internal.

LARYNGEAL CAVITY

The laryngeal cavity extends from the laryngeal inlet (from the pharynx) down to the lower border of the cricoid cartilage, where it continues into the trachea (Fig-2). The walls of the cavity are formed of the fibroelastic membranes described above and are lined with mucous membrane which folds over the free edges of these fibroelastic membranes within the larynx. On either side, the continuity of the fibroelastic membrane is interrupted between the upper and lower folds.



The folds project into the lumen of the cavity and divide it into upper and lower parts, separated by a middle portion between the two sets of folds leading into the laryngeal ventricle. The upper folds are the vestibular (ventricular or false vocal) folds; the median aperture which they guard is the rima vestibuli. The lower pair are the (true) vocal folds (or vocal cords), and the fissure between them is the rima glottidis or glottis. The true vocal folds are the primary source of phonation, whereas
the vestibular folds normally do not contribute directly to sound production. The clinical term supraglottis refers to the part of the larynx that lies above the glottis and comprises the laryngeal inlet formed of the laryngeal surface of the epiglottis and arytenoid cartilages and the laryngeal aspects of the aryepiglottic folds, the laryngeal vestibule (introitus) and the vestibular folds.

MICROSTRUCTURE OF THE LARYNX

The laryngeal epithelium is mainly a ciliated, pseudostratified respiratory epithelium where it covers the inner aspects of the larynx, including the posterior, laryngeal surface of the epiglottis, and it provides a mucociliary clearance mechanism shared with most of the respiratory tract. However, the vocal folds are covered by non-keratinized, stratified squamous epithelium where they contact each other: this important variation protects the tissue from the effects of the considerable mechanical stresses that act on the surfaces of the vocal folds.

The laryngeal mucosa has numerous mucous glands, especially over the epiglottis, where they pit the cartilage, and along the margins of the aryepiglottic folds anterior to the arytenoid cartilages, where they are known as the arytenoid glands.

UPPER PART

The upper part of the laryngeal cavity contains the laryngeal inlet (aditus), the aryepiglottic fold and the laryngeal vestibule (introitus).

Laryngeal inlet (aditus)

The upper part of the laryngeal cavity is entered by the laryngeal inlet (Fig-3), the aperture between the larynx and pharynx. This faces backwards and somewhat upwards, because the anterior wall of the larynx is much longer than the posterior.

The inlet is bounded anteriorly by the upper edge of the epiglottis, posteriorly by the transverse mucosal fold between the two arytenoids (posterior commissure), and on each side by the edge of a mucosal ridge, the aryepiglottic fold, that runs between the side of the epiglottis and the apex of the arytenoid cartilage.



Figure No 3 : Laryngoscopic View Of Inlet Of Larynx

Aryepiglottic fold

The aryepiglottic fold contains ligamentous and muscular fibres. The ligamentous fibres represent the free upper border of the quadrangular membrane. The muscle fibres are continuations of the oblique arytenoids. The posterior part of the aryepiglottic fold contains two oval swellings, one above and in front, the other behind and below, that mark the positions of the underlying cuneiform and corniculate cartilages respectively. They are separated by a shallow vertical furrow which is continuous below with the opening of the laryngeal ventricle.

Laryngeal vestibule (introitus)

Vestibule is a clinical term that denotes the space between the laryngeal inlet and vestibular folds. It is wide above, narrow below, and higher anteriorly than posteriorly. Its anterior wall is formed by the posterior surface of the epiglottis, the lower part of which (epiglottic tubercle) bulges backwards a little. Its lateral walls, which are higher in front and shallow behind, are formed by the medial surfaces of the aryepiglottic folds. Its posterior wall consists of the interarytenoid mucosa above the ventricular folds.

MIDDLE PART

The middle part of the laryngeal cavity is the smallest, and extends from the rima vestibuli above to the rima glottidis below. On each side it contains the vestibular folds, the ventricle and the saccule of the larynx.

Vestibular folds and ligaments

The narrow vestibular ligament represents the thickened lower border of the quadrangular membrane. It is fixed in front to the thyroid angle below the epiglottic cartilage and behind to the anterolateral surface of the arytenoid cartilage above its vocal process. With its covering of mucosa, it is termed the vestibular (ventricular or false vocal) fold. The presence of a loose vascular mucosa lends the vestibular folds a pink appearance *in vivo*, as they lie above and lateral to the vocal cords.

Ventricle (sinus) of the larynx

The laryngeal ventricle is a slit between the vestibular and vocal cords. It opens into a fusiform recess on each side of the larynx and extends upwards into the laryngeal wall lateral to the vestibular fold, opening into the saccule.

Vocal folds (cords) and ligaments

The free thickened upper edge of the conus elasticus forms the vocal ligament. It stretches back on either side from the mid level of the thyroid angle to the vocal processes of the arytenoids. When covered by mucosa, it is termed the vocal fold or vocal cord. The vocal folds form the anterolateral edges of the rima glottidis.

Rima glottidis

The rima glottidis or glottis is the fissure between the vocal cords anteriorly and the arytenoid cartilages posteriorly. It is bounded behind by the mucosa that passes between the arytenoid cartilages at the level of the vocal cords.

LOWER PART

The lower part of the laryngeal cavity, the subglottis or infraglottic cavity, extends from the vocal cords to the lower border of the cricoid. In transverse section it is elliptical above and wider and circular below, and is continuous with the trachea. Its walls are lined by respiratory mucosa, and supported by the cricothyroid ligament above and the cricoid cartilage below.

MUSCLES

The muscles of the larynx may be divided into extrinsic and intrinsic groups. The extrinsic muscles connect the larynx to neighbouring structures. They include the infrahyoid strap muscles, thyrohyoid, sternothyroid and sternohyoid, and the inferior constrictor muscle of the pharynx. Two of the three elevator muscles of the pharynx, stylopharyngeus and palatopharyngeus, are also connected directly to the thyroid cartilage, mainly to the posterior aspect of the thyroid laminae and cornua. The role of the extrinsic muscles during respiration appears to be variable: the larynx has been seen to rise, descend or barely move during inspiration.

The intrinsic muscles are the cricothyroid, posterior and lateral cricoarytenoid, transverse and oblique arytenoid, aryepiglotticus, thyroarytenoid and its subsidiary part, vocalis, and thyroepiglotticus: all are confined to the larynx in their attachments, and all but the transverse arytenoid are paired, the cricothyroids appear on the outer aspect of the larynx.

The intrinsic laryngeal muscles may be placed in three groups according to their main actions. The cricothyroids, posterior cricoarytenoids, thyroarytenoids and vocales regulate the tension of the vocal ligaments. The oblique arytenoids, aryepiglottic and thyroepiglottic muscles modify the laryngeal inlet.

INTRINSIC MUSCLES

Lateral cricoarytenoid is attached anteriorly to the upper border of the cricoid arch. It ascends obliquely backwards to be attached to the front of the muscular process of the ipsilateral arytenoid cartilage.

Innervation

Lateral cricoarytenoid is innervated by one to six branches of the anterior terminal division of the recurrent laryngeal nerve, with the most frequent pattern consisting of three branches.

Actions

Lateral cricoarytenoid rotates the arytenoid cartilage in a direction opposite to that of posterior cricoarytenoid, and so closes the rima glottidis. As it does so, it brings the tips of the vocal processes together, closing the ligamentous part of the rima glottidis, an action known as medial compression. The action of lateral cricoarytenoid in adducting the vocal folds is therefore distinct and complementary to that of the interarytenoid muscles. Contraction of lateral cricoarytenoid also results in shortening and relaxing of the vocal folds.

Cricothyroid

Cricothyroid is attached anteriorly to the external aspect of the arch of the cricoid cartilage. Its fibres pass backwards and diverge into two groups, a lower 'oblique' part which slants backwards and laterally to the anterior border of the inferior cornu of the thyroid, and a superior 'straight' part which ascends more steeply backwards to the posterior part of the lower border of the thyroid lamina. The medial borders of the paired cricothyroids are separated anteriorly by a triangular gap.

Innervation

Unlike the other intrinsic muscles of the larynx, cricothyroid is innervated by the external branch of the superior laryngeal nerve, and not by the recurrent laryngeal nerve.

Actions

Cricothyroid lengthens and affects tension in the vocal folds. It does this by shortening the space between the inferior border of the thyroid cartilage and the cricoid cartilage. Rotation occurs at the cricothyroid joint. At the same time, the posterior part of cricothyroid pulls the thyroid cartilage forwards, and this gliding action also lengthens the vocal folds.

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VASCULAR SUPPLY AND LYMPHATIC DRAINAGE

The blood supply of the larynx is derived mainly from the superior and inferior laryngeal arteries. Rich anastomoses exist between the corresponding contralateral laryngeal arteries and between the ipsilateral laryngeal arteries. The superior laryngeal arteries supply the greater part of the tissues of the larynx, from the epiglottis down to the level of the vocal cords, including the majority of the laryngeal musculature. The inferior laryngeal artery supplies the region around cricothyroid, while its posterior laryngeal branch supplies the tissue around posterior cricoarytenoid.

Venous return from the larynx occurs via superior and inferior laryngeal veins which run parallel to the laryngeal arteries and are tributaries of the superior and inferior thyroid veins respectively.

INNERVATION

The larynx is innervated by the internal and external branches of the superior laryngeal nerve, the recurrent laryngeal nerve and sympathetic nerves. Conventionally, the internal laryngeal nerve is described as sensory, the external laryngeal nerve as motor, and the recurrent laryngeal nerve as mixed.

Autonomic innervation

Parasympathetic secretomotor fibres run with both the superior and recurrent laryngeal nerves to mucous glands throughout the larynx. Postganglionic sympathetic fibres run to the larynx with its blood supply; they originate in the superior and middle cervical ganglia.

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PLMA & I-GEL

ProSeal -LMA

The PLMA has four main parts: the cuff, inflation line with pilot balloon, airway tube, and drain tube (gastric access)^{20,21,22,23}. All components are made from silicone and are latex-free. It is available in six sizes. Studies indicate that the size 4 is preferable for most adult women and the size 5 for most adult men. The airway (breathing, ventilation) tube of the PLMA is shorter and smaller in diameter than that of the LMA-Classic and is wire reinforced, which makes it more flexible. There is a locating strap on the anterior distal tube to prevent the finger slipping off the tube and to provide an insertion slot for the introducer tool. An accessory vent under the drainage tube in the bowl prevents secretions from pooling and acts as an accessory ventilation port. The PLMA has a deeper bowl than the LMA-Classic and does not have aperture bars. There is a bite block between the tubings at the level where the teeth would contact the device.

The drain (drainage, esophageal drain) tube is parallel and lateral to the airway tube until it enters the cuff bowl, where it continues to an opening in the tip that is sloped anteriorly. When the PLMA is correctly positioned, the cuff tip lies behind the cricoid cartilage at the origin of the esophagus. It allows liquids and gases to escape from the stomach, reduces the risks of gastric insufflation and pulmonary aspiration, allows devices to pass into the esophagus, and provides information about the PLMA. The drain tube is designed to prevent the epiglottis from occluding the airway tube, eliminating the need for airway bars. A gastric tube, Doppler probe, thermometer, stethoscope, or medication can be passed into the esophagus through the drainage port. A plastic supporting ring around the distal drain tube prevents the tube from collapsing when the cuff is inflated.



Figure No. 4 : ProSeal –LMA size 3 and 4

The PLMA has a second dorsal cuff. This pushes the mask anteriorly to provide a better seal around the glottic aperture and helps to anchor the device in place²³. The dorsal cuff is not present on sizes $1^{1}/_{2}$ to $2^{1}/_{2}$. The cuff is softer than that on an LMA-Classic. The ventral cuff is larger proximally to improve the seal.

A silicone-coated malleable metal introducer to facilitate placement of the PLMA is available. It has a curved, malleable silicone-coated blade with a guiding handle. The distal end fits into the locating strap, and the proximal end fits into the airway tube.

Insertion:

Insertion Methods

It is recommended that the PLMA cuff be deflated into a wedge shape, as with the LMA-Classic. The patient should be in the "sniffing" position (lower neck flexion and head extension). It may be necessary to briefly release cricoid pressure to allow the PLMA to pass²⁴.

Introducer Technique

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

As the PLMA is inserted, the introducer is kept close to the chin. The cuff should be observed to make certain that it has not folded over. The introducer is inserted inward in a smooth circular movement. The jaw can be pulled downward by an assistant or pushed downward with the middle finger until the cuff has passed the teeth, but the jaw should not be held widely open, because this may cause the tongue and epiglottis to drop downward, blocking the mask's passage. The PLMA is advanced until resistance is felt. The non dominant hand should be used to stabilize the airway tube as the introducer is removed by following the curvature backward out of the mouth, taking care to avoid damage to the teeth. The bite block should be at the teeth²⁵.

Insertion in patients with a stereotactic frame or neck collar is probably best performed without the introducer to increase maneuverability.

Digital Method

The digital method for insertion is similar to the introducer method except that the tip of the index finger is placed at the junction of the cuff and the two tubes. As the index finger passes into the mouth, the finger joint is extended and the PLMA is pressed backward toward the other hand that exerts counter pressure to maintain the sniffing position²⁶. Depending on patient and user finger size, the finger may need to be inserted to its fullest extent before resistance is encountered. The non dominant hand should be used to stabilize the LMA as the finger is withdrawn.

The thumb may be used to aid insertion when it is difficult to get access to the patient from behind. The thumb is inserted into the strap. As the thumb enters the mouth, the fingers are stretched forward over the patient's face. The thumb is advanced to its fullest extent. The pushing action exerted by the thumb against the

hard palate serves to press the head into extension²⁶. A lateral approach is required more frequently with this method.

Guided Method

With this technique, a lubricated stylet, bougie, fiberoptic endoscope, suction catheter, lightwand, or gastric tube is first placed through the drain tube. The patient end of the device is then inserted into the esophagus under laryngoscopic or fiberscopic guidance. The bougie should be pointing posteriorly, opposite to when it is used for intubation. The PLMA is then advanced into place over the device. This method avoids folding the tip backward. It is more successful and less traumatic than using the introducer tool or digital methods. This method has been used for patients with known difficult airways^{27,28}, after failed positioning of an LMA-Flexible²⁹, and to exchange a PLMA³⁰.

Cuff Inflation

After the PLMA has been inserted, the cuff should be inflated with enough air to achieve an intracuff pressure of up to 60 cm H_2O . During insertion and cuff inflation, the front of the neck should be observed to see if the cricoid cartilage moves forward, indicating that the mask has correctly passed behind it. The cuff volume required for the PLMA to form an effective seal with the respiratory tract is lower than for the LMA-Classic. In fact, an adequate seal can be obtained in most patients with no air in the cuff; however, the cuff should be inflated with at least 25% of the maximum recommended volume to ensure an effective seal with the gastrointestinal tract.

Use

The PLMA can be used for both spontaneous and controlled ventilation, but is more suited to controlled ventilation^{31,33}. The sealing pressure is higher than with the LMA-Classic in adult and pediatric patients, making it a better choice for situations where higher airway pressures are required, where better airway protection is desirable, and for surgical procedures in which intra operative gastric drainage or decompression is needed³². Case reports show no aspiration of gastric contents despite regurgitation or vomiting unless the PLMA is malpositioned³⁴. However, aspiration has been reported with malpositioning³⁵.

It may be easier to place the PLMA than the LMA-Classic during manual inline neck stabilization. It has been used in cases of known difficult airway and has been successfully used after failure with an LMA-Classic.

The PLMA may be useful in cases where it is important to avoid airway trauma, as it exerts lower pressures against the pharyngeal mucosa than the LMA-Classic. However, airway trauma as evidenced by blood on the device after removal is higher for the PLMA than for the LMA-Classic.

The PLMA has been found to be safe for use in an MRI unit, but imaging quality may be compromised, depending on the pulse sequence that is used and whether the area of interest is near the LMA³⁶.

I-GEL AIRWAY

The I-gel is the most recent development in supraglottic airway devices. It was developed by Dr. Mohammad Aslam Nasir in January 2007. The I-gel is a new single use non inflatable supraglottic airway device. It is composed of a soft gel like transparent, thermoplastic elastomer. It is designed to achieve a mirrored impression of the pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation.

The I-gel is a truly anatomical device³⁷. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work, mirroring the shape of the epiglottis, aeryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation.

As a supraglottic airway without an inflatable cuff, it has several potential advantages including easier insertion, minimal risk of tissue compression and stability after insertion (No position change with cuff inflation). The I-gel is designed as a latex free, single patient use device. The buccal cavity stabilizer has a widened; elliptical symmetrical and laterally flattened cross sectional shape providing good vertical stability upon insertion.

The firmness of tube section and its natural orophryngeal curvature allows device to be inserted by grasping the proximal end of the I-gel and helps to glide the leading edge against the hard palate into pharynx. It is not necessary to insert fingers into the mouth of the patient for full insertion. An integrated gastric channel is provided for suction of gastric contents or to allow the passage of a nasogastric tube into empty stomach. I-gel has an artificial epiglottis called the "Epiglottis blocker". This helps to prevent the epiglottis from down folding. In the very unlikely event that an epiglottis should still down-fold, the airway channel exits so deeply into the bowl of cuff, there is no danger of epiglottis to interfere with fresh gas flow.

When correctly inserted, the tip of the I-gel will be located into the upper oesophageal opening, providing a conduit via the gastric channel to oesophagus and stomach. This allows suctioning, passing of a nasogastric tube and facilitates venting.

The I-gel is indicated in :

- 1. Securing and maintaining a patent airway in routine and emergency operations of fasting patients during spontaneous or intermittent positive pressure ventilation (IPPV).
- 2. Establishing a clear airway in pre-hospital or intra-hospital cardio-respiratory arrest patients, where techniques to intubate the patient have failed, expertise to intubate the patient is not available.
- 3. Used by an ambulance crew in difficult or unexpectedly difficult intubations in a pre-hospital stage in order to achieve and maintain a clear airway.
- 4. Securing a clear airway in difficult or unexpectedly difficult intubations in airway management of a patient in operating theatre.
- 5. In an elective, difficult or unexpectedly difficult intubation, for intubating the patient, by passing an endotracheal tube (ETT) through the device.

Figure No 5 : I - Gel Airway Size No 3 And 4



I-gel size	Maximum size of Endotracheal tube	Maximum size of Naso- gastric tube (FG)
3	6.0mm	12
4	7.0mm	12
5	8.0mm	14

Its shorter and wider stem suggests that it may be an ideal conduit for intubation. It is also possible to pass a fiberscope through it in rescue intubation. Initial studies have confirmed its fast and easy insertion with high 1^{st} attempt and overall success. The I-gel provides a reliable clear airway with interventions rarely required. Airway seal^{38,39} is 25-30 cm H₂O, between that of the LMA-classic and PLMA ventilation. It is highly effective with excellent anatomical positioning and laryngopharyngeal trauma is rare.

- 6. In difficult or unexpectedly difficult intubation, to pass a gum-elastic bougie blindly but gently, through the device in-situ, into the trachea and to rail-road the ETT over it.
- In a known difficult or unexpectedly difficult intubation, to pass a fibre-optic scope through the device, to provide visualisation of the glottis opening to aid intubation.
- 8. In the intensive care patient, for weaning a certain category of the population, where an endotracheal tube is not well tolerated.
- 9. In difficult mouth opening situations, I-gel can be inserted under direct vision with the help of a laryngoscope.

Size selection

Select the appropriate size of I-gel by assessing the patient's anatomy. Please note, the I-gel may look smaller than traditional supraglottic devices with an inflatable cuff :

i-gel size	Patient size	Patient weight guidance
		(kg)
3	Small adult	30-60
4	Medium adult	50-90
5	Large adult +	90+

If the seal is not adequate, particularly during intermittent positive pressure ventilation (IPPV), one size larger may be required.

Recommended insertion technique

A proficient user can achieve insertion of the I-gel in less than 5 seconds.

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

Do not apply excessive force on the device during insertion. 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 or insertion with deep rotation is recommended.

HEMODYNAMICAL CHANGES WITH INSERTION OF LMA

Hemodynamical changes like blood pressure and heart rate increase are similar to insertion of oral airway in LMA⁴⁰, but less marked and of shorter duration than those associated with tracheal intubation.

There is minimal increase in intraocular pressure following insertion.

There no change in intracranial pressure with insertion of LMA.

MATERIALS AND METHODS

This randomized clinical trial was carried out in the Department of Anesthesiology, BLDE University Shri B M Patil Medical College, Hospital and Research Center, Bijapur from Dec2012 – Sept 2013.

Ethical clearance was obtained from the institution for this study.

126 patients in the age group of 20-60 years fulfilling inclusion and exclusion criteria scheduled to undergo surgery under General anesthesia lasting for less than 2 hours were randomly allocated to two groups- A and B (Group A- Even numbered patients, Group B- Odd numbered patients).

Group A - PLMA was inserted.

Group B- I-gel airway was inserted.

SAMPLE SIZE: According to hospital statistics in 2011, out of 4000 patients who underwent general anesthesia, LMA was inserted in 300 patients for surgeries lasting for less than 2 hours. Considering 7.5% proportion and \pm 5% margin of error with 95% confidence limit, calculated sample size was 106.

$$n = Z\alpha^2 x P x (1-p)$$

$$d^2$$

Group (A) 53 patients and Group (B) 53 patients.

In each group 10 cases were added, to overcome problems such as non- cooperation of patients and other follow up problems, so total sample size was 126.

Group (A) 63 patients and Group (B) 63 patients.

INCLUSION CRITERIA:

- 1) ASA physical status I and II
- 2) Age between 20-60 yrs of both sexes
- 3) Elective cases undergoing GA.

EXCLUSION CRITERIA:

- 1) ASA physical status III and above.
- 2) Anticipated difficult airway.
- 3) Patients with coagulation disorders.
- 4) Patients with renal and liver diseases.

STATISTICAL DATA:

Data were compiled and analyzed statistically using

- 1) Mean \pm SD
- 2) Chi square test
- 3) Student t- test or z test
- 4) p value of < 0.05 significant and >0.05 not significant.

PREANAESTHETIC EVALUATION:

Patient's detailed history was taken and detailed airway assessment was done. General physical examination and systemic examination was carried out. Basic demographic data like age, sex, findings of cardiovascular, respiratory & other systems were recorded. Routine investigations like Hb, urine for sugar, albumin, microscopy, RBS, blood urea, Sr. creatinine, HIV, Hbs Ag, chest X ray and ECG were done depending on the age and clinical condition. Patients were kept nil orally for 8hrs before surgery. A written & informed consent was taken from the patient.

PREMEDICATION:

All patients of group A & B were premedicated intravenously with Inj midazolam 0.05mg/kg, Inj glycopyrrolate 0.005mg/kg, and Inj fentanyl 1-2 μ g/kg 5 mins before induction. Before and after premedication all vital data (PR, NIBP, SPO₂, and RR) were taken.

PROCEDURE:

Patients were preoxygenated with 100% oxygen for 3 mins with facemask and Bain's circuit.

Induction:

Patients of group A & B were induced with

Inj. Propofol 2-2.5 mg/kg i.v. slowly

Inj. Succinylcholine 1.5-2 mg/kg iv stat

Securing airway:

In group A patients the airway was secured with PLMA while in group B patients airway was secured with I-gel airway of appropriate sizes.

INSERTION METHODS:

PROSEAL LMA (PLMA): All components are made from silicon and are latex-free. It is available in six sizes. Studies indicate that the size 4 is preferable for most adult women and the size 5 for most adult men. It is shorter and smaller in diameter which makes it more flexible. A vent under drain tube in the bowl is to prevent secretions from pooling. The drain tube is parallel and lateral to the airway tube. Cuff should be deflated into a wedge shape and jelly applied over the posterior aspect. The patient should be in sniffing position (head extension and neck flexion).

PLMA can be inserted by 3 techniques:

- 1) Introducer technique.
- 2) Digital method.
- 3) Guided method.

In the present study PLMA was inserted by digital method.



Figure No 6 : Proseal LMA after Insertion and fixation

I-GEL AIRWAY:

This is non inflatable latex free supraglottic airway device. It is soft gel like transparent thermoplastic elastomer. Gastric channel is provided for suction of gastric contents or allow passage of nasogastric tube into the stomach.

Size selection

Appropriate size selected by assessing the patient's anatomy. I-gel may look smaller than traditional supraglottic devices with an inflatable cuff:

If the seal is not adequate, particularly during intermittent positive pressure ventilation (IPPV) one size larger may be required.



Figure No 7 : I-GEL Airway after Insertion and fixation

A proficient user can achieve insertion of the I-gel in less than 5 seconds.

Maintenance:

Patients of both groups were maintained with O_2+N_2O+ intermittent positive pressure ventilation, isoflurane and Inj. Vecuronium.

Monitoring:

All vital data (PR, NIBP, RR, SPO₂, ECG and ETCO2) recorded before and after induction at regular intervals.

Reversal:

Reversal of anaesthesia achieved using inj. Neostigmine 0.05mg/kg and inj. Glycopyrolate 8 mcg/kg given intravenously.

PLMA and I-gel airway removed only after establishment of all reflexes, adequate muscle power and when patient was fully conscious.

Observations:

Following observations were done:

- 1. No of attempts of insertion of each device.
- 2. Mean time for insertion (time from insertion of device into the mouth to time of confirmation by ventilation)
- 3. Pulse rate, blood pressure, SPO₂ monitored
 - a) Before premedication.
 - b) After premedication.
 - c) During Induction.
 - d) During Insertion.
 - e) 1^{st} , 3^{rd} , 5^{th} , 10^{th} and 15^{th} mins after insertion.

- 4. Patients were also observed for possible blood on device, coughing, laryngospasm, bronchospasm, regurgitation and aspiration.
 Failure of the device was considered when airway was not secured with effective ventilation even after second attempt and excluded from study.
- 5. All patients were observed in the post operative period for possible complications like-
 - Mouth laceration/oedema
 - Trauma to oropharyngeal structures
 - Complaint of sore throat/hoarseness
 - Nausea/Vomiting

OBSERVATIONS AND RESULTS

126 patients were selected for this study for evaluation of efficiency of Proseal LMA compared with I-gel airway. They are grouped as group-A(63 patients using Proseal LMA) and group-B(63 patients using I-gel)

	GROUP-A	GROUP-B	p-Value	S
MEAN AGE (YRS)±SD	37.11±10.37 (1.32)	36.88±11.39 (1.43)	P=0.9090	NS
MEAN WEIGHT (KG)±SD	51.968±4.856 (0.6118)	50.524±5.193 (0.65)	P=0.1892	NS
SEX (MALE : FEMALE)	28:35	25:38	>0.05	NS
ASA GRADE-	1.634±0.48	1.63±0.485	P>0.999	NS
MEAN DURATION OF SURGERY (MIN)±SD	67.52±32.47 (4.091)	64.44±36.22 (4.56)	P=0.4089	NS

TABLE-1 DEMOGRAPHIC DATA

Table-1, Bar chart -1 shows the demographic data of both the groups. The mean age in group-A was $37.11(\pm 10.37)$. The mean age in group-B was $36.88(\pm 11.39)$. Statistically age in both groups is comparable, there is no significant difference.

Mean weight in group-A was $51.9(\pm 4.85)$. The mean weight in group-B was $50.5(\pm 5.19)$. Statistically weight in both groups is comparable, there is no significant difference.

Graph 1:



DEMOGRAPHIC DATA

In group-A there were35 female and 28 male patients while in group-B there were 38 female and 25 male patients. There were 23 ASA grade-I and 40 ASA grade - II patients in group-A. There were 23 ASA grade-I and 40 ASA grade-II patients in group-B.

Mean duration of surgery in group-A was 67.5 min (\pm 32.47),while in group-B it was 64.44 min (\pm 36.22).Thus both the groups are comparable ,there was statistically no significant difference between the two groups with regards to demographic data.

	GROUP-A (n=63)	GROUP-B (n=63)	p-value	S
Before premedication	82.86±5.56	81.04±8.92	0.174	NS
After premedication	78.682±5.811	77.095±6.98	0.176	NS
Induction	77.523±6.33	76.825±5.868	0.553	NS
Insertion	84.349±3.673	82.746±5.524	0.156	NS
1min	86.492±4.154	84.857±3.345	=0.0139	S
3min	89.333±4.131	84.126±3.190	< 0.05	S
5min	90.11±3.655	83.793±3.781	< 0.05	S
10min	89.936±3.22	83.206±4.677	< 0.05	S
15 min	87.714±3.024	82.730±5.498	< 0.05	S

TABLE-2 MEAN PULSE RATE/MIN OF BOTH GROUPS

Table-2, Graph-2 and line chart-2 shows mean pulse rates/min of both groups compared statistically using mann-whitney U-test.

Difference between the two groups was considered significant if p-value <0.05.

Before premedication, mean pulse rate of group-A was $82.86(\pm 5.56)$ while in group-B it was $81.045(\pm 8.92)$ with p-value of 0.174. So the groups are comparable with regard to mean pulse rate. After premedication mean pulse rate of group-A was $78.682(\pm 5.811)$ while in group-B it was $77.095(\pm 6.98)$ with p-value of 0.1763. So the changes in mean pulse rate after premedication are comparable.

Mean pulse rates of both groups at induction, insertion, intraoperatively at 1,3,5,10,15 mins were compared. There is significant change in mean pulse rates in both groups at 3,5,10 and 15mins with p- value<0.05.

In group-A 57 patients were inserted with PLMA-no-3 and 6 patients needed PLMA-size-4.

In group-B 59 patients were inserted with I-gel no- 3 and 4 patients required I-gel no-4.

GRAPH – 2:

SHOWING MEAN PULSE RATE/ MIN OF BOTH GROUPS





SHOWING MEAN PULSE RATE/ MIN OF BOTH GROUPS



	GROUP-A(n=63)	GROUP-B(n=63)	p-value	S
Before premedication	93.825±4.207	94.068±3.077	0.6204	NS
After premedication	89.952±3.996	90.645±3.099	0.2787	NS
Induction	87.465±3.381	86.227±4.179	0.069	NS
Insertion	91.804±2.334	92.534±4.059	0.1323	NS
1min	98.264±3.158	93.629±3.002	< 0.05	S
3min	100.195±2.493	93.925±2.403	< 0.05	S
5min	101.793±2.108	95.005±2.561	< 0.05	S
10min	101.83±2.199	93.884±2.586	< 0.05	S
15min	98.280±2.064	94.106±3.126	< 0.05	S

TABLE-3 : MEAN ARTERIAL PRESSURE (mmHg) OF BOTH GROUPS

Table-3, Bar chart-3 and line chart-3 shows mean arterial pressures(MAP) of both groups .Before premedication MAP of group-A was $93.825(\pm 4.207)$,while of group-B was $94.068(\pm 3.077)$ with p-value 0.6204(>0.05) when compared by student-t test. So both groups are comparable with regards to MAP before premedication and there is no significant difference between the two groups.

MAP of both groups are compared intraoperatively for 15mins.

Changes in MAP is not significant in both groups before premedication, after premedication, induction and insertion with p-value > 0.05 as shown in the table-3.

Changes in MAP is significant intraoperatively at 1min,3 min ,5min,10min and15min with MAP being higher in group-A(PLMA group) than group-B(I-gel group) with p-value <0.05 as shown in the table-3.

GRAPH – 4:

SHOWING MEAN ARTERIAL PRESSURE(mmHg) OF BOTH GROUPS



GRAPH – 5:

SHOWING MEAN ARTERIAL PRESSURE(mmHg) OF BOTH

GROUPS


TABLE-4 : MEAN DURATION FOR INSERTION (SECONDS) OF DEVICE

	GROUP-A (PLMA)	GROUP-B (I-GEL)	p-value	S
DURATION (SEC)	11.698 ± 2.993	9.698 ± 2.423	<0.05	S

IN BOTH GROUPS

Table-4 shows mean duration (sec) of insertion of devices in both the groups. In group-A mean duration was $11.69(\pm 2.993)$ while in group-B it was $9.69(\pm 2.423)$. When compared by mann whitney u test, p-value was <0.05. So difference between the two groups with regard to mean duration of insertion was much significant indicating shorter time required for insertion of I-gel airway than PLMA.

TABLE-5 : COMPARISON OF EASE OF INSERTION AND INSERTION ATTEMPTS

EASE OF INSERTION(n)	GROUP-A	GROUP-B	p-value
EASY	51	61	p <0.05 S
DIFFICULT	12	2	
INSERTION ATTEMPTS	5		
1	59	61	
2	4	2	p >0.05 NS
3	0	0	
FAILED	2	2	

In Table-5, Group-A there are 2 attempts in 4 cases for securing airway, while there are 2 attempts in 2 cases for securing airway in group-B.So the number of attempts in securing airway in both the groups are comparable and there is no significant difference. p- value is >0.05.

In group-A there were two incidents of failure to secure airway and in both the cases airway was secured by endotracheal tubes.

In group-B also there were two incidents of failure to secure airway, later secured by endotracheal tubes.

Failure rate in both the groups is similar

EASE OF GASTRIC TUBE INSERTION	GROUP-A	GROUP-B	p-value	S
EASY	59	63	=0.1190	NS
DIFFICULT	4	0		
FAILED	0	0		
BLOOD STAINING OF I	DEVICE			
YES	3	1	>0.05	NS
NO	60	62		
BRONCHOSPASM/	0	0		
LARYNGOSPASM				
REGURGITATION/				
ASPIRATION	0	0		

TABLE-6 : COMPARISON OF OTHER PARAMETERS

Table-6 shows, group-A ease of gastric tube were 59 patients compared to 63 patients in group-B, and no failure of insertion of gastric tube. There was no significant difference in both the groups, p-value-0.1190 which is not significant.

Blood staining of device was seen in 3 patients of group A and in one patient of group B. There was no significant difference between both the groups with p>0.05 which is not significant.

There was no incidence of bronchospasm/laryngospasm, aspiration/ regurgitation and hoarseness in both groups.

Type of surgeries in GROUP-A are shown below:

SURGERIES	NUMBER OF CASES
Gynecology	13
Otolaryngology	5
General surgery	39
Orthopaedics	6

Type of surgeries in GROUP-B are shown below:

SURGERIES	NUMBER OF CASES
Gynecology	12
Otolaryngology	5
General surgery	43
Orthopaedics	3

TABLE-7 : POSTOPERATIVE OBSERVATIONS:

Complications	Group A (n=63)	Group B (n=63)	p- value
COUGHING	0	0	
HOARSNESS	0	0	
SORE THROAT			
YES	4	3	p>0.05 NS
NO	59	60	

All the patients were observed in the recovery phase for hoarseness, coughing and sore throat.

No significant complications were noted in any patients. Only four patients in group-A and three in group-B complained of sore throat and none had coughing or hoarseness of voice. No patient developed cyanosis, hypotension, bradycardia, tachycardia. There was no edema, bruising, erythema on throat examination.

DISCUSSION

LMA is an established safe airway device for procedures, lasting less than $2hrs^{41}$.LMA is also a safe device for controlled ventilation, where airway pressure is maintained at 15 to 20 cm of H2O⁴².

I-gel airway is found to be easier to insert when compared to PLMA¹⁴.I-gel is also found to produce less haemodynamic changes than PLMA¹⁴.

In the present study a total of 126 patients were randomly selected from the routine list of surgical procedures under general anesthesia lasting≤2hr from BLDEA hospital. Mean age, sex, weight were comparable in both the groups as shown in table-1.All the ptatients were from ASA Physical status 1 and 2. Mean duration of surgery in both groups is also comparable as shown in table-1

In group-A airway was secured with PLMA, while in group-B airway was secured with I-gel airway.57 patients in group-A required PLMA no.3 and 6 patients required PLMA no.4 for securing airway while in group-B, 59 patients required I-gel no.3 and four patients required I-gel no. 4.

In group-A, insertion of airway was easy in 51 patients, while in group -B, insertion of airway was easy in 61 patients. There was significant difference in ease of insertion; I-gel was found to be easier to insert compared to PLMA.

Number of attempts for insertion of devices in both the groups is also comparable. In group-A number of attempts in four patients is 2, while in group-B number of attempts in two patients is 2.Hence most of the patients in both the groups required only single attempt. Number of attempts in both groups is not significant. In group-A ease of gastric tube were59 cases and in group-B it was 63 cases, there was no significant difference between both the groups.

All the insertion attempts in both the groups were done by consultants.

There was considerable difference between the two groups with regard to mean time of insertion of the device. In group-A in which PLMA was used to secure airway mean time of insertion was $11.69(\pm 2.993)$ sec. while in group-B in which I-gel airway was used to secure airway mean time of insertion was $9.69(\pm 2.423)$ sec. The p-value in this case is <0.05 when tested by mann whitney u- test which is significant. Hence I-gel airway required significantly lesser insertion time than PLMA.

Ishwar Singh Monika Gupta Mansi Tandon studied comparison of clinical performance of I-gel with LMA proseal in elective surgeries^{15,43}. They found that the success rate of first attempt insertion was more with I-gel airway compared to PLMA, and I-gel was easier to insert than PLMA, insertion of gastric tube was easy in both, incidence of dental trauma, lip trauma and blood staining of the device was more with PLMA. There were no incidences of laryngospasm, bronchospasm, regurgitation, aspiration and hoarseness in either group.

There was significant difference in ease of insertion of the device in both groups. In the present study also I- gel was easy to insert than PLMA.

There was no significant difference in insertion of gastric tube in both the groups in our study also.

There was no significant difference between the two groups with regard to mean pulse rates before premedication, after premedication and at induction. Mean pulse rates were compared at insertion, 1,3,5,10, and 15mins .Changes in mean pulse

rates at before and after premedication, induction and insertion between the two groups were not significant and hence were comparable as shown in table-2.

There was significant difference between both the groups in mean pulse rates at 1min, 3min, 5min, 10min and 15mins as shown in table-2.I-gel was found to be hemodynamically more stable than PLMA.

There was no significant difference between the two groups with regard to mean arterial pressure(MAP) before and after premedication, at induction and at insertion. MAPs were compared at insertion,1,3,5,10and15mins.

Changes in MAP were significant in intraoperative period at insertion, 1,3,5,10 and 15mins with mean arterial pressure being higher in group-A with p-value <0.05 as shown in table-3.

Parul Jindal, Aslam Rizvi J. P. Sharma have done a study to evaluate and compare the hemodynamic changes during insertion of supraglottic devices LMA, SLIPA or I-gel¹⁴.

They concluded that I-gel produced less haemodynamic changes than LMA.

In the present study also I-gel airway produced less rise in MAP when compared to PLMA in intraoperative period at 1, 3, 5, 10 and 15 mins. Hence I-gel produced less haemodynamic changes than PLMA.

The study conducted by Ishwar Singh et al¹⁵ also shows that haemodynamic changes are less in I-gel when compared to PLMA.

Postoperatively patients were observed.

There were four cases of sore throat in group-A and three cases of sore throat in group-B. Postoperative sore throat was not significant in both the groups. Later sore throat resolved on its own without the need of any active treatment. There was no coughing or hoarseness in both the groups.

There were two cases of failure to secure airway in each group in which case patients required endotracheal intubation. So the failure rate in both groups is similar. Failure of devices in all four cases of both the groups was attributed to improper size selection and fitting of the device.

No other complications were found in both groups.

Other complications like nerve damage, oral cavity injury, pain, restlessness, respiratory obstruction etc were not observed in any patients of both the groups.

C.A.Alexander, Royal East Sussex Hospital, studied 321 unselected patients who had general surgical, orthopaedic, gynaecological and genitourinary procedure under general anaesthesia were surveyed to ascertain the incidence of sore throat, some of these patients airway was secured with LMA and some of them was secured with ET. He concluded that incidence of sore throat in skilled hands is significantly reduced by the use of LMA⁴⁴.

CONCLUSION

From present study we conclude that I-gel airway is a better alternative supraglottic airway device than PLMA, with controlled ventilation and for securing airway in difficult airway management, since it is easy to insert and produces lesser haemodynamic changes than PLMA.

SUMMARY

In present study, 126 patients of ASA gr-I & II, with 63 patients in each group, were selected from routine gynaecologic, general surgical, ENT and orthopaedic procedures.

In group-A, PLMA was used and in group-B, I-gel airway was used as airway device.

Premedication was given with inj. glycopyrrolate 0.2mg Iv, inj midazolam 0.05mg/kg, inj fentanyl 1-2 μ g/kg, all these drugs were given IV prior to surgery. After preoxygenation, induction of anaesthesia was done with inj. Propofol 2-2.5mg/kg i.v slowly, inj. Succinylcholine 1.5-2mg/kg i.v for insertion of the device. In group-A, airway was secured with PLMA and in group-B airway was secured using I-gel airway. After ensuring correct position of mask, all patients of both groups were maintained with N2O + O2 + inj. Vecuronium + IPPV + isoflurane using bain circuits. In group-A, PLMA was inserted at first attempt in all patients except four patients who required second attempt of insertion, with mean duration of insertion being 11.698(±2.993) second. In group-B, I-gel was inserted at first attempt in all patients except in two patients who required second attempt of insertion, with mean duration of insertion, with mean duration of insertion being 9.698(±2.423) second.

In Group –A, Insertion was easy in 51 patients and in Group –B, insertion was easy in 61 patients. There was significant difference in both groups, I-gel was easy to insert than PLMA. p value<0.05.

In group-A, gastric tube insertion was easy in 59 patients compared to 63 in group-B, there was no significant difference in ease of gastric tube insertion in both groups and no failed insertion in both the groups.

Intraoperative monitoring was done for pulse rate, NIBP, ECG, ETCO2 and SPO2.The changes in mean pulse rates in both groups are insignificant, before and after premedication, induction and insertion but there was significant difference seen at 1min,3 min,5min,10 min and 15mins.

There was significant difference in both groups in regard to mean arterial pressure at 1,3,5,10 and 15 mins, with p- value<0.05 which is significant.

Postoperative observations were made. There were 2 cases in each group where devices were failed to secure airway. There were two cases of sore throat in each group. No major complications were observed in any patients of both groups

From present study we recommend the use of I-gel as an alternative to PLMA in routine surgical patients with better haemodynamic stability and easier insertion than PLMA.

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ANNEXURES

PROFORMA

Name:	Date:
Age:	IP No.:
Sex:	Height:

PREOPERATIVE EVALUATION

GPE:	RR:
Pulse rate:	Weight:
Blood Pressure:	Temperature:

SYSTEMIC EXAMINATION

CVS:	Mallampati grading of airway:
RS:	Spine:
Others:	

INVESTIGATIONS

Hb%:	Urine-R:	CXR and ECG:
BT:	RBS:	HbsAg;
CT:	Bl Urea and S.crt:	HIV:

PREOPERATIVE DIAGNOSIS:

Proposed surgery:

ASA grade:

Anesthetic technique:

PREMEDICATION:

All patients of group A & B were premedicated intravenously with

Inj midazolam 0.05mg/kg

Inj glycopyrrolate 0.005mg/kg,

Inj fentanyl 1-2µg/kg 5 mins before induction. Before and after premedication all vital data (PR, NIBP, SPO₂, and RR) were taken.

Induction:

Preoxygenation for 3 mins prior to induction

Patients of group A & B were induced with

Inj. Propofol 2-2.5 mg/kg i.v. slowly

Inj. Succinylcholine 1.5-2 mg/kg iv stat

Technique & devices :

- 1. Proseal LMA
- 2. I-gel airway

Securing airway:

In group A patients the airway was secured with PLMA while in group B patients airway was secured with I-gel airway of appropriate sizes.

Number of attempts of insertion :

<u>Mean time of insertion</u> (time taken to insert the device and confirmation by ventilation)

Maintenance :

 $N_2O + O_2 + IPPV + Inj$ vecuronium+ isoflurane

INSERTION CHART

COMPARISON OF EASE OF INSERTION IN TWO GROUPS.

Parameters	LMA-Proseal	I-gel
Ease of insertion- Easy/difficult		
Insertion attempts-1/2/3		
Failed		

Aiway inserted: Proseal LMA/I- gel

Hemodynamic parameters before, during and after insertion.

Time	Pulse	Sys B.P	Diast.B.P	MAP
Before pre med				
After pre med				
DuringInduction				
During insertion				
1 min				
3 mins				
5 mins				
10 mins				
15 mins				

COMPARISON OF OTHER PARAMETERS

EASE OF GASTRIC	GROUP-A	GROUP-B
TUBE INSERTION		
EASY		
DIFFICULT		
FAILED		
BLOOD STAINING OF		
DEVICE		
YES		
NO		
BRONCHOSPASM/		
LARYNGOSPASM		
REGURGITATION/		
ASPIRATION		

POSTOPERATIVE OBSERVATIONS:

	Group A (n=63)	Group B (n=63)
COUGHING		
HOARSNESS		
SORE THROAT		
YES		
NO		

Reversal :

Inj. Glycopyrrolate 0.008mg/kg i.v.

Inj. Neostigmine 0.05mg/kg i.v

Comments:

Both the groups are compared statistically and difference between the two groups was considered significant if p<0.05.

STUDY SUBJECT CONSENT STATEMENT

I confirm that Dr. Pratibha. S. D., has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

(Participant)

Date

(Witness to above signature)

Date

KEY TO MASTER CHART

- Sr. No- Serial number
- IP.No In patient number
- M Male
- F Female



B.L.D.E.UNIVERSITY'S SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR - 586103 <u>INSTITUTIONAL ETHICAL COMMITTEE</u> Ref NO. 26c/48f12 29~12-2012

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 28 - 12 - 2012 at 03 - 30 pm scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.

Title "A Randonized chinical comparative study of
proseof langageal mark airway verses I-get air
way for ease of insertion and hemodynamic stability"
Name of P.G. Student br. Argfibla. S.D.
Sept of Anaesthe 85010971
· / · /
Name of Guide/Co-investigator <u>br. Vidya, A. PaH/</u>
profession of Anaesthesiology
/ /

DR.TEJASWINI VALLABHA CHAIRMAN CHAIRMAN Institutional Ethical Committee BLDEU's Shri B.M. Patil Medical College,BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization
1)Copy of Synopsis/Research Project
2)Copy of informed consent form.
3)Any other relevant documents.

Group - B

									Befo	re pre	medication			Afte	er pre
Sr no	Name	Age(yrs)	Sex	Weight(kg)	IP no	Posted for	ASA grading	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	systolic BP	Diastolic BP
1	Jettappa	20	М	55	29612	Hernioplasty	1	84	126	80	95.333333	99%	78	120	78
2	Sandeep	17	М	45	30284	Hemorroidectomy	2	78	118	81	93.333333	98%	74	116	76
3	Susheela	35	F	50	27022	Abd tubectomy	2	80	124	76	92	97%	76	122	72
4	Anitha	40	F	50	27206	Abd tubectomy	1	82	122	82	95.333333	98%	78	120	78
5	Saraswati	25	F	40	29195	Abd hysterectomy	2	84	126	82	96.666667	99%	80	124	76
6	Shreya	31	F	55	30372	Inscisional hernioplasty	2	68	116	78	90.666667	100%	66	114	76
7	Sachin	42	М	60	28713	Fistulectomy	2	88	116	79	91.333333	98%	80	112	74
8	Rajesh	17	М	40	30529	Appendicectomy	1	74	114	74	87.333333	98%	70	112	70
9	Laxmi	50	F	55	30600	Fibroadenoma breast	2	86	118	76	90	100%	84	116	73
10	Suresh	35	М	45	2997	Tympanoplasty	2	78	126	84	98	98%	76	123	82
11	Gowramma	60	F	50	30567	Fibroadenoma breast	2	86	120	80	93.333333	97%	82	117	78
12	Ameenamma	21	F	55	30649	Cholecystectomy	1	80	118	78	91.333333	99%	78	116	76
13	Mallappa	43	М	56	30103	Hernioplasty	1	82	124	82	96	100%	80	123	80
14	Raghu	32	М	45	30729	Appendicectomy	2	84	114	78	90	99%	78	112	73
15	Mohini	40	F	50	27208	Abd tubectomy	2	76	125	84	97.666667	98%	74	122	80
16	Bharati	25	F	40	27175	Abd tubectomy	1	78	123	80	94.333333	99%	76	120	76
17	Chandrika	30	F	45	27260	Abd hysterectomy	2	84	120	76	90.666667	98%	80	115	73
18	Devendrappa	37	М	55	822	Hernioplasty	2	88	128	74	92	98%	80	126	70

									Befo	re pre	medication			Afte	er pre
Sr no	Name	Age(yrs)	Sex	Weight(kg)	IP no	Posted for	ASA grading	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	systolic BP	Diastolic BP
19	Chandrakanth	50	М	54	268	Hemorroidectomy	1	90	120	85	96.666667	99%	86	118	83
20	Asharani	35	F	48	30607	Fibroadenoma breast	1	86	130	83	98.666667	98%	82	126	78
21	Rekha	40	F	55	27633	Escharotomy	2	90	116	78	90.666667	100%	86	114	74
22	Shantha	65	F	57	27638	Debridement	2	80	124	84	97.333333	98%	76	122	80
23	Hanumanthraya	50	Μ	48	452	Skin grafting	1	86	118	80	92.666667	98%	82	114	78
24	Kashibai	32	F	52	136	Radius ulna plating	2	82	123	78	93	98%	80	120	75
25	Asha	24	F	48	418	Tympanoplasty	2	80	116	76	89.333333	98%	76	110	74
26	Sunil	30	Μ	56	846	Clavicle plating	1	76	118	81	93.333333	99%	72	113	76
27	Neetha	30	F	47	60	Abd tubectomy	2	88	122	76	91.333333	98%	84	118	72
28	Malathi	27	F	45	236	Fissurectomy	1	90	118	83	94.666667	98%	88	114	78
29	Urvashi	46	F	58	354	Appendicectomy	2	84	122	82	95.333333	97%	80	120	76
30	Shashi	40	F	56	1086	Hernioplasty	2	88	115	80	91.666667	98%	86	113	77
31	Mallappa	46	Μ	48	1067	Cholecystectomy	1	80	128	78	94.666667	97%	78	126	75
32	Surekha	58	F	58	1090	Tympanoplasty	2	68	122	82	95.333333	98%	64	118	80
33	Vanamala	45	F	47	482	Fibroadenoma breast	2	74	126	78	94	98%	72	123	75
34	Tejaswini	27	F	54	429	Cholecystectomy	1	86	116	84	94.666667	98%	80	113	80
35	Shashikala	26	F	46	1359	Debridement	2	78	124	74	90.666667	98%	70	120	70
36	Kamala	30	F	56	1362	Escharotomy	2	100	113	76	88.333333	98%	90	111	73
37	Yamunabai	45	F	50	802	Cholecystectomy	2	80	118	84	95.333333	98%	74	116	82
38	Rachappa	35	М	46	1564	Hernioplasty	1	82	124	80	94.666667	100%	80	122	77
39	Shrishail	22	М	47	1999	Humerus plating	2	84	122	78	92.666667	99%	82	120	75

									Befo	re pre	medication			Afte	er pre
Sr no	Name	Age(yrs)	Sex	Weight(kg)	IP no	Posted for	ASA grading	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	systolic BP	Diastolic BP
40	Ashwini	60	F	53	1649	Skin grafting	2	76	126	82	96.666667	98%	74	124	77
41	Suma	45	F	56	903	Abd tubectomy	2	78	116	74	88	98%	72	114	69
42	Mallamma	24	F	57	770	Vaginal hysterectomy	1	67	116	90	98.666667	99%	64	112	86
43	Sangawwa	38	F	48	698	Abd hysterectomy	1	94	114	85	94.666667	98%	90	112	80
44	Basavaraj	60	Μ	57	1908	Hernioplasty	2	64	118	88	98	98%	64	116	84
45	Siddu	25	М	53	2004	Cholecystectomy	2	86	126	83	97.333333	97%	82	123	80
46	Shobha	30	Μ	48	2186	Tympanoplasty	1	90	114	86	95.333333	98%	86	110	84
47	Mallikarjun	42	Μ	51	2182	Appendicectomy	2	80	118	80	92.666667	97%	76	115	76
48	Meenakshi	36	F	55	816	Fibroadenoma breast	2	82	122	82	95.333333	98%	80	118	78
49	Yellappa	30	Μ	42	2625	Hernioplasty	1	66	126	82	96.666667	98%	64	120	80
50	Siddramappa	29	Μ	45	1039	Debridement	1	80	118	78	91.333333	99%	76	115	75
51	Leela	52	F	50	1176	Tympanoplasty	2	70	126	86	99.333333	98%	68	120	80
52	Muddappa	35	Μ	46	641	Cholecystectomy	2	68	114	78	90	99%	70	112	76
53	Sharanappa	48	М	50	5390	Hernioplasty	1	76	120	90	100	98%	74	117	87
54	Shreedevi	50	F	55	5794	Umbilical hernia repair	2	102	128	80	96	98%	88	126	77
55	Narayan	28	Μ	40	5727	Hemicolectomy	2	72	120	78	92	99%	70	116	76
56	Priya	46	F	55	5207	Fistulectomy	1	82	122	82	95.333333	98%	80	120	77
57	Nagamma	36	F	54	5933	Abd tubectomy	2	67	128	74	92	98%	66	124	69
58	Salim	45	М	46	5463	Hemorroidectomy	1	110	120	90	100	99%	90	117	86
59	John	21	Μ	54	6362	Varicocelectomy	2	64	122	85	97.333333	98%	64	118	80

									Befo	re pre	medication			Afte	er pre
Sr no	Name	Age(yrs)	Sex	Weight(kg)	IP no	Posted for	ASA grading	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	systolic BP	Diastolic BP
60	Shreya	30	F	45	5591	Fibroadenoma breast	2	90	116	88	97.333333	97%	79	113	84
61	Sarojini	44	F	56	6603	Skin grafting	2	84	124	83	96.666667	98%	82	122	80
62	Rajkumar	33	Μ	54	2272	Appendicectomy	1	70	123	80	94.333333	98%	68	118	76
63	Laxmi	34	F	46	6527	Abd tubectomy	2	76	117	78	91	100%	72	113	72

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MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Device used	No.of attempts o insertion	Mean time of ins seconds	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse/min	systolic BP	Diastolic BP
92	99%	82	118	78	91.33333	98%	I-gel-3	1	15	88	120	85	96.66667	97%	90	126	76
89.33333	98%	76	116	80	92	98%	I-gel-4	1	10	90	122	87	98.66667	98%	92	128	78
88.66667	98%	76	118	79	92	98%	I-gel-3	1	11	91	124	84	97.33333	98%	84	132	84
92	98%	80	126	72	90	98%	I-gel-3	1	7	73	126	70	88.66667	98%	86	128	73
92	98%	81	110	68	82	98%	I-gel-3	1	10	90	120	86	97.33333	98%	88	124	78
88.66667	100%	68	120	70	86.66667	99%	I-gel-3	1	11	86	118	81	93.33333	99%	82	122	80
86.66667	98%	83	124	76	92	99%	I-gel-3	1	9	92	122	87	98.66667	98%	88	128	81
84	98%	72	116	74	88	98%	I-gel-3	1	12	90	120	82	94.66667	98%	82	118	80
87.33333	99%	77	128	70	89.33333	98%	I-gel-3	1	8	82	130	78	95.33333	98%	86	126	86
95.66667	99%	79	114	74	87.33333	98%	I-gel-4	1	10	86	118	80	92.66667	98%	82	120	81
91	98%	75	124	80	94.66667	98%	I-gel-3	1	6	80	128	77	94	98%	86	130	78
89.33333	98%	80	122	83	96	98%	I-gel-3	1	9	84	126	82	96.66667	98%	80	120	84
94.33333	100%	84	110	72	84.66667	100%	I-gel-3	1	12	89	118	83	94.66667	100%	84	126	83
86	98%	82	112	71	84.66667	98%	I-gel-3	1	12	77	116	72	86.66667	98%	76	110	80
94	98%	78	120	74	89.33333	98%	I-gel-3	1	6	81	124	81	95.33333	98%	84	120	84
90.66667	99%	83	118	72	87.33333	99%	I-gel-3	1	8	88	120	84	96	99%	86	120	80
87	98%	80	118	75	89.33333	98%	I-gel-3	1	10	80	120	76	90.66667	98%	86	122	84
88.66667	98%	82	120	70	86.66667	98%	I-gel-3	1	11	85	120	80	93.33333	99%	82	124	80

emedication	ı			Ind	uction				on in								
								of	erati		Du	iring	insertion				1n
MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Device used	No.of attempts c insertion	Mean time of ins seconds	Pulse	systolic BP	Diastolic BP	МАР	SPO2	Pulse/min	systolic BP	Diastolic BP
94.66667	98%	86	98	74	82	99%	I-gel-3	1	9	88	108	87	94	98%	80	110	76
94	99%	80	100	72	81.33333	98%	I-gel-3	1	9	80	112	76	88	98%	88	120	82
87.33333	99%	78	120	71	87.33333	98%	I-gel-3	1	8	80	118	78	91.33333	98%	92	120	78
94	99%	80	94	72	79.33333	98%	I-gel-3	1	9	86	100	81	87.33333	98%	86	104	78
90	99%	76	118	76	90	98%	I-gel-3	1	10	80	124	78	93.33333	98%	86	126	78
90	98%	86	120	72	88	98%	I-gel-3	1	9	88	126	86	99.33333	98%	82	128	80
86	98%	74	100	70	80	98%	I-gel-3	1	15	80	112	75	87.33333	98%	84	118	80
88.33333	98%	86	114	72	86	98%	I-gel-4	1	12	89	120	86	97.33333	98%	86	126	80
87.33333	99%	81	114	73	86.66667	98%	I-gel-3	1	8	87	120	82	94.66667	98%	84	122	78
90	98%	69	114	71	85.33333	98%	I-gel-3	1	7	77	114	71	85.33333	98%	90	116	77
90.66667	98%	81	116	72	86.66667	98%	I-gel-3	1	8	84	118	82	94	98%	88	116	78
89	98%	71	94	74	80.66667	98%	I-gel-3	1	8	75	106	73	84	98%	78	106	82
92	98%	82	108	72	84	98%	I-gel-3	1	15	86	110	82	91.33333	99%	84	122	82
92.66667	98%	70	118	74	88.66667	99%	I-gel-3	1	10	78	120	72	88	98%	86	128	80
91	98%	78	114	71	85.33333	98%	I-gel-3	2	11	79	120	80	93.33333	98%	88	124	79
91	98%	80	120	72	88	98%	I-gel-3	1	7	84	120	81	94	98%	82	118	80
86.66667	98%	86	108	73	84.66667	99%	I-gel-3	1	10	90	110	87	94.66667	98%	88	112	80
85.66667	99%	84	120	72	88	100%	I-gel-3	1	11	87	124	85	98	99%	82	118	76
93.33333	98%	74	110	68	82	98%	I-gel-3	1	9	81	112	76	88	98%	86	124	76
92	100%	80	110	70	83.33333	99%	I-gel-3	1	12	85	124	80	94.66667	98%	82	120	80
90	98%	82	97	69	78.33333	98%	I-gel-3	1	8	87	103	83	89.66667	98%	80	112	76

emedication	ı			Ind	uction				on in								
								Jf	erati		Du	iring	insertion				1n
MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Device used	No.of attempts c insertion	Mean time of ins seconds	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse/min	systolic BP	Diastolic BP
92.66667	98%	73	102	76	84.66667	99%	I-gel-3	1	10	78	118	75	89.33333	98%	88	120	82
84	98%	78	118	69	85.33333	98%	I-gel-3	1	6	82	118	80	92.66667	98%	92	130	80
94.66667	99%	68	108	73	84.66667	98%	I-gel-3	1	9	72	116	73	87.33333	98%	84	120	82
90.66667	98%	81	108	73	84.66667	98%	I-gel-3	1	12	83	118	83	94.66667	98%	86	114	78
94.66667	98%	71	90	71	77.33333	98%	I-gel-3	1	12	79	102	74	83.33333	98%	88	103	80
94.33333	98%	76	124	76	92	98%	I-gel-3	1	6	83	130	78	95.33333	98%	84	122	86
92.66667	98%	70	112	71	84.66667	98%	I-gel-3	1	8	74	123	73	89.66667	98%	82	120	80
89	98%	80	108	78	88	99%	I-gel-3	1	10	84	117	81	93	98%	80	118	76
91.33333	99%	71	108	72	84	98%	I-gel-3	1	9	79	116	75	88.66667	97%	84	120	82
93.33333	98%	66	98	71	80	98%	I-gel-4	1	15	86	103	84	90.33333	98%	84	110	80
88.33333	98%	79	120	78	92	99%	I-gel-3	1	12	84	126	80	95.33333	98%	84	124	82
93.33333	98%	72	126	70	88.66667	98%	I-gel-3	1	8	92	127	89	101.6667	98%	86	126	78
88	98%	73	128	72	90.66667	98%	I-gel-3	2	7	80	128	76	93.33333	98%	84	116	78
97	98%	72	114	73	86.66667	98%	I-gel-3	1	8	74	126	77	93.33333	99%	86	122	82
93.33333	98%	83	105	74	84.33333	98%	I-gel-3	1	8	87	118	84	95.33333	98%	84	128	84
89.33333	99%	67	120	76	90.66667	98%	I-gel-3	1	15	72	123	70	87.66667	98%	86	128	82
91.33333	98%	74	103	73	83	98%	I-gel-3	1	10	84	120	76	90.66667	98%	88	124	86
87.33333	98%	69	98	70	79.33333	98%	I-gel-3	1	11	86	116	83	94	98%	82	118	78
96.33333	99%	85	105	72	83	98%	I-gel-3	1	7	88	118	87	97.33333	99%	88	123	80
92.66667	98%	68	115	78	90.33333	98%	I-gel-3	1	8	75	123	74	90.33333	98%	80	128	80

emedication	n			Ind	uction				on in								
								đ	serati		Dı	ıring	insertion				1n
MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Device used	No.of attempts of insertion	Mean time of ins seconds	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse/min	systolic BP	Diastolic BP
93.66667	98%	72	101	71	81	99%	I-gel-3	1	7	82	118	75	89.33333	100%	88	124	82
94	98%	80	100	70	80	98%	I-gel-3	1	8	83	114	84	94	98%	82	118	78
90	98%	63	111	75	87	98%	I-gel-3	1	8	70	120	67	84.66667	98%	88	124	80
85.66667	99%	67	128	73	91.33333	100%	I-gel-3	1	15	73	130	70	90	99%	82	118	80

					Intra	operati	ve m	onitor	ing								
nin				3 ו	min				5	min				10	min		
МАР	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	МАР	SPO2	Pulse	Systolic BP	Diastolic BP	МАР	SPO2	Pulse
92.66667	98%	90	128	78	94.66667	98%	94	130	84	99.33333	98%	90	130	80	96.66667	98%	88
94.66667	98%	88	122	80	94	98%	86	126	82	96.66667	98%	84	122	78	92.66667	98%	82
100	98%	86	130	80	96.66667	98%	84	130	82	98	98%	86	132	80	97.33333	98%	80
91.33333	99%	84	130	78	95.33333	99%	82	128	84	98.66667	98%	88	130	80	96.66667	98%	84
93.33333	98%	86	130	80	96.66667	98%	86	124	78	93.33333	98%	90	120	72	88	98%	84
94	99%	78	118	82	94	98%	80	116	78	90.66667	98%	80	118	81	93.33333	98%	8
96.66667	98%	88	126	82	96.66667	99%	84	132	80	97.33333	98%	88	128	86	100	98%	9
92.66667	99%	80	122	78	92.66667	99%	82	124	80	94.66667	98%	84	120	80	93.33333	98%	82
99.33333	98%	84	124	80	94.66667	98%	86	128	73	91.33333	99%	90	120	78	92	99%	8
94	98%	78	120	80	93.33333	98%	76	124	86	98.66667	98%	82	120	82	94.66667	100%	8
95.33333	98%	86	128	84	98.66667	98%	88	126	78	94	98%	88	124	83	96.66667	99%	8
96	99%	84	118	80	92.66667	98%	83	124	82	96	99%	84	124	78	93.33333	98%	8
97.33333	99%	80	120	82	94.66667	99%	78	124	78	93.33333	99%	80	118	84	95.33333	98%	8
90	99%	82	116	76	89.33333	100%	86	120	73	88.66667	98%	84	122	78	92.66667	99%	80
96	98%	88	120	80	93.33333	98%	86	124	81	95.33333	98%	82	118	82	94	99%	84
93.33333	98%	84	118	82	94	98%	88	124	78	93.33333	99%	84	120	76	90.66667	98%	8
96.66667	98%	82	120	82	94.66667	98%	84	124	81	95.33333	98%	88	120	76	90.66667	98%	8
94.66667	98%	84	120	82	94.66667	98%	86	126	76	92.66667	98%	78	120	80	93.33333	98%	82

					Intra	operati	ve m	onitor	ing								
nin	3 min					5 min					10 min						
MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	MAP	SP02	Pulse
87.33333	98%	78	116	84	94.66667	98%	82	120	80	93.33333	98%	76	118	80	92.66667	98%	84
94.66667	98%	80	120	78	92	98%	84	122	82	95.33333	98%	82	120	84	96	98%	88
92	98%	90	126	80	95.33333	100%	92	128	81	96.66667	98%	92	128	78	94.66667	98%	84
86.66667	98%	82	110	81	90.66667	98%	88	112	82	92	98%	86	114	83	93.33333	98%	80
94	98%	84	118	80	92.66667	98%	78	116	82	93.33333	98%	80	122	80	94	98%	82
96	98%	86	122	86	98	98%	84	122	84	96.66667	99%	88	130	78	95.33333	98%	84
92.66667	98%	82	122	82	95.33333	98%	86	122	80	94	98%	82	120	76	90.66667	98%	88
95.33333	98%	88	126	82	96.66667	98%	84	124	86	98.66667	98%	80	122	80	94	100%	86
92.66667	98%	86	128	80	96	99%	84	128	84	98.66667	98%	86	124	86	98.66667	98%	84
90	98%	90	118	80	92.66667	98%	92	118	82	94	98%	88	116	76	89.33333	98%	88
90.66667	98%	82	118	82	94	98%	84	118	86	96.66667	98%	78	122	78	92.66667	97%	82
90	99%	84	108	80	89.33333	99%	82	110	84	92.66667	98%	88	112	80	90.66667	98%	80
95.33333	100%	86	124	80	94.66667	99%	80	126	81	96	99%	90	130	83	98.66667	98%	78
96	98%	84	130	78	95.33333	98%	88	124	82	96	99%	84	122	81	94.66667	99%	76
94	99%	86	130	80	96.66667	98%	84	122	82	95.33333	98%	86	132	80	97.33333	98%	84
92.66667	98%	78	118	83	94.66667	98%	86	128	86	100	98%	88	130	81	97.33333	99%	74
90.66667	98%	88	118	82	94	98%	82	126	84	98	98%	84	120	80	93.33333	98%	88
90	98%	84	118	80	92.66667	98%	78	116	78	90.66667	98%	80	118	81	93.33333	98%	86
92	99%	80	120	81	94	99%	84	122	84	96.66667	98%	88	128	86	100	100%	84
93.33333	99%	86	116	76	89.33333	98%	82	122	80	94	98%	84	120	83	95.33333	98%	70
88	98%	88	118	80	92.66667	98%	84	124	86	98.66667	98%	88	130	78	95.33333	98%	86
	Intra operative monitoring																
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nin			3 min			5 min				10 min							
MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	MAP	SPO2	Pulse
94.66667	98%	84	118	78	91.33333	99%	82	124	80	94.66667	98%	86	120	76	90.66667	98%	88
96.66667	99%	82	120	82	94.66667	98%	88	124	78	93.33333	98%	80	122	80	94	99%	84
94.66667	98%	86	122	86	98	98%	80	124	82	96	98%	72	126	83	97.33333	98%	70
90	98%	82	123	84	97	99%	82	126	76	92.66667	98%	88	116	78	90.66667	99%	86
87.66667	98%	86	110	82	91.33333	99%	80	113	81	91.66667	98%	70	122	78	92.66667	99%	68
98	99%	86	128	84	98.66667	98%	84	122	82	95.33333	99%	82	128	80	96	100%	88
93.33333	99%	90	118	82	94	98%	92	128	83	98	98%	80	119	80	93	98%	86
90	99%	82	110	82	91.33333	98%	82	126	84	98	98%	88	121	86	97.66667	98%	80
94.66667	98%	84	109	83	91.66667	98%	78	116	78	90.66667	98%	84	120	80	93.33333	98%	78
90	98%	80	114	82	92.66667	98%	78	117	81	93	99%	76	128	78	94.66667	99%	70
96	98%	82	116	76	89.33333	98%	84	126	78	94	98%	82	120	82	94.66667	98%	88
94	99%	88	120	80	93.33333	98%	82	124	82	96	98%	84	118	78	91.33333	98%	84
90.66667	98%	84	118	80	92.66667	98%	88	124	78	93.33333	98%	78	118	82	94	99%	70
95.33333	100%	82	120	83	95.33333	99%	82	118	84	95.33333	99%	84	119	76	90.33333	98%	82
98.66667	98%	86	122	86	98	99%	84	124	82	96	98%	82	120	76	90.66667	98%	84
97.33333	99%	82	122	84	96.66667	98%	82	126	76	92.66667	98%	78	120	80	93.33333	99%	88
98.66667	98%	82	116	76	89.33333	98%	80	126	84	98	98%	76	118	80	92.66667	98%	86
91.33333	98%	88	120	80	93.33333	98%	78	118	82	94	98%	74	124	78	93.33333	98%	72
94.33333	98%	84	118	78	91.33333	99%	82	128	84	98.66667	98%	80	118	80	92.66667	99%	82
96	98%	82	120	82	94.66667	99%	86	124	78	93.33333	98%	84	120	83	95.33333	98%	74

	Intra operative monitoring																
nin 3 min				5 min				10 min									
MAP	SPO2	Pulse	systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	MAP	SPO2	Pulse	Systolic BP	Diastolic BP	МАР	SPO2	Pulse
96	99%	84	118	80	92.66667	98%	80	116	78	90.66667	99%	82	115	82	93	98%	88
91.33333	98%	80	120	82	94.66667	98%	88	132	80	97.33333	98%	84	120	76	90.66667	98%	86
94.66667	98%	82	116	76	89.33333	98%	82	124	80	94.66667	98%	82	120	76	90.66667	99%	84
92.66667	100%	88	120	81	94	99%	88	124	78	93.33333	100%	78	120	80	93.33333	100%	88

	15	ery	ation		
Systolic BP	Diastolic BP	MAP	SPO2	Duration of surg	post op complica
126	78	94	99%	60	nil
124	84	97.33333	98%	30	nil
130	86	100.6667	99%	30	nil
128	78	94.66667	98%	30	nil
120	76	90.66667	99%	120	nil
132	80	97.33333	98%	60	Sore Throat
130	83	98.66667	98%	30	nil
120	85	96.66667	99%	30	nil
118	80	92.66667	99%	30	nil
118	80	92.66667	98%	90	nil
128	84	98.66667	98%	30	nil
120	88	98.66667	98%	120	nil
120	76	90.66667	98%	90	nil
120	80	93.33333	100%	30	nil
138	84	102	98%	30	nil
124	73	90	98%	30	Sore Throat
118	83	94.66667	99%	120	nil
120	78	92	99%	90	nil

	15	ery	ition		
Systolic BP	Diastolic BP	MAP	SPO2	Duration of surg	post op complica
120	82	94.66667	98%	30	nil
118	73	88	98%	30	nil
126	77	93.33333	98%	45	nil
106	80	88.66667	98%	45	nil
130	78	95.33333	100%	30	nil
120	76	90.66667	98%	120	nil
126	78	94	98%	90	nil
124	78	93.33333	99%	100	nil
118	82	94	99%	30	nil
120	78	92	98%	30	nil
118	82	94	98%	45	nil
120	76	90.66667	98%	90	nil
120	80	93.33333	99%	120	nil
120	78	92	98%	90	nil
120	79	92.66667	99%	30	nil
138	80	99.33333	98%	120	nil
124	78	93.33333	98%	45	nil
118	84	95.33333	99%	30	nil
124	80	94.66667	99%	120	nil
124	80	94.66667	98%	90	nil
120	74	89.33333	98%	120	nil

	15	ery	ation		
Systolic BP	Diastolic BP	MAP	SPO2	Duration of surg	post op complica
118	83	94.66667	99%	45	nil
126	75	92	98%	30	nil
124	78	93.33333	99%	90	nil
118	84	95.33333	98%	120	nil
103	80	87.66667	98%	90	nil
132	78	96	99%	120	nil
118	78	91.33333	98%	90	nil
128	82	97.33333	98%	30	nil
123	81	95	99%	30	nil
124	80	94.66667	98%	90	nil
130	80	96.66667	98%	30	nil
120	72	88	99%	90	nil
123	81	95	98%	120	nil
120	78	92	98%	90	nil
118	80	92.66667	100%	90	nil
128	85	99.33333	98%	120	nil
120	83	95.33333	98%	30	nil
120	76	90.66667	99%	30	nil
128	82	97.33333	98%	30	Sore Throat
123	82	95.66667	98%	45	nil

	15	ery	ation		
Systolic BP	Diastolic BP	MAP	SPO2	Duration of surg	post op complic
118	81	93.33333	99%	30	nil
120	78	92	99%	45	nil
128	81	96.66667	98%	45	nil
130	82	98	99%	30	nil