“COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY AND ENDOTRACHEAL TUBE FOR INTUBATION IN PAEDIATRIC PATIENTS FOR SURGICAL PROCEDURES OF SHORT DURATION”

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For the award of degree of

M.D. ANAESTHESIOLOGY - (Branch X)

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CHENNAI, TAMILNADU

APRIL 2015

CERTIFICATE

This is to certify that the dissertation entitled "**Comparison of Proseal Laryngeal Mask Airway and Endotracheal for Intubation in Paediatric Patients for Surgical Procedures of Short duration"**, by **Dr. S. CHITRA DEVI** for the partial fulfilment of the requirements for M.D. (Anaesthesiology) Examination of The TamilNadu Dr. M.G.R. Medical University, Chennai to be held in April 2015, is a genuine work done by her in Chengalpattu Medical College, Chengalpattu.

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DECLARATION

I, **Dr. S. CHITRA DEVI,** solemnly declare that the dissertation, titled "**Comparison of Proseal Laryngeal Mask Airway and Endotracheal for Intubation in Paediatric Patients for Surgical Procedures of Short duration"**, is a bonafide work done by me in the Department of Anaesthesiology, Chengalpattu Medical College Chengalpattu, after getting approval from the Ethical committee during the period between November 2013 and July 2014, under the able guidance and supervision of **Dr. SUGANTHARAJ ANURADHA** M.D, D.A., Prof and Head of the Department of Anaesthesiology, Chengalpattu Medical College, Chengalpattu.

This thesis is submitted to The Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of the rules and regulations for the M.D. degree examinations in Anaesthesiology to be held in April 2015.

Chengalpattu **Dr. S. CHITRA DEVI**

Date:

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ABSTRACT

The laryngeal mask airway is a supraglottic device to secure the airway. Proseal laryngeal mask airway has several modification compared to the classic laryngeal mask airway with respect to a modified cuff design, gastric drainage tube placed lateral to main airway tube helps in passage of gastric contents and to prevent aspiration. This study was conducted to compare the efficacy of proseal laryngeal mask airway with the endotracheal tube in paediatric patients undergoing surgical procedures with respect to number of attempts of device placement, haemodynamic response and postoperative respiratory complication.80 of patients ASA1 and 11 category of 2-8 years of age of weight 10-20 kg were randomly divided into two groups of 40 patients. The number of attempts of insertion of endotracheal tube is less than the proseal laryngeal mask airway. Significant changes in haemodynamic parameters were observed in the endotracheal tube group. The post-operative respiratory complication of cough and bronchospasm was found to be more in the endotracheal group. The proseal laryngeal mask airway produced more of soft tissue trauma. There were no significant difference in SPO2 and Etco2 levels between the two groups .There is no incidence of aspiration in either of group. It is

concluded that proseal laryngeal mask airway can be used as a safe and effective alternative device to the endotracheal tube for the paediatric patients undergoing elective short duration procedure.

Key Words: Proseal LMA. Haemodynamic response, Endotracheal tube.

INTRODUCTION

The important role of an anaesthesiologist is to provide continuous oxygenation and ventilation to the patient.And in the process securing airway forms the vital element.

Macewan in 1880 introduced the endotracheal tube and the management of the airway progressed from there to the most modern airway devices.

The endotracheal tube remains the gold standard in securing the airway because of its features of maintaining positive pressure ventilation,prevention of gastric inflation and aspiration.The expertise of the airway physician is enormous in handling the device.Endotracheal intubation is associated with increased haemo-dynamic response,injury to oro-pharyngeal structures and sometimes failed intubation.

There may be difficulty in securing the airway inspite of numerous predictors of difficult intubation.It is of paramount importance to have alternate strategy of securing the airway to combat the complications of hypoxia and cardiovascular instability.

The major decisions of the difficult airway algorithm must be familiarised and is always best to use safe, affordable airway devices suitable for the anaesthetic setup.

Supraglottic airway devices forms an important adjunct in securing the airway with minimal injury to oro-pharyngeal structures and maintaining anaesthesia.The first laryngeal mask airway was introduced by Dr. Archie Brain in1981 and is being used extensively in airway management.It produced less haemodynamic response compared to endotracheal tube.The classic LMA forms a less effective glottic seal resulting in gastric distension,regurgitation leading to pulmonary aspiration.

The PROSEAL LMA was introduced by Dr. Archie Brain in 2000, has a modified cuff which produces an effective glottic seal favouring positive pressure ventilation.It has a gastric drainage tube lateral to the main airway tube.It forms a channel for the drainage of gastric contents,prevents gastric distension and aspiration.A gastric tube can be passed to confirm the position of the device. Paediatric ProsealLaryngeal mask is being used in anaesthetic practise for the ease of insertion of device,less haemodynamic response to insertion and less postoperative complications of cough, bronchospasm and sore throat.

Hence a prospective randomised single blinded study was designed to compare the paediatric Proseal LMA with the endotracheal tube in terms of placement of device, haemodynamic response and postoperative complications.

AIM OF THE STUDY

The aim of the study is to compare the paediatric proseal laryngeal mask airway with the endotracheal tube for intubation in paediatric patients undergoing elective surgeries short duration under general anaesthesia.Comparison between the two devices were done with respect to

1. Number of attempts of placement of device
2. Haemo dynamic response during placement
3. Post-operative respiratory complications.

PAEDIATRIC AIRWAY ANATOMY

The fundamental skills of anaesthesiologist is the management of airway. Children are not mere adults and this makes paediatric anaesthesia more challenging. The difference that occurs in the process of growth and development in children requires different approach, technique and devices to be used in them.

The head of the infant is larger to body size and there is difficulty in positioning prior to induction.Large occiput and short neck makes laryngoscopy difficult.

The tongue is larger,mandible is shorter, prominent adenoids and tonsils reduce the upper airway space resulting in difficult mask ventilation and intubation difficult.They are obligate nasal breathers until 5 months of age.

There is weakness in intercostal and diaphragmatic muscles due to paucity of type I fibres.The horizontal ribs, protrubent abdomen,flexible cartilaginous rings of trachea can produce dynamic obstruction with negative pressure ventilation.The tone of the upper airway muscles are reduced due to anaesthetic drugs.

There is paucity of smaller airways in the lungs and alveolar maturation is not complete.

The hypopharynx is shorter in height and narrower in width. The larynx is anteriorly placed at C4 and narrowest the part is the cricoid cartilage.Epiglottis is U shaped and more floppy lies across the glottis opening.The vocal cords are in right angle with the trachea and this makes endotracheal intubation traumatic and higher tendency to collide with the anterior commissure of vocal cord.

The difficulty experienced in positioning of the head can be decreased by keeping a folded towel behind the shoulders of the child. This will reduce the neck flexion and makes laryngoscopy easier.

The head should not to be extended more because it makes the larynx more anterior and visualisation difficult.

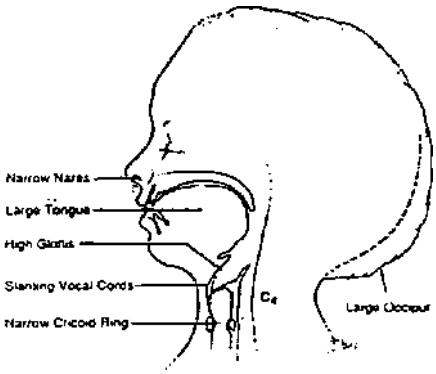
The noncompliant heart and poorly developed left ventricle makes the stroke volume entirely dependent on heart rate.Residual foetal circulation is present.There is difficulty in venous and arterial access in these patients.

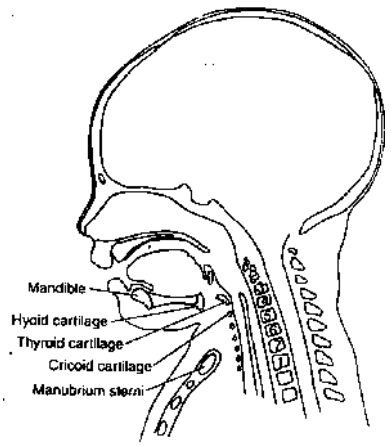
The abdominal muscles are immature in development and are protrubent .The organs are in close approximation and injury produces more damage to the organs .Liver and spleen are highly vascular and larger.

The bones are softer and porous and injury to growth can stunt the bone growth. The children are more prone for green stick fractures and union of the bone is attained in early manner.

The paediatric group have an increased body surface area. The skin is more elastic and thinner with less subcutaneous fat.

The spinal cord ends at the lower level of L 3 or L 4 space makes that the regional technique to be given with caution. Caudal anaesthesia is commonly performed for infra umbilical and lower limb surgeries. The caudal space is thesacral portion of the epidural space.





PAEDIATRIC PHYSIOLOGY

RESPIRATORY SYSTEM:

The paediatric patients are highly susceptible to hypoxemia because of varying physiological challenges in them.Oxygen consumption is 6ml/kg /body wt. and they have lower functional residual capacity. Higher demand and lower reserve make them de-saturate quickly during apnoea.

During intra uterine life after 34 weeks of gestation alveoli appears mature with the reduction of alveolar membrane thickness .The surfactant is being produced by TYPE 2 alveolar epithelial cells.It helps in reducing the surface tension based on Laplace law and maintain alveolar structure and stability.The surfactant forms an important element in prevention of respiratory distress syndrome.

There is increase in chest wall compliance and reduced lung compliance produce chest wall collapse in inspiration.

Carbon dioxide production is increased up to 100-150ml/kg/min.As tidal volume and dead space remain constant during development,they need a higher respiratory rate to eliminate CO2.

The resistance to airflow is inversely proportional to radius and any airway edema or inflammation decreases the space and cause

obstruction of the already narrowed airway .Any manipulation in the paediatric airway requires extreme caution and should be done in a non-traumatic way.

In neonates hypoxia causes hypoventilation producing apnoea. The anaesthetic drugs causes respiratory depression.The term neonates have periods of apnoea for five seconds followed by tachypneoa.But in preterm neonates the apnoeic period is present for more than fifteen seconds leading to desaturation and bradycardia.

CARDIOVASCULAR SYSTEM:

The paediatric patients have higher body surface area and high body water content. Cardiac output is determined on heart rate and blood pressure is low.

The sympathetic and baroreceptor reflexes are not fully developed. They have low catecholamine stores and exogenous response to them is also decreased.The vascular response of vasoconstriction is poor and hypotension in infants produce bradycardia.

Thin skin, low fat content,higher body surface area make them susceptible to greater amount of heat loss. They are alsoexposed to cold operating room,cold infusion,wound exposure,dry anaesthetic gases and depressant effects of anaesthetic drugs.

Transport of oxygen is higher because of the presence of HbF which has a greater affinity for oxygen and delivery to tissues is also high.The foetal haemoglobin declines after birth and by 6 months it is being replaced by adult haemoglobin by 90%.

Age	Respiratory rate	Heart rate	Systolic BP	Diastolic BP
Neonate	40	140	65	40
12 month	30	120	95	65
3 years	25	100	100	70
12 years	20	80	110	60

FOETAL CIRCULATION:

The placenta forms a major role in foetal circulation .The oxygenated blood pass through the umbilical vein to the inferior vena cava through ductus venosus.The blood is passed via the foramen ovale into the left

The deoxygenated blood passes through right atrium and right ventricle and because of higher pulmonary resistance it flows through ductus arteriosus in to the descending aorta.

The transition from the foetal to adult circulation at birth and is due to the following changes of

- There is increase in the Pao2 ,adrenergic stimulation and decrease in PaCO2----causes the closure of the ductus arteriosus
- There is decrease in pulmonary vascular resistance and this allows the perfusion and ventilatory function of lungs to develop.
- There occurs a decrease in PGE2 as the placenta is removed after birth.

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12 years	20	80	110	60

TEMPERATURE REGULATION:

The heat production in neonate is by non-shivering thermogenesis of brown fat. Hypothermia results in delayed awakening, cardiac irritability, increase in pulmonary vascular resistance and altered drug response.

KIDNEYS:

The normal kidney function is achieved in TWO years. Preterm neonate has decreased creatinine clearance, impaired sodium retention, glucoseexcretion, bicarbonate reabsorption and poor concentrating and diluting effect. Meticulous planning in fluid management is essential.

NERVOUS SYSTEM:

The infants have a higher cerebral blood flow compared to the adult .The blood brain barrier is less developed and substances like unconjugated bilirubin crosses it producing kernicterus.

There is increase diffusion of anaesthetic drugs and it causes respiratory depression, hence guarded dose is given in neonates.

The parasympathetic nervous system is dominating than the sympathetic system and infants are more prone for bradycardia.

There occurs an increased incidence of intra cranial haemorrhage due to acute stress response and it should beattenuated.

Neuro muscular junction:

The neuromuscular junction is yet to develop and increased sensitivity to blocking drugs. Patients have high gastro oesophageal reflux, impaired conjugation by liver, and prone for hypoglycaemia.

FLUIDS AND ELECTROLYTES:

The fluid requirements in the paediatric age group is calculated with reference in weight in kg,

The increase in body surface area of the infants requires 100-120 ml/kg per day. The nephrogenesis is complete by 9 months of gestational age and the ratio of medullary to cortical nephrons is decreased resulting in dilute urine.

40% of neonates body is made up of extracellular water which gets reduced by 30—35% within weeks of birth.

The infants poorly tolerate the electrolyte imbalances and it should be identified and corrected in a phased manner.

The increase of fluid requirement is seen in infants with pyrexia which also causes increases in the oxygen consumption.

Pre warmed fluids are used to decrease the heat loss by infusion of intravenous fluids.

FASTING GUIDELINES:

The fasting protocol for children varies according to the institutional guidelines. Any elective surgery requires the fasting period well within the safety range.

Solids are allowed up to	6 hrs before surgery.
Milk is given up to	4 hrs of surgery
Clear fluids up to	2 hrs of surgery.

PAEDIATRIC PHARMACOLOGY

PHARMACOLOGICAL DIFFERENCES

The paediatric drug dosing depends on its body weight. They have a larger intra vascular volume and extra cellular fluid compartments. The immature hepatic bio transformation, increased organ blood flow, decreased protein binding and a higher metabolic rate makes weight adjustment drug dosing ineffective.

INHALATIONAL ANAESTHETICS:

There is a greater alveolar ventilation and reduced functional residual capacity in neonates and infants compared to older children. This increased minute ventilation to FRC ratio and increased blood flow to vessel rich organs leads to rapid increase in alveolar concentration which speeds up inhalational induction.

The minimum alveolar concentration of halogenated agents is greater in infants and children.Nitrous oxide does not reduce the MAC of desflurane and sevoflurane in them.

The blood pressure in children is sensitive to volatile agents due to less developed compensatory mechanism of vasoconstriction, tachycardia andgreatersensitivity of immature myocardium to depressants.Bradycardia,arrhythmias,cardiovasculardepression,respirato

-ry effects is less with sevoflurane and emergence from anaesthesia is faster making it an ideal induction agent in paediatric patients.

NONVOLATILE ANAESTHETIC:

Theincrease in volume of distribution, shorter elimination half-life and increase in plasma clearance requires larger dose of propofol for induction.Prolonged infusion in critically ill patients in ICU causes “propofol infusion syndrome associated with metabolic acidosis, hepatomegaly,and haemo-dynamic instability.

The dose of thiopental sodium is larger due to high volume of distribution and neonates appear more sensitive to the drugdue to less proteinbinding, longerhalf-life and impaired clearance.

OPIOIDS:

Opioids is more potent in children due to increased respiratory sensitivity,decreased metabolic capability,increased permeability of blood brain barrier.Morphine sulphate should be used with caution due to decreased hepatic conjugation and renal clearance of metabolites. Sufentanil,alfentaniland fentanyl clearance is increased.Neonates appear to be resistant to the hypnotic effect of ketamine.Midazolam has fastest clearance of all benzodiazepines.

MUSCLE RELAXANTS:

They have faster onset because of shorter circulation time.Infants require 2-3mg /kg of succinylcholine because of larger volume of distribution.They are more susceptible to the complications like bradycardia, hyperkalaemia, masseter spasm and malignant hyperthermia. Atropine pre-treatment is always given prior to succinylcholine.

Non depolarizing muscle relaxant response is variable due to the immature neuro muscular junction, reduced drug concentration and larger extracellular compartment. The duration of pancuronium, vecuronium and rocuronium depending on hepatic metabolism is increased. Atracurium, cisAtracurium behave as intermediate acting agents.

Rocuronium is the drug of choice of routine intubation in paediatric patients.All increment dosing require peripheral nerve stimulator and neuro- muscular monitoring. Non depolarizing blockade can be reversed with neostigmine (0.03—0.07mg/kg) and anticholinergic agent atropine (0.002mg/kg) or glycol-pyrrolate (0.01mg/kg) body weight.

AIRWAY ASSESSMENT

Paediatric patients pose unique difficulties in airway assessment due to the factors of

1. **Anatomical:** large occiput, large epiglottis, vocal cord between C1-C4
2. **Physiological:** airway obstruction in general anaesthesia, smaller FRC, faster desaturation during apnoea, higher metabolism
3. Pre-op difficulties in airway assessment in children < 3 yrs
4. Regional anaesthesia is not an option
5. Awake fibre optic intubation is also not an indication

The assessment begins with the good history taking from the informer of the patient. It includes H/o of complication during delivery, birth, delayed milestones, medication, medical illness any prior surgery to airway and adjacent structures. Review of previous anaesthetic records in view of oro-pharyngeal injury, damage to teeth,awake tracheal intubation, and postponement of surgery following anaesthetic. H/o of snoring, stridor, hoarsevoice, radiation treatment to head and neck is taken.

Physical examination:

Evaluation of size and shape of head, mandibular space and symmetry, shape of tongue, palate, prominent incisors and movement of jaws, head and neck ,presence of congenital anomalies and syndromes.

Presence of any suprasternal, sternal, infrasternal retractions.

Examination of breathsounds, H/O of upper respiratory tract infection, febrile seizures.

Obtaining O2 saturation and blood gas analysis report.

COPUR scale of difficult airway assessment which includes **C**hin viewing from side normal, hypo plastic, markedly recessive, extreme hypo plastic (scores 1 - 4)

Opening of mouth with inter dental space--- >40mm, 20-40mm, 10-20mm,<10 mm (scores from 1 - 4)

Previous intubation attempts, OSA (easy intubation, no previous attempt or obstructive sleep apnoea)

Visibility of UVULA (whole uvula visible, partially visible, concealed, soft palate not visible)

Range of motion of looking up and down. (>120degree,60—120,30—60,<30 degree).Scores of 1-4 is given descending order.

Prediction points: 5-7 easy normal intubation and scores above 10 indicates difficult intubation.

PAEDIATRIC ANAESTHETIC PROTOCOL

PRE OPERATIVE VISIT:

The fear of the paediatric patients is the fear of pain and separation from the parents.This could be addressed by a pre operative visit by the child .It is reassuring to the children.

The presence of the parent,nurse and other persons whom they know well makes a great difference in them.A calm child goes through the anaesthetic procedure in a smooth manner.The presence of pre induction room in the paediatric hospital helps in achieving the goal.

ASSESMENT OF CO-MORBID ILLNESS;

The child is seen as whole in assessment for surgery giving more importance of the pathological process.The history of past illness,surgery,drug intake of the patient is recorded.Any history of recurrent respiratory tract infection,febrile seizures,bronchial asthma were elicited .

LAB INVESTIGATION:

The healthy child undergoing minor procedures are taken for the procedure with the history and clinical examination.

Patients undergoing major procedures, long duration surgery, anticipated fluid shifts were subjected to relevant investigation to the disease process.

PRE OPERATIVE FASTING RULES:

Paediatric fasting guidelines are used in children taking into account the large body surface area compared to the adult and the dehydration associated with them.

SOLIDS are given upto------6 hours

MILK upto-----4 hours

BREAST MILK upto-----3 hours

CLEAR FLUIDS upto-----2 hours.

PREMEDICATION:

The aim of giving premedication is to allay the fear and to decrease the secretions. This gives a smooth conduct of anaesthesia and helps in good recovery. The commonly given premedicant drugs consists of anticholinergic, opioids, and continuation of drugs like bronchodilators, aspiration prophylaxis drugs, antiepileptic should be continued in the pre-operative period.

Midazolam is given in oral dose of 0.5 mg /kg gives adequate results.The drug can be given in I.M form of dose 0.1-0.15mg /kg and in intravenous dose of 0.05mg /kg body weight.Atropine in the dose of 0.02 mg /kg is given in the pre-operative period to decrease the incidence of bradycardia and hypotension and to make an effective airway manipulation by decreasing the secretions.

MONITORING:

The instruments used for monitoring should be made compatible for the age of the paediatric patients.Blood pressure cuffs should be of adequate size.The electrographic leads should have a good connection with the body.The pulse oximeter probe is to be of adequate sizeand preferably placed in the right finger and ear lobe for preductal values.This gives a continuous value of the oxygenation status of the patient.

The precordial stethoscope is an useful device to assess the heart rate,breath sounds and the adequacy of ventilation from a patent airway.

Capnograph confirms the position of the endotracheal tube, adequacy of ventilation and aids in early detection of malignant hyperthermia. The values are kept between 35-45 mm hg.

Temperature monitoring forms important part in the anaesthetic care. The physiological and anatomical changes in the paediatric patients make them vulnerable to heat loss and dehydration. The temperature should be maintained in order to prevent hypothermia and hyperthermia.

The measures taken are to keep the operating room temperature to in a warm condition, using of warm and humidified anaesthetic gases,warm intravenous and irrigation fluid and providing warm blankets.

Urine output monitoring forms an important parameter in assessing the intravascular status and the cardiac output. It gives value of the perfusion of organs and circulatory volume condition of the patient.

Invasive monitoring are selectively used in deserving cases.Air bubbles in the fluid port is taken out to decrease the incidence of air embolism due to patent foramen ovale.

INDUCTION :

The induction of the paediatric patients are done either using intravenous induction or inhalational agents.

INTRAVENOUS AGENTS:

The commonly used agents are propofol (2-3 mg / kg body weight) along with the neuro muscular blocking drugs like Atracurium, Cis Atracurium or Rocurium. The difficult intubation cases are managed with succinylcholine (1-1.5 mg /kg body weight)

INHALATIONAL AGENTS:

Paediatric anaesthetic practice has become more patient friendly with the use of inhalational agent like sevoflurane which gives a pleasant induction for the patients.The MAC of sevoflurane can be increased in either a gradual manner from 2—6-8% the STEP UP

Method or gradually reduced from a higher concentration—STEP DOWN method with N2O and O2 .

The induction and recovery from the inhalational technique is faster and smoother for the children and is becoming an ideal method of induction.

MAINTANENCE OF ANAESTHESIA:

They are maintained on spontaneous ventilation after securing the airway or controlled ventilation is used. The dead space in the adult circle system has been effectively reduced by the use of JACKSON

REES modification of Ayers T piece. This system has a breathing bag attached to the breathing tube and can be used for both spontaneous and controlled ventilation.

Fresh gas flow for spontaneous ventilation---2-3 of minute ventilation.

Fresh gas flow for controlled ventilation ----2 of minute ventilation.

The maintenance of anaesthesia by N2O and O2 with inhalational agent or with neuro muscular blocking agent.

Patients are continuously monitored and extubated after good recovery.

PERI-OPERATIVE FLUID REQUIREMENT:

The peri- operative fluid requirement is divided into

- Maintenance Fluid
- Deficit Correction
- Replacement Fluid

Maintenance fluid is calculated by the 4-2-1 formula based on weight of the patient .The fluid of choice is half normal saline with dextrose 5%. It is given in the value of 2—6ml/kg/body wt.

Deficit fluid replacement is done with balanced salt solution (Ringer lactate solution and half normal saline).

The fluid requirement is calculated for the fasting level and in that 50% of the volume is given in the first hour.

Remaining 50 % of the fluid is given divided in the second and third hour.

The deficit, maintenance for that hour and loss incurred is calculated and given for that particular hour.

Replacement for blood loss is done with crystalloids or with packed cells

- 1 ml blood loss---replaced by 3ml of fluids (Ringer lactate)
- 1 ml of blood loss---replaced by same volume of blood/ albumin.

The infusion of platelets and fresh frozen plasma is done in cases where more than 1-2 volumes of blood is given.

The third space loss is calculated depending on the surgical procedure .0-2 ml /kg is given for small procedures while it is raised to 6-8 ml /kg for long duration surgery resulting in fluid loss.

EMERGENCE AND RECOVERY:

The problems encountered in the recovery phase are

- Laryngospasm
- Post Intubation Croup
- Pain in the Post-Operative Period

The paediatric are continuously monitored for these problems in the post-operative period.

Laryngospasm is treated by giving positive pressure ventilation,forward jaw thrust,I.V lignocaine 1-1.5 mg /kg and I.V succinylcholine 0.5—1 mg /kg body weight.Patients recover well with these measures.

Post intubation stridor which occurs with repeated intubation attempts, large size endotracheal tube, prolonged surgery, head and neck movements is treated with I.V dexamethasone 0.25-0.5 mg /kg body weight.The use of racemic mixture of epinephrine in the dose of 0.25-0.5 ml of 2.25% solution in 2.5 % normal saline effectively cures the problem.

Pain management:

The pain management in paediatric patient has acquired a great significance in recent years .Various methodology is followed for pain relief in them.

The opioids form an important part in the pain management and is widely used in practice.

Midazolam (0.5 mg /kg and Fentanyl 1-2 micro gram /kg) forms mainstay of treatment.

Regional anaesthetic technique –caudal analgesia, nerve blocks makes a difference in pain management.

PROSEAL-LARYNGEAL MASK AIRWAY

Proseal laryngeal mask airway was introduced by Dr. Archie Brain in the year 2000 and used as a supraglottic airway device both in adults and paediatric patients.

It is made up of medical grade silicone and reusable.

The components of the PLMA are modified cuff, integral bite block, gastric drain tube, main airway tube and inflatable pilot balloon.

MODIFIED CUFF:

The proseal LMA has a modified ventral and dorsal cuff integrated with it. The paediatric sizes of 1.5,2 and 2.5 do not have the dorsal cuff enabling the ease of placement. There is increase in depth of the bowl to produce an effective oro-pharyngeal seal favouring positive pressure ventilation.

GASTRIC DRAINAGE TUBE:

Proseal LMA has a gastric drainage tube placed lateral to the main airway tube. This tube is connected to the tip of the cuff which is above the oesophagus when correctly placed.It allows the channelling of the gastric contents and help in the separation of the respiratory and gastric tract.It prevents gastric insufflation, distension and regurgitation.

The nasogastric tube which can be passed into this helps in the drainage of gastric contents and also aids in confirmation of the position of the device.

Doppler probe,oesophagealstethoscope, upper gastro intestinal endoscope, temperature probe can be passed into the drain tube.

The gastric and the airway tube is placed side by side to enhance the stability while securing the airway in the oral cavity.

size	**1**	**1/2**	**2**	**2/2**	**3**	**4**	**5**
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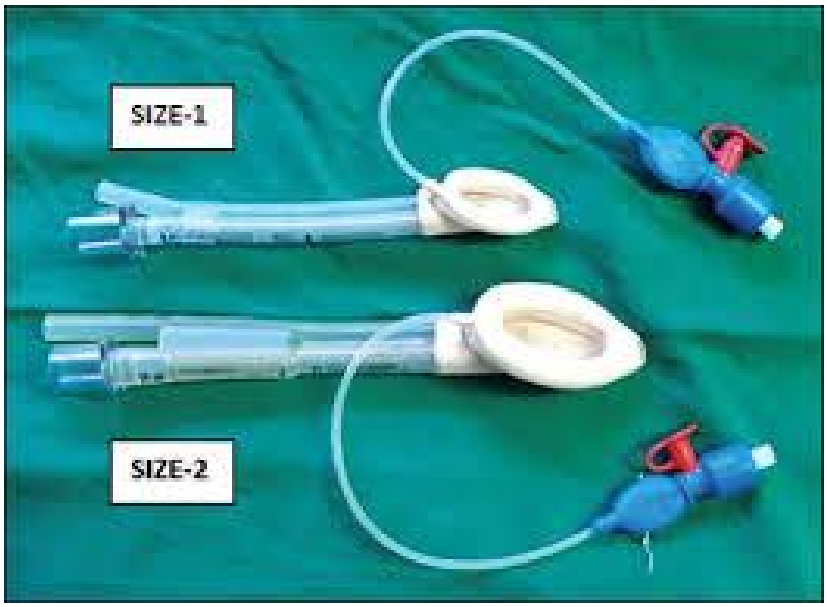
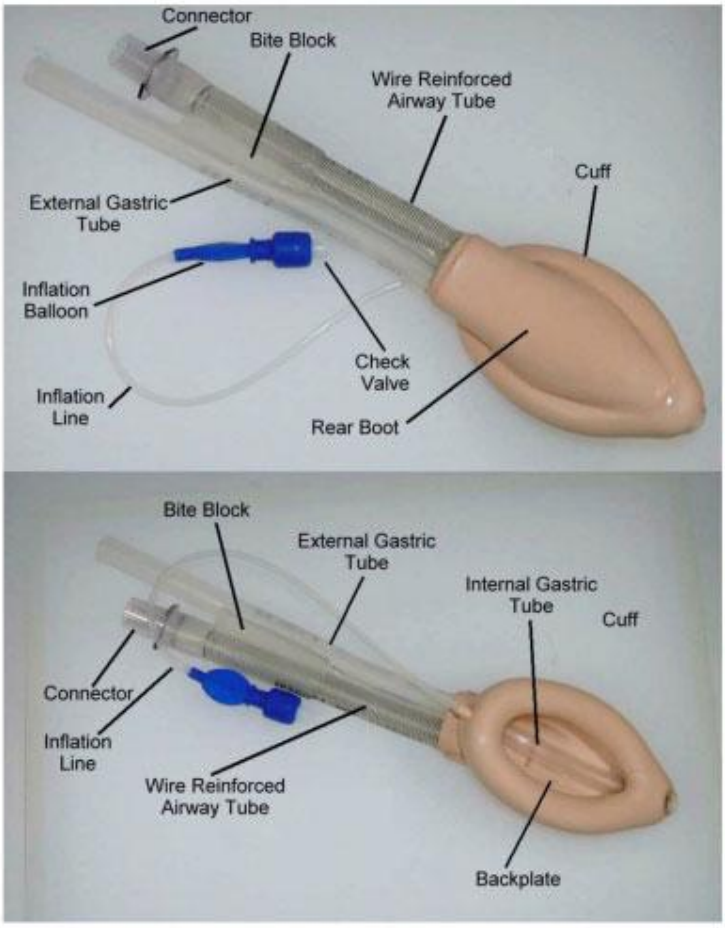
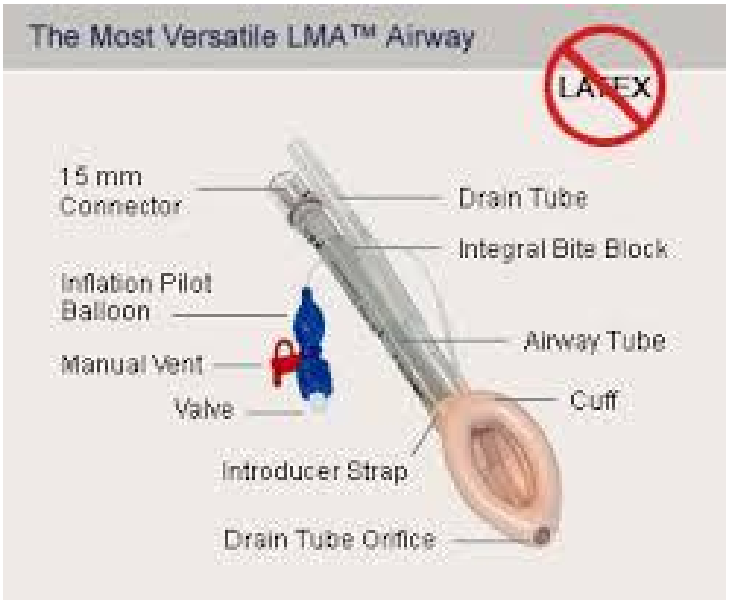
Gastric tube no.	8	10	10	14	10	16	18

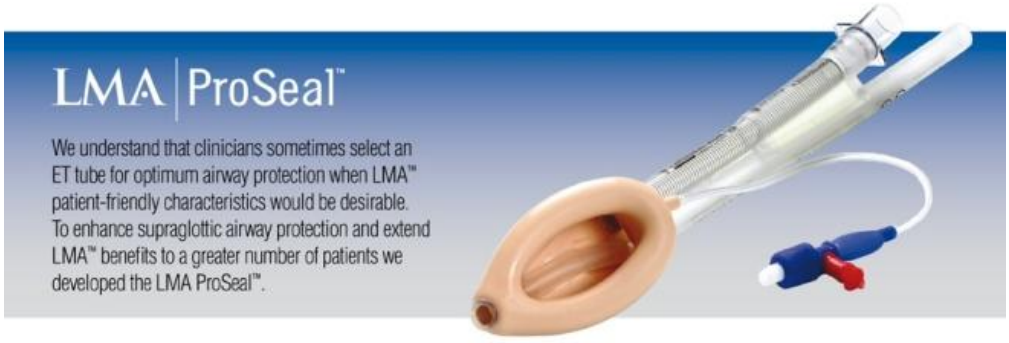



Connector
Bite Block
Wire Reinforced Airway Tube
Cuff
External Gastric Tube
Inflation Balloon
Check Valve
Inflation Line
Rear Boot
Bite Block
External Gastric Tube
Internal Gastric Tube
Cuff
Connector
Inflation Line
Wire Reinforced Airway Tube
Backplate


The Most Versatile LMA™ Airway
LATEX
15 mm Connector
Drain Tube
Integral Bite Block
Inflation Pilot Balloon
Airway Tube
Manual Vent
Valve
Cuff
Introducer Strap
Drain Tube Orifice

INTEGRAL BITE BLOCK:

An integral bite block is present in the proximal end ofR both the ends of the tubes prevents the biting of the airway by the patient which produces airway obstruction.



Location strap added to the junction of the shaft of tube with the bowl on the ventral surface facilitates placing of the index finger into it and prevents slippage of the device during introduction and places it in mid line.

SIZE:

Proseal LMA comes in 7 different sizes with the corresponding weight of the patient and size of the gastric drain tube to be inserted.

TECHNIQUE OF INSERTION:

The device can be introduced by index finger technique or by using gum elastic bougie.

The effective placement and confirmation of the proseal LMA is by bilateral chest movement, auscultation of bilateral air entry, square wave capnograph and gel displacement test.

ENDOTRACHEAL TUBE

Endotracheal tube used for securing the airway are made of red rubber, polyvinyl chloride or silicone. PVC tubes are preferred. They are nontoxic, thermo labile, and inexpensive. They can be used only once.

Endotracheal tubes made of polymeric material are reusable and autoclavable.They are expensive and less thermo labile.

Red rubber tubes are toxic to tissues, less opaque and have high pressure and low volume cuffs producing mucosal injury.

Commonly used polyvinyl tubes have high volume and low pressure cuff .They cover a larger area of tracheal wall, effects a better seal with less pressure on the mucosa. The flow of air through the tube is seen visibly by the moisture content.

The endotracheal tube have the markings on the concave surface, connector to the breathing circuit, bevelled tip, murphy eye, inflatable pilot balloon.

Resistance of the tube depends on the tube diameter, length and curvature.

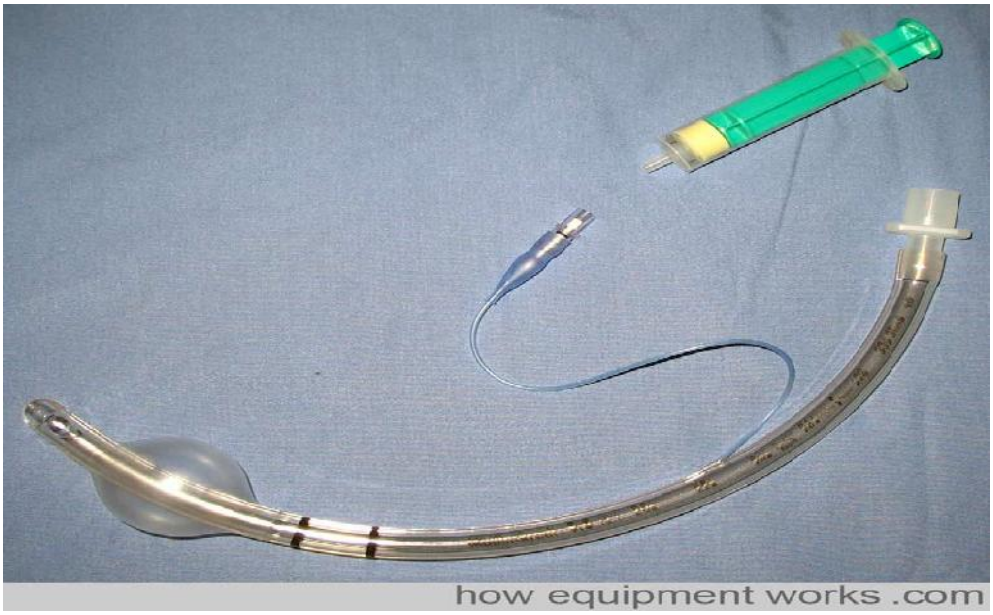
Various types of tubes available are flexible spiral tube, reinforced armoured tube, RAE (Ring, Adair, andElwin) tube, micro laryngeal tubes,double lumen tubes, laser compatible tubes.

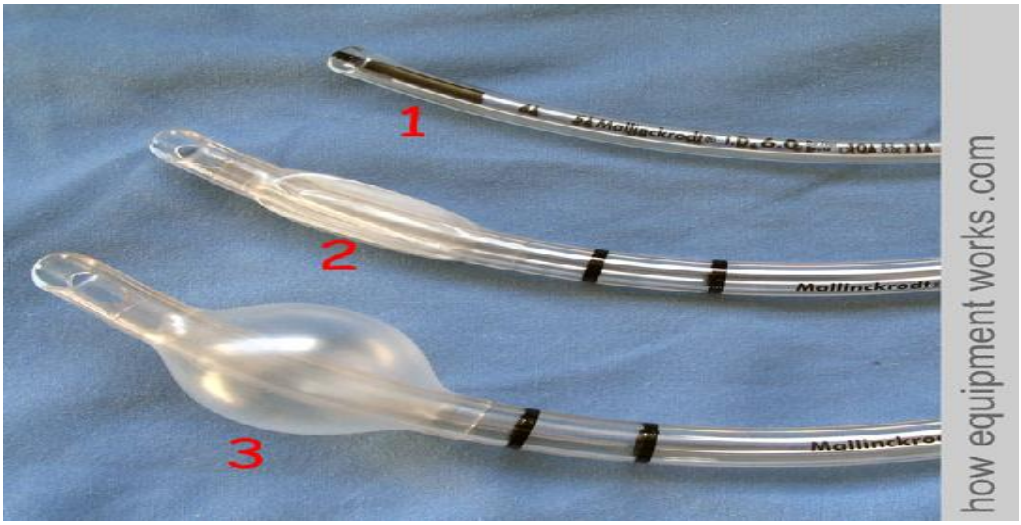
Armoured tubes resist kinking and are used in head and neck surgeries.

RAE tubes used in oral and palatal surgeries.

Micro –laryngeal tubes in vocal cord surgeries

Double lumen tubes helps in lung isolation and used in one lung ventilation for pnuemonectomy, segmental resection of lungs, tracheal reconstructionandsurgeries.

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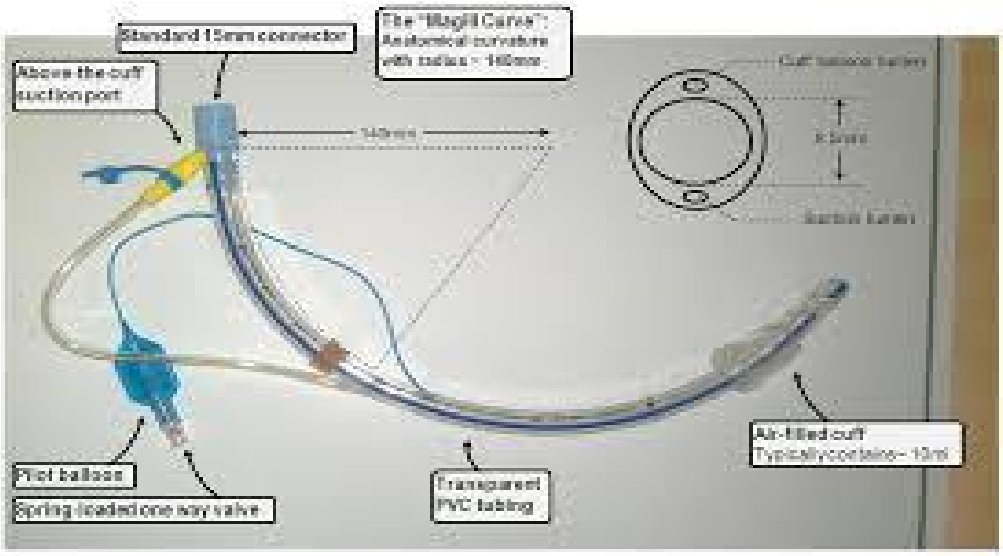

Standard 15mm connector
The "Magill Curve":
Above the cuff
suction port
Pilot balloon
Spring loaded one way valve
Transparent
PVC tubing
Air-filled cuff

INDICATIONS OF ENDOTRCHEAL INTUBATION:

SURGICAL:

In emergency surgery with full stomach patients

In positive pressure ventilation

During laparoscopy

Prone positioning

In mechanical ventilated patient

When using neuro muscular blocking drugs

Intra-abdominal, intra thoracic, neurosurgical procedures.

Dental procedures

In lung isolation techniques

NON SURGICAL INDICATION:

To maintain airway in unconscious patients

For mechanically ventilated patients

Tracheal-bronchial toileting

REVIEW OF LITERATURE

Mamta G Patel, et al. - Indian J Anaesthesia 2010 Mar-Apr; 54(2):109-115

Conducted a randomized prospective study of 60 ASA I and II patients between age of 3-10yrs who were undergoing surgical procedure under general anaesthesia with proseal LMA and the endotracheal tube regarding ease of insertion, number of attempts of insertion and haemo-dynamic parameters. They concluded that the haemodynamic parameters were increased in the group of endotracheal tube when compared with the pro-seal LMA group.

Parvesh Kanthed, et al - Indian J Anaesthesia 2008; 52(1):44-48

Compared efficacy of pro-seal LMA and C-LMA in 100 anaesthetised children undergoing lower abdominal procedures. They divided the group into two of fifty each. They found that the number of attempts of insertion and ease of placement of device were comparable in both groups. Pharyngeo-laryngeal morbidity is also found comparable in both the groups. Oro pharyngeal seal pressure found to be higher in the pro-seal LMA group and they concluded that it produced a good effective seal for positive pressure ventilation.

Rauf Gul, et al – Saudi Medical J 2012; Vol.33 (4)

A prospective randomised clinical study of 80 patients 1-12 year of weight 10-30 kg divided into 40 groups 40 each.They are undergoing paediatric strabismus surgery,anaesthesia was induced with 8% sevoflurane with 50% of oxygen and nitrous oxide.Atracurium was used as neuromuscular blocking agent.The patients were intubated with proseal Laryngeal mask airway or appropriate size endotracheal tube was used to secure the airway. They concluded that the haemodynamic response was less with proseal laryngeal mask group and it had a safety features of gastric drain tube to prevent aspiration .Hence the PLMA could be used to alternative to endotracheal tube in children undergoing paediatric strabismus surgery.

Jaya Lalwani, et al - Indian J Anaesthesia 2010 Nov-Dec; 54(6) : 541-545

Conducted randomized study of sixty paediatric patients between 2 – 8 years of age and weight between 10 – 20 kg undergoing short duration surgical procedures using Pro-seal LMA and Endo Tracheal Tube with respect to the placement of device, haemo-dynamic response during insertion and peri-operative respiratory complications. Their

study revealed that PLMA is a useful alternative to Endo Tracheal Tube, which produces less haemo-dynamical response.

K. Goldmann and C. Jacob – British J Anaesthesia 94 (3) : 385 – 389 (2005)

Randomized cross-over investigation was conducted on thirty children comparing pro-seal LMA with a standard laryngeal mask airway with respect to ease of insertion, quality of airway, airway leak pressure, maximum tidal volume and fibre-optic position. The above parameters measured and led to a conclusion that air way leak pressure and maximum tidal volume were significantly higher for the PLMA group.

M. Misraand B. Ramamurthy – The Internet Journal of Anaesthesiology, 2007 Vol 16 Number 2

Study conducted on hundred patients undergoing laparoscopy abdominal surgeries under general anaesthesia on PLMA and ETT. The study revealed that markedly haemo-dynamic response at insertion of PLMA is definite advantage over ETT.

M. Lopez Gil, et al. – British J Anaesthesia 95 (6) : 827 – 830 (2005)

Two hundred forty children of ASA I, II and III aged 1 – 16 years were included for a randomized non cross-over study comparing the

pro-seal and classic laryngeal mask airway. They tested the hypothesis of ease of insertion, oro-pharyngeal leak pressure, gastric insufflation and frequency of mucosal trauma. They also assessed the ease of gastric tube placement in PMLA group and measure the gastric volume. The conclusion was that the ease of insertion, fibreoptic position and frequency of mucosal trauma are similar for PLMA and CLMA in children. However for PLMA group oropharyngeal leak pressure was higher and gastric insufflation was less common.

A.I.J. Brain, et al. – British J Anaesthesia 84 (5) : 650 – 654 (2000)

Authors compared that laryngeal mask airway with the drain tube to the standard classic laryngeal mask airway with regard to the ease of insertion of the device, with or without special introducer tool. They compared the airway seal pressure between the two devices.They found that the proseal laryngeal mask airway has several advantages compare to the standard laryngeal mask airway with respect to increase in oral laryngeal seal pressure which enables positive pressure ventilation.The passage of naso- gastric tube through the drain tube help in the drainage of gastric contents.

BIHRAMJIT DAS SAHIR N et al (JOURNAL OF ANAESTHESIOLOGY AND CLINICAL PHARMACOLOGY JULY SEPTEMBER 2010 VOL. 28 ISSUE 3)

They conducted a randomise simple blind study of 60 ASA 1 and 2 paediatric patients of age 1-6 years undergoing lower abdominal inguinal and upper extremity procedures under general anaesthesia. They comparedthe time of insertion of devise, number of attempts, haemodynamic parameters like heart rate, blood pressure, spo2 and the post op complications. They found that the proseal laryngeal mask airway was found to be a good ventilatory device.It produced less haemodynamic response and increased oral pharyngeal seal pressure and helps in positive pressure ventilation.

WAKLOO, GUPTA,ssRANBUSHAM. Et al (THE INTERNET JOURNAL OF ANAESTHESIOLOGY)2006 vol. 14 number 2)

They conducted a prospective randomised study to examine the incidence of perioperative complications in children with mild allergic rhinitis undergoing elective lower abdominal surgery under anaesthesia.They divided 40 children into 20 of each group for using proseal laryngeal mask airway and endotracheal tube to secure the airway.They found that the incidence of cough ,secretions with

breathholding spells were less in the group of proseal laryngeal mask airway.The incidence of bronchospasm and laryngeal spasm occur more in endotracheal group. They concluded that children with mild allergic rhinitis could be taken up for surgery and the proseal laryngeal mask airway provided a good ventilator device.

KAI GOLDMAN MD JACOB et al (ANAESTH ANALG 2005;100:1605-10)

The authors compares the size two and a half proseal laryngeal mask airway with classic laryngeal mask airway of the same size in the paediatric patient with regard to attempts of insertion airway quality and airway leak pressure and vocal cord morbidity in both groups.

30 children of ASA 1 and 2 schedule to undergo elective orthopaedic and urological procedures were included in the studies.They found that the size two and a half proseal laryngeal mask airway is advantages over the same size classic LMA in terms of ease of gastric tube placement and increased peak airway pressure which is produced in proseal laryngeal mask airway.

DAVID R.R LARDNER, ROBIN G COX (CANADIAN JOURNAL OF ANAESTHESIA) 2088/55:1/ PAGE 29-35)

The authors conducted a single blinded study of 51 paediatric of age 2-8 years ASA 1 and 2 weighing 10-20 kg to determine whether functional difference exist between size 2 classic laryngeal mask airway and proseal laryngeal mask airway of same size.The children were taken under inhalational anaesthesia without using neuromuscular blockade.

Airway leak pressure and fibre optic laryngeal view were study as primary parameters.They found that oro pharyngeal leak pressure was higher with pro seal laryngeal mask airway and it improved the fibre optic view of glottis was found through bronchoscopy

MICHELLE WHITE,TIM N COOK,PETER STOODART PAEDIATRIC ANAESTHESIA/19 SUPPLEMENT (1:55-65)

The authors wrote a review article of (critique of elective paediatric supraglottic airway device.

In that they discuss the evolution of the supraglottic airway device as an alternative to endotracheal tube

They divided the supraglottic airway device into 1st and 2nd generation.They describe proseal laryngeal mask airway as a 2nd

generation. Airway device for controlled ventilation and increase airway protection.They describe the paediatric PLMA(Proseal laryngeal mask airway) tobe extensively studied in various randomised protocol and found to be consistent in performance.They further stated that the ease of placement of devise, effective airway management mean oro pharyngeal leak pressure and fibre optic view of larynx are superior with PLMA compare to 1st generation devise.

Oesophageal drain tube is an added safety feature in the proseal laryngeal mask airway,hence they concluded that the PLMA is and optimal paediatric supraglottic airway device for routine anaesthesia.

KAI GOLDMAN MD et al (ANAESTH ANALOG 2006; 102:405-10)

The author conducted a randomised cross over investigation with size one and a half proseal LMA with the same size classic LMA in the paediatric age group.

They compare the ease of insertion quality of initial airway,fibre optic position ,airway leak pressure and maximum tidal volume with respect to above two devises.

30 infants of 15 months age weighing 9 kgwere taken for study.

The mean airway leak pressure in neutral and maximum head flexion position were found to be higher with proseal laryngeal mask airway group.The passage of the gastric tube acted as an added safety feature.They concluded that the size 1 and a half proseal laryngeal mask airway seems tobe more suitable for airway maintenance compare with classic laryngeal mask airway.

SEBASTIAN RUSSO et al (ANAESTHESIOLOGY; 2009; 111; 116-21)

The design of their study was to examine the hypothesis that proseal laryngeal mask airway is an adequate tool for elective post-operative care in ICU patients and it has less haemodynamicalterations during extubation comparing to endotracheal tube.

48 patients were enrolled for the study and they were allocated one of either endotracheal tube or proseal laryngeal mask airway group.They found that the haemodynamic parameters of heart rate, systolic blood pressure and mean arterial pressure were less in proseal laryngeal mask airway group.The patients also showed less haemodynamic response during the extubation phase with the above device.Hence they concluded that in elective cases endotracheal tube to

be replaced by the proseal laryngeal mask airway which has a clear advantage over the other.

TIM M COOK et al (CANADIAN JOURNAL ANAESTH ESIOLOGY) 2005/52:7/PAGE 739-760

The purpose of the study is to analyse and summarise the published literature relating to proseal laryngeal mask airway with oesophageal drain tube with respect to improved controlled ventilation, airway protection and diagnosis of misplacement.

They concluded that the 1st attempt success rate is lower for PLMA but it improved with subsequent attempts and enabled to secure the airway.The drainage tube allowed the diagnosis of misplacement of the device.It also helped in gastric drainage, reducing the gastric inflation and aspiration.

They concluded that proseal laryngeal mask airway has significant benefit over both the classic LMA and endotracheal tube in clinical circumstances.

J BRIMACOMBE etal (BRITISH JOURNAL ANAESTHESIA 2007; 99:576-80)

The author tested the hypothesis of postoperative nausea and vomiting,inthe 2nd generation supra glottis airway devise proseal laryngeal mask airway with endotracheal tube.

The study was conducted in 200 female patients ASA 1 and 2 status whoare underwent breast surgeries.

They found that ventilation was better with proseal laryngeal mask airway. It produced lesser haemodynamic response,less airway trauma and patients needed lesser doses of morphine as an analgesic.They concluded that the post op nausea, vomiting,airway morbidity and analgesic requirements is lower for proseal laryngeal mask airway when endotracheal tube is used for surgeries even in adults.

Namita Saraswat et al (I Indian journal of anaesthesia 2011 March-April; 55(2) : 129-134)

The author compare the proseal laryngeal mask airway and the endotracheal tube in patients undergoing laparoscopic surgical procedures under general anaesthesia.60 patients were randomly divided into 2 groups of 30 each by simple randomisation method.

They compare the number of attempts,time taken for insertion of devised, haemodynamicparameters, oxygen saturation and ventilation.

The intra operative and postoperative laryngeo–pharyngeal morbidity is noted.

They concluded that the positive pressure ventilation with PLMA proved tobe suitable and safe alternative to endotracheal tube for maintaining airway in patients undergoing elective surgery. It provided effective ventilation and oesophageal drain tube prevented the gastric distention,inflation and aspiration of gastric contents.

MATERIALS AND METHODS

Study Design:

This study is prospective simple randomization study involving 80 paediatric patients of age 2 – 8 years of weight 10 – 20 kg belonging to ASA I and II category attending the department of paediatric surgery at Chengalpattu Medical college for the period from November 2013 to August 2014. Institutional ethical committee approval was obtained. The procedures were explained to the parents of patients in their own language and written informed consent were obtained from them.

A thorough pre-operative assessment was done before surgery with detailed history of the patient, clinical examination with appropriate investigations and they were assessed for the respective surgeries. Pre-operative fasting guidelines were given to them.

Patients who fulfilled the inclusion criteria and who gave the consent for the study were allocated to one of the study group using proseal laryngeal mask airway and endo tracheal tube by simple randomization method.

Inclusion Criteria:

Age of the patients	:	2 – 8 years
Weight	:	10 – 20 Kg
ASA	:	I and II
MPC	:	I and II

Patients undergoing short duration surgery

Exclusion Criteria:

Anticipated difficult airway, previous history of difficult airway

Hiatus hernia

Gastro oesophageal reflux disease

History of obstructive sleep apnoea, febrile seizures

Upper respiratory tract infection, History of full stomach

MATERIALS NEEDED:

1. 2cc,5cc,10cc syringes, intravenous fluids
2. 22 gauge venflon
3. Monitors—precordial stethoscope, pulse oximeter,non-invasive blood pressure,temperature monitoring,electro cardiogram
4. Boyles machine,laryngoscope
5. Good working suction
6. Size 2 proseal laryngeal mask airway
7. various size endotracheal tubes

METHODOLOGY:

After getting consent,he patients were assessed and kept on fasting guidelines.They were randomly allocated into one of the 2 groups of GROUP P---Proseal laryngeal mask group and GROUP T-Endotracheal group with the closed envelope method predictors being single blinded

Patients were brought into the theatre,monitors of pulse oximeter, non-invasive blood pressure, precordial stethoscope,ECG were connected, and intra venous line secured and base line parameters were recorded.

They were pre-medicated with inj.glyco-pyrrolate 0.01mg/kg/ body weight and inj. fentanyl 2micro gram /kg/body weight five minutes prior to induction.Pre oxygenation was done for 3 minutes. Anaesthesia was induced with inj. propofol as an inducing agent with 2mg/kg/body weight with inj.IV lignocaine 0.5mg/kg body weight.Atracurium 0.5 mg/kg body weight was used as neuro muscular blocking agent with incremental boluses of 0.1 mg /kg/body weight when required.

GROUP P

PROSEAL laryngeal mask airway size 2 was selected, cuff deflated after checking the patency .Posterior surface of the device was

lubricated with 2% lignocaine jelly.The child's head was kept in neutral position.The proseal laryngeal mask was inserted through the oral cavity using index finger technique.The cuff was inflated with 7—10 ml of air. After obtaining an effective airway which was confirmed by normal thorocoabdominal movements, bilaterally audible breath sounds on auscultation, square wave form on capnograph, pulse oximeter readings the PLMA was fixed to the chin by tape.

Three attempts were allowed for securing the airway before the device was considered as failure and it was replaced with an ET tube. This is termed as a failed attempt.Gastric tube number 10 was introduced through the drain tube,in this two attempts were allowed for gastric tube insertion before it was considered as a failure, and repositioning of the PLMA was done.

GROUP T

In group T patients, appropriate size endotracheal tube was used for securing the airway.

All the patients were maintained with nitrous oxide 66 % and oxygen 33% with sevoflurane 0.2-0.4% and manually ventilated with Jackson Rees paediatric circuit.Vital parameters were recorded post intubation immediately after placing the PLMA or endotracheal tube.

Haemodynamic monitoring was done at the interval of 5 minutes and subsequently after 10 minutes of placing the device.

After the procedure was over, the patients had spontaneous ventilator efforts and were reversed with inj. neostigmine 0.05mg and injection glyco-pyrrolate 0.01mg per kg body weight. Thoroughly oral suctioning done and PLMA group gastric drain tube suctioning done. The patients were extubated after good recovery.

At the time of emergence any complications of cough,bronchospasm, or laryngospasms were noted in both the groups. After removal of airway device, blood staining of the endotracheal tube and posterior aspect of proseal laryngeal mask airway were assessed.

Patients were continuously monitored in post anaesthesia care unit and followed up for next 24 hours for any complication of sore throat or hoarseness of voice.

Parameters monitored:

Heart rate

Systolic and diastolic blood pressure

Mean arterial blood pressure

SPo2 and EtCo2 values

Comparison made for:

Number of intubation attempts

Haemodynamic parameters

Complication during emergence and in post-operativeperiod

Statistical analysis were done by using SPSS software 16 version. Descriptive standards like mean, median, range, are calculated for all the variables.Student T tests and chi square tests are used to find the significance between two groups at the level of 5% confidence (alpha error). Student t test is used for descriptive data and Chi square test for categorical variables.

OBSERVATION AND RESULTS

Our study included 80 patients randomly allocated to either Group P (proseal laryngeal mask airway) or Group T (endotracheal tube)in those who were undergoing elective surgical procedures under general anaesthesia.

Data collection and analysis were done by using SPSS software version 16.

The initial patient character of age, height, and ASA status and comorbid conditions were compared.

The outcome measure are haemodynamic status of the patients, post intubation then recorded for 5 and 10 minutes. Other parameters observed are mean arterial blood pressure, SPO2 and temperature of patient. The post-operative complications of bronchospasm, laryngospasm, cough that occurs during emergence period were noted. The patients were observed for the next 24 hours for sore throat and hoarseness of voice in the post-operative unit.

Study method :

After obtaining ethical committee approval, the patients were randomized into one of two groups using closed envelope method with pre determine group number and then single blinded.

Group P –Pro seal laryngeal mask airway.

Group T-Endotracheal tube placement.

Patients were advised the appropriate fasting guidelines. IV lines secured with 15G venflon,premedicated with injection glyco-pyrrolate 0.01mg per kg body weight and inj i.v fentanyl 2 micro gm per kg body weight, 5 minutes before anaesthetic induction.

Standard monitor of pulse oximetry, non-invasive blood pressure, heart rate monitoring, continuous ECG monitoring, and capnograph was used.

Patient were placed in supine position and the operation theatre temperature is kept at the optimum level for the paediatric patients.Warm blankets were used. Intravenous fluids were also pre warmed.Pre oxygenation done for 3 minutes with 100% oxygen and anaesthesia was induced with inj. propofol 2 mg per kg body weight with inj. IV lignocaine0.5 kg per kg body weight. And ventilated done for 3 minutes with inj. Atracurium 0.5 per kg body weight as neuromuscular blocking agent. Anaesthesia was maintain with nitrous oxide with oxygen (66 and 33% respectively) and sevoflurane was used in0.2-0.8 % and the airway was secured by using proseal mask airway or appropriate size endotracheal tube in the assai signed group.

Group P

The patients head kept in neutral position, the posterior surface of the proseal laryngeal mask airway was lubricated with 2% lignocaine jelly and the device was firmly grasped along the integral bite block with the leading index finger. The soft tip of the device was introduced into the mouth of the patient pressing against the hard palate.

The device was glided downwards and backwards along the hard palate until a definitive resistance was felt.The inflatable cuff is inflated with 7-10 ml of air. After connecting the circuit to PLMA adequate placing of device was confirmed by observing bilateral chest movement, auscultation of breath sounds, square wave capnograph and with no oro pharyngeal leak.

The number of attempts of placement of device was noted .Three attempts were allowed before it was considered as a failure and replaced with appropriate size endotracheal tube. Haemodynamic monitoring was done post induction, 5minutes and 10 minutesfor the study of haemodynamic monitoring after that and for every 5minutes till the end of surgery.

Group T-

The patient's airway was secured with appropriate size lubricated endotracheal tube. Here the number of placement of device was noted. Continuous haemodynamic monitoring was done post intubation, 5minutes 10 minute for the haemodynamic monitoring study after that for every 5 minutes till the end of surgery.

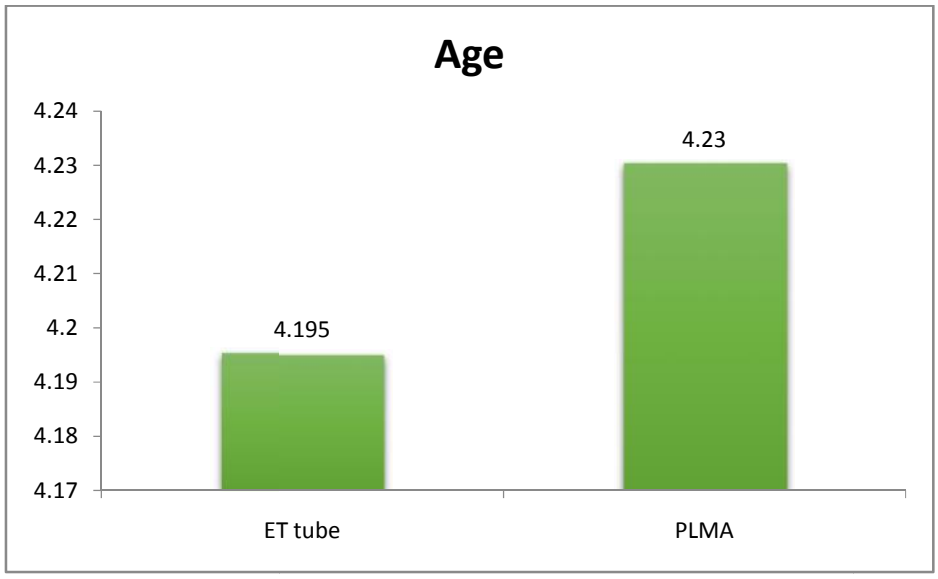
OBESERVATIONANDRESULTS :

Patient character.

Age (student t test)

Group	N	Mean	Standard deviation	P value
ETT	40	4.195	1.748	0.93
PLMA	40	4.23	1.7022	0.93

Age distribution was comparable within the two groups. The mean age for both the groups was found to be 4.1 years. The variables in the above two groups were comparable with regard to age and there is no statistical difference between them. (p value =0.93)



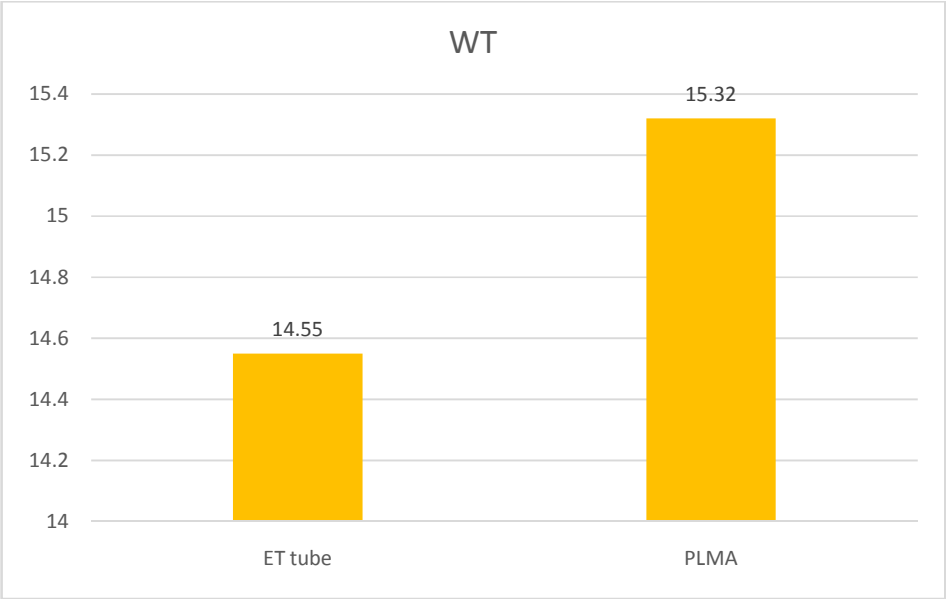
WEIGHT DISTRIBUTION-(Student t test):

The weight of the patients enrolled for the study group was taken during the preassessment period. This is done to exclude the children who are underweight and who are suffering from chronic malnutrition problem.The weight of the child forms an important parameter reflectingthe health of the child in long duration.

Group	N	Mean	Standard deviation	Student T test values
ETT	40	14.55	3.129	T value=1.023
PLMA	40	15.32	3.626	P value=0.31

The mean weight of the patients in the two groups compared for the study is 4 kg. The parameter is comparable between two groups.This forms an important guide for calculation of drug therapy in paediatric age group.The growth and monitoring of the child is being assessed in

terms of weight. Hence it forms an important data. The value found to be statistically not significant. The p value was found to be 0.31.

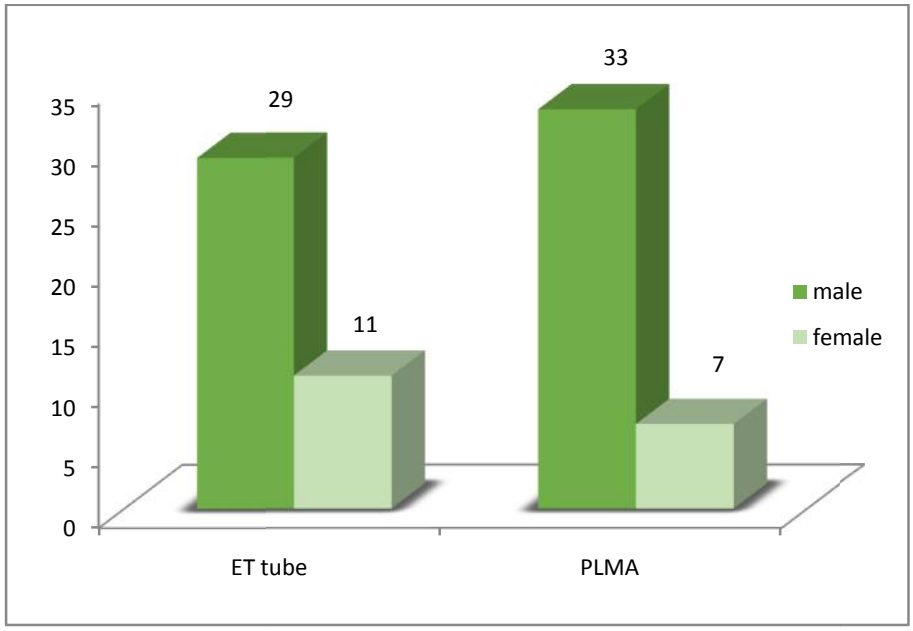


COMPARISON OF SEXDISTRIBUTION :

The comparison of sex distribution is done in the children to be included in the study group to evaluate the prevalence of the commonly occurring disease process in children and it is used for the statistical analysis of the problem in them.

Group	N	Frequency		Percentage
ETT	40	M	29	72.5
		F	11	27.5
PLMA	40	M	33	82.5
		F	7	17.5

There appears to be slight preponderance of the male patients in the comparison of the two groups studied. This may be due to the fact that the surgical intervention is needed in male children due to the problems encountered in them. The type of surgeries commonly performed was circumcision, process us vaginalis sac ligation for congenital hydrocoel and herniotomies for congenital hernia.This value found to be statistically not significant.



NUMBER OF ATTEMPTS OF DEVICE PLACEMENTS:

Group	Attempts	Frequency	Placement
ETT	1	37	92.5
	2	3	7.5
		40	100
PLMA	1	31	77.5

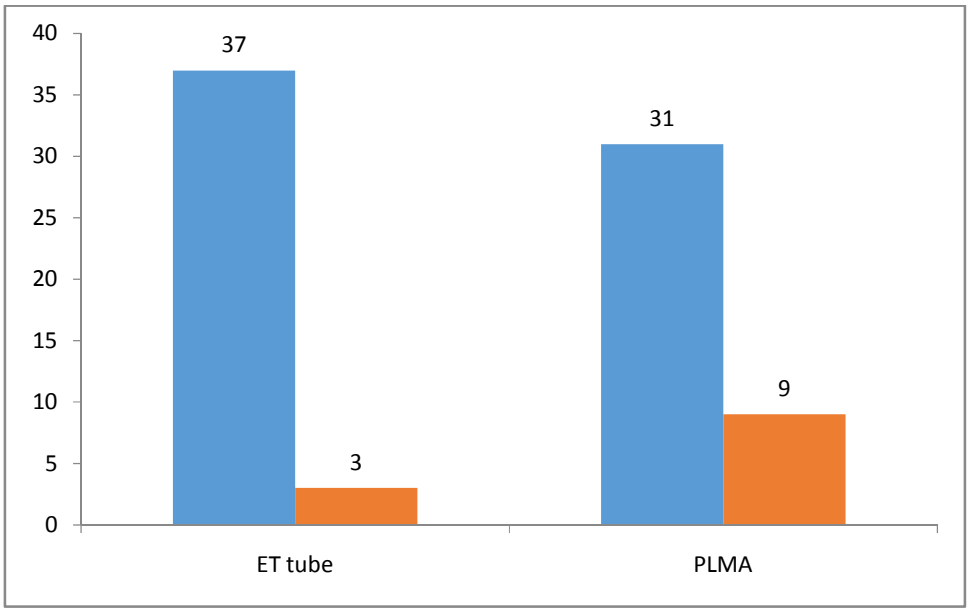
The attempts in placement of device were comparable in both the groups. The endotracheal tube was placed in 92.5%(37 out of 40 patients) in first attempt andin7.5 %(3 patients out of 40 required second attempt) in placement.

The proseal laryngeal mask airway was placed in 77.5% (31 patients out of 40 patients) in 1st attempt and 22.5% (9 out of patients required 2nd attempt for insertion).

The observation made in our study coincided with the findings in the study RAUF GUL et al who found that the proseal laryngeal mask airway and endotracheal tube was placed in 95% of patients successfully in the first attempt.

MAMTA et al and MISRA in their study reported that the insertion rate of both the devices was found to be 100% in the first attempt .

JAYA LALWANI et al reported that the success rate to intubate the patient with the endotracheal tube was 96.6% in first attempt and 3.3% of patients' required second attempt.They also that proseal laryngeal mask airway was placed in 83.33% in first attempt and 16.67% of patients required second attempt in placement of the device.



HAEMODYNAMIC MONITORING OF THE PATIENTS :

The patients were monitored for the haemodynamic parameters of heart rate, mean blood pressure,Spo2 and Etco2 values at the baseline level, post intubation, after 5 min and 10 minutes interval.The data were collected and statistically analysed for the various effects.

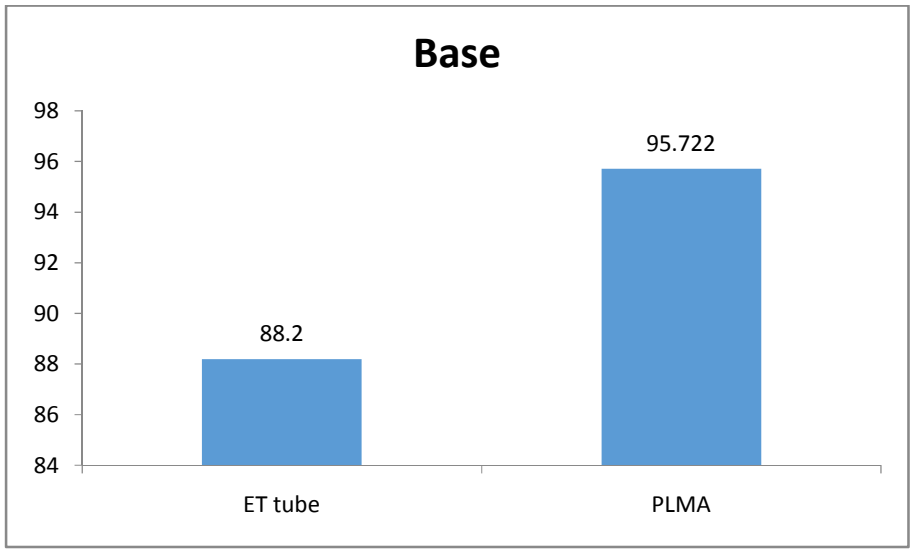
VARIATION IN PARAMETERS AT THE BASELINE LEVEL (student's t test)

BASE LINE HEART RATE:

The baseline heart rate was monitored in the study group of eighty children.

Group	N	Mean	S .D	T value	P value
ETT	40	88.2	4.8685	5.49	0.00
PLMA	40	95.722	7.1693		

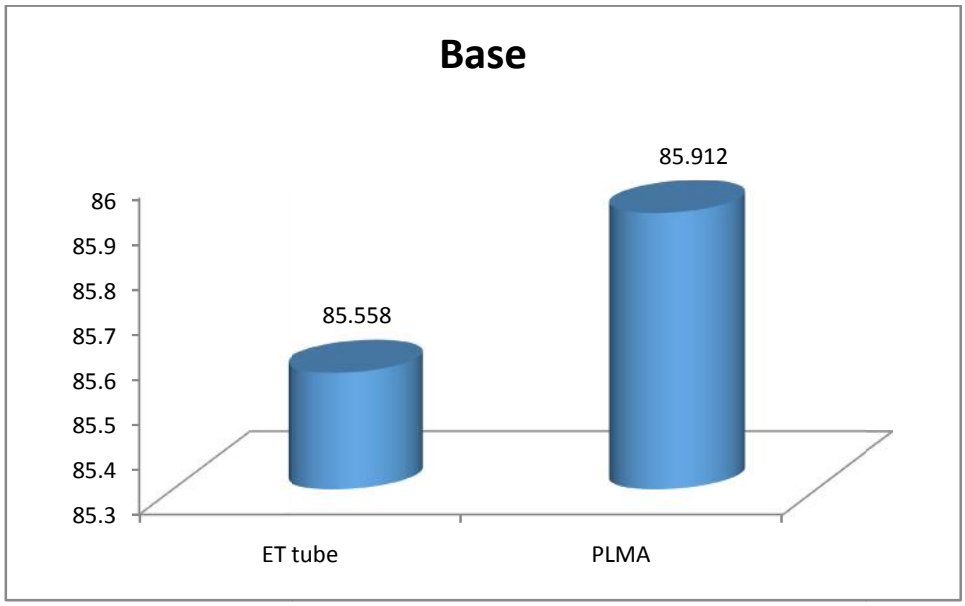
The finding from the above table is that the patients randomly allocated the proseal laryngeal mask air way group have an increased heart rate observed in them compared to the endotracheal group . The value is found to **be statistically significant p value being <0.05 .**



BASE LINE MEAN BLOOD PRESSURE:

Group	N	Mean	Standard deviation	T value	P value
ETT	40	85.55	3.29	0.47	0.64
PLMA	40	85.912	3.44		

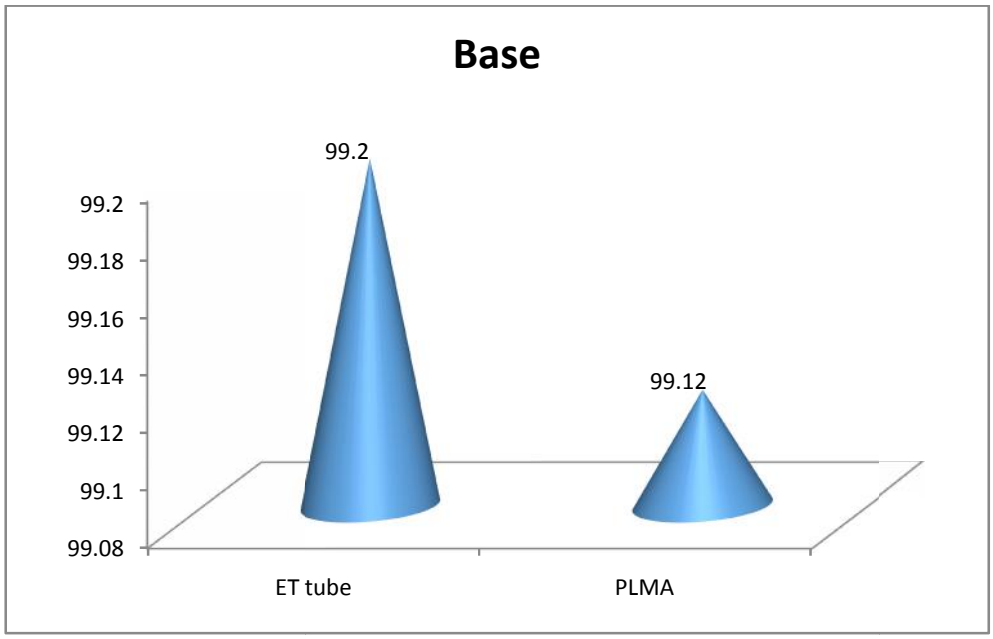
The baseline mean blood pressure is comparable between the two groups and the value is found to be not statistically significant. The p value being 0.64.



BASE LINE SPO2:

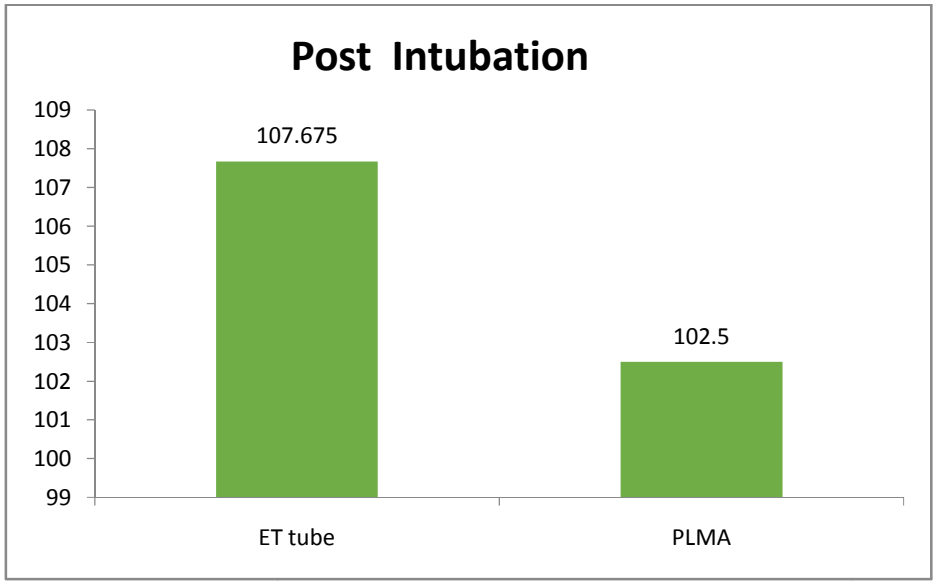
Group	N	Mean	Standard deviation	T value	P value
ETT	40	99.2	0.405	0.902	0.51
PLMA	40	99.12	0.375		

The base line saturation of oxygen is found to be comparable between the two groups and the value is found not to be statistically significant. The p value being 0.51.



POST INTUBATION HEART RATE

Group	N	Mean	S.D	T	P value
ETT	40	107.675	5.336	3.735	0.00
PLMA	40	102.65	6.950		



The haemodynamic response post intubation was found tobe higher with endotracheal tube group compared with the proseal laryngeal mask airway and it was found tobe statistically **significant pvalue <0.05)**

This observation was supported by the studies of following authors who compared the devices of endotracheal tube and proseal laryngeal mask airway as an intubating aid.

MISRA et al while comparing the data of 100 patients intubated with either proseal laryngeal mask airway or endotracheal tube they found that rise in heart rate is significantly increased in the endotracheal group compared to proseal laryngeal mask group.

MAMTA PATEL et al also found that there is significant increase in heart rate after intubation with endotracheal tube compared to the proseal laryngeal mask airway group.

NAMITA SARASWAT –The author in their study of 60 patients undergoing surgery under general anaesthesia they found that there is increase in heart in endotracheal intubation which is found to be statistically significant. This effect was seen immediately after intubation and it is prolonged for another three minutes.

They also noted that there is increase in heart rate in the proseal laryngeal mask airway group which also found to be significant from the base line value, the effect lasted for 10 seconds only.The patients haemodynamic status became stable after the initial response.

JAYA LALWANI et al –They conducted a randomized study in sixty children of 2 to 8 years of age ,weighing 10 -20 kg , ASA1&11 status comparing the proseal laryngeal mask airway with the endotracheal tube for intubation to secure the airway in children undergoing procedures under general anaesthesia.They found that there is a significant increase in heart rate from the baseline value after intubation with endotracheal tube.In the proseal laryngeal mask airway group the increase in heart rate is lesser when compared to the endotracheal tube group.

POST INTUBATION MEAN BLOOD PRESSURE:

Group	N	Mean	Sd	T value	P value
ETT	40	87.372	3.9542	1.276	0.21
PLMA	40	86.421	3.9686		

The increase in blood pressure as an intubation response after using endotracheal tube to secure the airway is found to be greater than the proseal laryngeal mask airway group.The valueis found to be not

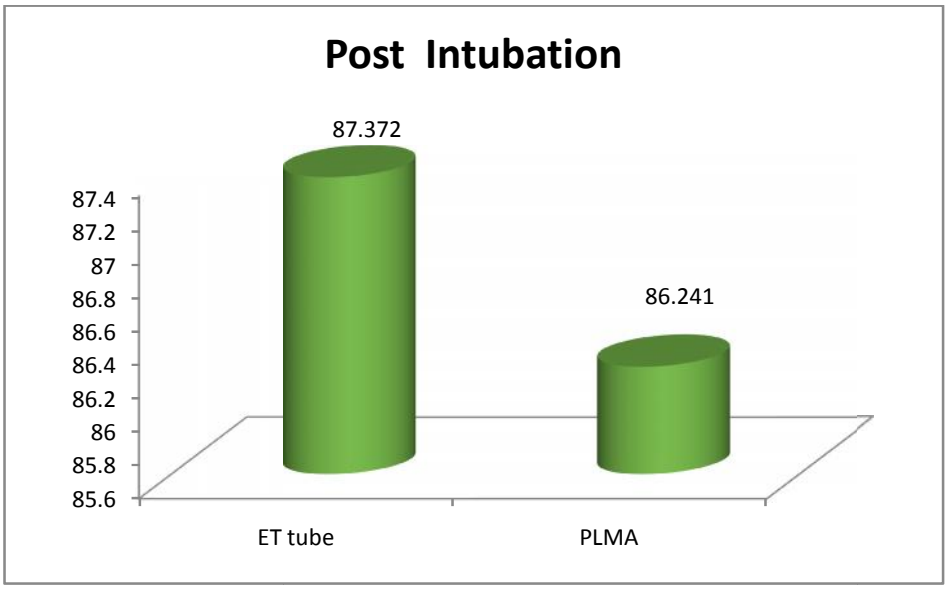
statistically significant . The p value is 0.21. This finding coincides with observation of the authors in the following studies who reported a similar incidence.

MAMTA et al in their study observed that there is increase mean blood pressure after endo tracheal intubation which is found to be statistically significant when compared to the proseal laryngeal mask airway.

NAMITA et al found in their study that there is a significant increase in mean blood pressure in the endo tracheal group compared to the proseal laryngeal mask airway group after intubation .The response produced assumes importance to maintain a haemo dynamic stability.

JAYA LALWANI et al found a similar response in endotracheal group where the increase in mean blood pressure is comparable to the proseal laryngeal mask air way group and it was not statistically significant.

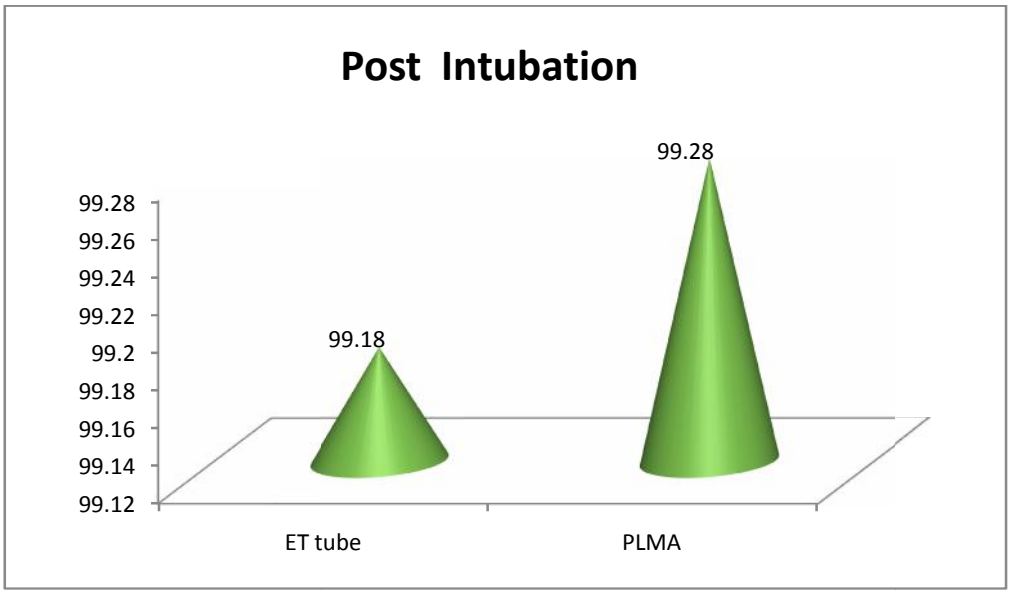
MISRA et al also described that there is a significant increase in the mean blood pressure in the endo tracheal group of patients compared to the proseal laryngeal mask airway group and they found the p value is less than 0.01.



POST INTUBATION SPO2:

Group	N	Mean	Sd	T value	P value
ETT	40	99.18	0.385	1.065	0.29
PLMA	40	99.28	0.452		

The finding in the above table comparing the oxygen saturation SPO2 valueafter intubation with either of the endo tracheal tube or the proseal laryngeal mask airway shows there is no significant difference in them with respect to the parameter observed.The value is found to be statistically insignificant .p value being 0.29.



AFTER 5 MINUTES OF INSERTION OF DEVICE---HEART RATE:

The monitoring of heart rate after five minutes of insertion of the device of either of the device shows significant difference in the two groups taken for study .This parameter forms an important assessment of the haemodynamic response produced by either of the device used in the study.

GROUP	N	MEAN	SD	T value	P value
ETT	40	99.225	5.12	2.1	0.04
PLMA	40	97.225	4.35		

The finding in the above table states that there is a significant change observed in the parameter of heart rate after 5 minutes ofintubation using endotracheal tube than the proseal laryngeal mask

airway group.The increase in heart rate is seen with the endotracheal tube patients is greater when compared to the proseal laryngeal mask airway group.

The stress response produced in the endotracheal intubation is found to be persistent for the above period of 5 minutes after intubation.

The value is statistically significant the **p value being 0.04**

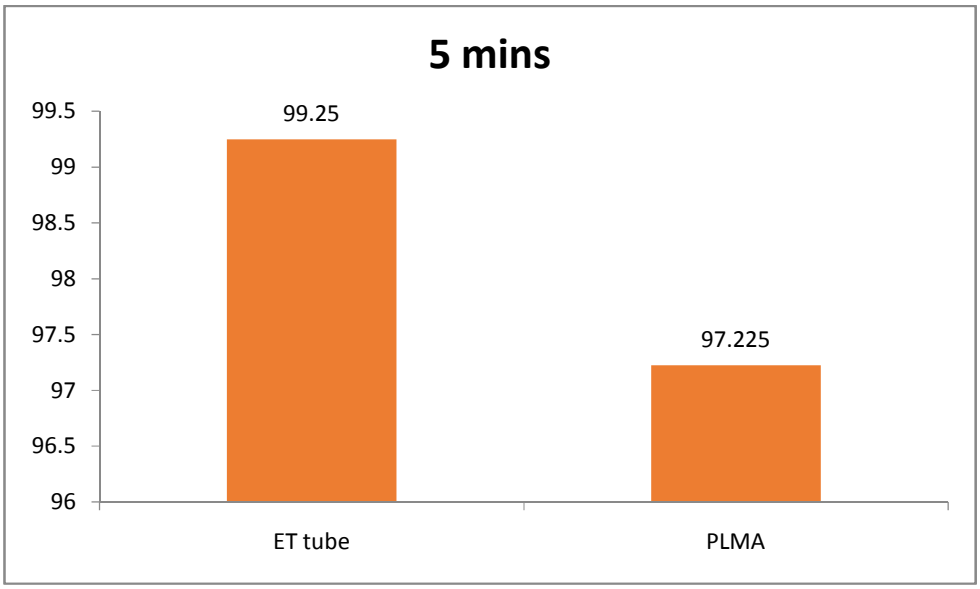
This finding is supported in the study by the following authors:

JAYA LALWANI et al who observed that the increase in heart rate is seen with the endo tracheal tube group after 5 minutes of insertion of the device.They also noted that the in the proseal laryngeal mask airway patients there happens to be decrease in response in heart rate after placement of the device.

MISRA et al also observed that the haemodynamic response of increase in heart rate and blood pressure is seen to be significantly increased in the endotracheal group in comparison to the proseal laryngeal mask airway group.

MAMTA PATEL – The author reported in their study that the increase in haemodynamic response is found to be present in the endotracheal intubation group and the effect is seen for a longer time in it.

RAUF GUL et al observed in their study that there is no significant difference noted with respect to the intubation response while using endotracheal tube or the proseal laryngeal mask airway .



AFTER 5 MINUTES OF INSERTION OF DEVICE ----MEAN BLOOD PRESSURE:

Group	N	Mean	Sd	T value	P value
ETT	40	78.648	3.2725	1.476	0.14
PLMA	40	79.755	3.4249		

The above observed data of the parameter of mean blood pressure after 5 minutes of insertion of insertion of using either of the device of endotracheal tube or the proseal laryngeal mask airway reveals that

there is increase in blood pressure in the endotracheal tube group after five minutes of insertion.

The proseal laryngeal mask airway group patients show a decreased response compared to the endotracheal tube group.

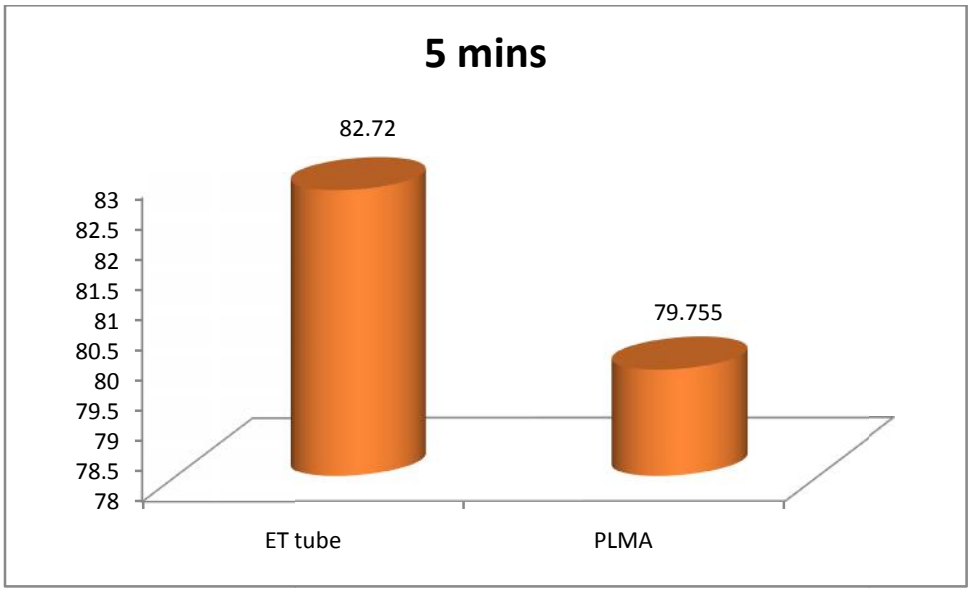
This is consistent with the observation made by authors in their study.

JAYA LALWANI et al noted that there is a decrease in systolic pressure noted in the proseal laryngeal mask airway group after fiveminutesof insertion and it is said to be statistically significant.

They also noted a decrease in the diastolic and mean blood pressure in the proseal laryngeal mask airway group after 5minutes of insertion and is significant.

NAMITA SARASWAT in their of comparing the proseal laryngeal mask airway with endotracheal tube used for intubation in their patients found an increase in the heart rate and blood pressure observed in the endotracheal tube group patients.This finding proves that to attenuate the haemodynamic response not only drugs to be used like i.v lignocaine, Fentanyl, Esmolol or Dexmedotomidine the choice of the airway gadgets also forms an important part in securing the airway.

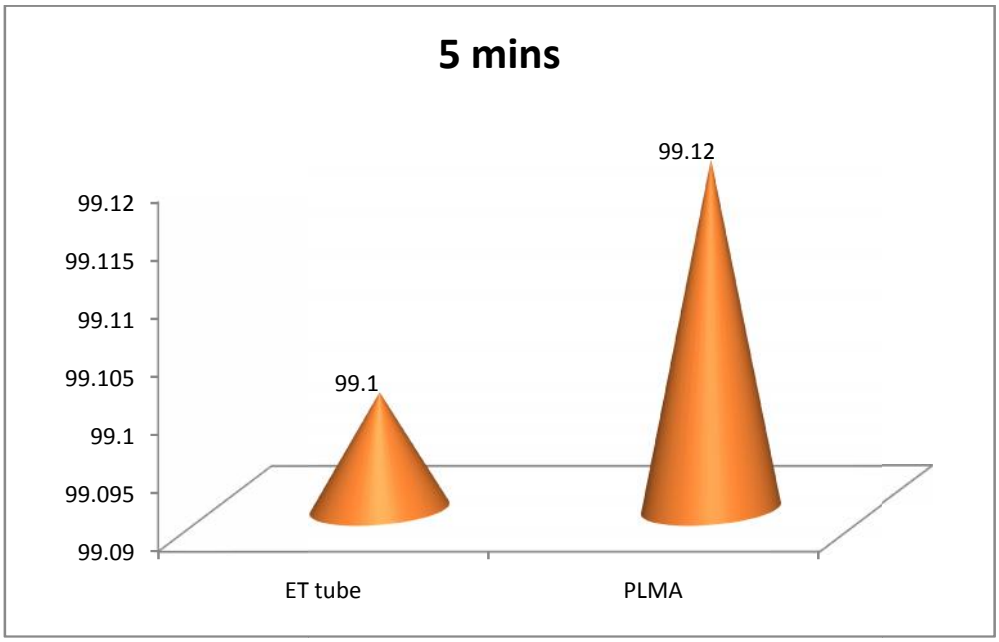
Thi haemo dynamic response is present in the endotracheal tube patients and strategies should be planned for containing the effect.



AFTER 5 MINUTES INTUBATION OF DEVICE---SPO2 VALUE

Group	N	Mean	StandardDeviation	T value	P value
ETT	40	99.1	0.304	0.35	0.73
PLMA	40	99.12	0.335		

There appears to be no significant difference in the value of oxygen saturation observed in this time interval between the two groups studied and the value is found to be comparable.



AFTER 10 MINUTES INSERTION OF DEVICE –HEART RATE

Group	N	Mean	S.D	T value	P value
ETT	40	96.75	5.5597	3.457	0.001
PLMA	40	92.15	6.3187		

The parameter observed after ten minutes of insertion of either proseal laryngeal mask airway or the endotracheal group. We found that there is a persistent increase in heart rate in the intubated with the endotracheal tube even after ten minutes of the insertion and it proved to be significant also.**p value is found to be <0.001.**

The proseal laryngeal mask airway group presents a stable haemo dynamic status with the reduced heart rate from the initial value.

The finding in our study is consistent with the following authors :

MAMTA et al –They noted an increase in haemodynamic response of increase in heart rate in the group of endotracheal tube compared to the proseal laryngeal mask airway group producing a stable status after securing the airway.

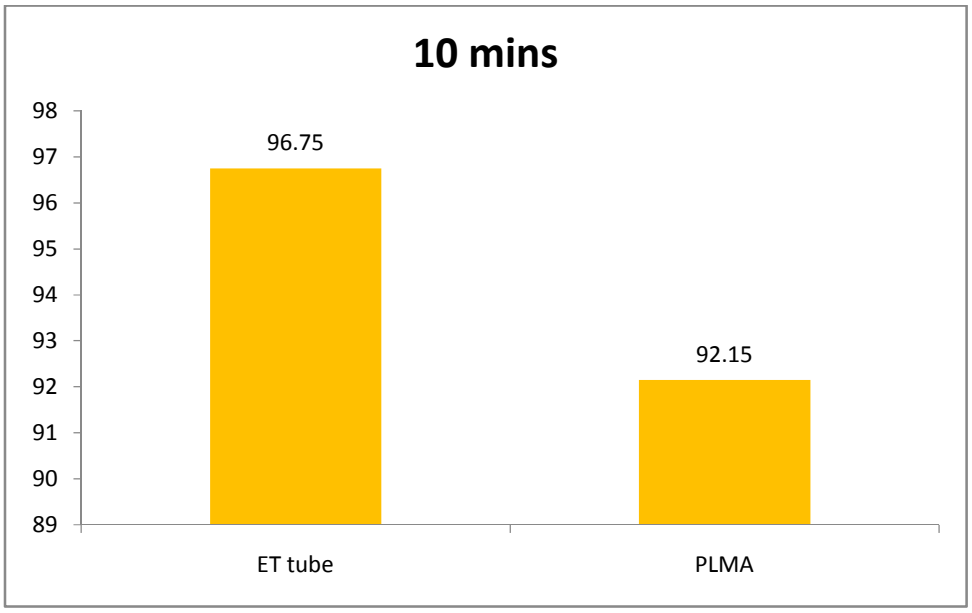
LALWANI et al found that the endotracheal tube group showed an increase in heart rate after ten minutes of intubation.The proseal laryngeal mask airway group patients showed a decrease in the heart rate and proved to be a device of stability.

MISRA et al---In their study noted an increase in the haemodynamic parameter of heart rate following tracheal intubation in comparison to proseal laryngeal mask airway.

SHROFF P et al in their randomized study of patients using proseal laryngeal mask airway and endotracheal tube found that the haemodynamic response is more pronounced in the endotracheal tube group compared to the other device.

MALTBY et al in their study found a similar response of increase in heart rate noted in the endotracheal tube group than the pro seal laryngeal group.

LAMB et al in their study of patient with the laryngeal mask airway noted that this device produced a decreased effect in the increase of haemodynamic parameter of heart rate, blood pressures and intraocular pressures.



AFTER 10 MINS OF INSERTION OF DEVICE-- MEAN BLOOD PRESSURE:

Group	N	Mean	S.D	T value	P value
ETT	40	83.128	3.5763	6.075	0.001
PLMA	40	78.303	3.5265		

We found in our study that the increase in mean blood pressure was higher in the patients intubated with the endotracheal tubes group.

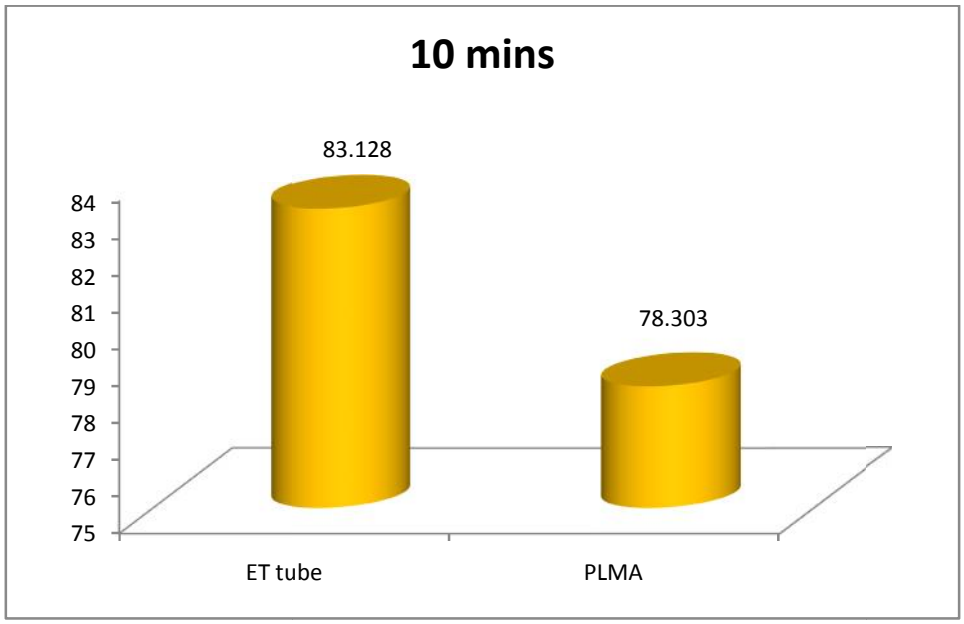
The patients in the proseal laryngeal mask airway group showed a decrease in the mean blood pressure values to the base line value of the patients.

There appears to be a statistically significant difference between the two groups studied. The patients in the endotracheal group showed an increased haemodynamic response even after 10minutes of intubation proving to be detrimental inpatients whom require a stable vital parameters in the intubation period.

The p value found to be highly significant (p 0.001).

The supra glottic airway device helps in achieving a stable haemodynamic status prevents the deleterious effect of increase in sympathetic stimulation and its effect.

This finding seems to be concordant with the finding of authors of MAMATA PATEL, RAUF GUL et al, JAYA LALWANI who in their study found an increased in haemodynamic parameter of heart rate and blood pressure in the endotracheal group compared to the proseal laryngeal mask airway group.



AFTER 10 MINS OF INSERTION OF DEVICE--- (SPO2)

Group	N	Mean	Sd	T value	P value
ETT	40	99.2	0.405	0.902	0.37
PLMA	40	99.12	0.335		

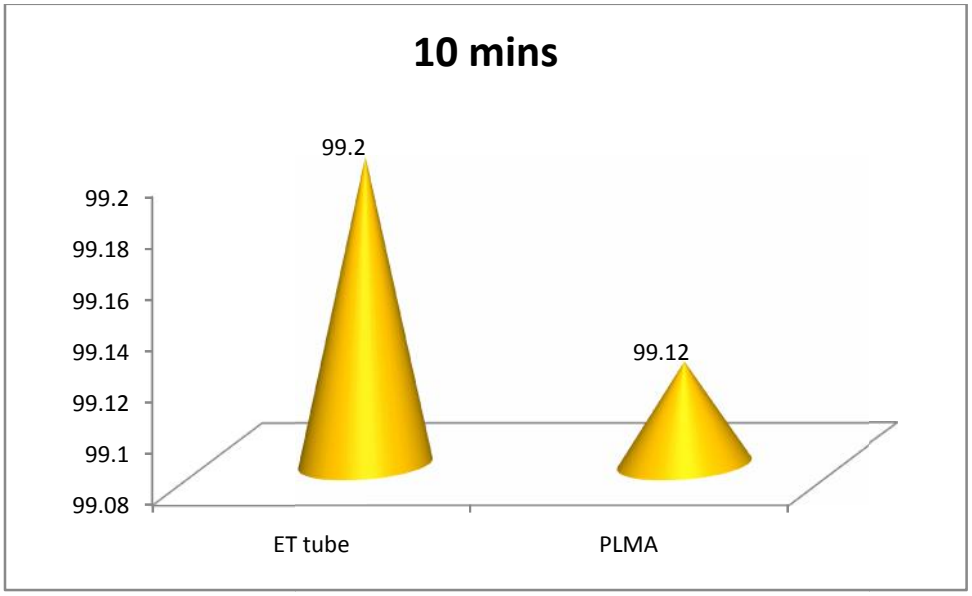
There was no difference in the oxygenation and ventilation of the patients noted in both the groups of either endotracheal tube or the proseal laryngeal mask airway group. This value is found to be comparable between the groups and thereis no statistical difference between them.

The p value is found to be 0.37.

The maintenance of stable ventilatory performance forms the basis of effective airway management which ever device is used to secure the airway.

The finding of authors who endorse the view are MALTBY et al, MAMTA et al, SHARMA et al showed that there is no significant difference in this parameter of oxygen saturation observed among the two groups studied using either an endotracheal tube or the proseal laryngeal mask airway for securing the airway.

The proseal laryngeal mask airway produces a good effective seal of the pharynx and helps in positive pressure ventilation and maintains a stable ventilatory status throughout the surgical procedure.



END TIDAL CARBONDIOXIDE MONITORING:

The air way management requires mandated basic standards of monitoring to be in place before conductance of ANAESTHESIA. The modified guidelines of the ASA protocol instructs minimum monitoring standards of TWO types of standards in the anaesthetic practise.

STANDARD 1:---requires the presence of a qualified personnel all through the procedure whether it is general anaesthesia or regional.

STANDARD 2:----during the course of the procedure patient's oxygenation,ventilation and circulation should be continuously monitored by the personnel.

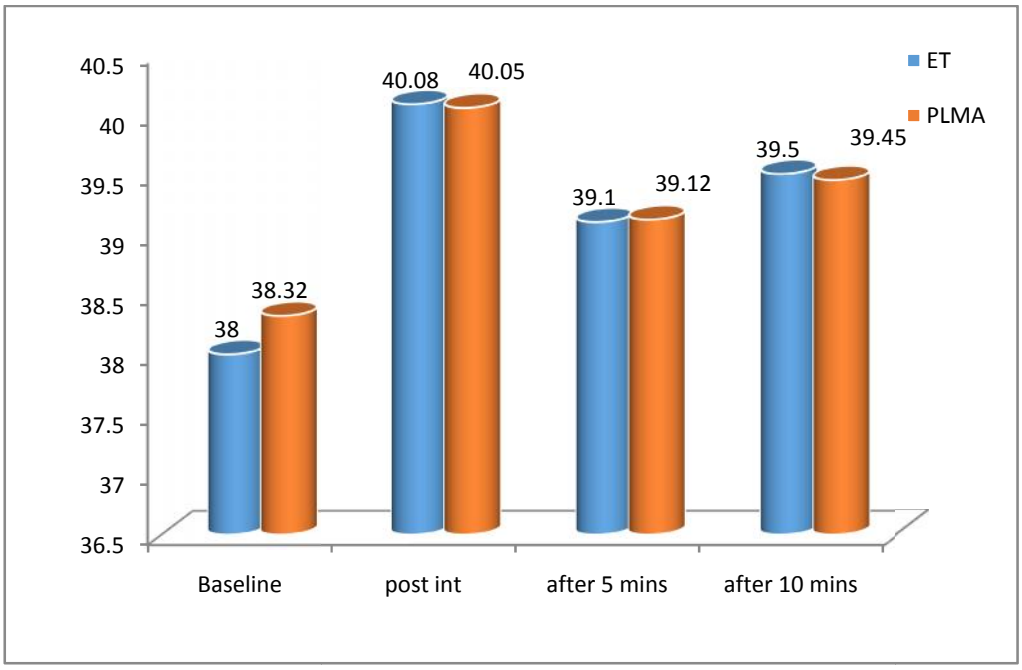
The main objective of maintaining ventilation is to have continuous supply of oxygen to the tissues in both the spontaneously breathing patient or in controlled ventilation.

SPO2 and ETCO2 monitors gives the important data of adequacy of ventilation and oxygenation.

End tidal CO2 ---forms the basis to confirm the securing of airway in anaesthetized patients by using either the endotracheal tube or the supraglottic devices.

The following table shows the results of the end carbon dioxide values of the patients in our study:

ETCO2 values



The above table shows the continuous analysis of the end carbon dioxide values in our patients throught the procedure.

The value gives the confirmed position of airway and helps in identifying causes of failed intubation.

In our study from the baseline value,post intubation by using either the endotracheal tube or proseal laryngeal mask airway, and subsequently after 5minutes and 10 minutes shows no difference in the

parameter and it is observed. The range is maintained well within 38 --- 41 mmhg (normal value 35—45mmhg).

The monitoring is done continuously till the end of the procedure, during extubation and in the post-operative period.

This is consistent with the finding of following authors:

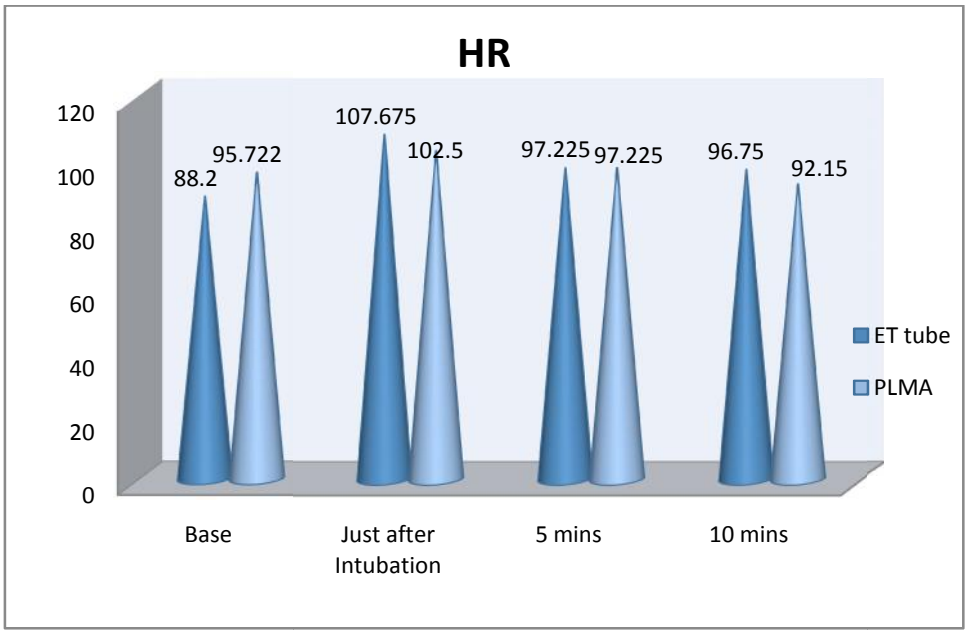
MAMTA PATEL et al observed in their study that there is no change in the ETCO2 levels in all patients during the procedure.

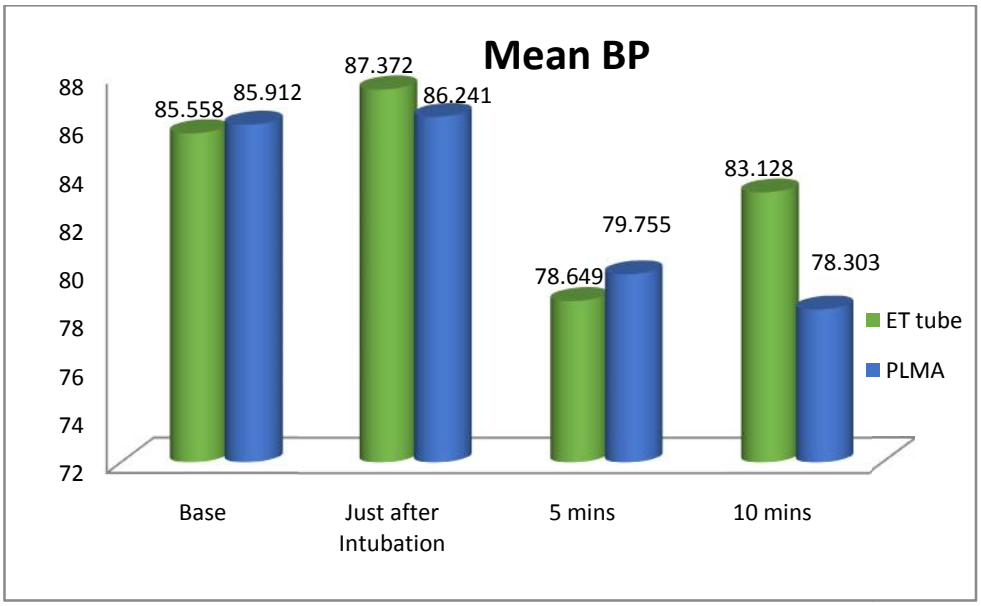
NAMITA et al in their study noted that ETCO2 was comparable in both groups throught out the procedure and it did not increase above 45mm Hg.

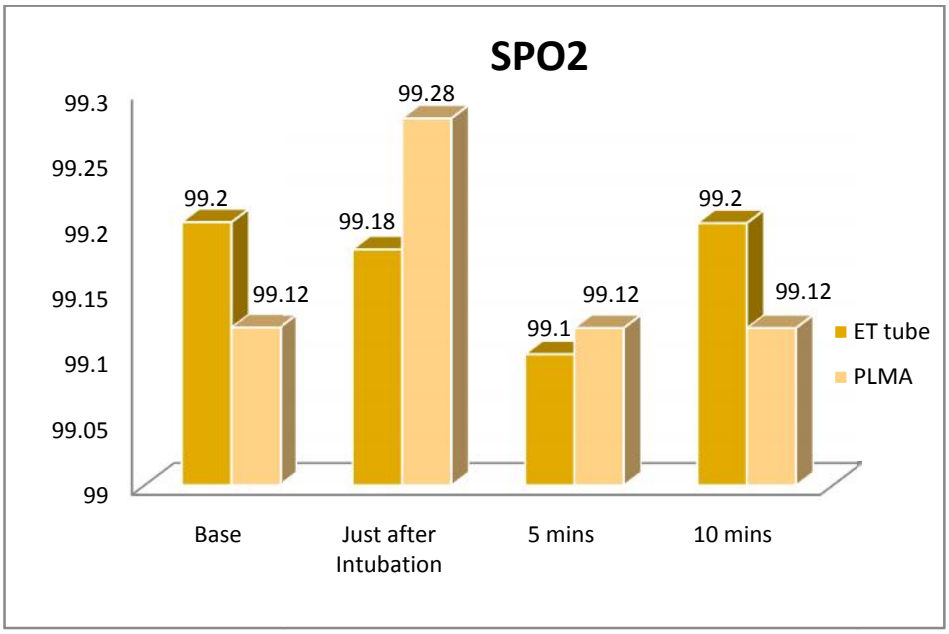
PRAVESH KANTHED in their study stated that all patients in both the groups of using either Proseal LMA or LMA classic had ETCO2 values of <45 mmHg.There was no case of displacement or obstruction of the device.

Thus as discussed by the authors ETCO2 monitoring forms a part of minimum monitoring standards and is useful to assess the adequacy of ventilation in cardio pulmonary resuscitation protocol.

The following graph shows the variation in the heart rate, blood pressure and SPO2 values comparing the baseline value, post intubation, after 5 minutes and after 10 minutes of both devices of Proseal Laryngeal Mask Airway and the Endotracheal Tube.







COMPLICATION DURING EMERGENCE AND IN THE POST-OPERATIVE PERIOD:

COUGH---CHI SQUARE TEST

	Cough	ETT	PLMA	Total	Chi square	P value
COUGH	NO	30	34	67	4.07	0.03
	YES	10	3	13		

The presence of cough forms an important complication in the endotracheal intubation and this finding is observed in our study.

10 patients out of 40 in our study had cough in the post extubation period.

The patients in the proseal laryngeal mask airway group revealed a lesser incidence of the symptom. The device being placed in the

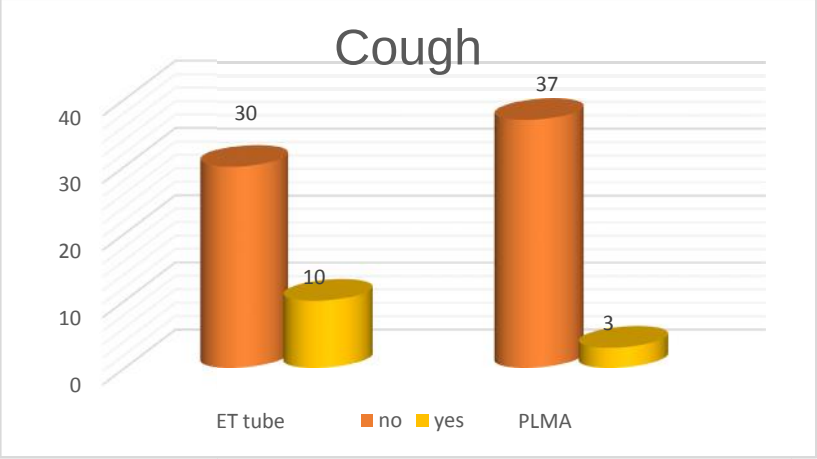
supraglottic area has less stimulation of the airway and is associated with less morbidity.

This finding is confirmed by the following authors:

RAUF GUL et al reported an incidence of cough in 3 out of 40 patients in the endotracheal tube intubation compared to the proseal laryngeal mask airway group which saw a lesser incidence of the symptom.

MAMTA et al observed a incidence of 40 % patients reported cough in their study with the endotracheal intubation which was found to be statistically significant. The symptom was not associated with the proseal laryngeal mask airway patients.

LALWANI et al ---observed that the incidence of cough occurred much in the endotracheal tube group patients compared to the patients in whom airway was secured using proseal laryngeal mask airway.



BRONCHOSPASM:

Broncho-spasm	ETT	PLMA	Total	Chi square	P value
NO	36	39	75	1.92	0.17
YES	4	1	5		
TOTAL	40	40	8		

The above table shows the incidence of bronchospasm in the endotracheal tube intubated patients compared to the other group where proseal laryngeal mask airway was used to secure the airway.

This complication in the patient with endotracheal tube intubation needed immediate treatment and stabilisation.

Supraglottic airway device proseal laryngeal mask airway does not have these complication as observed in our study because it does not irritate the airway.

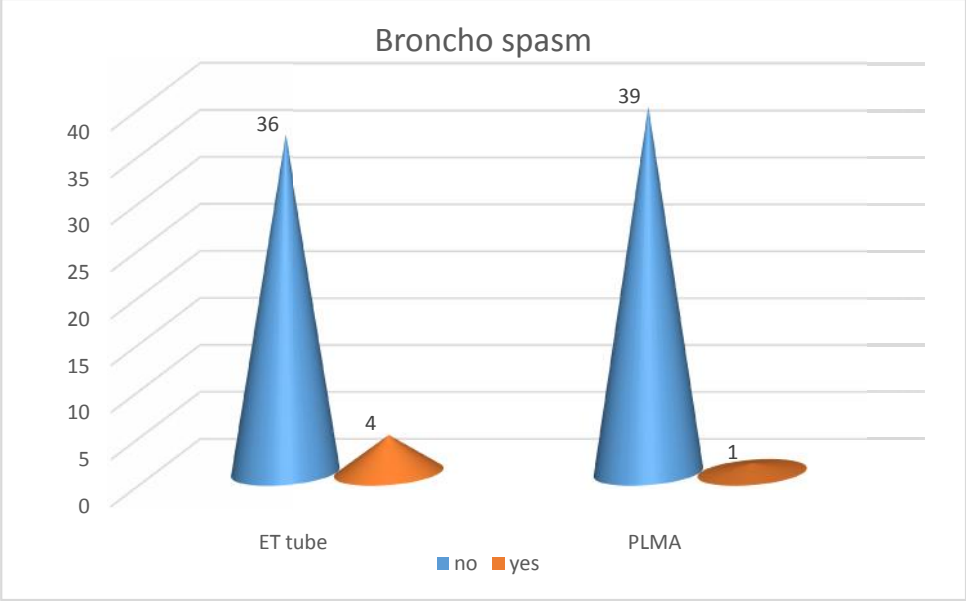
This finding is supported by the study by following authors:

RAUF Gul et al observed that the incidence of bronchospasm occurred in the endotracheal group compared to the proseal laryngeal airway mask group patients.

PRAVESH KANTHED et al in their study observed that there is no incidence of the complication in the proseal laryngeal mask airway patients when it is compared with the Classic LMA in 100 anaesthetized

children with 50 patients in each group with respect to ease of insertion, oro-pharyngeal seal pressure and laryngeal morbidity.

JAYA LALWANI et al in their study observed that there is increase of Broncho spasm in the patients who are intubated with the endotracheal tube in comparison to proseal laryngeal mask airway group.



BLOOD ON DEVICE:

Blood on device	Blood	ETT	PLMA	Total	Chi square	P value
	NO	36	29	65	4.02	0.01
	YES	4	11	15		

The blood on device was observed more with the proseal laryngeal mask airway group.This finding of having 11 out of 40

patients reporting the incidence is statistically significant p value being <0.01.

This may be due to the sensitive soft mucosa in children ,soft tissue damage while insertion of PLMA and the over inflation of the device may produce the trauma. This can be avoided by selecting an appropriate size device for securing the airway.

This finding is in concordance with observation of the following authors in their study:

M.LOPEZ, J.BRIMACOMBE –reported an increased incidence of blood staining in the proseal laryngeal mask airway group patients .

BIMLA SHARMA, ET AL –observed in their study that there is an increased incidence of blood staining of the device is seen with the PLMA group when used for securing the airway.

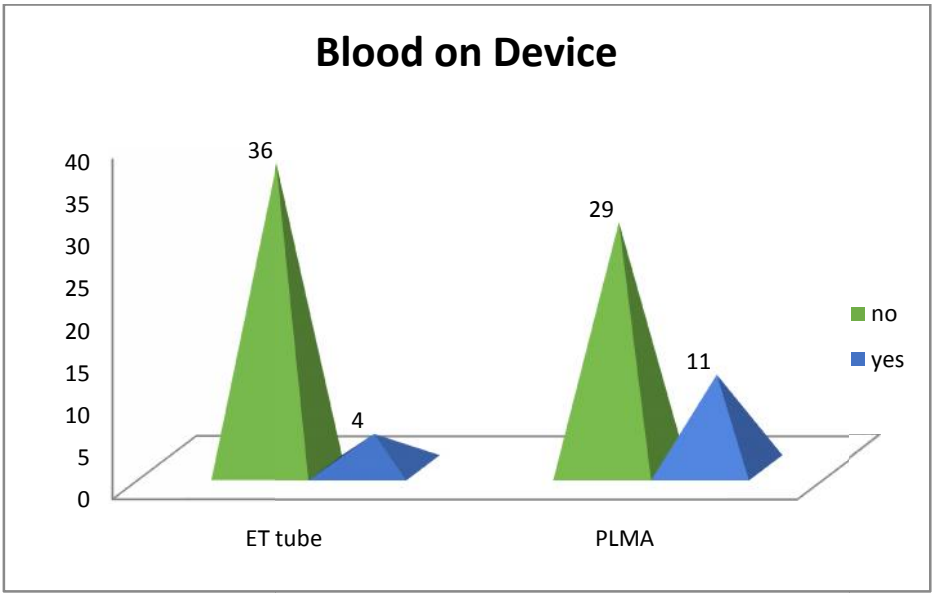
BIKRAMJIT et al found in their randomized controlled study of comparing PLMA size 2 with the corresponding size CLMA found that there is an increased incidence of blood staining associated with the proseal laryngeal mask airway .

WAKHLOO,S.GUPTA et al in their study of comparing the proseal laryngeal mask airway with the endotracheal tube in paediatric

patients found an increase in of blood staining of the proseal mask airway group.

PRAVESH KANTHED et al in their study found an increased incidence of blood staining in the proseal laryngeal mask airway group while securing airway in anesthetized children.

RAUF GUL AND LALWANI et al in study also observed an increased in blood staining of the proseal laryngeal mask airway compared to the endotracheal tube group patients.



ASPIRATION:

There is no incidence of aspiration noted in any of the eighty patients in both the groups of proseal laryngeal mask airway or the endotracheal group.

This finding is supported by the study of MAMTA PATEL and JAYA LALWANI et al who reported that there is no incidence of aspiration noted with either of endotracheal or proseal laryngeal mask airway group when used to secure the airway.

SORE THROAT:

We in our study found an increased incidence of sore throat in the endotracheal tube patients compared to the proseal laryngeal mask airway group. The difference is not statistically significant.

This finding is consistent with the observation of the authors;

NAMITA et al, RAUF GUL who found an increase incidence of sore throat in the endotracheal tube patients compared to the proseal laryngeal mask airway group.

JAYA LALWANI et al reported that there is no incidence of sore throat in any of the group of either the endotracheal or the proseal laryngeal mask airway group.

DISCUSSION

The supra glottic airway device is being used widely in paediatric practise and have become a pivot component in airway management in children.[1,2,4]

It have been introduced as a replacement of face mask but now been used successfully for airway management in areas where endotracheal tube was considered mandatory.[19,20,21,22]

The Classic laryngeal mask airway provides a lesser effective oro- pharyngeal seal, leading to gastric distension inflation, regurgitation and aspiration of gastric contents.[6,9,10]

It could not be used for positive pressure ventilation because of the ineffective seal produced at the laryngeal inlet.[3,10,11]

The Proseal laryngeal mask airway introduced in 2000 provided many added features for an effective and safe airway.It has become a modified form of Classic laryngeal mask airway.[4]

The main features of Proseal laryngeal mask airway are oesophageal drain tube, integral bite block, modified cuff design, increased depth of the bowl which makes an effective oropharyngeal seal. This enables the device to be used for positive pressure ventilation.[1,4,7,9,10,14]

The presence of the drainage tube forms an effective channel for passive drainage of gastric contents. A gastric tube inserted through the drainage tube helps in the prevention of gastric aspiration and also it is useful to identify the position of the device.[6]

In our study we compared the number of attempts of the insertion of the device, hemodynamic parameters, heart rate, systolic & diastolic and mean arterial blood pressures, SPO2 and ETCO2 values. Further we observed the post-operative complications the emergence and in 24 hour post-op period.

INTUBATION OF DEVICE:

In our study we were able to intubate the patients in 92.5% in the first attempt using an endotracheal tube. 3 of them (7.5%) required a second intubation attempt.

In the proseal laryngeal mask airway group, the first attempt success rate was 82.7% (31 patients).A second attempt was required in 17.3% (9 patients) in this group.

This result coincided with the studies conducted by the following authors.

JAYA LALWANI[4] – who reported that the incidence of first attempt endotracheal intubation was 96.67% and correspondingly proseal laryngeal mask airway was used to intubate in 83.3%

BRIMACOMBE[13]– reported successful first attempt intubation of both endotracheal tube and proseal laryngeal mask airway of 85% each of the devices.

MAMTHA G. PATEL[1] – also reported the first time insertion of the endotracheal tube was found to be 100% and for the proseal laryngeal mask airway was 90%.

MISRA[5]et al reported 100% placement of the endotracheal tube in patients in first attempt and was able to place the proseal laryngeal mask airway in 88%.

RAUFGUL[2] – also reported the same incidence of placement in both the proseal laryngeal mask airway and endotracheal tube as mentioned above.

HEMODYNAMIC STABILITY:

The proseal laryngeal mask airway provided a stable hemodynamic status when used as a supraglottic airway device in paediatric patients undergoing elective surgery. The increase

inhemodynamic response is minimal and the effect is sustained for a short time compared to the endotracheal tube intubation.

The baseline parameters of heart rate, mean arterial blood pressure, Spo2 and ETCO2 values were compared in both the groups.

The endotracheal tube intubation is associated with an increase in heart rate and blood pressure and this is established in various studies.

The proseal laryngeal mask airway as an intubation device produced a lesser increase in heart rate, systolic, diastolic and mean arterial blood pressure after intubation and subsequently in 5 and 10 minutes of the observation.

The increase in heart rate and blood pressure after 5 minutes of intubation with the proseal laryngeal mask airway group was found to be lesser than the endotracheal tube.

After 10 minutes of intubation with proseal laryngeal mask airway the hemodynamic parameters were much reduced compared to the endotracheal tube. The hemodynamic response was found to be present even after 10 minutes of intubation with an endotracheal tube.

The results obtained were found to be consistent with the work of other authors like

1. MISRA et al, SINHA, SHANI, SOOD[5,18] – they reported that there is increase in hemodynamic response with the endotracheal tube intubation which was sustained for a longer time than the proseal laryngeal mask airway when it was used as an airway device.
2. JAYA LALWANI et al[4]– who compared the proseal laryngeal mask airway and the endotracheal tube in paediatric patients undergoing short surgical procedures also found that the endotracheal tube group patients had an increased hemodynamic response to intubation which was found to be statistically significant.
3. LIM Y GOEL, S BRIMACOMBE[25] et al observed that hemodynamic response to endotracheal intubation was found to be greater when compared to the proseal laryngeal mask airway group.
4. MAMTA PATEL[1] – compared the study of proseal laryngeal mask airway with the endotracheal tube for airway management in children under general anaesthesia and reported a significant change in hemodynamic parameters observed with endotracheal airway group compared to the proseal laryngeal mask airway group.

Changes in Spo2 and ETCO2 values:

The above values were comparable in both the groups during intraoperative and post-operative periods providing a good ventilator

strategy. There were no significant changes observed by us in our study in both the groups.

MALTY et al[35] and SHARMA et al[18] also reported that there was no significant difference observed while using proseal laryngeal mask airway and endotracheal tube while securing the airway.

COMPLICATIONS DURING EMERGENCE:

We found in our study that there is an increase in incidence of cough in the endotracheal tube group compared with the proseal laryngeal mask airway and it is found to have an important effect during emergence in anaesthesia and in the postoperative period. This result coincided with the study of the following authors who reported the same findings.

MAMTA G. PATEL[1] – reported an incidence of 13.3% of patients reported cough after surgery

RAUF GUL[2]- also reported proseal mask airway when it was used as an intubation device an increased incidence of cough with the endotracheal tube group patients compared to the proseal laryngeal mask airway group

JAYA LALWANI[4] – the author observed that when using endotracheal tube as an intubation device cough was present in 30% of

patients and it continued in the post-op period also and it was treated with bronchodilators.

There was no such incidence noted in the proseal laryngeal mask group.

BRONCHOSPASM:

This complication was found to be more with the endotracheal group compared with the proseal laryngeal mask airway group.

This finding is in concordance with the study of the following authors who reported that the complication of bronchospasm was found to be more with the endotracheal group compared to the proseal laryngeal mask airway.

MAMTA G. PATEL[1] – reported an incidence of increased bronchospasm with the endotracheal group when it was used as an intubating device.

JAYA LALWANI[4] – also reported that the endotracheal tube intubation was associated with an increased incidence of bronchospasm of 6.6% in the group. She also noted that the proseal laryngeal mask airway group produced less laryngeal irritation.

RAUF GUL[2] – found that there is an increased incidence of bronchospasm noted in the endotracheal tube group compared with the proseal laryngeal mask airway when it was used as an airway device.

BLOOD ON DEVICE:

In our study we found that the blood staining on the posterior surface of proseal laryngeal mask airway was found in 9 persons (22%) when used for airway intubation.

There was only a reduced percentage in (4%) in the endotracheal group.

MAMTA[1] and RAUF GUL[2] – observed the same incidence of parameters of blood staining on the device following intubation.

The above result was found to be consistent with the finding of various other authors also.

ASPIRATION:

In our study we found that there was no incidence of aspiration in either of the groups , proseal laryngeal mask airway or the endotracheal tube group during the entire induction, intra-operative and post-operative periods.

This coincided with the report of the authors.

SORE THROAT:

The incidence of hoarseness and sore throat was not associated with any of our patients in the immediate post-operative period and also for 24 hours following the surgery.

HIIGGINS et al[37] and SHROFF et al[34]– found a greater incidence of sore throat in the patients undergoing intubation with endotracheal tube than with the proseal laryngeal mask airway when it was used as an intubation device.

POSITIVE PRESSURE VENTILATION:

The proseal laryngeal mask airway which has a modified cuff that produce a good effective oropharyngeal seal preventing air leak. This enhanced seal pressure helped in positive pressure ventilation in paediatric patients who were undergoing surgeries under general anaesthesia.

This is confirmed by various studies comparing the classic laryngeal mask airway and the proseal laryngeal mask group by the following authors.

DAVID RR LARDNER[10], BIKRAM JITDAS[7] reported an increased incidence of oropharyngeal seal pressure observed with

proseal laryngeal mask airway and it provided effective positive pressure ventilation.

GOLDMAN AND JACOB[3] – found the modified cuff of proseal laryngeal mask airway provided an effective oropharyngeal seal enhancing the positive pressure ventilation.

M LOPEZ, BRIMACOMBE[13] – found that the proseal laryngeal mask airway with an increased oropharyngeal seal provided effective positive pressure ventilation in patients undergoing general anaesthesia.

ESOPHAGEAL DRAIN TUBE:

The proseal laryngeal mask airway has a drainage tube placed lateral to the main airway tube. This helps in the channelling of gastric contents and prevents gastric inflation, regurgitation and gastric aspiration.

A gastric tube passed into the drainage tube helped in the assessment s of placement of the device.

This is supported by the author AIJ BRAIN[6] who stated that the aim of the drainage tube is to provide a safe effective airway device to be used for positive pressure ventilation.

SUMMARY

This study was done to compare the size 2 proseal laryngeal mask airway a second generation supraglottic device with the endotracheal tube of appropriate sizes for securing the airway in the paediatric patients. They were undergoing elective surgical procedures under general anaesthesia.

A total of 80 patients of age 2 to 8 years weighing 10 to 20 kilograms were randomly divided into two groups of proseal laryngeal mask airway (group P) and the other being endotracheal tube group (group T).

The number of attempts of insertion, hemodynamic response and the post-op complications were studied during intubation and after that for 1, 5 and 10 minutes.

The observations noted are the following:

- The number of insertion attempts of endotracheal tube was less compared to the proseal laryngeal mask airway and it improved in subsequent attempts with the later device.
- The proseal laryngeal mask airway provided a stable hemodynamic status in the patients when compared with endotracheal intubation

which caused in increase in heart rate and mean arterial blood pressure.

- The post-operative complications of cough and bronchospasm was found to be higher in the endotracheal tube group compared to the proseal laryngeal mask airway group.
- The proseal laryngeal mask airway provided an effective oropharyngeal seal for positive pressure ventilation and oxygenation.
- The gastric drainage tube is an added safety feature which prevented the gastric distension, regurgitation and aspiration of gastric contents.

CONCLUSION

The observation of the study showed that the proseal laryngeal mask airway proves to be as safe and suitable airway device in paediatric patients undergoing elective surgical procedures.

Hence we arrived at the conclusion that the proseal laryngeal mask airway could be used as an effective alternative to endotracheal intubation in children undergoing short duration elective procedures under general anaesthesia.

PRE OPERATIVE ASSESSMENT

Name : Age : Sex : Wt :

IP No. : Diagnosis :

Procedure: Date :

Group :

Pre-Op Assessment :

PR: BP:

RS: CVS:

Airway: ASA Status:

Investigations :

Hb: Blood Sugar:

Bl.Urea: Sr.Creatinine: Blood Grouping:

CXR: ECG:

S.Electrolytes: LFT:

PROFORMA

Name :

Age :

Sex :

Weight :

Diagnosis :

Surgery :

MPC :

ASA PS Class :

Parameters	Group PLMA	Group ETT
No. of Attempts		
Increase in Pulse Rate		
Increase in Blood Pressure		
Post-operative complications		

No. of attempts of intubation

Author	Attempts	Group P	Group ETT
Self			

Comparison of increase in Pulse Rate

Group	Baseline	Just after Intubation	After 5 mins.	After 10 mins.
PLMA				
ETT				

Comparison of increase in Blood Pressure

Group	Baseline	Just after Intubation	After 5 mins.	After 10 mins.
PLMA				
ETT				

Post-operative Complications

Parameters	Group PLMA	Group ETT
Cough		
Bronchospasm		
Sore throat		
Hoarseness of voice		
Blood on device		

S No	Group	Name	Age (Years)	Sex	Weight (Kg)	IP No.	Diagnosis	Procedure	MPC	ASA	Co-Morbid	No. of Attempts of Insertion		Baseline			
												Device	Gastric Drain Tube	HR (/min)	Mean BP (mm Hg)	SPO_2 (%)	Etco 2
1	PLMA	Monish	3	M	15	5998	Lhydrocoel	Pvsacligatic	I	I	Nil	1	1	102.9	90.0	99	38
2	PLMA	jagadeswaran	3 ½	m	14	5910	Rhydrcoel	Pvsacligatic	I	I	nil	1	1	108.0	87.0	99	36
3	PLMA	Antony	6	M	20	5897	Lhydrocoel	Pvsacligatic	I	I	nil	1	1	98.0	87.3	99	38
4	PLMA	Joel	3	M	12	5896	phimosis	circumscisi	I	I	nil	2	2	108.0	84.7	99	36
5	PLMA	Jeevan	6	M	15	5451	rawareahan	SSG	I	I	nil	1	1	96.0	85.1	99	38
6	PLMA	Hemanth	4	M	17	6122	phimosis	circumscisi	I	I	nil	1	1	102.0	83.3	99	36
7	PLMA	Ritheesh	3	M	12	6184	Hydrocoel	Pvsacligatic	I	I	nil	2	1	108.0	93.3	99	38
8	PLMA	Arya	5	M	20	6200	LUDT	Orchidopex	I	I	nil	2	1	98.0	90.0	99	36
9	PLMA	Kalaivani	5	F	20	6231	ganglion	excision	I	I	nil	1	1	102.0	84.0	99	35
10	PLMA	Kishore	2	M	13	7638	Lgluabcess	I&D	I	I	nil	1	1	108.0	80.0	99	36
11	PLMA	Jayaraj	3	M	12	7644	phimosis	circumscisi	I	I	nil	1	1	96.0	88.0	99	38
12	PLMA	Prithivkumar	8	M	20	7810	Rhydrcoel	Pvsacligatic	I	I	nil	2	1	90.0	94.0	99	38
13	PLMA	Tamilselvi	7	F	14	7900	Abscess	I&D	I	I	nil	1	1	92.0	87.3	99	36
14	PLMA	Priya	7	F	20	8060	conhernia	herniotomy	I	I	nil	2	2	90.0	83.3	99	38
15	PLMA	Dilipkumar	3	M	12	7907	Rectalpoly	excision	I	I	nil	1	1	92.0	88.6	100	36
16	PLMA	Vinothkumar	7	M	20	7897	AcScrotum	Explorat	I	I	nil	1	1	96.0	83.3	99	38
17	PLMA	Kannan	3	M	11	7809	phimosis	circumscisi	I	I	nil	1	1	102.0	86.6	100	40
18	PLMA	Hariprasath	3	M	11	8445	Rhernia	herniotomy	I	I	nil	2	1	98.0	83.3	99	36
19	PLMA	Vetri	2 ½	M	10	8443	phimosis	circumscisi	I	I	nil	1	1	102.0	80.0	99	38
20	PLMA	Dharani	4	F	18	8500	Rhernia	herniotomy	I	I	nil	1	1	89.0	86.6	99	36
21	PLMA	Lakshmi	4	F	20	8578	Rhernia	herniotomy	I	I	nil	2	2	90.0	92.0	99	38
22	PLMA	Selvam	5	M	18	8809	Lhernia	herniotomy	I	I	nil	1	1	88.0	83.3	99	36
23	PLMA	Velmurugan	3	M	14	9123	Lhernia	herniotomy	I	I	nil	1	2	99.0	82.0	99	38

24	PLMA	Manimaran	2	M	10	9421	Rhydrocoel	Pvsaclig	I	I	nil	1	1	106.0	86.6	99	35
25	PLMA	Gunasekar	4	M	15	10398	Rhydrocoel	Pvsaclig	I	I	nil	1	1	90.0	82.6	99	36
26	PLMA	Gopi	6	M	18	10400	Rhernia	herniotomy	I	I	nil	2	1	92.0	84.6	100	40
27	PLMA	Rajesh	3	M	12	10543	Lhydrocoel	Pvsaclig	I	I	nil	1	1	102.0	83.3	99	38
28	PLMA	Poovarasan	4	M	16	10696	Lhydrocoel	Pvsaclig	I	I	nil	1	1	90.0	90.0	100	38
29	PLMA	Hariprakash	5	M	20	14786	Lhernia	herniotomy	I	I	nil	1	1	94.0	84.6	99	38
30	PLMA	Prassana	3	M	12	18900	Rhernia	herniotomy	I	I	nil	1	1	102.0	85.3	99	38
31	PLMA	Surya	2	M	10	24806	Phimosis	Circumscor	I	I	nil	1	1	98.0	88.0	99	40
32	PLMA	Suresh	5	M	18	24823	Lhydrocoel	Pvsaclig	I	I	nil	1	1	88.0	92.6	99	38
33	PLMA	Saranya	7	F	20	25891	Rhernia	herniotomy	I	I	nil	2	1	82.0	84.7	99	36
34	PLMA	Ardeepkumar	2	M	11	25902	Lhydrocoel	Pvsaclig	I	I	nil	1	2	101.0	82.0	99	37
35	PLMA	Divakar	7	M	20	27802	Phimosis	Circumscor	I	I	nil	1	1	86.0	88.0	99	38
36	PLMA	Jayaganesh	3	M	12	27806	Phimosis	Circumscor	I	I	nil	1	1	90.0	83.3	99	36
37	PLMA	Vasanthi	6	M	19	27804	Rhernia	herniotomy	I	I	nil	1	1	92.0	84.0	99	38
38	PLMA	Tarunkumar	2	M	11	28143	AcScrotum	Expolarat	I	I	nil	1	1	90.0	86.7	99	36
39	PLMA	Mohanraj	4	M	15	28839	Rhydrocoel	Pvsaclig	I	I	nil	1	1	87.0	83.3	100	38
40	PLMA	Anishkumar	4	M	16	28900	Phimosis	Circumscor	I	I	s	1	1	84.0	84.0	99	38

Hemodynamic Profile																Post-op Observations upto 24 hrs					
Post intubation					After 5 min					After 10 min											
HR (/min)	Mean BP (mm Hg)	SPO2 (%)	Etco 2		HR (/min)	Mean BP (mm Hg)	SPO2 (%)	Etco 2		HR (/min)	Mean BP (mm Hg)	SPO2 (%)	Etco 2		Cough	Broncho-spasm	Laryngo-spasm	Blood on device	Sore throat	Hoarseness of voice
108.0	84.3	100	40		102.0	79.3	99	42		92.0	80.0	99	36		-	-	-	+	-	-
114.0	85.3	100	38		106.0	78.0	99	39		104.0	80.0	99	40		-	-	-	-	-	-
106.0	85.2	99	40		102.0	80.0	99	42		98.0	80.6	99	38		-	-	-	-	-	-
118.0	84.0	100	39		112.0	79.3	99	40		100.0	82.0	99	38		-	-	-	+	-	-
103.0	87.3	100	40		99.0	78.6	99	38		93.0	83.3	99	40		-	-	-	-	-	-
108.0	82.6	99	38		101.0	78.0	99	40		98.0	79.3	99	38		-	-	-	-	-	-
114.0	91.3	99	40		107.0	84.6	99	38		94.0	89.3	100	36		-	-	-	+	-	-
104.0	91.0	99	42		98.0	81.6	99	40		92.0	78.0	99	38		-	-	-	-	-	-
108.0	83.3	99	38		106.0	74.6	99	36		98.0	72.6	99	40		+	-	-	-	-	-
104.0	80.3	99	40		106.0	70.6	99	38		104.0	77.3	99	42		-	-	-	-	-	-
102.0	92.1	99	40		98.0	79.3	99	38		92.0	76.0	99	36		-	-	-	+	-	-
97.0	96.6	100	42		95.0	86.0	99	38		87.0	82.8	99	36		-	-	-	-	-	-
98.0	89.3	99	40		92.0	82.3	99	42		88.0	81.0	99	40		-	-	-	+	-	-
97.0	83.0	99	36		94.0	78.0	99	40		88.0	74.6	99	38		-	-	-	-	-	-
99.0	88.0	99	38		90.0	81.3	99	40		90.0	78.0	99	38		-	-	-	-	-	-
104.0	82.1	99	40		98.0	76.6	99	42		92.0	75.0	99	40		-	-	-	-	-	-
109.0	88.0	99	38		103.0	82.6	99	36		100.0	81.0	99	42		+	-	-	-	-	-
107.0	81.6	100	38		101.0	77.3	99	38		96.0	74.3	99	40		-	-	-	-	-	-
109.0	82.0	99	40		103.0	76.6	100	38		99.0	73.3	100	36		-	-	-	-	-	-
106.0	84.6	99	38		100.0	79.3	99	40		96.0	75.3	99	38		-	-	-	+	-	-
97.0	92.6	99	40		91.0	82.6	99	42		87.0	80.7	99	38		-	-	-	-	-	-
94.0	86.6	99	38		87.0	78.0	99	40		84.0	79.0	99	42		-	-	-	+	-	-
106.0	83.6	100	39		100.0	78.2	99	41		96.0	75.3	99	42		-	-	-	-	-	-

	112.0	82.0	99	38		102.0	79.0	100	40		98.0	76.0	99	38		-	-	-	-	-	-
	99.0	82.0	99	38		93.0	76.6	99	40		90.0	77.3	99	42		-	-	-	-	-	-
	98.0	84.0	100	38		92.0	77.3	99	38		89.0	74.0	100	40		-	-	-	-	-	-
	109.0	82.6	99	40		103.0	76.0	99	38		99.0	72.7	99	40		+	-	-	+	-	-
	99.0	88.0	100	36		92.0	81.3	99	38		90.0	79.3	99	40		-	-	-	-	-	-
	100.0	83.0	99	42		96.0	76.0	99	40		92.0	79.3	99	38		-	-	-	-	-	-
	109.0	83.1	99	40		103.0	78.0	99	42		99.0	76.0	99	38		-	-	-	+	-	-
	105.0	91.3	99	42		97.0	83.0	100	38		94.0	79.3	99	40		-	-	-	+	-	-
	95.0	96.0	99	40		89.0	90.0	99	36		85.0	84.6	100	38		-	-	-	-	-	-
	90.0	87.3	100	38		84.0	82.0	100	40		80.0	80.0	99	36		-	+	-	-	-	-
	108.0	84.6	99	39		102.0	79.3	99	40		97.0	75.3	99	38		-	-	-	-	-	-
	93.0	90.6	99	40		97.0	84.6	99	42		82.0	82.0	99	38		-	-	-	-	-	-
	96.0	86.0	99	38		90.0	79.3	99	38		84.0	74.0	99	40		-	-	-	-	-	-
	91.0	86.1	99	40		91.0	79.2	99	42		88.0	78.4	99	40		-	-	-	+	-	-
	97.0	85.3	99	38		90.0	83.3	99	40		85.0	78.0	99	41		-	-	-	-	-	-
	96.0	86.6	100	40		92.0	82.0	100	38		86.0	79.3	100	39		-	-	-	-	-	-
	91.0	86.4	99	39		85.0	80.6	99	40		80.0	78.0	99	41		-	-	-	-	-	-

S No	Group	Name	Age (Years)	Sex	Weight (Kg)	IP No.	Diagnosis	Procedure	MPC	ASA	Co-Morbid	No. of Attempts of Insertion	Baseline			
													HR (/min)	Mean BP (mm Hg)	SPO_2 (%)	Etco 2
1	ET Tube	Rajan	3	M	12	49397	AcScrotum	Explration	I	I	Nil	1	90.0	83.0	99	36
2	ET Tube	Maniraj	2	M	11	44231	RUDT	Orchidop	I	I	Nil	1	88.0	88.0	99	38
3	ET Tube	Ajay Prasath	2	M	10	48321	Lhernia	Herniotomy	I	I	Nil	1	97.0	83.3	99	35
4	ET Tube	Sangeetha	4	F	11	48319	Rhernia	Herniotomy	I	I	Nil	1	92.0	80.6	100	38
5	ET Tube	Lingeswaran	3	M	13	51167	Rhernia	Herniotomy	I	I	Nil	1	90.0	84.0	99	36
6	ET Tube	Noorul	6	M	18	51183	Rhydrocoe	Pvsacligat	I	I	Nil	1	86.0	82.0	99	40
7	ET Tube	Logesh	5	M	15	51217	RUDT	Orchidop	I	I	Nil	1	88.0	84.0	99	38
8	ET Tube	Mohanprasath	3 ½	M	12	50990	Phimosis	Circumcisi	I	I	Nil	1	90.0	80.0	99	39
9	ET Tube	Kalpana	6	F	20	3633	Rhernia	Herniotomy	I	I	Nil	1	88.0	90.6	99	38
10	ET Tube	Monisha	5	F	18	4237	Cystits	scopy	I	I	Nil	2	90.0	86.0	99	40
11	ET Tube	Dhanraj	7	M	20	4400	AcScrotum	Exploration	I	I	Nil	1	96.0	83.3	99	38
12	ET Tube	Harini	2	F	11	4987	Analtag	Excision	I	I	Nil	1	90.0	80.7	100	36
13	ET Tube	Boopalan	2	M	12	5087	Rhydrocoe	Pvsaclig	I	I	Nil	1	88.0	80.0	99	38
14	ET Tube	Prasanth	4	M	14	5100	Acsrotum	Explorat	I	I	Nil	2	88.0	90.0	99	40
15	ET Tube	Deising	3 ½	M	12	6220	Phimosis	Circumcisi	I	I	Nil	1	96.0	88.0	100	37
16	ET Tube	Gopalakrishnan	7	M	16	6345	Phimosis	Circumcisi	I	I	Nil	1	90.0	87.3	99	38
17	ET Tube	Kalaiselvi	2	F	11	6489	Tonguetie	Release	I	I	Nil	1	86.0	90.2	99	38
18	ET Tube	Hemapriyan	4	M	17	6817	Phimosis	Circumcisi	I	I	Nil	1	78.0	87.3	99	36
19	ET Tube	Kanya	4	F	16	7628	Rhrenia	Herniotomy	I	I	Nil	1	81.0	90.6	99	38
20	ET Tube	Rakesh	9	M	15	8765	Pappiloma	Excision	I	I	Nil	1	84.0	88.6	99	36
21	ET Tube	Vellai	7	M	20	20357	VID	Exploration	I	I	Nil	1	90.0	86.6	99	38
22	ET Tube	Rajesh	3	M	13	20336	Dermoid	Excision	I	I	Nil	1	88.0	90.0	99	36

23	ET Tube	Bharathi	5	F	18	20330	Popltcyst	Excision	I	I	Nil	1	80.0	83.3	99	40
24	ET Tube	Ritheesh	2	M	12	21880	Lhernia	Herniotomy	I	I	Nil	1	86.0	86.6	100	38
25	ET Tube	Dhoni	5	M	20	21882	Lhernia	Herniotomy	I	I	Nil	1	88.0	90.0	100	36
26	ET Tube	Kavya	5	F	17	21900	Lhernia	Herniotomy	I	I	Nil	1	78.0	83.0	100	38
27	ET Tube	Vetrimaran	3	M	12	21902	Vesicalcal	Vlithotomy	I	I	Nil	1	86.0	92.0	99	36
28	ET Tube	Saipradap	2	M	13	22565	Phimosis	Circumcisio	I	I	Nil	1	98.0	87.2	99	36
29	ET Tube	Saranya	5	F	19	22600	Rectalpro	Repair	I	I	Nil	1	82.0	86.4	100	38
30	ET Tube	Jeevan Raj	2	M	11	23137	Phimosis	Circumcisio	I	I	Nil	1	92.0	87.3	99	35
31	ET Tube	Asif	5	M	18	26334	Rhernia	Herniotomy	I	I	Nil	1	82.0	84.1	99	36
32	ET Tube	Dinakar	6	M	17	24418	umbHernia	Repair	I	I	Nil	1	86.0	86.6	99	38
33	ET Tube	Jeevitha	3	F	13	27657	Abdflap	Revision	I	I	Nil	2	92.0	83.3	99	40
34	ET Tube	Jeyadeva	3	M	12	28853	Hypospads	Urethropl	I	I	Nil	1	90.0	87.3	100	38
35	ET Tube	Subash	4 ½	M	14	28842	Rhydrocoe	Pvsacligat	I	I	Nil	1	88.0	80.6	99	38
36	ET Tube	Partha	6	M	15	30860	Lhernia	Herniotomy	I	I	Nil	1	86.0	84.6	99	35
37	ET Tube	Nethaj	5	M	17	30823	Lhernia	Herniotomy	I	I	Nil	1	94.0	84.0	99	40
38	ET Tube	Kamini	6	F	15	30815	Rhernia	Herniotomy	I	I	Nil	1	82.0	86.6	99	38
39	ET Tube	Aswin	3	M	10	30802	Phimosis	Circumcisio	I	I	Nil	1	94.0	82.0	99	38
40	ET Tube	Gokul	3	M	12	31803	Rhernia	Herniotomy	I	I	Nil	1	90.0	83.3	99	38

Hemodynamic Profile																						
	Post Intubation					After 5 min					After 10 min					Post-op Observations upto 24 hrs						
	HR (/min)	Mean BP (mm Hg)	SPO_2 (%)	Etco 2		HR (/min)	Mean BP (mm Hg)	SPO_2 (%)	Etco 2		HR (/min)	Mean BP (mm Hg)	SPO_2 (%)	Etco 2		Cough	Broncho-spasm	Laryngo-spasm	Blood on device	Sore throat	Hoarseness of voice
	110.0	88.6	99	38		101.0	80.0	99	38		98.0	83.3	100	40		-	-	-	-	-	-
	108.0	94.2	99	40		101.0	80.6	99	42		106.0	88.0	99	40		+	-	-	-	-	-
	117.0	88.0	99	38		109.0	78.0	99	40		105.0	80.6	99	42		-	-	-	+	-	-
	112.0	82.6	99	40		103.0	72.0	99	38		102.0	78.0	99	38		-	+	-	-	-	-
	110.0	86.0	99	38		101.0	76.0	99	40		100.0	82.0	99	42		-	-	-	-	-	-
	106.0	84.0	100	38		95.0	74.2	99	38		93.0	81.3	99	42		+	-	-	-	-	-
	108.0	86.0	99	40		99.0	76.8	99	38		96.0	82.0	99	41		-	-	-	-	-	-
	110.0	82.0	100	42		101.0	72.0	99	38		98.0	78.4	99	40		-	-	-	-	-	-
	108.0	91.0	99	40		98.0	81.0	99	42		96.0	87.0	99	38		-	-	-	-	-	-
	110.0	88.0	99	38		100.0	78.0	99	39		96.0	84.0	99	40		+	-	-	-	-	-
	115.0	85.1	100	42		106.0	75.0	99	40		105.0	76.1	99	42		-	-	-	+	-	-
	112.0	83.8	99	38		100.0	73.8	99	40		98.0	79.0	99	38		-	-	-	-	-	-
	108.0	83.0	99	39		104.0	73.0	99	42		100.0	78.2	100	40		-	-	-	-	-	-
	107.0	93.0	99	38		98.0	83.0	100	36		95.0	89.0	99	41		+	-	-	-	-	-
	116.0	90.0	99	38		97.0	80.0	99	40		101.0	86.1	99	42		-	-	-	-	-	-
	109.0	89.1	99	39		100.0	79.1	99	42		97.0	85.1	99	41		-	-	-	-	-	-
	104.0	92.0	99	40		95.0	86.0	99	42		100.0	88.0	99	43		+	+	-	-	-	-
	98.0	89.2	99	38		89.0	79.6	99	40		86.0	85.0	99	42		-	-	-	-	-	-
	98.0	92.4	99	36		90.0	82.0	99	42		88.0	88.2	99	40		-	-	-	-	-	-
	104.0	90.0	99	40		96.0	81.0	99	41		92.0	86.1	100	38		-	-	-	-	-	-
	110.0	88.8	99	36		101.0	78.0	99	38		98.0	74.2	99	40		+	-	-	-	-	-
	106.0	87.3	99	40		96.0	77.3	99	38		92.0	83.0	99	40		-	-	-	-	-	-

	98.0	85.6	99	42		89.0	75.4	99	38		86.0	81.6	99	39		-	-	-	-	-	-
	116.0	88.0	100	40		97.0	78.0	99	36		102.0	84.0	100	40		+	-	-	-	-	-
	108.0	93.2	99	38		98.0	83.0	99	40		94.0	89.0	100	42		-	-	-	-	-	-
	97.0	85.0	99	40		86.0	75.0	99	40		85.0	81.1	99	42		-	-	-	+	-	-
	102.0	89.3	99	40		93.0	79.2	100	38		90.0	84.2	99	41		-	-	-	-	-	-
	107.0	89.0	100	38		98.0	79.0	99	40		95.0	85.0	99	42		+	+	-	-	-	-
	101.0	87.6	99	36		92.0	77.6	99	40		90.0	83.0	99	42		-	-	-	-	-	-
	112.0	85.3	99	38		93.0	80.0	99	39		96.0	78.0	99	40		-	-	-	-	-	-
	98.0	89.3	99	40		91.0	81.3	100	38		96.0	81.0	100	40		-	-	-	-	-	-
	106.0	90.6	99	40		97.0	85.3	100	42		94.0	86.6	99	40		+	-	-	-	-	-
	112.0	87.3	100	36		103.0	78.6	99	38		100.0	81.3	99	42		-	+	-	-	-	-
	110.0	89.3	99	39		101.0	80.6	99	40		98.0	84.6	100	42		-	-	-	-	-	-
	108.0	88.0	99	40		99.0	81.6	99	43		96.0	85.3	99	45		-	-	-	-	-	-
	106.0	88.7	99	38		97.0	80.1	99	40		94.0	86.6	99	42		+	-	-	-	-	-
	114.0	74.0	100	42		95.0	77.3	99	38		102.0	82.0	99	40		-	-	-	+	-	-
	102.0	78.1	99	39		94.0	80.0	99	40		110.0	84.6	99	42		-	-	-	-	-	-
	114.0	85.3	99	40		95.0	77.0	99	42		102.0	81.3	100	38		-	-	-	-	-	-
	110.0	87.3	99	40		91.0	80.6	99	42		98.0	83.3	99	s		-	-	-	-	-	-

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INSTITUTIONAL ETHICS COMMITTEE

CHENGALPATTU MEDICAL COLLEGE , CHENGALPATTU

APPROVAL OF ETHICAL COMMITTEE

To

Dr. NANDA KUMAR.R

Dear Dr.

The Institutional Ethical Committee of Chengalpattu Medical College reviewed and discussed your application to conduct the clinical / dissertation work entitled

A STUDY OF MANAGEMENT AND OUTCOME OF SNAKE BITE WITH ENVENOMATION PATIENTS IN CMCH GENERAL MEDICINE DEPARTMENT

On 05.06.2013

The following documents reviewed

a. Trial protocol, dated _____version no
b. Patient information sheet and informed consent form in English and / or vernacular language.
c. Investigators Brochure, dated _____version
d. Principal Investigators current CV
e. Investigators undertaking

The following members of the Ethics committee were present at the meeting held on

Date 05.06.2013 Time 12.00 Noon Place Chengalpattu Medical College

Approved _____ Chairman Ethics Committee

5/6/13
_____ Member secretary of Ethics Committee.

Name of each member with designation

Clinical Members

1. Dr.G.Raja Billy Graham MS.,
   Prof & HOD of Surgery, ChMC

2. Dr. E. Arumugam MD.,
   Prof & HOD of Medicine, ChMC

Biological Scientist

3. Dr.M.Kulandaiammal MD.,
   Asso Prof of Pharmacology, ChMC

Non Clinical Members

4. Dr.P.Parasakthi MD
   Prof & HOD of Forensic Medicine,ChMC

5. Member from Nongovernmental
   Voluntary Organisation : Mr.P.Durairaj

6. Philosopher : Mr.K.S.Ramprasad

7. Lawyer : Lr. I. M. Karimala Basha

8. Layperson : Mr.Dilli

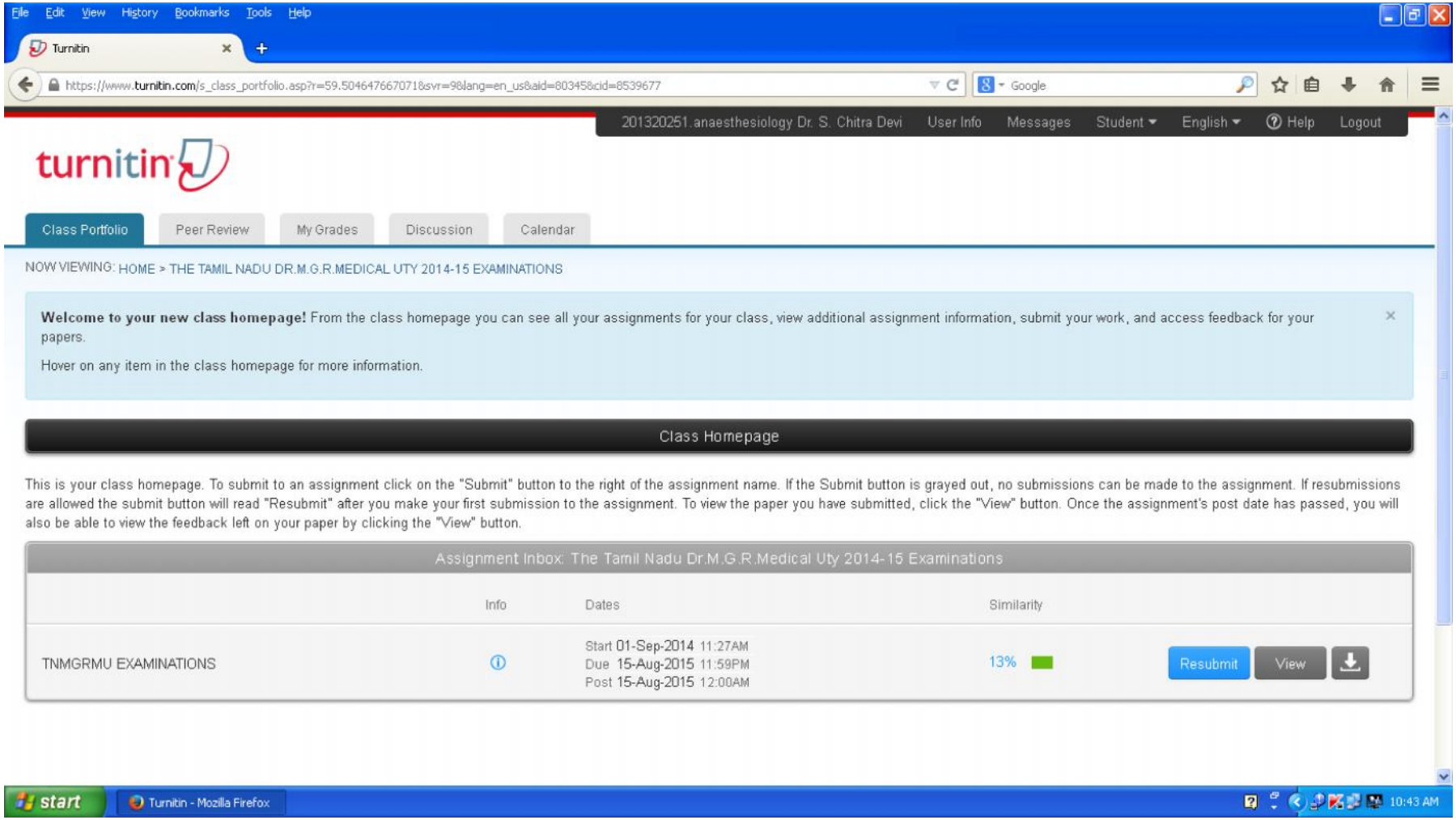
We approve the clinical trial to be conducted in its presented form

The Institutional Ethics Committee expects to be informed about the progress of the study and any SAE occurring in the course of the study, any changes in protocol and patient information / informed consent and asks to provide copy of final report.

Yours sincerely

5/6/13

Member secretary, Ethics Committee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