PROSPECTIVE RANDOMISED COMPARISON OF LMA-SUPREME AND ENDOTRACHEAL TUBE IN ELECTIVE LAPAROSCOPIC GYNAECOLOGICAL SURGERIES

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CERTIFICATE

This is to certify that the dissertation entitled, "**PROSPECTIVE RANDOMISED COMPARISON OF LMA - SUPREME AND ENDOTRACHEAL TUBE IN ELECTIVE LAPAROSCOPIC GYNAECOLOGICAL SURGERIES",** Submitted by Dr. N.C.USHA RANI in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide record of the work done by her in the INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical College, during the academic year 2009-2012.

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CONTENTS

INTRODUCTION

Supraglottic airway devices have become a standard fixture in airway management filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit outside the trachea but provide a hands free means of achieving a gas tight airway.

Originally created as hands free replacement for the face mask, the LMA has gone on to replace endotracheal tubes as the preferred airway in millions of cases each year. This remarkable shift has occurred for number of reasons including ease of placement, lower drug requirement, reduced hemodynamic response, smoother emergence and lower incidence of sore throat.

Though LMA provided all the above advantages, the risk of gastric distension, pulmonary aspiration of gastric contents and fear of inadequate ventilation acted as a deterrent to the widespread use of LMA.

To overcome the above complications Dr. Archie Brain designed the new airway device, LMA – Supreme in 2007, with the modifications to separate the respiratory and gastro intestinal tract. It represents the most advanced laryngeal airway yet developed by Archie Brain, the inventor of original LMA airway, the LMA Classic.

Laparoscopic surgery or more appropriately minimal access surgery is well established since last two decades. General anaesthesia with controlled ventilation remains the gold standard technique for laparoscopic surgeries.

The ETT has been proved to be a reliable method of securing the airway and is considered the standard of care for protecting the airway from aspiration. They carry an inherent risk of patient trauma, from vocal cord injury to pharyngeal soft tissue injury and also produces hemodynamic responses to rigid laryngoscopy.

Because of ease on insertion and reduced trauma, LMA airways have replaced ETT in many procedures. With its integrated gastric tube and verifiable placement, the LMA Supreme is an even more effective alternative.

LMA Supreme is a new airway device that combines the different features of its predecessors. It is curved like the LMA-Fastrach, it offers gastric access like LMA- Proseal and it is of single use like LMA- Unique.

The LMA-Supreme forms two seals: an effective first seal with the oropharynx (oropharyngeal seal) and an innovative second seal with the upper oesophageal sphincter (the oesophageal seal). The optimised distal tip with gastric access functionally separates the digestive and respiratory tracts thus effectively protecting against regurgitation and gastric distension.

With this background this study was conceptualized to compare the performance of LMA- Supreme and Endotracheal tube in elective laparoscopic gynaecological surgeries.

STRUCTURE AND FUNCTION OF THE UPPER AIRWAYS

Anatomically airway is the passage through which the air passes during respiration. It may be divided into upper and lower airway. The upper airway comprises nasal cavity, oral cavity, nasopharynx, oropharynx, pharynx and larynx.

Nasal cavity:

Nasal cavity extends from naris to end of the turbinates. The normal airway begins functionally at the nares. As air passes through the nose, the important functions of warming and humidification occur. The nose is the primary pathway for normal breathing. The nasal cavities are divided by nasal septum. The roof is formed by cribriform plate of the ethmoid bone. The bony lateral wall is the origin of the three bony turbinates that project into the nasal cavity. Openings in the lateral wall communicate with paranasal sinuses.

Oral cavity:

It extends from mouth opening to anterior tonsillar pillar[21]. Contracture of mouth and lips can lead to difficult laryngoscopy. The roof of the mouth is bounded by alveolar arch and teeth and consists of the hard palate anteriorly and soft palate posteriorly. The tongue makes up the most of the mouth, which is bounded by the mandible and teeth. The ability to achieve good mouth opening is important for many airway procedures. Initial mouth opening is achieved by

rotation within the temporomandibular joint and subsequent opening by sliding of the condyles of the mandible within the joint.

Pharynx[5]:

The pharynx is a fibromuscular tube that extends from the base of the skull to the lower border of cricoid cartilage. It joins the nasal and oral cavities above; with larynx and esophagus below. It is divided into nasopharynx and oropharynx.

The nasopharynx:

Extends from the posterior end of turbinates to posterior pharyngeal wall above the soft palate and consists of the nasal cavity, septum, turbinates and adenoids.

The oropharynx:

Extends from the soft palate above to epiglottis below; and anteriorly from tonsillar pillar to posterior pharyngeal wall. It includes the tonsils, uvula and the epiglottis. The tongue is the principal source of oropharyngeal obstruction, usually because of decreased tone of the genioglossus muscle. The latter contracts to move the tongue forward during inspiration and thus act as a pharyngeal dilator. The vallecula is the space between epiglottis and base of the tongue. It has paired depressions on both sides of glosso epiglottic fold. Laryngoscope blade tip is positioned in vallecula during conventional laryngoscopy. Gentle upward pressure on the vallecula with laryngoscope blade tensions hyoepiglottic ligament and indirectly elevates the larynx and helps in the alignment of laryngeal and pharyngeal axes.

Larynx:

The larynx, which lies at the level of the third through sixth cervical vertebrae, serves as the organ of phonation and acts as a valve to protect the lower airways from the contents of the alimentary tract.

The laryngeal cavity extends from the epiglottis to the lower level of the cricoid cartilage. The larynx bulges posteriorly into the laryngopharynx, with the pyriform fossa lying on each side. It is suspended from the hyoid bone by the thyrohyoid membrane.

The structure consists of muscles, ligaments, and a framework of cartilages. These include the thyroid, cricoid, arytenoids, corniculates, and the epiglottis. The latter, a fibrous cartilage, has a mucous membrane covering that reflects as the glossoepiglottic fold onto the pharyngeal surface of the tongue. The epiglottis projects into the pharynx and overhangs the laryngeal inlet. However, it is not absolutely essential for sealing off the airway during swallowing.

The inlet is formed by the epiglottis, which joins to the apex of the arytenoid cartilages on each side by the aryepiglottic folds. Inside the laryngeal cavity one first encounters the vestibular folds, which are narrow bands of fibrous tissue on each side. These extend from the anterolateral surface of each arytenoid to the angle of the thyroid where the latter attaches to the epiglottis. These folds are referred to as the false vocal cords and are separated from the true vocal cords by the laryngeal sinus or ventricle.

The true vocal cords are pale white ligamentous structures that attach to the angles of the thyroid anteriorly and to the arytenoids posteriorly. The triangular fissure between these vocal cords is termed the glottic opening, which represents the narrowest segment of the laryngeal opening in adults.

Cricoid cartilage is a complete ring shaped cartilage and continues with trachea. In young children (<10 years old), the narrowest segment lies just below the cords at the level of the cricoid ring.

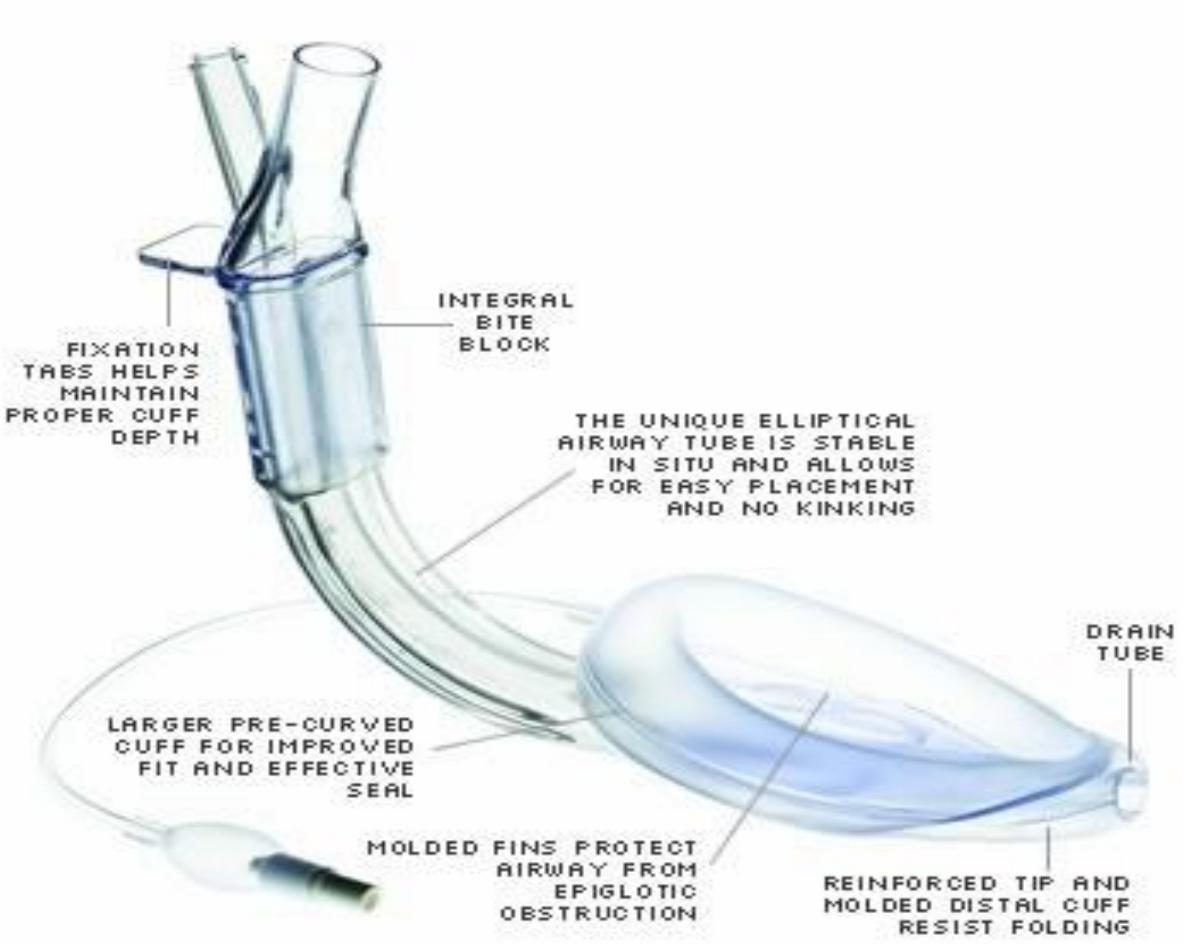
LMA – SUPREME

The laryngeal mask airway Supreme[7, 15] was designed and developed by Dr.Archie Brain in 2007, with primary goal to construct a laryngeal mask with improved ventilatory characteristics that also offered protection against regurgitation and gastric insufflations. It is a single use disposable airway device thus alleviating concerns of cross contamination.

DEVICE DESCRIPTION:

The LMA- Supreme is a innovative, sterile, single use, latex free supraglottic airway management device. It has following components,

1. Inflatable cuff with interlocking proximal and distal segments
2. Cuff inflation line with pilot balloon
3. Airway tube
4. Drain tube
5. Integral bite block
6. Fixation tab
7. A rigid molded proximal component which forms separate airway and drain tube ports.


FIXATION TABS HELPS MAINTAIN PROPER CUFF DEPTH
INTEGRAL BITE BLOCK
THE UNIQUE ELLIPTICAL AIRWAY TUBE IS STABLE IN SITU AND ALLOWS FOR EASY PLACEMENT AND NO KINKING
DRAIN TUBE
LARGER PRE-CURVED CUFF FOR IMPROVED FIT AND EFFECTIVE SEAL
MOLDED FINS PROTECT AIRWAY FROM EPIGLOTIC OBSTRUCTION
REINFORCED TIP AND MOLDED DISTAL CUFF RESIST FOLDING

The LMA – Supreme is considered as an evolution in the design of LMA. The special features are,

MASK:

- Elongated cuff

  It provides improved anatomical fit and support to the effective first and the second seal.

  The reinforced tip and molded distal cuff resists folding.

- First seal

  It forms an effective first seal with the oropharynx – **oropharyngeal seal**.

  It helps to deliver a measured oropharyngeal leak pressures upto 37 cm H_2O, for high ventilation performance.

  The first seal is considered to be important for:

  - Procedures requiring increased airway pressure during mechanical ventilation (e.g. laparoscopic surgeries)
  - Patients requiring increased airway pressure such as morbidly obese patients.

- Second seal

  It forms an innovative second seal with the upper oesophageal sphincter- **oesophageal seal**. It separates alimentary tract from respiratory tract.

  The second seal is considered to be important for:

  - Controlling the LMA Supreme tip position
  - Reducing the risk of gastric gas insufflations during ventilation

- Cuff bowl

  The patented epiglottic fins and the drain tube are positioned in the bowl. It prevents the epiglottic occlusion of the airway tube.

  With the cuff deflated, the thin wedge shape of the LMA Supreme feels smooth enough to allow comfortable insertion even in patients with restricted mouth opening. It allows reduced anaesthetic requirement for airway tolerance and smoother emergence.

INFLATION LINE:

- It is attached to the mask and terminates in pilot balloon with one way check valve for mask inflation and deflation.
- Low volume inflation enables conformity of mask to the anatomy.
- The seal is formed by matching the shape and not by the mucosal pressure.

AIRWAY TUBE:

- The LMA evolution curve is elliptical in cross section and anatomically shaped facilitating easy insertion.
- It permits easy insertion without digital or introducer guidance.
- It provides enough flexibility to permit the device to remain in place if the patients head is moved in any direction.
- The two lateral grooves prevent the airway tube kinking when flexed.

DRAIN TUBE:

- Emerges as a separate port proximally and continues distally along the anterior surface of the cuff bowl, passing through the distal end of the cuff to communicate distally with the upper oesophageal sphincter.
- Prevents gastric insufflation during ventilation, hence reduces likelihood of regurgitation
- Enables active and passive decompression of stomach.
- It is also used to monitor the correct positioning of LMA Supreme following insertion and for any displacement of mask during its use.

INTEGRAL BITE BLOCK:

- Reduces the potential for tube damage and obstruction by patient biting

FIXATION TAB:

- It is a specially designed rigid tab fixed above the bite block area that permits novel fixation method using adhesive tapes
- Facilitates optimal positioning in oropharynx, hypopharynx and upper oesophagus
- Whenever there is a leak around the cuff or the drain tube this tab can be manipulated easily to reposition the device to optimal position.
- It indicates correct sizing of LMA
    - Positioned flush against the patients upper lip indicates the need for larger sized LMA
    - Positioned > 2.5 cm from upper lip indicates the need for smaller sized device.

SIZES AVAILABLE

MASK SIZE	***PATIENT SIZE***	***MAXIMUM CUFF INFLATION VOLUME***	***MAXIMUM SIZE OG TUBE***
SIZE 1	< 5 kg	5 ml	6 FR
SIZE 2	10 – 20 kg	12 ml	10 FR
SIZE 3	30 – 50 kg	30 ml	14 FR
SIZE 4	50 – 70 kg	45 ml	14 FR
SIZE 5	70 – 100 kg	45 ml	14 FR

The appropriate size of LMA Supreme is selected by using fixation tab position as already described.

PERFORMANCE TESTS[23]:

The following inspections and tests must be conducted before use of the device. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimise contamination of the LMA Supreme before insertion.

1) VISUAL INSPECTION:

- Examine the surface of the LMA Supreme and drain tube for damage including cuts, tears, scratches or kinks.

- Examine the interior of the airway tube and drain tube to ensure they are free from blockages, loose particles and kinking of the drain tube within the airway tube. Any particles present in the tubes should be removed. Do not use the airway if the blockage or particle cannot be removed.

2) INFLATION AND DEFLATION:

- Deflate the cuff completely. Once deflated, check the cuff for spontaneous inflation. Do not use the airway if the cuff spontaneously inflates.

DEVICE DEFLATION:

- Firmly connect a syringe of at least 50 ml to the inflation port
- Move the connected syringe away from the device until the inflation line is slightly stretched.
- Compress the distal end of the device in between the index finger and thumb while withdrawing air until a vacuum is created.
- While deflating hold the device so that the distal end is slightly curled anteriorly.
- Deflate the device until the tension in the syringe indicates a vacuum in the mask.
- Keep the syringe under tension and rapidly disconnect it from the inflation port.

DEVICE INSERTION:

- Lubricate the posterior surface of the mask and airway tube just prior to insertion.
- Stand behind the patients head.
- Place the head in the neutral or slight “sniffing” position
- Hold the device at the bite block
- Press the tip of the mask against the hard palate
- Press the cuff further into the mouth, maintaining pressure against the palate.
- Swing the device inward with a circular motion, pressing against the contours of the hard palate and the soft palate.
- Advance the device into the hypopharynx until resistance is felt.

DEVICE FIXATION:

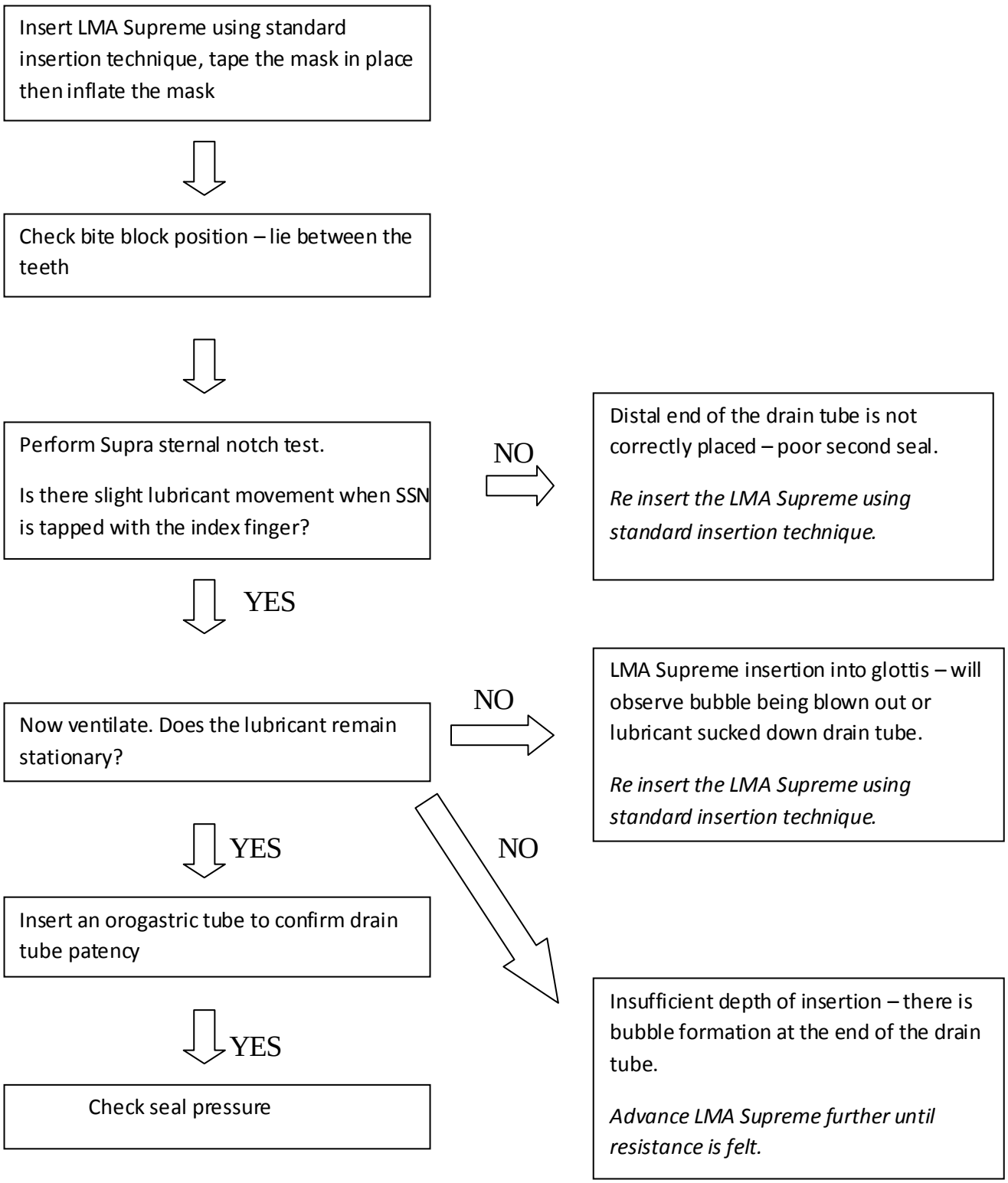
- Use a piece of adhesive tape 30 – 40 cm long, holding it horizontally by both hands.
- Press the adhesive tape transversely across the fixation tab with the middle of the tape pressing vertically downward over the tab.
- Do not rotate the tape around the proximal end of the device

DEVICE INFLATION:

- Inflate the cuff with air until relevant intra – cuff pressure is reached. The recommended intra-cuff pressure should never exceed 60 cm H_2O.

- If there is no manometer by hand, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

DIAGNOSTIC TESTS TO CONFIRM PLACEMENT



OROGASTRIC TUBE INSERTION:

The primary function of drain tube is to provide a separate conduit from and to the alimentary tract. The gastric tube is well lubricated and then passed down the drain tube of LMA Supreme without any haste or force. A slight resistance is normal and is felt as the tip passes against the upper oesophageal sphincter.

There may be difficulty in passing the gastric tube due to the following reasons

1. Selection of too large gastric tube
2. Inadequate lubrication
3. Use of cooled gastric tube
4. Cuff over inflation
5. Malposition of LMA Supreme

The advantages of inserting gastric tube are

1. It allows active and passive decompression of stomach
2. It helps to confirm correct placement of LMA Supreme
3. It acts as a monitor for any displacement during the use.

REVIEW OF LITERATURE

The literature was searched and reviewed to seek the advantages and disadvantages of LMA-Supreme use over ETT for general anaesthesia in elective laparoscopic gynaecological surgeries.

1)Abdi W, Amathieu R, Adhoum A, Poncelet C, Slavov V, Kamoun W, Combes X, Dhonneur G[1] compared the efficiency and post operative upper airway morbidity of LMA- Supreme and endotracheal tube in elective laparoscopic gynaecological surgeries.

One hundred and thirty eight elective pelvic laparoscopic ASA I-II female patients were enrolled in the study. They were randomly assigned into two groups – LMA Supreme group(SUP) and endotracheal tube group(ETT). Anaesthesia management was identical in both the groups and included induction with propofol/sufentanyl/atracurium, maintenance with sevoflurane and sufentanyl, muscle relaxation with atracurium and IPPV.

The airway management duration in LMA Supreme group was 2.2 mins and in ETT group was 3.8 mins. Post operative pharyngolaryngeal discomfort incidence was significantly less after SUP anaesthesia than ETT anaesthesia. Hoarseness of voice was less frequent in LMA-S group compared to ETT group both in PACU (16% vs 47%, respectively $P<0.05$) and before discharge (9% vs

37%, respectively P<0.05). Sore throat was less frequent in LMA-S group compared to ETT group both in PACU (19% vs 32%, respectively P<0.05) and before discharge (5% vs 15%, respectively P<0.05).

The study concluded LMA-Supreme as an effective pharyngolaryngeal morbidity sparing strategy and an equally effective airway device to ETT for gynaecological laparoscopic surgeries. *(Acta Anaesthesiologica Scandinavica 2010; 54: 141–146)*

2) Vila, P.; Sirvent, A.; Gomez, N.; Mazo, V.; Preciado, M. J.[2] compared the insertion conditions, airway seal and efficacy of ventilation of LMA- Supreme and Endotracheal tube in laparoscopic gynaecological surgeries in trendlenburg position.

Anaesthesia was induced with propofol/fentanyl and maintained with desflurane/air in both SLMA group and ETT group. No. of insertion attempts and time to establish an effective airway were recorded. Ease of placing gastric tube was measured. $EtCO_2$ was recorded at rest, after pneumoperitoneum and after trendlenburg positioning

.

Number of insertion attempts was similar in both the groups (1.1 vs 1; SLMA and ETT, respectively). The time taken to establish an effective airway were similar in both the groups (14s vs 17s; SLMA and ETT, respectively). $EtCO_2$ was similar in both the groups at all moments.

The study concluded LMA-Supreme as a practicable approach for gynaecological laparoscopic surgeries in trendlenburg position. *(European Journal of Anaesthesiology: 12 June 2010 - Volume 27 - Issue 47 - p 250–251, Airway Management)*

3) Pelikan, K.; Dadak, L.[9] assessed the efficacy of LMA- Supreme(SLMA) as airway management device in patients undergoing prolonged surgeries. Ease of insertion of SLMA, number of attempts for successful insertion, ease of insertion of gastric tube, postoperative sore throat were studied.

SLMA was successfully used in all cases. The first time insertion success rate was 93%. Gastric tube was inserted with ease, with first attempt success rate of 100%. Gastric content was 0 ml at the end of anaesthesia in 46%. Incidence of sore throat was 5%. No patient reported of hoarseness of voice.

The study concluded LMA-Supreme as a suitable and safe alternative to tracheal intubation in prolonged anaesthesia. *(European Journal of Anaesthesiology: 12 June 2010 - Volume 27 Issue 47 - p 251, Airway Management)*

4)Belena JM, Gracia JL, Ayala JL, Nunez M, Lorenzo JA, De los reyes A, Perez JL, Yuste J[16] evaluated the efficacy of LMA-Supreme in patients undergoing laparoscopic cholecystectomy with general anesthesia. Ease of insertion of the device and the drain tube, gastric distension, frequency of post operative sore throat, and other adverse events were recorded.

All patients were premedicated with midazolam and preoxygenated. Induced with propofol/remifentanyl. SLMA was inserted and the number of insertion attempts, the time taken for an effective airway was recorded. A 14 Fr drain tube was inserted via the drain tube, its ease of insertion and number of attempts were recorded. Gastric distension was noted by the surgeon and scored on an ordinal scale from 0 to 10. Hemodynamic parameters were recorded every 3 minutes. Post operative sore throat was assessed.

The success rate of SLMA insertion was 100% with 91 patients on first attempt and 9 patients on second attempt. The mean time for SLMA insertion was 12±4.6 seconds. The success rate of gastric tube insertion was 100% (easy in 97 pts, difficult in 3). Twelve patients (12%) complained of sore throat post operatively.

The study concluded LMA-Supreme as easy to insert and an effective ventilatory device for laparoscopic cholecystectomy. *(Journal of Clinical Anesthesia. 2011 Sep;23(6):456-60.)*

5)**Teoh WH, Lee KM, Suhitharan T, Yahaya Z, Teo MM, Sia AT**[11] compared the efficacy of LMA-Supreme and I-Gel in patients posted for laparoscopic gynaecological surgeries. The ease of insertion, success rate of insertion at first attempt, ease of gastric tube insertion, blood staining of devices and post operative sore throat were studied.

Ease of insertion was similar for both the devices, 88% graded easy in both the groups (p=1.000). The success rate of insertion at first attempt was comparable in both the groups (94% in LMA-S vs 96% in I-Gel). The time taken for insertion was comparable in both the groups (14.3 s in LMA-S vs 15.4 s in I-Gel; p=0.4).

Gastric tube insertion was easier and achieved more quickly with the LMA-Supreme group than I-Gel group (9.0 s vs 15.1 s, respectively; p<0.001). Ease of gastric tube insertion was easy in 100% of LMA-S group vs 78% of I-Gel group. (p<0.001)

The study concluded that both the devices as equally effective in gynaecological laparoscopic surgeries. *(Anaesthesia. 2010 Oct 19.)*

6) **Tan BH, Chen EG, Liu EH**[17] evaluated the efficacy of LMA-Supreme in 100 patients. The success rate of insertion at first attempt was 96% and at second attempt was 100%. Time to achieve effective ventilation was 15.0 sec (12 – 18 s). The success rate of gastric tube insertion was 100%. The incidence of sore throat and blood staining were found to be 7%.

The study concluded LMA-Supreme was easy to insert with high rate of optimal positioning at first attempt with less incidence of airway trauma. *(Anaesthesia and Intensive Care. 2010 May; 38(3):550-4)*

7)**Seet E, Rajeev S, Firoz T, Yousaf F, Wong J, Wong DT, Chung F**[18] compared the safety and efficacy of LMA-supreme and LMA-Proseal in elective ambulatory surgeries.

The success rate of first attempt insertion was higher with LMA-Supreme group than for Proseal group. (98% vs 88%; p = 0.04). None of the insertion graded difficult in LMA-Supreme group against 3 difficult insertion in proseal group. The incidence of blood staining in Supreme group was less than the proseal group (10% vs 16.3% respectively). The incidence of post operative sore throat was less in Supreme group compared to Proseal group (11.8% vs 16.3%, respectively).

The study concluded LMA-Supreme as safe, efficacious and easy-to-use disposable airway device in elective ambulatory surgeries. *(Europeon Journal of Anaesthesiology. 2010 Jul;27(7):602-7)*

8. Maltby J Roger, Beriault Michael T, Watson Neil C, Liepert David J, Fick Gordon H[4] compared the laryngeal mask airways (LMA), LMA-Classic(TM) (LMA-C) and LMA-ProSeal(TM) (PLMA) with the endotracheal tube (ETT) with respect to pulmonary ventilation and gastric distension during gynecologic laparoscopy.

There were no statistically significant differences between LMA-C/PLMA and ETT groups for SpO_2, P(ET)CO(2) or airway pressure before or during

peritoneal insufflation in short (< or = 15 min) or long (> 15 min) periods of peritoneal inflation. Differences between groups with respect to stomach size changes during surgery were not statistically significant.

The study concluded that a correctly placed LMA-C or PLMA provided equally effective ventilation as ETT without clinically important gastric distension. (*Can J Anaesth. 2003 Jan; 50(1):71-7)*

9) Lee AK, Tey JB, Lim Y, Sia A[20] compared the LMA-Supreme with Proseal LMA in seventy patients undergoing general anaesthesia with paralysis for gynaecological surgeries.

The ease of insertion were comparable between SLMA and PLMA with success rate of placement at first attempt being 94.3% vs 91.4%, respectively. The time for effective ventilation did not differ significantly (25±22 secs in SLMA vs 24±9 secs in PLMA; p=0.739).

Gastric tube insertion was completed in significantly less time with SLMA (5±1 s vs 7±3 s; p<0.001). The incidence of sore throat was similar, 9% in both groups. No patients in SLMA group complained of hoarseness of voice. *(Anaesthesia and Intensive Care. 2009 Sep;37(5):815-9.)*

10) **Chew E, Hashim N, Wang C**[22] compared the performance of the LMA Supreme (SLMA) with the I-Gel during anaesthesia in spontaneously breathing

adult patients. The overall insertion success rate, ease of insertion, adequacy of ventilation and incidence of complications were studied.

The first attempt and overall insertion success rates were similar between the two groups (SLMA 97.8 and 97.8%; I-Gel 93.3 and 100%, P=0.132). The SLMA was rated easier to insert than the I-Gel (P=0.011), but the time taken for insertion (P=0.433) was similar. The incidence of complications was low in both groups (9.5% in SLMA vs 4.4% in I-Gel).

The study concluded that SLMA was easier to insert compared I-Gel and provides better airway seal. *(Anaesthesia and Intensive Care 2010; 38: 1018-1022)*

11)**Ali A, Canturk S, Turkmen A, Turgut N, Altan A**[8] compared the LMA Classic with the LMA Supreme in assessing the success rate and time for insertion, number of attempts. In the LMA Classic group and the LMA Supreme group, the LMA was successfully inserted in the first attempt in 27 (77%) and 31 (88.5%) patients, respectively. The duration of insertion in the LMA Supreme group was shorter. (8.0±1.7sec vs 11.2±2.5sec, respectively;$p<0.001$) The incidence of sore throat was 2.8% with LMA-Supreme group vs 5.7% in LMA-Classic group.

The study concluded LMA Supreme as superior to LMA Classic as regards its ease of insertion and effective ventilation.*(Europeon Journal of Anaesthesiology. 2009 Dec;26(12):1010-4)*

12)**Eschertzhuber S, Brimacombe J, Hohlrieder M, Keller C**[24] evaluated the ease of insertion of airway device, their success rate and ease of gastric tube placement between the LMA ProSeal and the LMA Supreme in paralysed anesthetised patients. First attempt and overall insertion success were similar (LMA ProSeal, 92% and 100%; LMA Supreme 95% and 100%). The first attempt and overall insertion success for the gastric tube were similar (LMA ProSeal 91% and 100%; LMA Supreme 92% and 100%).*(Anaesthesia. 2009 Jan;64(1):79-83.)*

14)**Tham HM, Tan SM, Woon KL, Zhao YD**[26] tested the hypothesis that the SLMA is equally as effective as the PLMA as a supraglottic ventilatory device in anesthetized paralyzed adult patients. The success rate of insertion is 100% with 97% inserted in first attempt and 3% in second attempt. The time taken for insertion was 20 seconds comparable to that of PLMA, 20 secs(P=0.882)
The success rate of gastric tube insertion was 100%, with mean time for insertion being 10.3 seconds in SLMA against 11 seconds in PLMA.

The study concluded that the clinical performance of SLMA as a ventilator device was comparable with that of PLMA. *Canadian Journal of Anaesthesiology. 2010 Jul;57(7):672-8*

15)Lopez AM, Valero R, Brimacombe J[27] investigated whether insertion of an LMA Supreme and its use for maintenance of anaesthesia is feasible in the prone position. Ease of insertion, ease of ventilation, efficacy of seal, ease of

gastric tube insertion, blood staining, postoperative sore throat, and other complications were recorded.

Insertion was successful at the first and second attempt in 37 (92.5%) and 3 (7.5%) patients, respectively. The mean (SD) insertion time was 21 (15) s. Gastric tube placement was successful in all patients. The frequency of blood staining and sore throat was 7.5% each.

It was concluded that use of the LMA Supreme in the prone position by experienced users is feasible. *Anaesthesia. 2010 Feb;65(2):154-7*

AIM OF THE STUDY

To evaluate the advantages and disadvantages of LMA- Supreme (LMA-S) over Endotracheal tube (ETT) for general anaesthesia in women coming for laparoscopic gynaecological surgeries in terms of the following parameters.

1. Ease of insertion of airway device
2. No. of attempts for insertion of airway device
3. Time taken for insertion of airway device
4. Ease of insertion of gastric tube
5. No. of attempts for insertion of gastric tube
6. Gastric distension
7. Haemodynamic responses
8. Capnography
9. Blood staining of devices
10. Incidence of complications

MATERIALS AND METHODS

It was a prospective, randomised, single - blinded, case - controlled study conducted in the Department of Anaesthesiology, Kasturba Gandhi Hospital, Chennai. 60 adult patients satisfying the inclusion criteria were enrolled in the study.

INCLUSION CRITERIA:

- Age : 18 years and above
- Weight : BMI < 30 kg/m^2
- ASA : I & II
- Surgery : Elective
- Mallampatti scores : I & II
- Who have given valid informed consent

EXCLUSION CRITERIA:

- Not satisfying inclusion criteria
- Patients posted for emergency surgery
- Patients with difficult airway
- Lack of written informed consent
- Pregnant female

MATERIALS:

- LMA Supreme size 3 & 4
- Endotracheal tubes- 7 & 7.5 mm CETT
- Macintosh laryngoscope with blade size 3
- 20 ml syringe
- Lubricant jelly, 14 Fr orogastric tube
- Drugs: glycopyrolate, fentanyl, midazolam, ondansetron, propofol, atracurium, sevoflurane, neostigmine
- Monitors: ECG, Pulse oximetry, Capnography, NIBP
- Weighing machine calibrated to 1 kg

STUDY OUTCOME:

1. *Ease of Insertion of Airway Device*:

   The ease with which the patient was intubated was judged subjectively on nominal scale as "*easy (E)"* or *"difficult (D)".*

2. *No of insertion attempts*:

   The no. of attempts required for successful intubation was recorded. A "*failed attempt"* was defined as a removal of the device from the patient mouth or maximum of 3 attempts.

3. *Time taken for insertion:*

   It is defined as the time elapsed between picking up of airway device in the hand until the presence of square wave capnography trace.

4. *Ease of insertion of gastric tube:*

   The ease of insertion was graded subjectively as *Easy* or *Difficult*. It is considered difficult when there is a resistance to insertion, when more than one attempt is required, manoeuvres like lifting trachea or deflating cuff is required.

5. *No. of attempts for gastric tube insertion:*

   The no. of attempts required for successful gastric tube placement was recorded. The successful placement was defined as detection of injected air by auscultation of epigastrium and aspiration of gastric contents.

6. *Gastric distension:*

   It was measured by the operating gynaecologist before peritoneal deflation. It was graded on an ordinal scale from 0 – 10. (0 = empty stomach and 10 = distension of the stomach that interfered with surgical field)

7. *Haemodynamic reponses:*

   The patients pulse rate and blood pressure were recorded before intubation, immediately after intubation and one minute, 3 minutes and 5 minutes post intubation.

8. *End tidal carbondioxide:*

   The $EtCO_2$ was measured after intubation, after peritoneal inflation and after peritoneal deflation.

9. *Blood staining of the device:*

   At the end of surgery the airway device was removed after adequate recovery. The presence or absence of blood on the device was noted.

10. *Incidence of complications:*

    The patients were asked whether they experienced sore throat or hoarseness of voice after the removal of airway device.

    Sore throat was defined as a constant pain or discomfort in the throat independent of swallowing.

    Hoarseness of voice was defined as either change in the voice tone or a painful phonation.

CONDUCTION OF THE STUDY:

After obtaining institutional ethical committee clearance, all patients scheduled for elective laparoscopic gynaecological surgery under general anaesthesia were screened for any comorbid illness and difficult airway. Age, height and weight were assessed. 60 Patients satisfying the inclusion criteria were enrolled in the study. A written informed consent was obtained and the patients were allocated randomly into two groups, LMA-S and ETT, with 30 each by using closed

envelop method. The size of the airway was chosen in accordance to manufacturers recommendations.

All patients were premedicated with Inj. Midazolam 1 mg iv, Inj. Ondansetron 4 mg iv, Inj.glycopyrolate 0.2 mg iv in the pre anaesthesia room. The patients were shifted inside the operating room and placed in supine position. ECG monitor, pulse oximetry and non invasive blood pressure monitor were connected. Baseline BP, HR and SpO_2 were recorded.

All patients were preoxygenated with 100% oxygen at a flow rate of 6L/min for 3 minutes by using tight fitting mask. Patient was induced with Inj. Fentanyl 2µ/kg and Inj. Propofol 2 mg/kg. Inj. Atracurium 0.5mg/kg was administered for neuromuscular blockade after confirmation of successful manual bag-mask ventilation. Patient was ventilated for 3 mins. Pre intubation BP, HR and SpO_2 were recorded.

In ETT group conventional laryngoscopy was performed with macintosh 3 blade with the head in sniffing position . The trachea was intubated using a single use 7.0/7.5 mm internal diameter high-volume, low- pressure tracheal tube. The cuff was inflated until no leak was audible during manual ventilation.

In LMA-S group, the appropriate sized LMA-S was inserted in sniffing position as per manufacturers recommended technique and is taped in position. The cuff is inflated with just enough air to achieve a seal sufficient to permit ventilation without leaks. The appearance of first square end tidal carbon dioxide trace was noted as a indicator of effective ventilation. Otherwise the device was

completely removed for another insertion attempt, with a maximum of 3 attempts allowed. The ease of insertion, no of attempts taken for successful placement and the time taken for insertion were recorded in both the groups.

In LMA-S group, a water soluble lubricant was placed in the proximal 1 cm of the drain tube, and the suprasternal notch test was performed to confirm the placement.

The gastric tubes were lubricated well. In LMA-S group the appropriate sized gastric tube was inserted through the drain tube port. In ETT group the gastric tube was inserted nasally. Ease of insertion and no of attempts for successful insertion was noted. Gastric decompression was performed immediately after insertion.

Anaesthesia was maintained with sevoflurane 2% and N_2O: O_2 at 2:1 ratio. Muscle relaxation was maintained with Inj.atracurium 0.1mg/kg. The BP, HR and SpO_2 were recorded immediately after intubation and after one minute, 3 minutes and 5 minutes. Initial ventilator tidal volumes were set at 8ml/kg. Volume controlled positive pressure ventilation was used to achieve O_2 saturation of >95% and end tidal CO_2 of 30- 45 mm Hg through tidal volume 8-10ml/kg and respiratory rate of 10-16/min.

All patients were positioned head down. The trendelenberg tilt was provided as per the gynaecologists request. Pneumo peritoneum was created with CO_2 gas and intra abdominal pressure was maintained <15 mm Hg. $EtCO_2$ was recorded after peritoneal inflation. The gynaecologist was requested to grade the gastric distension before deflation. $EtCO_2$ was recorded after peritoneal deflation.

At the end of surgery, the effects of neuromuscular blockade was reversed with Inj. Neostigmine 0.04mg/kg and Inj. Glycopyrolate 0.01 mg/kg iv. After thorough oral suction the cuff was deflated and the airway device was removed upon return of spontaneous breathing and eye opening of the patient. The airway device was inspected for the presence of any visible blood.

The following complications were recorded –cough, stridor, laryngospasm and hypoxia. Patients were evaluated for the presence of sore throat and hoarseness of voice before leaving the operating room and 2 hours post operatively in the recovery room.

All recorded datas were analysed with SPSS software for Windows Version 15.0. The quantitative datas were analysed by students t-test and the qualitative data by chi-squared test. Power analysis was calculated using Minitab for windows and the power was well above the accepted level of 80%.

OBSERVATION AND RESULTS

This prospective, randomized, comparative, single blinded case control study compares LMA-Supreme insertion with Endotracheal tube in 60 adult females undergoing elective laparoscopic gynaecological surgery.

Results are expressed as mean and standard deviation. All statistical analyses were carried out using SPSS for Windows version 15.0. The *t*-test was used for comparison of quantitative variants. Qualitative variants were compared using the chi-squared test. A P value of less than 0.05 was considered statistically significant.

Table: 1 Demographic profile: Age

Group	N	Mean	SD	P value
LMA-S	30	28.43	6.71	0.879
ETT	30	28.20	4.99	

The mean age of group LMA-S is 28.43 and group ETT is 28.2. The data is statistically not significant ($p>0.05$) and this both groups are comparable in terms of age.

Table: 2 Demographic profile: BMI

Group	NO	Mean	SD	P value
LMA-S	30	23.19	1.67	0.375 ***Not significant***
ETT	30	22.63	2.96	

The mean BMI of group LMA-S is 23.19 and group ETT is 22.63.

The data is statistically not significant ($p>0.05$) and this both groups are comparable in terms of BMI.

Table: 3 Demographic profile: ASA PS Status

GROUP	ASA I		ASA II		P value
	NO	%	NO	%	0.739 ***Not significant***
LMA-S	25	83.3	5	16.7	
ETT	24	80.0	6	20.0	

In LMA-S group 25 patients were ASA I and 5 were ASA II patients. In ETT group 24 patients were in ASA I and 6 were ASA II patients.

The data is statistically not significant ($p>0.05$) and this both groups are comparable in terms of ASA PS Status.

Table: 4 Demographic profile: MPC

GROUP	MPC I		MPC II		P value
	NO	%	NO	%	1.000
LMA-S	21	70.0	9	30.0	***Not***
ETT	21	70.0	9	30.0	***significant***

In LMA-S group 21 patients were MPC I and 9 were MPC II patients. In ETT group 21 patients were in MPC I and 9 were MPC II patients.

The data is statistically not significant ($p>0.05$) and this both groups are comparable in terms of MPC.

Table: 5 Ease of insertion of airway device

Group	NO	Easy		Difficult		P value
		NO	%	NO	%	0.314
LMA-S	30	29	96.7	1	3.3	
ETT	30	30	100	0	0	***Not*** ***significant***

By using LMA-S, 29 cases were inserted easily and 1 case was inserted with difficulty. By using ETT all 30 cases were intubated easily.

Qualitative data values are compared by chi-square test. Statistical analysis reveals P value of 0.314 which is not statistically significant at 5% interval.

Table: 6 No of attempts

Group	No	Success in				P value
		1st attempt	%	2nd attempt	%	0.313 ***Not significant***
LMA-S	30	29	96.7%	1	3.3%	
ETT	30	30	100%	0	0	

LMA-S insertion was successful in 29/30 in first attempt while 1 patient required second attempt. ETT insertion was successful in all 30 patients in the first attempt.

Statistical analysis reveals P value of 0.313. the two groups are statistically insignificant in no of attempts required for successful insertion.

Table: 7 Time taken for insertion

Group	No	Mean	SD	P value
LMA-S	30	15.20	2.70	<0.001 ***Significant***
ETT	30	24.77	2.54	

The mean time taken for insertion in LMA-S group is 15.2 seconds and the mean time taken for insertion in ETT group is 24.77 seconds.

Student's t test reveals P value of <0.001 which is statistically significant.

Table: 8 Ease of insertion of Gastric tube

Group	NO	Easy		Difficult		P value
		NO	%	NO	%	0.005 ***significant***
LMA-S	30	30	100	0	0	
ETT	30	23	76.7	7	23.3	

In LMA-S group, gastric tube was inserted easily in all 30 cases. In ETT group gastric tube was inserted easily in 23 patients and with difficulty in 7 patients. Qualitative data values are compared by chi-square test. Statistical analysis reveals P value of 0.005 which is statistically significant at 5% interval.

Table: 9 No of attempts for gastric tube insertion

Group	No	Success in				P value
		1^{st} attempt	%	2^{nd} attempt	%	0.076 ***Not significant***
LMA-S	30	30	100%	0	0	
ETT	30	27	90%	3	10%	

In LMA-S group, gastric tube insertion was successful in all 30 patients in first attempt. In ETT group, gastric tube insertion was successful in 27 patients in the first attempt and in 3 patients in second attempt.

Statistical analysis reveals P value of 0.076. The two groups are statistically insignificant in no of attempts for gastric tube insertion.

Table: 10 Gastric distension

SCALE	LMA-S		ETT		P value
	NO	%	NO	%	
0	19	63.3	21	70.0	0.327
1	8	26.7	4	13.3	***Not significant***
2	3	10.0	2	6.7	
3	0	0	2	6.7	
5	0	0	1	3.3	

Student's *t*-test reveals P value of 0.327 which is not significant. This indicates that LMA-S provides good airway seal and adequate pulmonary ventilation

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Table: 11 SpO_2

	Group	No	Mean	SD	P value
Baseline	LMA-S	30	99.43	0.85	0.229
	ETT	30	99.67	0.60	***Not significant***
Pre insertion	LMA-S	30	99.70	0.65	0.479
	ETT	30	99.80	0.40	***Not significant***
Post insertion at 0 min	LMA-S	30	99.57	0.72	0.849
	ETT	30	99.60	0.62	***Not significant***
Post insertion at 1 min	LMA-S	30	99.77	0.43	0.325
	ETT	30	99.87	0.34	***Not significant***
Post insertion at 3 min	LMA-S	30	99.87	0.34	0.325
	ETT	30	99.77	0.43	***Not significant***
Post insertion at 5 min	LMA-S	30	99.97	0.18	0.168
	ETT	30	99.77	0.42	***Not significant***

SpO2 was measured preoperatively, before intubation, immediately after intubation, at 1 minute, 3 minutes and 5 minutes post intubation.

Statistical analysis by students *t* test reveals P value of 0.229, 0.479, 0.849, 0.325, 0.325 and 0.168 respectively which are not significant. Hence there is no significant oxygenation difference between two techniques.

Table: 12 Haemodynamic Responses

Table: 12a Heart Rate

	Group	No	Mean	SD	P value
Baseline	LMA-S	30	97.80	13.35	0.196
	ETT	30	93.13	14.28	***Not significant***
Pre insertion	LMA-S	30	90.13	14.06	0.468
	ETT	30	92.83	14.54	***Not significant***
Post insertion at 0 min	LMA-S	30	94.43	15.38	0.014
	ETT	30	104.2	14.55	***significant***
Post insertion at 1 min	LMA-S	30	91.53	12.98	0.008
	ETT	30	101.17	14.15	***significant***
Post insertion at 3 min	LMA-S	30	88.7	12.04	0.015
	ETT	30	97.03	13.76	***significant***
Post insertion at 5 min	LMA-S	30	87.47	11.58	0.018
	ETT	30	95.37	13.51	***significant***

Table: 12b Systolic Blood Pressure

	Group	No	Mean	SD	P value
Baseline	LMA-S	30	122.33	12.29	0.482 ***Not significant***
	ETT	30	120.13	11.78	
Pre insertion	LMA-S	30	97.60	10.79	0.299 ***Not significant***
	ETT	30	100.63	11.61	
Post insertion at 0 min	LMA-S	30	107.13	12.36	0.035 ***significant***
	ETT	30	114.03	12.38	
Post insertion at 1 min	LMA-S	30	107.77	9.65	0.028 ***significant***
	ETT	30	113.93	11.48	
Post insertion at 3 min	LMA-S	30	108.73	8.80	0.002 ***significant***
	ETT	30	116.83	10.44	
Post insertion at 5 min	LMA-S	30	107.70	7.53	0.001 ***significant***
	ETT	30	115.60	9.54	

Table: 12cDiastolic Blood Pressure

	Group	No	Mean	SD	P value
Baseline	LMA-S	30	81.40	8.66	0.071 ***Not significant***
	ETT	30	77.50	7.73	
Pre insertion	LMA-S	30	63.63	9.24	0.230 ***Not significant***
	ETT	30	66.13	6.46	
Post insertion at 0 min	LMA-S	30	65.90	9.04	<0.001 ***significant***
	ETT	30	75.00	6.82	
Post insertion at 1 min	LMA-S	30	67.80	8.07	0.001 ***significant***
	ETT	30	74.40	6.17	
Post insertion at 3 min	LMA-S	30	68.13	7.68	<0.001 ***significant***
	ETT	30	76.00	5.73	
Post insertion at 5 min	LMA-S	30	67.13	4.99	<0.001 ***significant***
	ETT	30	75.33	5.37	

Table: 12d Mean Arterial Pressure

	Group	No	Mean	SD	P value
Baseline	LMA-S	30	94.98	9.12	0.155 ***Not significant***
	ETT	30	91.40	8.63	
Pre insertion	LMA-S	30	74.90	9.04	0.192 ***Not significant***
	ETT	30	77.43	7.80	
Post insertion at 0 min	LMA-S	30	79.76	8.52	<0.001 ***significant***
	ETT	30	87.70	7.88	
Post insertion at 1 min	LMA-S	30	80.08	7.94	0.002 ***significant***
	ETT	30	87.20	7.04	
Post insertion at 3 min	LMA-S	30	81.43	7.26	<0.001 ***significant***
	ETT	30	89.26	6.33	
Post insertion at 5 min	LMA-S	30	80.33	4.98	<0.001 ***significant***
	ETT	30	88.43	5.86	

Heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were measured pre operatively, pre intubation, immediately after intubation and at 1mt, 3mt, 5mts after intubation. The actual values are documented in the tabular column.

Statistical analysis by students t test reveals significant blood pressure and heart rate changes immediate post intubation, 1mt, 3mt, and 5mts after intubation.

Hence there is a significant haemodynamic response with ETT when compared to LMA-S.

Table: 13 $EtCO_2$

	Group	No	Mean	SD	P value
Baseline	LMA-S	30	36.97	0.85	0.835
	ETT	30	37.03	1.52	***Not significant***
Post inflation	LMA-S	30	39.03	1.32	0.951
	ETT	30	39.07	2.67	***Not significant***
Post deflation	LMA-S	30	37.07	1.55	0.058
	ETT	30	37.97	1.88	***Not significant***

$EtCO_2$ was recorded after intubation, after peritoneal inflation with CO_2 and after peritoneal deflation. The actual values are documented in the tabular column.

Student's t test reveals P value of 0.835, 0.951 and 0.058 respectively which are not significant. This indicates that LMA-S provides good pulmonary ventilation.

Table: 14 Blood staining of devices

Group	No	Blood staining				P value
		Yes	%	No	%	
LMA-S	30	2	6.7	28	93.3	0.150
ETT	30	0	0	30	100	***Not significant***

Blood staining in the airway noted after extubation indicates airway trauma. It occurred in 2/30 cases with LMA-S and not seen with ETT. Chi square test reveals P value of 0.150 which is not significant.

Table: 15 Incidence of complications

	Group	No	Yes		No		P value
Sore throat	LMA-S	30	0	0	30	100	0.001
	ETT	30	9	30	21	70	***Significant***
Hoarseness of voice	LMA-S	30	0	0	30	100	0.002
	ETT	30	8	26.7	22	73.3	***Significant***
Laryngospasm	LMA-S	30	1	3.3	29	96.7	0.313
	ETT	30	0	0	30	100	***Not significant***

Sore throat occurred in no cases with LMA-S and 9/30 cases with ETT. Statistical analysis reveals a P value of 0.001 which is significant.

Laryngospasm occurred in 1/30 of LMA-S group and is not seen with ETT group. Statistical analysis reveals P Value of 0.313 which is not significant.

Hoarseness of voice did not occur with LMA-S group and seen in 8/30 patients in ETT group. Statistical analysis reveals P Value of 0.002 which is significant.

DISCUSSION

LMA-Supreme, with its unique first and second seal provides effective positive pressure ventilation without the risk of gastric distension, regurgitation and aspiration of gastric contents.

This study is designed to compare the clinical performance of LMA-Supreme with the conventional Endotracheal tube.

Ease of insertion of airway device

Insertion of LMA-Supreme was easy in vast majority of population. In our study LMA-Supreme is inserted with ease in 96.7% of patients. Both ETT and LMA-S are inserted with similar ease.

This is in concurrence with the study conducted by **Abdi et al**[1]. They compared LMA-Supreme and ETT in gynaecological laparoscopic surgeries. In this study all the LMA-S insertion was graded easy (100%). **Seet et al**[18] in 2010 conducted a study to compare LMA-S and PLMA. Insertion was graded easy in 100% of patients in LMA-S group. The small amount of difficulty in insertion found in our study can be explained by the inexperienced hands.

Number of attempts to successful placement

LMA-Supreme was successfully inserted and allowed optimal controlled ventilation in all patients. The first attempt success rate was 96.7% with overall insertion success of 100%.

The studies conducted on LMA-Supreme by **Tan et al**[17] and **Belena et al**[16] reported 100% and 91% first attempt success rate and as with our study, reported no failures of use.

The overall success rate in many previous studies is 100%, and is achieved in 2 attempts.

Time taken for insertion of airway device:

Securing an effective airway was rapid compared to ETT. The mean time to ventilation was 15.2 seconds, which is shorter than that required for ETT. Abdi et al in 2010 showed similar results by comparing LMA-Supreme and ETT.

This is also strongly supported by the studies conducted by **Tan et al**[17], **Belena et al**[16] and **Teoh et al**[11] with LMA-S. The mean insertion time was found to be 15, 12 and 14.3 seconds, respectively. This smaller mean insertion time can particularly be beneficial when it is used as an airway rescue device.

Ease of insertion of gastric tube

The smoother and more rigid gastric drain channel in the LMA-Supreme appears to facilitate the insertion of 14 Fr gastric tube with more ease compared to the conventional method employed with ETT.

In our study, 100% of gastric tube insertions were graded as easy against 76.7% in ETT group. The study conducted by **Abdi et al**[1] supports our observation.
All the insertions made were successful. This indicates that in all cases the reinforced tip of LMA-S was never folded over.

Belena et al[16] and **Teoh et al**[11] also showed that gastric insertion was easier and achieved more quickly with LMA-Supreme compared to other supraglottic airway devices.

Number of attempts for gastric tube insertion

In our study gastric tube was placed successfully in first attempt in all patients with the success rate of 100%. The first attempt success rate in ETT group was 90%. This observation is strongly supported by **Pellikan et al**[9] who evaluated the efficacy of LMA-S over ETT in laparoscopic surgery.

Gastric distension

In our study there was no significant gastric distension with both the groups. LMA-Supreme thus provides an added advantage over older supraglottic devices by preventing aspiration. **Kohama et al[25]** compared Supreme with SoftSeal laryngeal masks. The amount of air entering the stomach was significantly lower with the Supreme than the Soft Seal (14.6±11.8 ml vs 180.2±123.0 ml, respectively; $P<0.005$).

Pulmonary ventilation

In our study there was no significant difference in SpO_2 between two groups. $EtCO_2$ did not differ significantly before inflation, after inflation and after deflation between both groups. This is supported by the study done by **Vila et al[2]** who compared LMA-Supreme with ETT in laparoscopic gynaecological surgeries. Etco2 were similar in both the groups at all moments. Thus LMA-Supreme provides good pulmonary ventilation and can act as an alternate device for ETT.

Haemodynamic responses

The smoother, thin wedge shaped cuff bowl allows comfortable insertion, good airway tolerance and smoother emergence. It resulted in less change in heart rate, SBP, DBP and MAP after insertion. **Vila et al[2]** observed similar haemodynamic conditions in their study. The intubation response to ETT is well known and this can be overcome by employing LMA-Supreme as an alternative.

Blood staining

The smoother and easier insertion observed with LMA-Supreme results in less airway trauma. The drain tube by facilitating easier insertion of gastric tube also reduces the chances of airway injury. In our study blood staining was noted in 6.7% patients with LMA-S. **Tan et al[17], Seet et al[18], Lopez et al[27]** evaluated the efficacy of LMA-S and found similar incidences of blood staining.

Incidence of complications

The unique design of LMA-Supreme makes it a pharyngolaryngeal sparing strategy. **Abdi et al**[1] showed lesser incidence of sore throat and hoarseness compared to ETT. In our study none of the patients in LMA-S group complained of sore throat and hoarseness of voice against 9/30 and 8/30, respectively in ETT group. The difference is significant, thus incidence of complications is less with LMA-S. **Tan et al[17]**, **Kohama et al[25]**, **Seet et al[18]** showed reduced incidences of pharyngo laryngeal discomfort.

The LMA-Supreme has the advantage of being a single-use device. There is an increased tendency towards single-use devices due to the awareness that protein and bacteria persist on surgical and anaesthetic instruments following decontamination and sterilisation. Being a single use device it can reduce or even eliminate this problem.

Our study has certain limitations. First, we studied a female population with normal airways undergoing elective laparoscopic gynaecological surgeries. The

data collected cannot be directly extrapolated to the use of LMA-Supreme in males. Second, blinding was not practically possible, which may be a possible source of bias. Finally, being a single-use device the cost effectiveness was not addressed.

SUMMARY

From this Prospective, Randomised, Comparative single blinded case control study which evaluated the effectiveness of LMA-S and ETT, it is found that,

- Both LMA-S and ETT were intubated with similar ease (P = 0.314).

- Number of attempts required for successful insertion of LMA-S was more than that of ETT but not statistically significant.

- Time taken for insertion of LMA-S was lesser than ETT, which is statistically significant (P <0.001).

- Ease of insertion of Gastric tube with LMA-S was better than that of ETT, which is statistically significant (P = 0.005)

- Number of attempts required for successful insertion of gastric tube was lesser with LMA-S than with ETT but not statistically significant.

- No significant gastric distension occurred intra operatively with both LMA-S and ETT. So, LMA-S provides good oropharyngeal seal and pulmonary ventilation.

- Both the techniques had no significant differences in SpO_2 and $EtCO_2$ before inflation, after inflation and after deflation. Thus LMA-S is also a good airway device for laparoscopic surgeries.

- Haemodynamically there was a significant difference between two groups with regard to heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure after insertion. LMA-S was found to be a better device in this aspect.

- Blood staining on LMA-S and ETT were comparable and was not statistically significant.

- Incidence of post operative sore throat and hoarseness of voice was less with LMA-S than with ETT and was statistically significant.

CONCLUSION

LMA-Supreme is an equally effective airway device to ETT in laparoscopic gynaecological surgeries. It has potential advantages like rapid placement, less haemodynamic response, less airway trauma, less pharyngolaryngeal morbidity and better oesophageal seal resulting in reduced risk of gastric distension and aspiration.

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PATIENT CONSENT FORM

Study title : Prospective comparison of LMA-Supreme and Endotracheal Tube in Elective
Laparoscopic Gynaecological Surgeries.
.

Study centre : Department of Anaesthesiology,
Govt. Kasturba Gandhi Hospital for Women and Children, Chennai.

Participant name : Age: Sex:
I.P.No:

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

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that i am free to withdraw at anytime without giving any reason.

I understand that the investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if i withdraw from the study. I understand that my identity will not be revealed in any information released to the third parties or published, unless as required under the law . I agree not to restrict the use of any data or results that arise from the study.

Time:

Date: signature / thumb impression of Patient

Place: Patient name:

Signature of the investigator:

Name of the investigator:

PROFORMA

DATE: ROLL NO: AIRWAY DEVICE:

NAME: AGE: SEX:

IP NO: DIAGNOSIS: SURGICAL PROCEDURE DONE:

Ht: CVS: HB:

Wt: RS:

AIRWAY: MMC - IID - DENTITION -

PRE OP ASSESSMENT: ASA I / ASA II

HISTORY: Any Co-morbid illness

H/O Documented Difficult Airway

H/O previous surgeries

MEASURES OF STUDY OUTCOME:

1) INTUBATION RESPONSE:

HR SBP DBP MAP SPO2

PRE OP:

PRE INTUBATION:

POST INTUBATION:

1 MIN:

3 MIN:

5 MIN:

5) ENDTIDAL CO2

BASELINE:

POST INFLATION:

POST DEFLATION:

2) AIRWAY DEVICE

EASE OF INSERTION: EASY DIFFICULT

NO OF ATTEMPTS:

INSERTION TIME:

3) GASTRIC TUBE:

EASE OF INSERTION: EASY DIFFICULT

NO OF ATTEMPTS : GASTRIC DISTENSION:

4) **COMPLICATIONS AT EXTUBATION**:

POST OP SORE THROAT:

LARYNGOSPASM:

BLOOD STAINING OF AIRWAY DEVICE:

HOARESNESS OF VOICE:

.

S.NO	NAME	AGE	DEVICE	BMI	ASA	MPC	AD			OGT			COMPLICATION			
							EOI	NOA	TTI	EOI	NOA	GD	ST	LS	BS	HV
1	HAMSA	27	LMA-S	21.6	I	I	E	1	15	E	1	0	N	N	Y	N
2	MAHALAKSHMI	37	LMA-S	22.5	I	I	E	1	12	E	1	1	N	N	N	N
3	ELAVARASI	28	LMA-S	26.5	II	I	E	1	16	E	1	0	N	N	N	N
4	GUNA	24	LMA-S	21.5	I	II	E	1	12	E	1	0	N	N	N	N
5	PUSHPA	22	LMA-S	20.4	I	I	E	1	13	E	1	0	N	N	N	N
6	SATHIYA	29	LMA-S	22.2	I	II	E	1	15	E	1	0	N	N	N	N
7	RAJALAKSHMI	31	LMA-S	24.9	I	II	E	1	14	E	1	1	N	N	N	N
8	UMA	31	LMA-S	21.5	II	I	E	1	16	E	1	2	N	N	N	N
9	REKHA	22	LMA-S	23.5	I	II	D	2	25	E	1	1	N	Y	Y	N
10	PREMASHEELA	29	LMA-S	23.3	II	I	E	1	19	E	1	1	N	N	N	N
11	DEEPA	23	LMA-S	24.1	I	I	E	1	16	E	1	0	N	N	N	N
12	DHAVAMANI	36	LMA-S	22.8	I	I	E	1	13	E	1	0	N	N	N	N
13	SELVAMUTHA	26	LMA-S	21.9	I	I	E	1	13	E	1	0	N	N	N	N
14	PARIMALA	21	LMA-S	22	I	I	E	1	17	E	1	0	N	N	N	N
15	RENUKADEVI	24	LMA-S	23.4	I	I	E	1	16	E	1	1	N	N	N	N
16	SUBITHA	35	LMA-S	26	I	II	E	1	15	E	1	2	N	N	N	N
17	GEETHA	19	LMA-S	22.4	I	I	E	1	12	E	1	1	N	N	N	N
18	SUGANTHY	30	LMA-S	25	I	II	E	1	18	E	1	1	N	N	N	N
19	DESAM	30	LMA-S	21.1	I	II	E	1	12	E	1	0	N	N	N	N
20	SEETHA	27	LMA-S	23.7	I	I	E	1	13	E	1	0	N	N	N	N
21	SHANKARI	32	LMA-S	21.3	I	I	E	1	15	E	1	0	N	N	N	N
22	SUGANTHA	24	LMA-S	23.6	I	I	E	1	14	E	1	0	N	N	N	N
23	DURGALAKSHMI	31	LMA-S	24.6	I	I	E	1	16	E	1	0	N	N	N	N
24	SARGUNAM	32	LMA-S	27.3	I	I	E	1	17	E	1	0	N	N	N	N
25	BANU	53	LMA-S	23.5	I	I	E	1	19	E	1	0	N	N	N	N
26	KAMATCHI	26	LMA-S	22.2	I	I	E	1	16	E	1	1	N	N	N	N
27	JEYALAKSHMI	35	LMA-S	23.4	II	II	E	1	14	E	1	0	N	N	N	N
28	DHANALAKSHMI	26	LMA-S	25.1	II	I	E	1	15	E	1	2	N	N	N	N
29	SANGEETHA	23	LMA-S	21.9	I	II	E	1	13	E	1	0	N	N	N	N
30	SARANYA	20	LMA-S	22.4	I	I	E	1	15	E	1	0	N	N	N	N

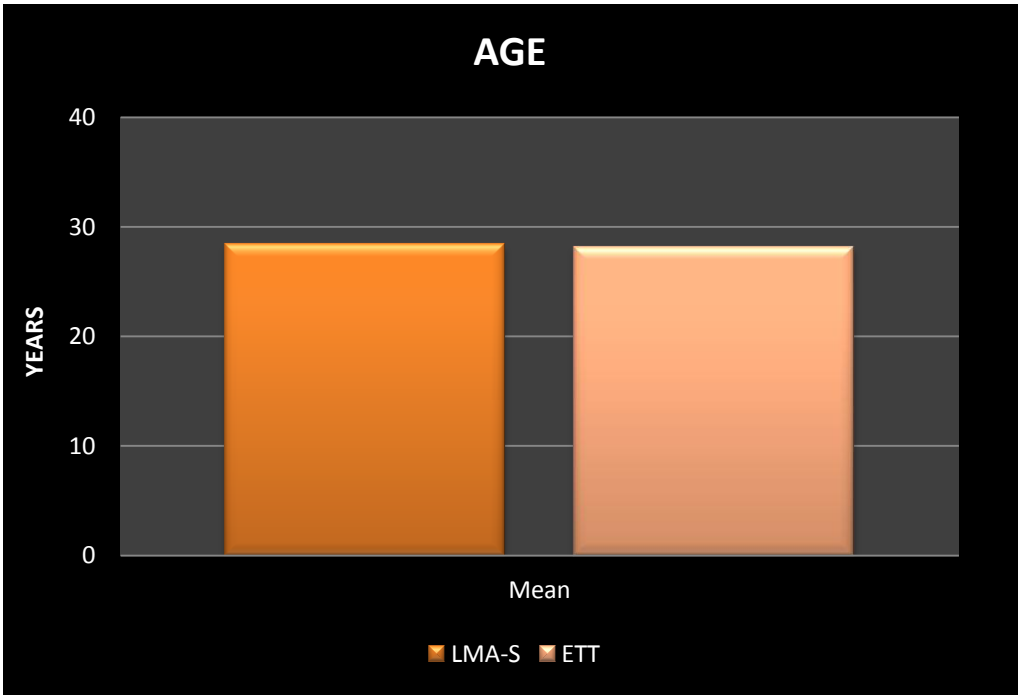
S.NO	DEVICE	SPO_2 (%)						HEART RATE (beats/min)						$ETCO_2$ (mm Hg)		
		PRE OP	PRE IN	POST IN	1 MIN	3 MIN	5 MIN	PRE OP	PRE IN	POST IN	1 MIN	3 MIN	5 MIN	BASELINE	PI	PD
1	LMA-S	100	100	98	99	100	100	86	85	90	92	92	91	36	38	36
2	LMA-S	100	100	100	100	100	100	95	86	87	87	85	80	38	39	37
3	LMA-S	98	100	100	100	100	100	72	74	70	75	68	71	36	38	35
4	LMA-S	99	98	100	100	100	100	98	90	90	85	80	76	37	39	38
5	LMA-S	100	99	100	100	100	100	110	116	123	115	112	105	38	40	36
6	LMA-S	100	98	100	100	100	100	95	112	110	105	109	98	38	40	38
7	LMA-S	100	99	100	100	100	100	86	80	96	95	83	86	37	38	36
8	LMA-S	100	100	100	100	100	100	79	82	81	84	73	75	37	41	39
9	LMA-S	100	100	100	100	100	100	122	126	125	116	110	102	36	38	37
10	LMA-S	100	100	100	100	100	100	88	85	95	94	82	82	39	40	38
11	LMA-S	97	100	99	99	100	100	92	92	80	80	75	70	37	40	38
12	LMA-S	98	100	98	99	100	100	94	90	85	83	86	89	37	39	38
13	LMA-S	99	100	98	99	99	100	109	112	120	122	109	105	38	41	37
14	LMA-S	99	100	100	100	99	100	116	115	119	107	105	102	37	39	36
15	LMA-S	100	100	100	99	100	100	116	100	102	83	89	99	37	40	41
16	LMA-S	100	100	100	100	99	100	82	86	89	85	88	89	36	38	36
17	LMA-S	100	100	100	100	100	100	90	92	100	93	95	100	38	39	39
18	LMA-S	100	100	100	100	100	100	116	82	106	91	99	112	36	38	37
19	LMA-S	100	100	100	100	100	100	105	85	83	90	94	86	38	37	35
20	LMA-S	100	100	99	99	100	99	96	75	82	86	84	89	36	38	36
21	LMA-S	99	100	99	100	100	100	112	90	115	110	96	80	38	43	40
22	LMA-S	99	99	99	100	99	100	93	82	91	85	86	73	37	38	36
23	LMA-S	100	100	98	100	100	100	89	86	89	79	76	92	37	41	40
24	LMA-S	99	98	99	100	100	100	82	68	68	72	75	70	36	37	36
25	LMA-S	100	100	100	99	100	100	119	90	100	101	95	93	37	39	35
26	LMA-S	98	100	100	100	100	100	102	86	90	93	91	85	37	38	36
27	LMA-S	98	100	100	100	100	100	81	65	69	75	71	78	36	39	37
28	LMA-S	100	100	100	100	100	100	110	91	96	89	85	86	37	38	37
29	LMA-S	100	100	100	100	100	100	95	86	88	75	79	75	36	39	36
30	LMA-S	100	100	100	100	100	100	104	95	94	99	89	85	36	39	36

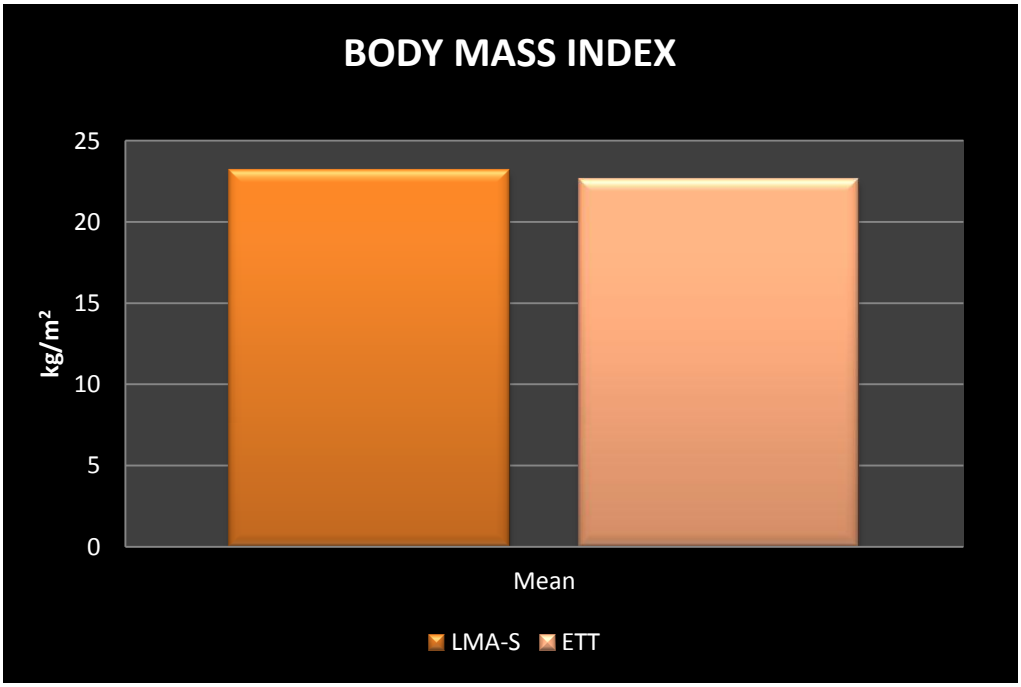
S.NO	DEVICE	PRE OP			PRE IN			POST IN			1 MIN			3 MIN			5 MIN		
		SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP
1	LMA-S	128	76	93	96	69	78	100	60	73	107	65	79	108	72	84	107	70	82
2	LMA-S	133	85	101	102	63	76	110	69	83	105	62	76	111	69	83	106	65	78
3	LMA-S	116	83	94	98	56	70	109	68	82	115	65	81	119	79	92	115	71	85
4	LMA-S	145	92	109	113	69	84	115	68	84	114	72	86	116	59	78	110	61	77
5	LMA-S	105	76	85	86	60	69	90	61	71	95	68	77	100	72	81	101	70	80
6	LMA-S	112	65	80	95	64	74	96	68	77	102	71	81	108	75	86	105	68	80
7	LMA-S	124	89	101	106	59	75	117	68	84	116	75	88	116	80	92	114	76	88
8	LMA-S	118	86	96	101	69	80	105	63	77	109	65	79	110	63	78	110	65	80
9	LMA-S	120	80	93	80	61	67	93	65	74	99	72	81	97	56	69	99	63	75
10	LMA-S	96	72	80	86	65	72	93	68	76	99	65	76	100	60	73	99	75	83
11	LMA-S	121	80	94	90	50	63	103	41	62	105	58	73	97	52	67	100	56	70
12	LMA-S	136	89	105	105	65	78	112	72	85	109	68	81	105	72	83	96	63	74
13	LMA-S	99	56	70	82	51	61	101	62	75	113	72	85	116	72	86	110	76	87
14	LMA-S	130	90	103	91	52	65	103	60	74	93	52	65	96	58	70	95	60	71
15	LMA-S	135	77	96	81	58	66	95	65	75	94	56	68	99	61	73	101	65	77
16	LMA-S	124	84	97	94	72	79	100	62	75	93	61	72	100	69	79	110	65	80
17	LMA-S	120	80	93	90	60	70	92	46	61	94	50	64	99	56	70	105	60	75
18	LMA-S	121	72	88	85	46	59	149	59	89	108	58	74	115	64	81	112	66	81
19	LMA-S	145	96	112	119	82	94	115	79	91	116	76	89	112	73	86	110	69	82
20	LMA-S	133	94	107	114	81	92	125	81	96	122	74	90	118	70	86	115	65	81
21	LMA-S	115	81	92	99	53	68	115	72	86	110	75	87	112	77	88	111	73	85
22	LMA-S	126	85	99	102	59	73	119	73	88	121	75	91	120	72	88	113	69	83
23	LMA-S	118	75	89	98	68	78	110	75	87	125	78	94	122	65	84	120	65	83
24	LMA-S	114	81	92	90	56	67	95	53	67	99	62	74	92	65	74	95	64	74
25	LMA-S	126	95	105	111	78	89	114	80	92	113	85	94	116	82	93	112	73	86
26	LMA-S	106	75	85	91	63	72	100	71	84	106	75	85	108	72	84	110	65	80
27	LMA-S	110	81	91	96	64	75	97	60	73	101	64	76	99	63	75	98	65	76
28	LMA-S	135	82	100	112	64	80	119	68	85	128	72	90	121	76	91	125	74	91
29	LMA-S	122	81	95	100	73	82	110	76	87	112	74	86	116	70	85	114	68	83
30	LMA-S	137	84	102	115	79	91	112	64	80	110	69	82	114	70	84	113	69	83

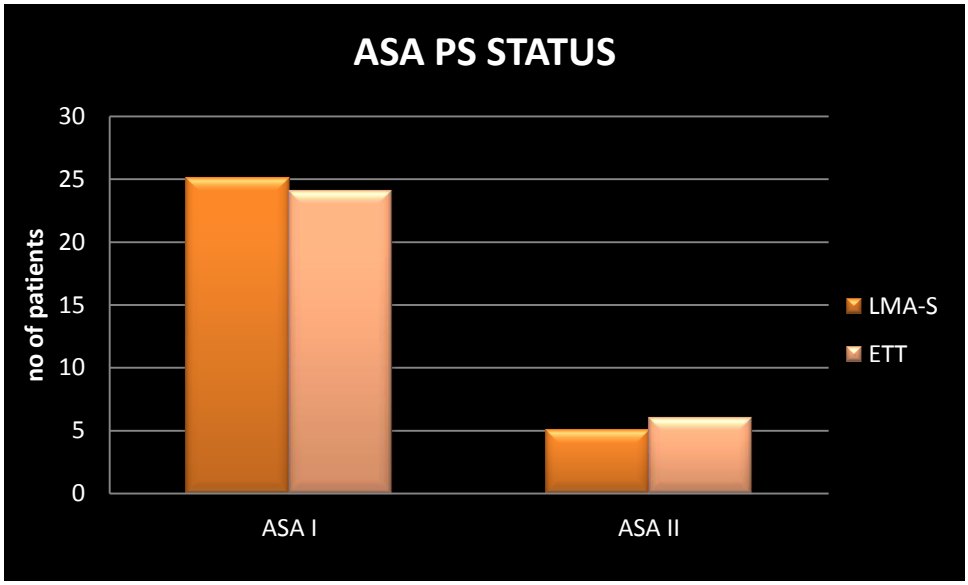
S.NO	NAME	AGE	DEVICE	BMI	ASA	MPC	AD			NGT			COMPLICATION			
							EOI	NOA	TTI	EOI	NOA	GD	ST	LS	BS	HV
1	MEENA	27	ETT	22.3	I	I	E	1	22	E	1	0	N	N	N	N
2	UMA	33	ETT	21.6	I	II	E	1	24	D	1	0	N	N	N	N
3	SARANYA	20	ETT	24.5	I	I	E	1	25	E	1	0	N	N	N	Y
4	KALAISELVI	28	ETT	21.5	I	I	E	1	21	E	1	0	Y	N	N	N
5	POONGODI	25	ETT	22.8	I	I	E	1	21	E	1	2	N	N	N	N
6	KANAGA	22	ETT	23.4	I	I	E	1	20	E	1	1	Y	N	N	N
7	PANJALAI	29	ETT	26.5	II	I	E	1	26	E	1	3	N	N	N	N
8	JANANI	26	ETT	21	I	II	E	1	24	D	2	0	N	N	N	N
9	NAJMA	35	ETT	9	II	I	E	1	23	E	1	0	N	N	N	N
10	SUJATHA	30	ETT	20.9	I	I	E	1	26	E	1	0	Y	N	N	Y
11	VICTORIA	19	ETT	24.1	II	I	E	1	26	D	1	5	Y	N	N	N
12	KUMUTHA	28	ETT	25	I	II	E	1	31	E	1	1	Y	N	N	Y
13	KANAGAVALLI	30	ETT	23.8	I	I	E	1	27	E	1	0	N	N	N	N
14	DHATCHAYINI	25	ETT	23.7	I	I	E	1	22	D	1	0	N	N	N	N
15	MALATHI	30	ETT	24.6	II	I	E	1	26	E	1	1	N	N	N	N
16	SANGARESHWARI	36	ETT	22.5	I	I	E	1	23	D	2	0	Y	N	N	N
17	BHAVANI	27	ETT	22.8	I	I	E	1	25	E	1	0	N	N	N	Y
18	SUDHA	35	ETT	21.9	I	II	E	1	26	D	2	0	Y	N	N	Y
19	KRITHIKA	22	ETT	20.6	I	II	E	1	22	E	1	1	N	N	N	N
20	ANBARASI	26	ETT	26	I	II	E	1	27	E	1	0	N	N	N	Y
21	DEVIKA	30	ETT	21.9	II	I	E	1	28	E	1	0	N	N	N	N
22	RAJESWARI	32	ETT	25.4	I	I	E	1	23	E	1	0	N	N	N	N
23	SASIKALA	33	ETT	22.3	I	II	E	1	24	E	1	0	N	N	N	N
24	NASREEN	24	ETT	24	I	I	E	1	29	E	1	0	N	N	N	Y
25	NASEEMA	24	ETT	21.6	II	I	E	1	26	E	1	3	N	N	N	N
26	BHARATHI	20	ETT	23.4	I	II	E	1	24	D	1	0	N	N	N	N
27	VARALAKSHMI	34	ETT	22.9	I	II	E	1	28	E	1	0	N	N	N	N
28	TAMILSELVI	28	ETT	22.8	I	I	E	1	23	E	1	0	Y	N	N	Y
29	VAIJEYANTHI	38	EET	23.1	I	I	E	1	25	E	1	0	N	N	N	N
30	SHAKILA	30	EET	23	I	I	E	1	26	E	1	2	Y	N	N	N

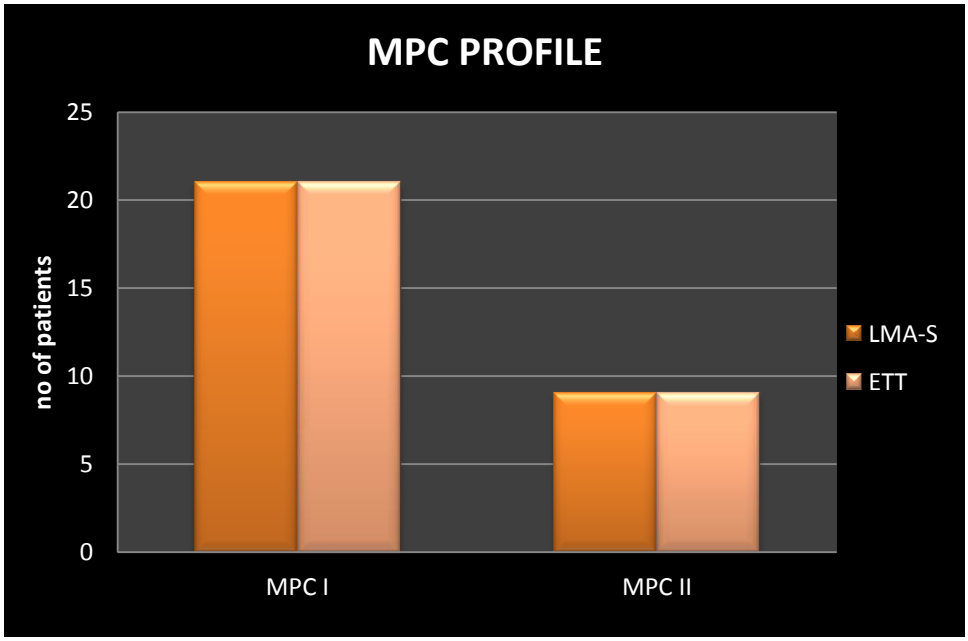
S.NO	DEVICE	SPO_2 (%)						HEART RATE (beats/min)						$ETCO_2$ (mm Hg)		
		PREOP	PRE IN	POST IN	1 MIN	3 MIN	5 MIN	PRE OP	PRE IN	POST IN	1 MIN	3 MIN	5 MIN	BASELINE	PI	PD
1	ETT	100	100	99	99	100	100	80	78	96	94	82	85	39	42	40
2	ETT	99	100	100	100	100	100	102	105	116	112	113	112	36	45	42
3	ETT	100	100	99	100	99	99	84	86	94	90	83	86	38	38	41
4	ETT	99	99	99	100	100	100	91	95	106	105	101	95	35	36	35
5	ETT	100	100	100	100	100	100	81	86	93	91	92	89	34	38	37
6	ETT	100	99	98	99	99	99	118	116	121	120	115	101	39	39	36
7	ETT	98	100	100	100	100	100	122	125	136	130	120	121	36	44	40
8	ETT	98	99	100	100	99	100	88	80	100	80	85	90	39	42	36
9	ETT	99	100	100	100	100	100	85	89	99	96	92	91	37	40	38
10	ETT	100	100	100	100	100	99	84	82	100	96	98	89	36	39	37
11	ETT	100	100	99	100	99	100	69	68	73	75	72	69	36	41	40
12	ETT	100	100	100	100	100	100	96	94	99	96	90	95	38	39	35
13	ETT	100	100	100	100	100	100	90	95	99	92	92	98	34	38	39
14	ETT	100	100	100	100	99	100	85	83	100	102	102	96	36	39	36
15	ETT	100	100	100	100	100	100	106	105	116	115	98	107	37	35	38
16	ETT	100	100	99	99	100	99	96	91	106	101	89	98	39	36	37
17	ETT	99	100	100	100	100	99	108	98	120	116	118	112	38	37	40
18	ETT	100	99	100	100	100	100	85	89	99	94	92	86	39	41	40
19	ETT	100	100	100	100	99	100	75	79	81	85	80	76	35	36	39
20	ETT	100	100	100	100	100	100	110	115	127	124	126	123	36	39	38
21	ETT	100	100	100	100	100	99	76	79	89	88	84	82	38	38	36
22	ETT	99	99	99	99	100	100	92	85	106	99	95	91	38	35	40
23	ETT	99	100	98	100	100	100	90	90	99	96	94	92	37	42	38
24	ETT	100	100	99	100	100	100	89	89	96	96	91	86	36	39	37
25	ETT	100	99	100	100	100	100	122	125	131	129	116	117	38	36	39
26	ETT	100	100	100	100	100	99	80	76	92	90	86	79	39	42	38
27	ETT	100	100	100	100	100	100	99	98	115	112	106	104	36	36	36
28	ETT	100	100	100	100	99	100	80	82	95	94	89	86	38	43	38
29	ETT	100	100	100	100	100	100	95	88	98	97	91	89	36	39	38
30	ETT	100	100	99	100	100	100	116	114	124	120	119	116	38	38	35

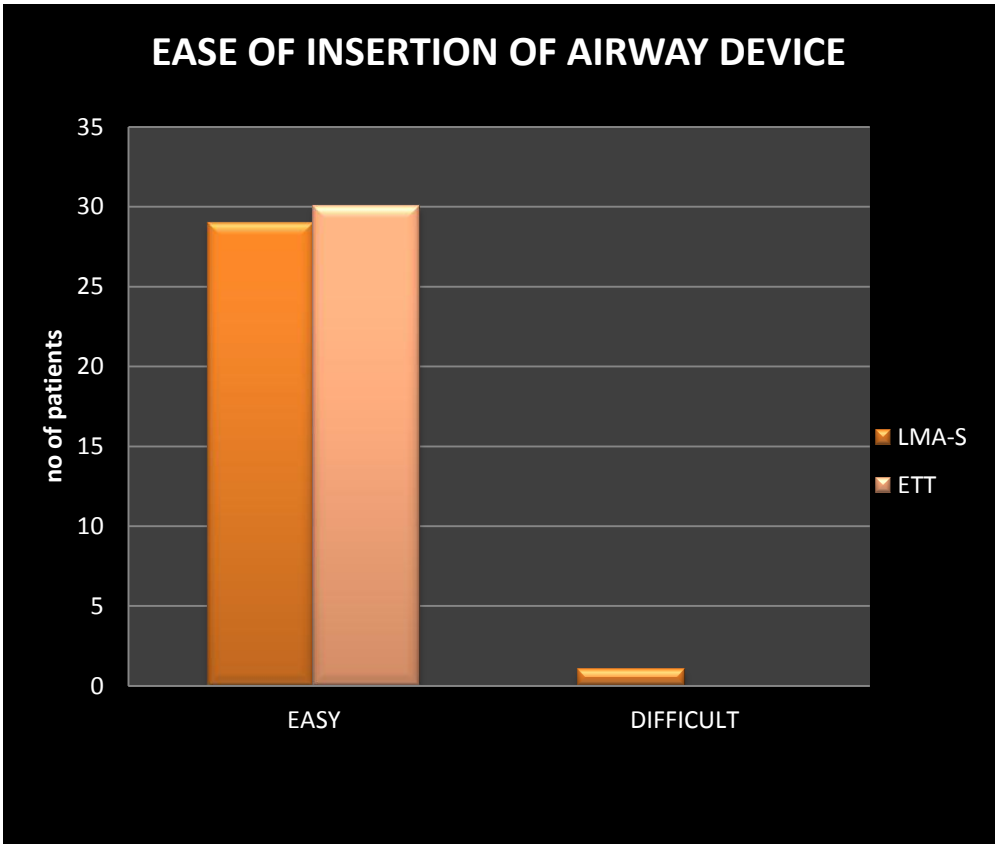
S.NO	DEVICE	PRE OP			PRE IN			POST IN			1 MIN			3 MIN			5 MIN		
		SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP
1	ETT	121	78	92	103	72	82	109	76	87	106	75	85	110	76	87	111	75	87
2	ETT	132	85	100	116	73	87	129	81	97	125	80	95	126	89	101	124	86	98
3	ETT	113	75	87	100	65	76	111	71	84	115	72	86	116	78	90	115	76	89
4	ETT	121	84	96	108	72	84	126	84	98	129	85	99	130	80	96	129	81	97
5	ETT	113	65	81	96	72	80	112	89	96	114	84	94	113	82	92	110	79	89
6	ETT	106	72	83	86	61	69	99	63	75	98	69	78	110	75	86	107	75	85
7	ETT	120	80	93	103	71	81	116	75	88	120	72	88	130	80	96	126	76	92
8	ETT	104	70	81	90	61	70	117	67	83	108	70	82	129	79	96	121	85	97
9	ETT	131	91	104	109	72	84	129	73	91	125	71	89	126	76	92	125	78	93
10	ETT	126	81	96	103	69	80	115	81	92	114	73	86	115	75	88	116	72	86
11	ETT	117	69	85	109	65	79	121	72	88	125	73	90	124	71	87	124	68	86
12	ETT	118	76	90	106	65	78	123	72	89	125	76	92	121	71	88	120	72	88
13	ETT	106	65	78	85	59	67	96	72	80	95	76	82	100	76	84	102	75	84
14	ETT	103	71	81	82	56	64	95	71	79	98	72	80	100	72	81	99	63	75
15	ETT	117	68	84	91	59	69	102	68	79	105	63	77	100	65	76	101	68	79
16	ETT	126	81	96	103	65	77	116	72	86	115	73	87	117	75	89	119	75	89
17	ETT	102	75	84	81	56	64	92	61	71	94	65	74	98	64	75	95	69	77
18	ETT	96	72	80	84	56	65	93	71	78	94	72	79	96	72	80	98	73	81
19	ETT	131	82	98	113	75	87	126	81	96	124	86	98	125	80	95	124	82	96
20	ETT	116	75	88	96	64	74	110	75	86	109	75	86	112	79	90	111	78	89
21	ETT	124	79	94	90	65	73	112	72	85	115	74	87	120	75	90	119	74	89
22	ETT	122	76	91	108	62	84	116	75	88	113	72	85	119	79	92	120	80	93
23	ETT	112	72	85	90	65	73	101	75	83	105	71	82	116	78	90	114	76	88
24	ETT	125	78	93	89	64	72	99	69	79	100	69	79	109	75	86	110	73	85
25	ETT	136	82	100	115	72	86	129	81	97	127	80	95	125	74	91	119	75	89
26	ETT	145	96	112	119	81	93	132	90	104	129	91	103	126	92	103	121	86	97
27	ETT	137	91	106	115	75	88	126	79	94	125	70	88	124	72	89	126	73	90
28	ETT	134	89	104	117	71	86	131	85	100	130	80	97	134	75	94	130	76	94
29	ETT	119	72	87	100	61	74	112	75	87	115	72	86	114	70	84	113	71	85
30	ETT	131	75	93	112	60	77	126	74	91	121	71	87	120	75	90	119	70	86

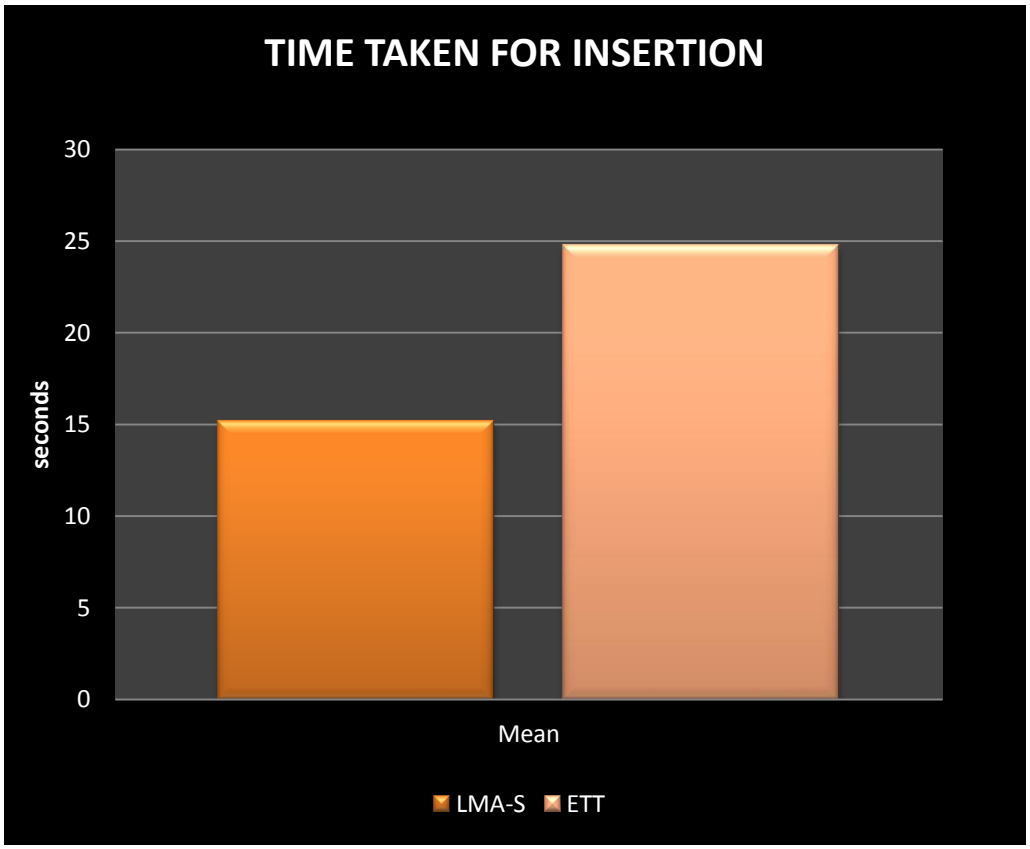

AGE
40
30
20
10
0
YEARS
Mean
LMA-S
ETT

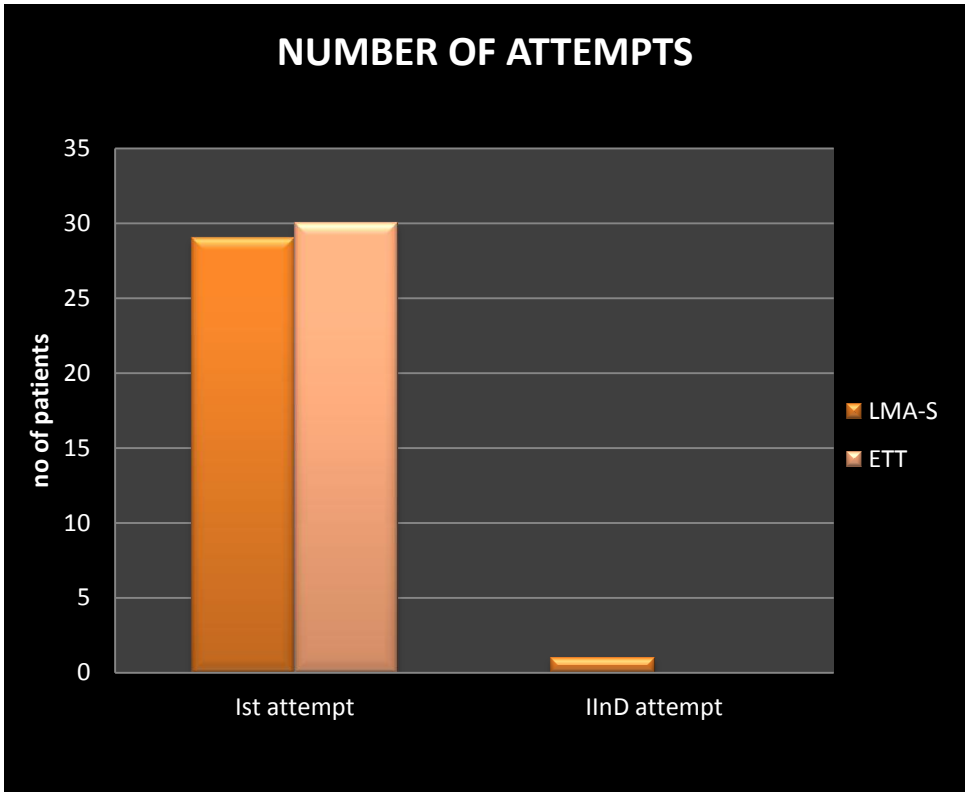

BODY MASS INDEX
25
20
15
10
5
0
kg/m2
Mean
LMA-S
ETT

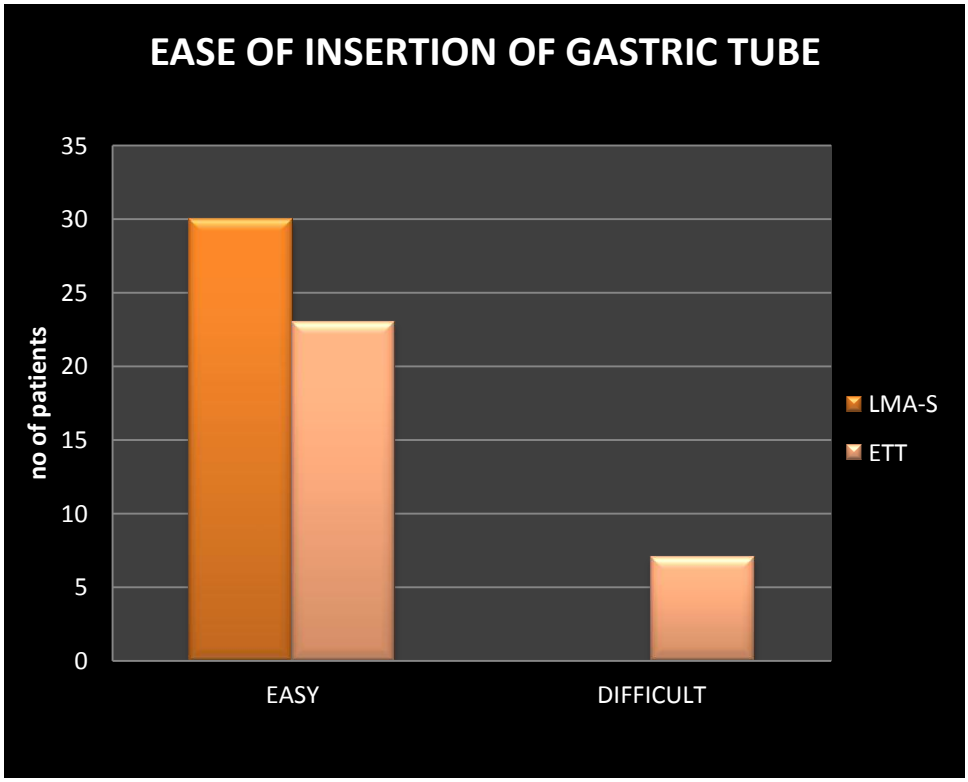

ASA PS STATUS
30
25
20
15
10
5
0
no of patients
ASA I
ASA II
LMA-S
ETT

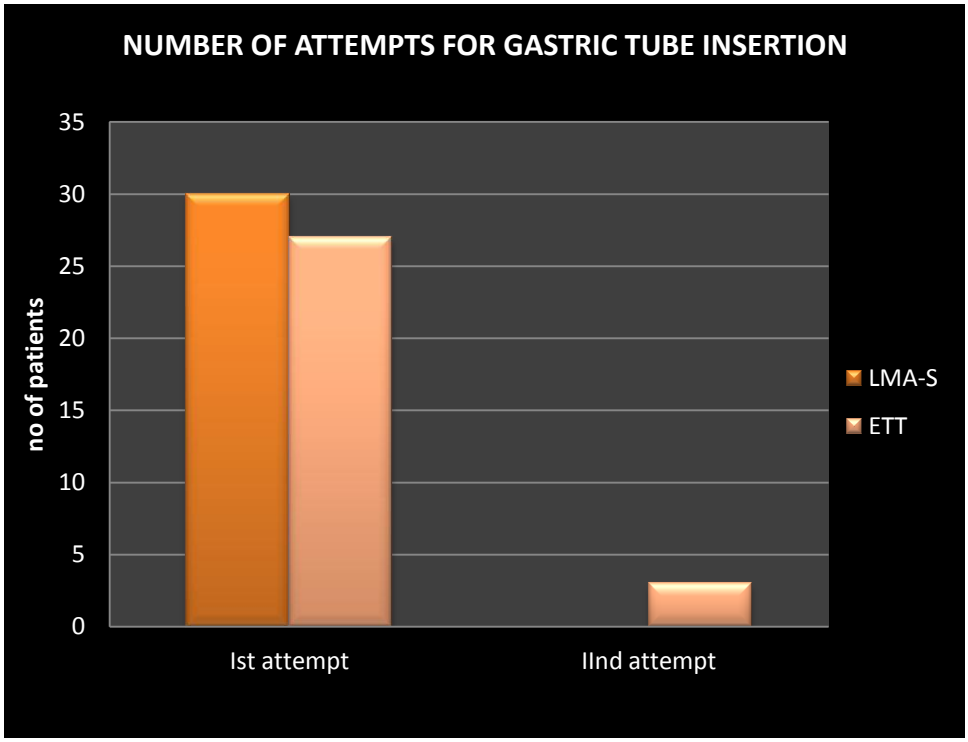

MPC PROFILE
25
20
15
10
5
0
no of patients
MPC I
MPC II
LMA-S
ETT

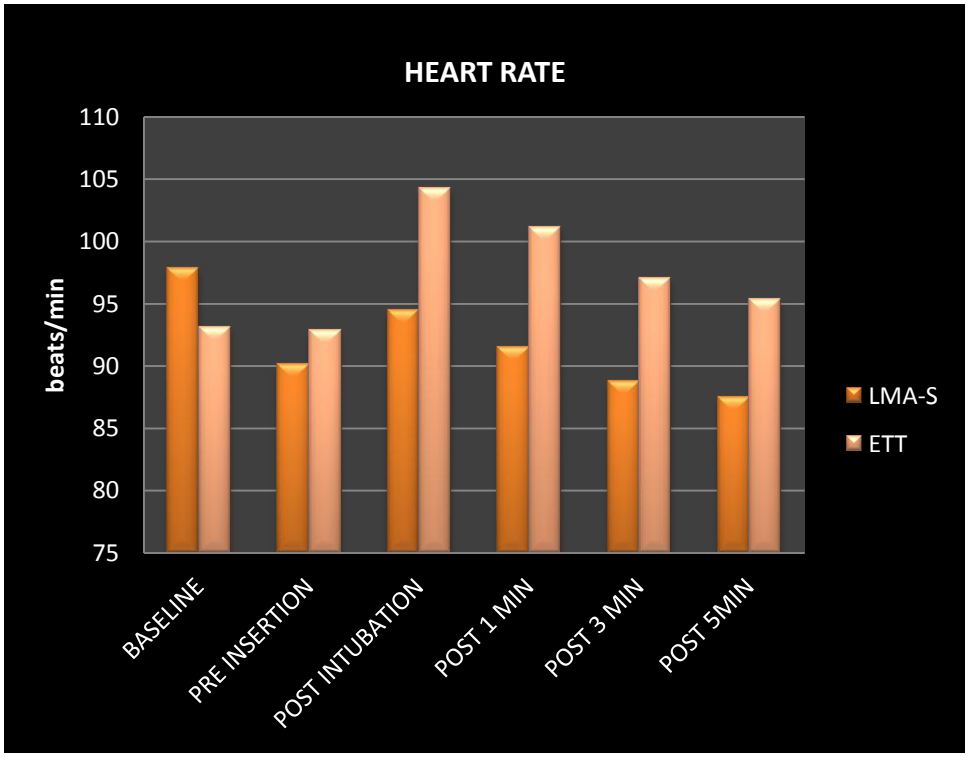

EASE OF INSERTION OF AIRWAY DEVICE
35
30
25
20
15
10
5
0
no of patients
EASY
DIFFICULT
LMA-S
ETT

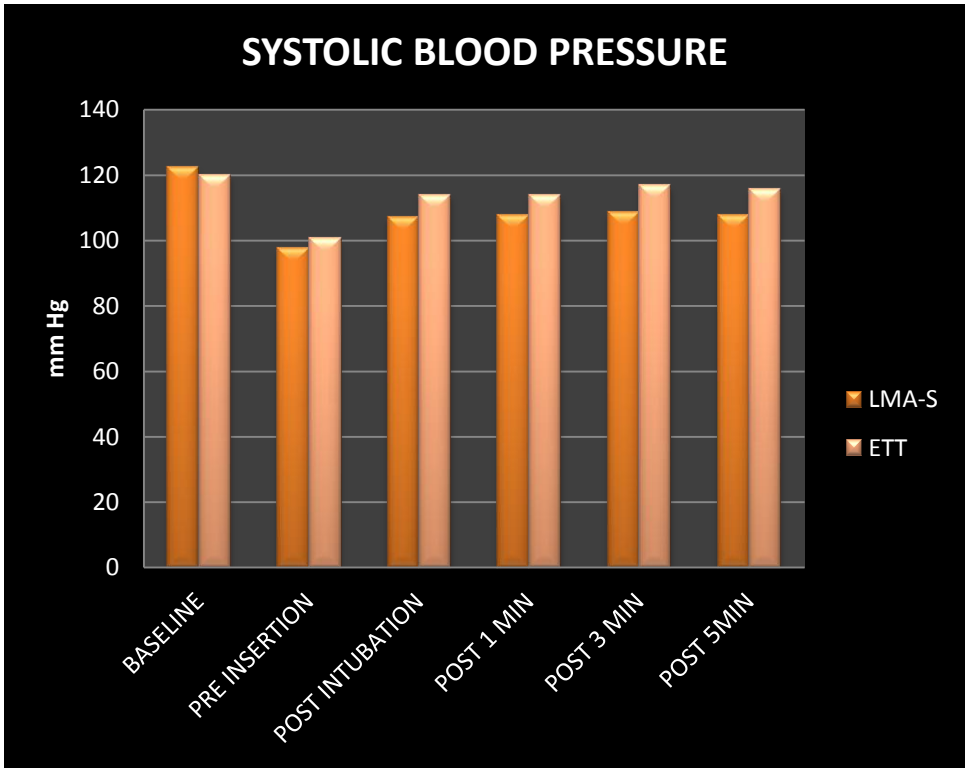

TIME TAKEN FOR INSERTION
30
25
20
15
10
5
0
seconds
Mean
LMA-S
ETT

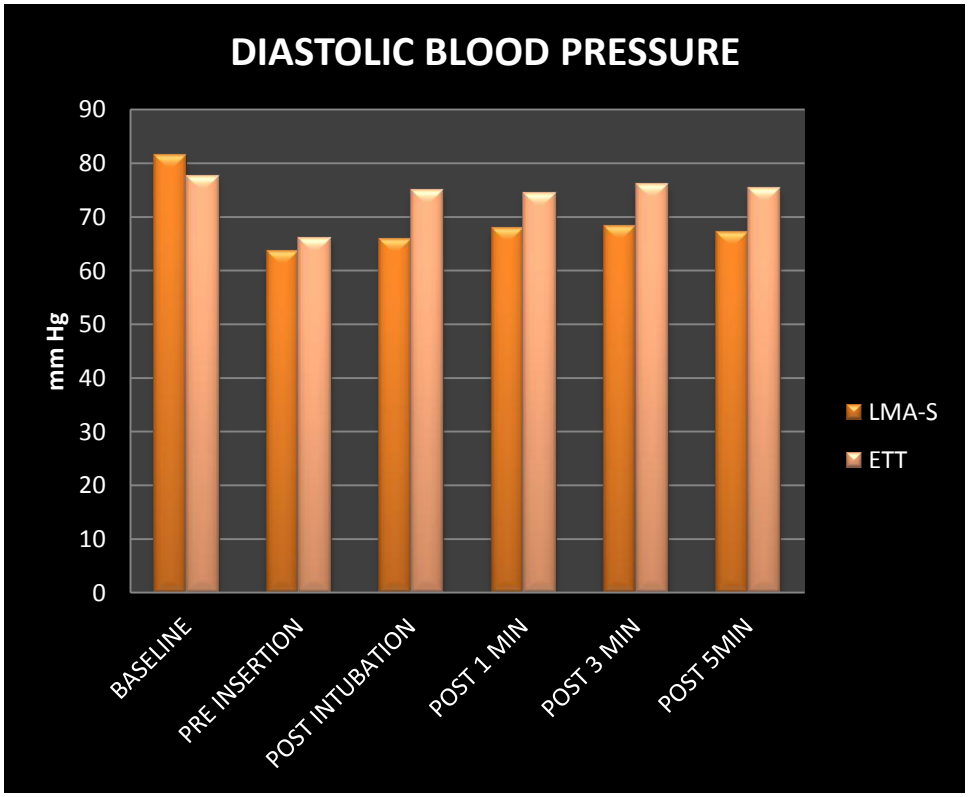

NUMBER OF ATTEMPTS
35
30
25
20
15
10
5
0
no of patients
Ist attempt
IInD attempt
LMA-S
ETT

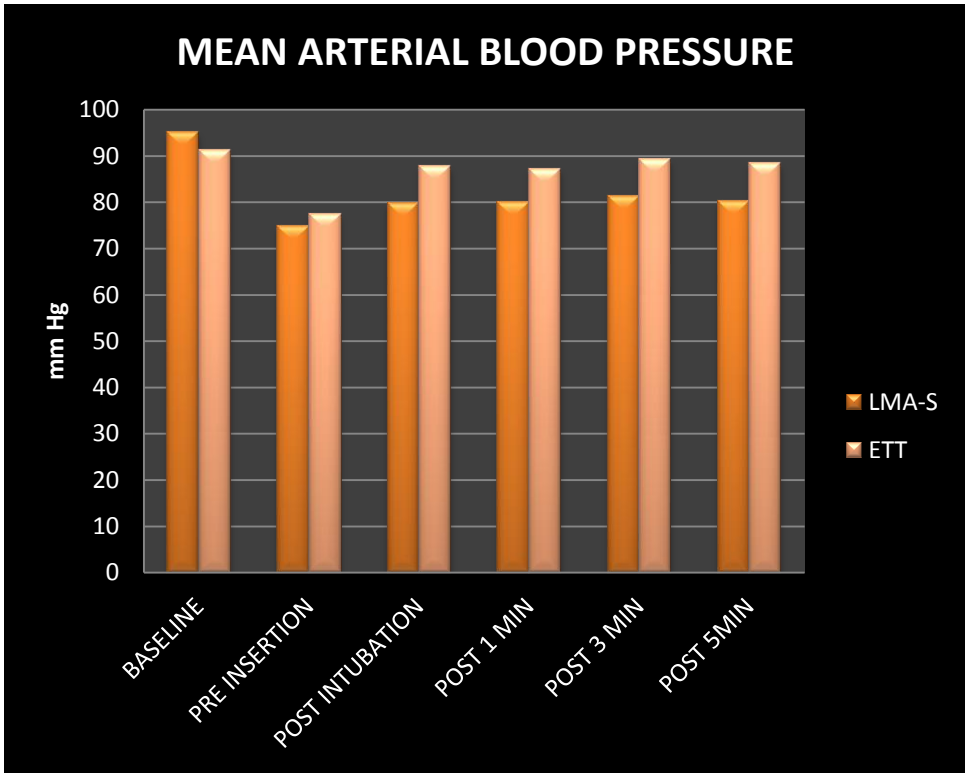

EASE OF INSERTION OF GASTRIC TUBE
35
30
25
20
15
10
5
0
no of patients
EASY
DIFFICULT
LMA-S
ETT

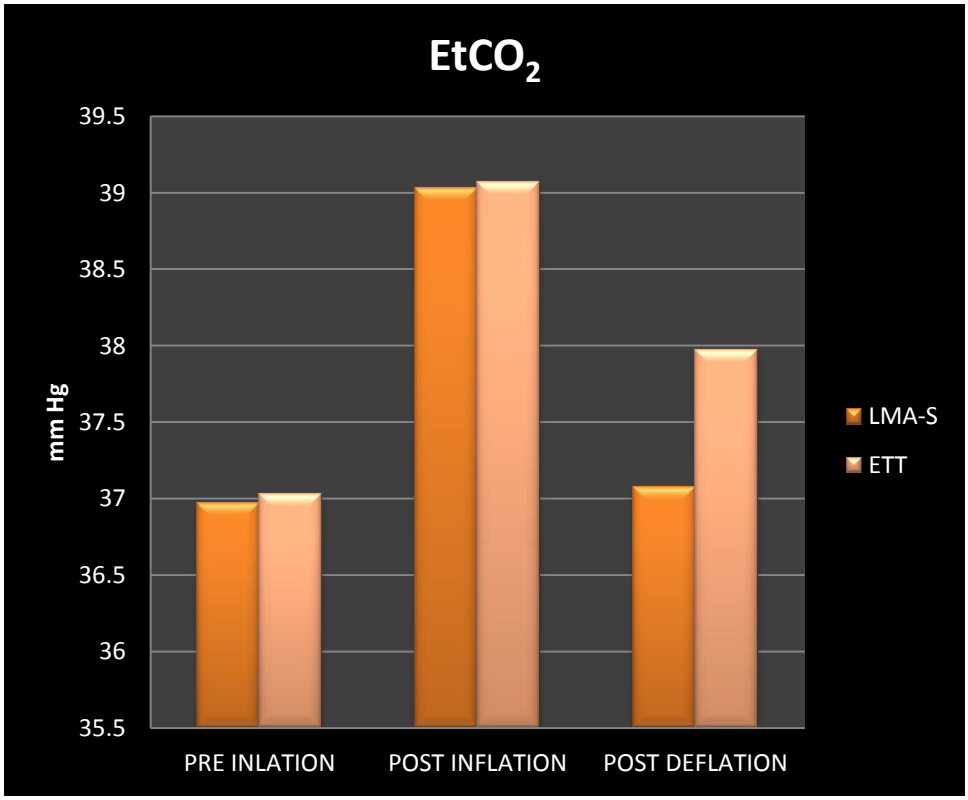

NUMBER OF ATTEMPTS FOR GASTRIC TUBE INSERTION
no of patients
35
30
25
20
15
10
5
0
Ist attempt
IInd attempt
LMA-S
ETT


HEART RATE
beats/min
110
105
100
95
90
85
80
75
BASELINE
PRE INSERTION
POST INTUBATION
POST 1 MIN
POST 3 MIN
POST 5MIN
LMA-S
ETT

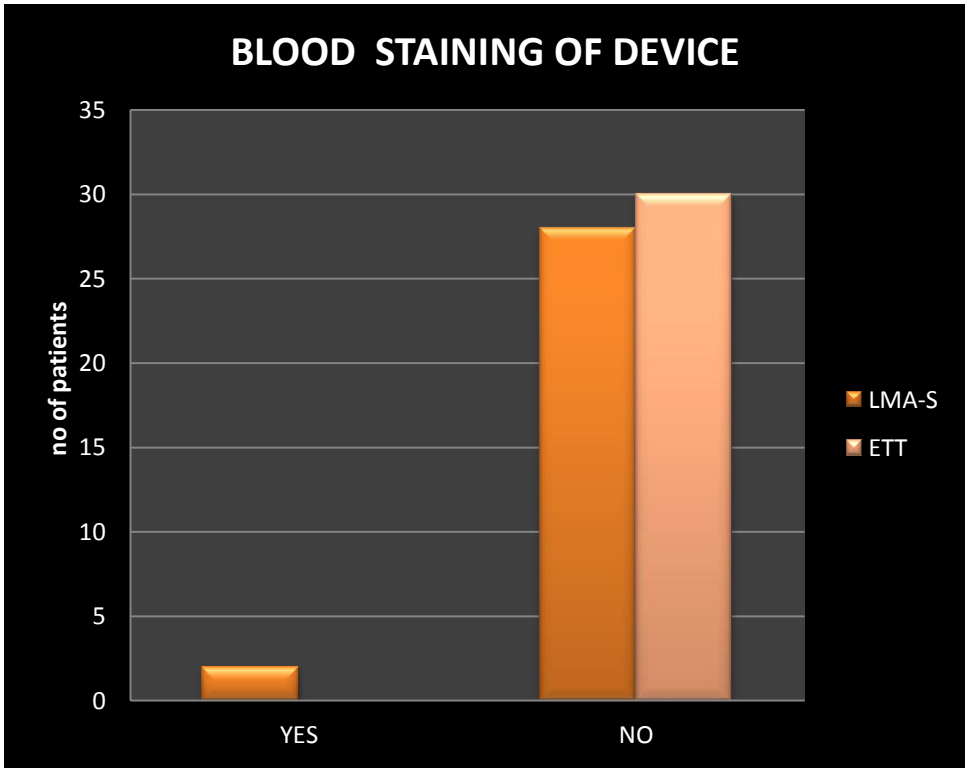

SYSTOLIC BLOOD PRESSURE
mm Hg
140
120
100
80
60
40
20
0
BASELINE
PRE INSERTION
POST INTUBATION
POST 1 MIN
POST 3 MIN
POST 5MIN
LMA-S
ETT

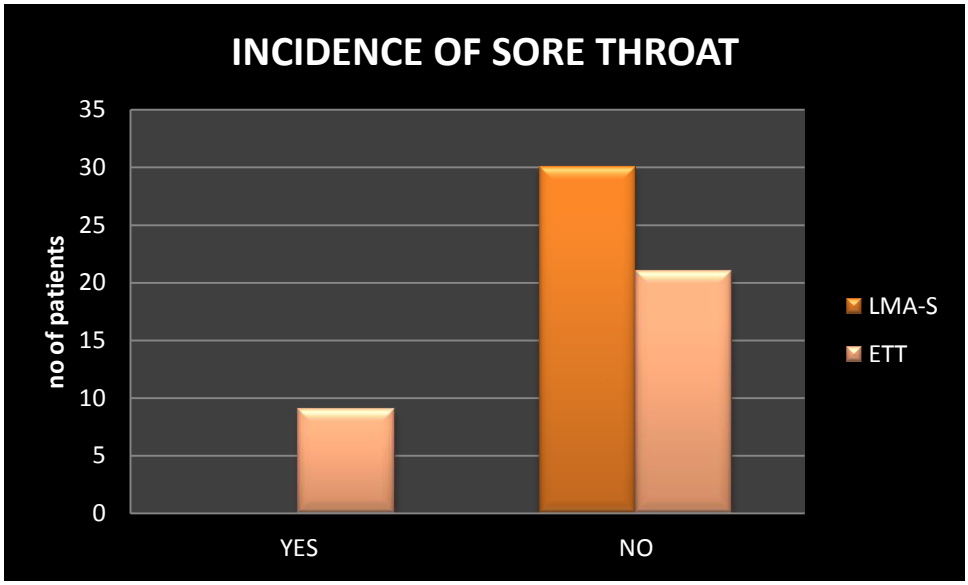

DIASTOLIC BLOOD PRESSURE
mm Hg
90
80
70
60
50
40
30
20
10
0
BASELINE
PRE INSERTION
POST INTUBATION
POST 1 MIN
POST 3 MIN
POST 5MIN
LMA-S
ETT

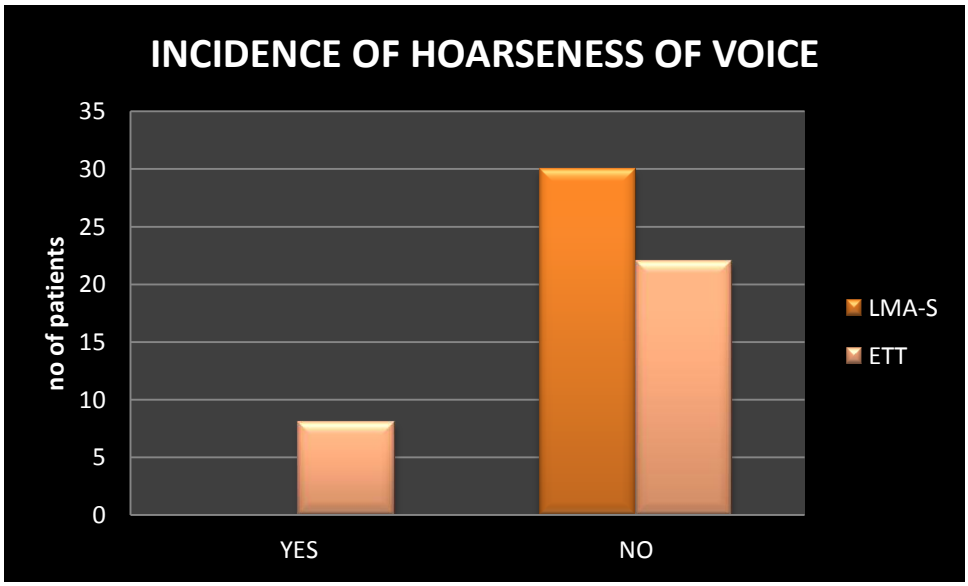

MEAN ARTERIAL BLOOD PRESSURE
mm Hg
100
90
80
70
60
50
40
30
20
10
0
BASELINE
PRE INSERTION
POST INTUBATION
POST 1 MIN
POST 3 MIN
POST 5MIN
LMA-S
ETT

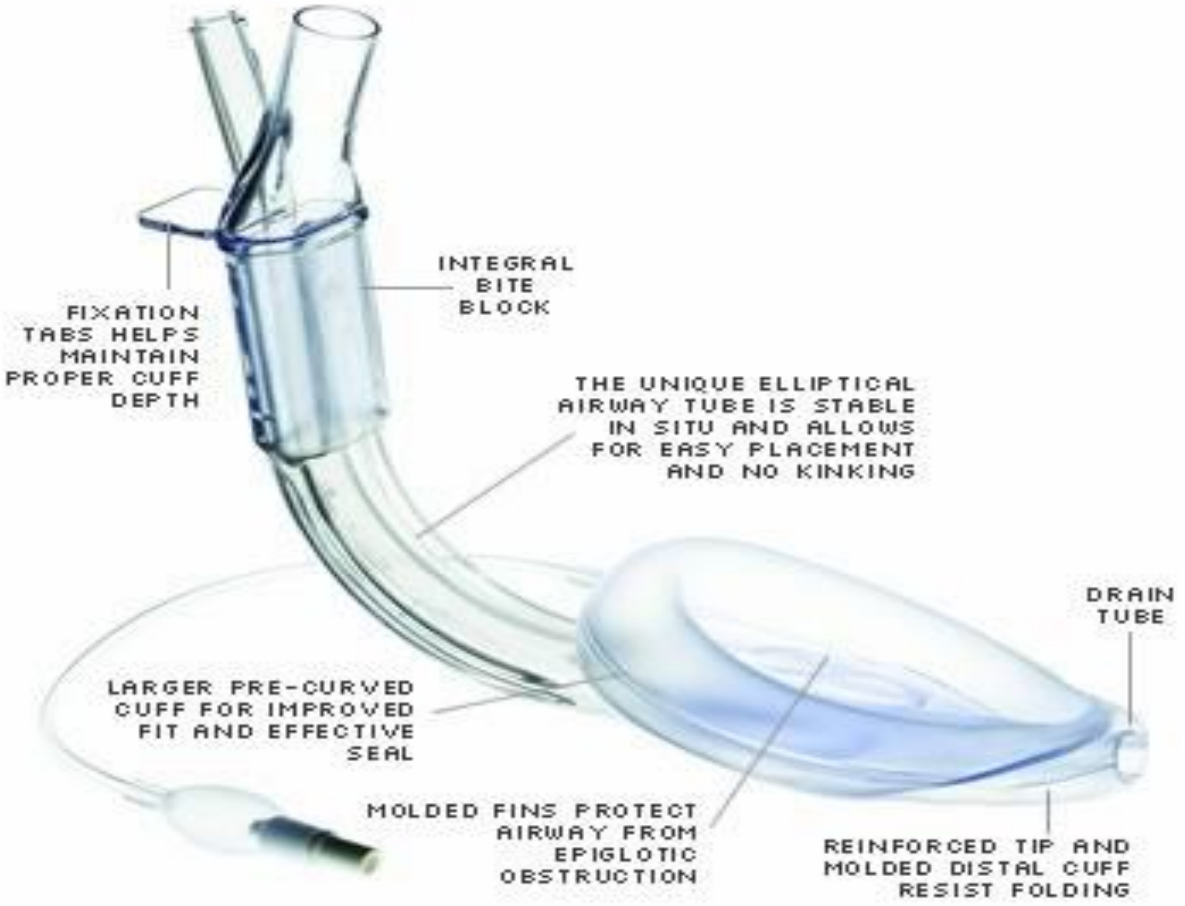

EtCO2
mm Hg
39.5
39
38.5
38
37.5
37
36.5
36
35.5
PRE INLATION
POST INFLATION
POST DEFLATION
LMA-S
ETT


SpO2
100.1
100
99.9
99.8
99.7
99.6
99.5
99.4
99.3
99.2
99.1
percentage(%)
BASELINE
PRE INSERTION
POST INTUBATION
POST 1 MIN
POST 3 MIN
POST 5MIN
LMA-S
ETT


BLOOD STAINING OF DEVICE
35
30
25
20
15
10
5
0
no of patients
YES
NO
LMA-S
ETT


INCIDENCE OF SORE THROAT
no of patients
35
30
25
20
15
10
5
0
YES
NO
LMA-S
ETT


INCIDENCE OF HOARSENESS OF VOICE
no of patients
35
30
25
20
15
10
5
0
YES
NO
LMA-S
ETT


FIXATION TABS HELPS MAINTAIN PROPER CUFF DEPTH
INTEGRAL BITE BLOCK
THE UNIQUE ELLIPTICAL AIRWAY TUBE IS STABLE IN SITU AND ALLOWS FOR EASY PLACEMENT AND NO KINKING
DRAIN TUBE
LARGER PRE-CURVED CUFF FOR IMPROVED FIT AND EFFECTIVE SEAL
MOLDED FINS PROTECT AIRWAY FROM EPIGLOTIC OBSTRUCTION
REINFORCED TIP AND MOLDED DISTAL CUFF RESIST FOLDING

PROSPECTIVE RANDOMISED COMPARISION OF LMA-SUPREME AND ENDOTRACHEAL TUBE IN ELECTIVE LAPAROSCOPIC GYNAECOLOGICAL SURGERIES

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ABSTRACT

BACKGROUND: The Laryngeal Mask Airway Supreme (LMA-S) is a new supraglottic airway incorporating features of the LMA-Proseal, LMA Fastrach and LMA Unique. We designed a prospective, randomised, single blind case control study to evaluate the advantages and disadvantages of LMA-Supreme over Endotracheal tube (ETT) for general anesthesia in laparoscopic gynaecological surgeries. We compared the insertion conditions, adequacy of ventilation and incidence of complications.

METHODS: After obtaining institutional ethics committee approval, sixty ASA PS I & II adult patients undergoing elective laparoscopic gynaecological surgeries were randomised to receive either the LMA-S or ETT for airway management. Anaesthesia was induced with propofol/fentanyl/atracurium, maintained with sevoflurane/atracurium and IPPV. Ease of insertion, No. of attempts required for successful insertion, time taken for insertion, ease of gastric tube insertion, haemodynamic changes, $EtCO^2$, blood staining of device and post operative sore throat/hoarseness of voice were recorded.

RESULTS: Both the devices were inserted with similar ease (96.7% in LMA-S vs 100% in ETT). The first attempt success rate of insertion was similar in both groups, 96.7% in LMA-S vs 100% in ETT. The effective airway was established rapidly with LMA-S compared to ETT (15.2 vs 24.7 seconds, respectively $P < 0.01$). Gastric tube insertion was easier with LMA-S than ETT (100% vs 76.7%, respectively). The intubation was smooth with less haemodynamic response in LMA-S group. The incidence of sore throat and hoarseness of voice was less in LMA-S group, with P value of 0.001and 0.002, respectively.

CONCLUSION: We concluded LMA-Supreme as an equally effective airway device to ETT in laparoscopic gynaecological surgeries with potential advantages of rapid placement, less haemodynamic response, less airway trauma, less postoperative pharyngolaryngeal morbidity and better oesophageal seal preventing risk of gastric distension and aspiration.

KEY WORDS: LMA-Supreme, Endotracheal tube, Laparoscopic gynaecological surgeries