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Original Research Article

Comparison of laryngeal mask airway supremeTM versus endotracheal intubation in positive pressure ventilation with muscle relaxant for intraoperative and postoperative conditions

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ABSTRACT

Background: Laryngeal Mask Airways are increasingly being used now a day as an option to endotracheal intubation, as it is less invasive and causes less discomfort in the postoperative period. The aim of this study was to evaluate the clinical use of the laryngeal mask airway SupremeTM in patients undergoing elective gynaecological surgeries under general anaesthesia and compare it with endotracheal intubation.

Methods: 60 ASA I and II females, having BMI <30kg.m⁻² in the range of 20-50 years of age, scheduled for elective gynaecological surgeries were randomly allocated to one of the two groups according to the device used (LMAS or ETT). Time required for insertion, number of attempts, hemodynamic response to insertion/removal and incidence of immediate and late postoperative complications such as coughing, laryngospasm, sore throat, dysphagia etc. were assessed.

Results: Number of attempts for successful insertion was similar but time required for LMA SupremeTM insertion was significantly less (25.40±12.90 versus 33.27±14.82 sec) similarly, time required for nasogastric tube insertion was significantly more in ETT group (30.28±16.22 versus 21.93±12.64 sec). No episode of failed ventilation or hypoxia was recorded. The changes in hemodynamic parameters were significantly higher after endotracheal intubation and during extubation. Incidence of postoperative complications was significantly higher after endotracheal intubation (p<0.05).

Conclusions: The LMA SupremeTM is a suitable alternative to endotracheal intubation during general anaesthesia for elective gynaecological surgeries with the added advantage of less hemodynamic response during airway management and lower incidence of postoperative complications.

Keywords: Endotracheal intubation, LMA supremeTM, Positive pressure ventilation

INTRODUCTION

Routine technique for airway management during surgical procedures under general anaesthesia is endotracheal intubation. However, this procedure is associated with considerable risk of laryngotracheal injury. Complications with tracheal intubation range from

minor events like sore throat and hoarseness of voice to tracheal stenosis. 1,2

Supraglottic airway devices provides a useful alternative for airway management during spontaneous or controlled ventilation in adults, as they do not require the use of laryngoscope for insertion, are non-invasive so, associated with less hemodynamic changes and airway manipulation.³

The laryngeal mask airway supreme (LMA SupremeTM) is a single use supraglottic airway device made of polyvinyl chloride has a firm airway tube shaped at a 90° angle to facilitate insertion without digital guidance. It has a modified conical cuff which gives it a high-pressure seal and better performance during mechanical ventilation and a gastric channel running along the posterior midline through the airway tube to facilitate the passage of a gastric tube which allows functional separation of the respiratory and digestive systems.^{4,5}

The aim of this study was to evaluate the efficacy and superiority of LMA SupremeTM, if any compared to endotracheal intubation for positive pressure ventilation with muscle relaxation for intraoperative and postoperative conditions.

METHODS

This prospective randomized study was conducted in the Department of Anaesthesiology, JNMC, Sawangi (Meghe), Wardha from April 2014 to July 2016. After taking permission from institutional ethics committee, 60 female patients, aged 20-50years, ASA physical status I and II, Mallampati class I and II and body mass index less than 30kg.m⁻², posted for gynaecological surgeries under general anaesthesia were included in this study. All patients gave informed consent. Patients with suspected difficult airway, mouth opening less than 2 fingers or increased risk of aspiration (gastro-oesophageal reflux disease, hiatus hernia and pregnant patients) were excluded.

Patients were randomly divided into two groups of 30 each according to the airway device used by using computer generated random number table. In group ETT, cuffed endotracheal tube size 7.5 and in group LMAS, LMA SupremeTM size 4 was used.

Pre-anaesthetic evaluation of the patients was done a day prior to surgery and patients were asked to have 8 hours of fasting. At the operating room, 20G iv cannula was secured and infusion of Ringer's lactate was started at the rate of $2ml.kg^{-1}.hr^{-1}$, all patients received inj. glycopyrrolate $0.004mg.kg^{-1}$, inj. midazolam $0.05\ mg.kg^{-1}$ and injection fentanyl $2\mu g.kg^{-1}$ as premedication. Standard monitoring was performed with pulse oximetry, non-invasive measurements of blood pressure, ECG and capnography.

Patients were preoxygenated with 100% O₂ for three minutes and anaesthesia was induced with injection propofol 2.5mg.kg⁻¹, and inj. vecuronium 0.10mg.kg⁻¹. After manual ventilation under face mask for 3minutes, the airway device was inserted. LMA Supreme[™] was inserted after totally deflating and lubricating on its posterior surface with lignocaine jelly 2%. Endotracheal

tube was inserted through a conventional laryngoscopy with a curved Macintosh blade, number 3 or 4. The cuffs of both devices were inflated up to 25cm H₂O for endotracheal tube and up to 60cm H₂O for LMA SupremeTM, which were confirmed by a manometer. Successful insertion was confirmed by visible thoracic expansion, auscultation and identification of capnography curve.

For confirmation of correct positioning of the laryngeal mask bubble test was done i.e. absence of air leakage through the gastric access channel during ventilation and passage without resistance of a nasogastric tube (size 14) lubricated with lignocaine jelly through the same channel.⁶ Nasogastric tube placement was not attempted with LMA SupremeTM if there was an air leak in gastric access channel. If a test indicated inappropriate position, the mask was withdrawn, and the insertion was considered a failure. A failed insertion attempt was defined as the removal of the device from the mouth.

In case of failure after a maximum of three attempts, LMA SupremeTM was replaced by an endotracheal tube. Interventions such as head and neck adjustment or change in depth of mask insertion were allowed to obtain satisfactory ventilation. A nasogastric tube was also inserted in patients of ETT group, and after initial aspiration of gastric contents, it was kept open for free drainage in both groups. Correct placement of nasogastric tube was confirmed by epigastric stethoscopy.

Anaesthesia was maintained with oxygen, nitrous oxide, sevoflurane and neuromuscular blockade with intermittent doses of vecuronium. The lungs were ventilated with volume-controlled mechanical ventilation anaesthesia delivery workstation with a closed circuit having carbon dioxide absorber. Ventilatory settings included tidal volume of 7ml.kg⁻¹ and inspiratory: expiratory time ratio of 1:2. The respiratory rate kept was 12 min⁻¹ initially and then adjusted to maintain an EtCO₂ below 40 mmHg and O₂ saturation above 95% using a fresh gas flow of 4 l.min⁻¹.

Parameters recorded were insertion time (time interval between the beginning of insertion of airway device and confirmation by first capnography curve), number of attempts required for successful insertion, hemodynamic response to insertion (heart rate and mean arterial pressure 30seconds before and immediately after insertion confirmation). After this, nasogastric tube was inserted and insertion time (time interval between the beginning of insertion of nasogastric tube and confirmation by epigastric stethoscopy) was noted.

At the end of surgery, neuromuscular blockade was reversed with intravenous injection glycopyrrolate 0.008mg.kg⁻¹ and injection neostigmine 0.05mg.kg⁻¹. After recovery of spontaneous ventilation and eye opening, the device used was removed, at this point of time haemodynamic parameters were noted. Till 1hour

after removal of the LMA SupremeTM or endotracheal tube, the patient received oxygen at 4 l.min⁻¹ via a Hudson's mask. Any adverse events such as regurgitation, coughing, bronchospasm, laryngospasm, gagging and hiccup were recorded. Rescue analgesic used was intramuscular inj. diclofenac sodium 1.5mg.kg⁻¹ whenever patient demands.

Airway trauma was assessed by presence of blood on device used laryngoscope or endotracheal tube in case of intubation, and LMA SupremeTM itself at the end of the procedure. All patients were reassessed at 12 hours after surgery for presence of neck pain, sore throat, hoarseness or dysphonia (difficulty in speaking) and dysphagia (difficulty in swallowing).

Statistical analysis

Continuous data was expressed as means ± standard deviation or number and percentile. Comparison of data was done using the Statistical Package for the Social Sciences (SPSS for Windows, version 17). Categorical data was analysed using Chi-square test while continuous data was analysed using Student's unpaired t-test. p values <0.05 were considered statistically significant.

RESULTS

Data were analysed from sixty patients recruited in this study. Demographic data, total anaesthesia time and surgery time were similar in both the groups (Table 1).

Table 1: Patient and surgical characteristics.

Variables	ETT	LMAS	P- value
	Tri-i	LIVIAS	1 - varue
Age (years)	40.24±10.22	38.89±12.41	t=0.45; $p=0.64$,ns
BMI (kg.m ⁻²)	22.8 ± 2.3	24.1 ± 3.62	t= 1.66; p=0.10,ns
Asa class (I/II)	18/12	16/14	$x^2=0.26$; p=0.60,ns
Mallampati class (I/II)	20/10	19/11	$x^2 = 0.07$; p=0.78,ns
Anaesthesia time (min)	48.65 ± 9.54	46.32±11.76	t=0.84; p=0.40,ns
Surgery time (min)	39.48 ± 7.82	37.61±8.94	t=0.86; p=0.39,ns

There was no failure in placement of both airway devices and crossovers between groups. LMA Supreme[™] was correctly placed on the first attempt in 88.66% patients.

Tracheal intubation was successful on the 1ST attempt in 93.33% patients. The mean time required for insertion of ETT was 33.27±14.82 which was significantly more

compared to time required for LMA SupremeTM insertion which was 25.4 ± 12.9 and seconds (p=0.032). After successful insertion of the device, nasogastric tube placement was attempted, and time requited for insertion was 21.93 ± 12.64 in LMAS group which was significantly less compared to 30.28 ± 16.22 in ETT group(p=0.030) (Table 2).

Table 2: Data regarding device insertion.

Variables	ETT	LMAS	P- value
Insertion attempts (n) 1/2/3.	28/2/0	26/4/0	$x^2 = 0.72$; p=0.39,ns
Insertion time (sec)	33.27±14.82	25.40±12.90	t=2.19; p= 0.032,s
Nasogastric tube insertion time (sec)	30.28±16.22	21.93±12.64	t=2.22; $p=0.030$,s

In all patients with both investigating airway devices, it was possible to maintain oxygenation, ventilation, and pulmonary mechanics for the entire duration of surgery.

Baseline and before insertion of airway device haemodynamic variables were similar in both groups. However, in the post-insertion period, ETT group had significant increased values of heart rate and mean blood pressure, compared to the LMAS group. Similarly, significant increase in heart rate and mean blood pressure were seen postoperatively after removal of airway device (Table 3).

Emergence outcome revealed that complications like coughing and laryngospasm/bronchospasm were associated more with use of endotracheal tube than LMA SupremeTM which were statistically significant. 2 patients in ETT group and 1 patient in LMAS group had airway trauma which was assessed by presence of blood on device (Table 4).

Follow-up after 12hours postoperatively revealed no differences in the incidence of sore throat and dysphagia in both the groups. Whereas, dysphonia and neck pain were more in the intubated patients.

This indicates that use of endotracheal tube was associated with significant number of complications in late postoperative period compared to LMA SupremeTM (Table 4).

Table 3: Hemodynamic variables before and after insertion of ETT and LMAS.

Variables	Heart rate(beats. Min ⁻¹)			Mean blood pressure(mmHg)		
variables	ETT	LMAS	P-value	ETT	LMAS	P-value
Baseline	78.2±14.43	76.24±15.86	t=0.50;p=0.61,ns	97.34±15.81	99.10±12.71	t=0.47;p=0.63,ns
Before insertion	77.34±13.78	74.88±16.48	t=0.62;p=0.53,ns	95.82±16.38	97.10±14.57	t=0.31;p=0.75,ns
After insertion	92.87±18.64	80.65±14.62	t=2.82;p=0.006,s	110.62±13.53	101.41±13.52	t=2.63;p=0.010,s
Postoperatively	101.63±12.70	89.41±16.65	t=3.19;p=0.002,s	112.58±14.72	102.85±11.74	t=2.83;p=0.006,s

Table 4: Postoperative complications.

Complications	ETT (n)	LMAS (n)	P-value		
A) Emergence outcome					
Regurgitation	0	0			
Coughing	6	2			
Laryngospasm	4	1	$\chi^2 = 6.53$;		
Bronchospasm	1	0	p=0.010,s		
Gagging	0	0	_		
Airway trauma	2	1			
(B) After 12 hours					
Neck Pain	7	1			
Dysphonia	4	0	$\chi^2 = 4.37$;		
Sore Throat	3	4	p=0.036, s		
Dysphagia	2	3			

DISCUSSION

From this study it is clear that LMA SupremeTM effectively and safely can replace endotracheal tube for airway control during general anaesthesia in gynaecological surgeries.

Frequency of Supraglottic airway devices development has increasing following the overwhelming success of the LMA ClassicTM. LMAs have been shown to be perfectly suitable for airway management during routine anaesthesia and in emergency situations particularly when tracheal intubation may be challenging or may delay oxygenation.⁷⁻¹⁰ The criterion that endotracheal intubation is a technique to have a patent airway during positive pressure ventilation has changed remarkably. Many surveys and studies showed that surgical procedures carried out under general anaesthesia including laparoscopic surgeries are routinely performed with a supraglottic airway device. ¹¹⁻¹³

LMA was invented in 1981 by Dr. Brain with an objective of providing a better method of maintaining a patient's airway than by face mask and less hemodynamically stressful than insertion of an endotracheal tube. 14 LMA has undergone many design

changes since then, most important was incorporation of oesophageal vent, it had a greatest impact on its functionality. ^{15,16} The presence of gastric channel allows the functional separation between respiratory and gastrointestinal tracts, another advantage is after insertion, various tests can be performed for confirmation of correct position. ⁶

LMA SupremeTM is a disposable, latex-free, LMA with gastric access. Anatomical shape of a stiff airway tube with fixed curvature and an elliptical cross-section have advantage that insertion can be done without placing fingers in patient's mouth, this feature makes rotational mal-positioning of the airway unlikely. The design of cuff is such that it provides higher seal pressures than the LMA-ClassicTM. LMA SupremeTM is combination of features of the LMA ProsealTM, FastrachTM UniqueTM. The integral oesophageal drainage tube prevents passively regurgitated liquid from contaminating the airway. Its performance during mechanical ventilation has improved because the airway has a fixation tab designed to improve both drain tube position and facilitate easy fixation. All these modifications suited for easier placement by users who are inexperienced with laryngeal masks.¹⁷ This study shows that mechanical ventilation is satisfactorily maintained with the LMA SupremeTM throughout the surgery.

However, this study was too small to determine the safety of the LMA SupremeTM with respect to pulmonary aspiration. Many studies concluded that the LMA SupremeTM insertion technique is simple, associated with great success both in the insertion and maintenance of ventilation and it is equivalent to the standard technique of endotracheal intubation for airway maintenance during general anaesthesia.^{9,18}

It is very important to monitor carefully the ventilation and LMA SupremeTM position after insertion. The patient should be intubated, if LMA SupremeTM is malpositioned or ventilation is inadequate. No patient in our study in LMAS group needed intubation. Gastric tube was

inserted in all patients in our study, in LMAS group it was inserted after confirmation of no evidence of leak via drain tube. The time required to place nasogastric tube was more in ETT group compared to LMAS group.

There was no clinical evidence of regurgitation or aspiration in our study which was evidenced by the maintenance of SpO_2 and $EtCO_2$ within normal limits during the entire duration of the surgery. Similar results were cited by Kahla and Alhusaimy in 2009.¹⁸

Patients belonging to LMAS group were having less airway complications than those belonging to ETT group immediately after extubation as well as after 12hours postoperatively. A meta-analysis of 29 randomized prospective clinical trials showed that when LMA was used during general anaesthesia complications like hoarseness, coughing, and laryngospasm during emergence were less compared to use of endotracheal tube. 19

The hemodynamic response by tracheal intubation as well as extubation was much more compared to that of insertion and removal of laryngeal mask, as shown by our results. This was related to laryngoscopy which increases airway manipulation and increased release of catecholamines during tracheal intubation; this may be of concern in patients with high cardiac risk or low cardiovascular reserve. ^{20,21} We have only evaluated very specific population i.e. female patients without significant comorbidities posted for small surgical procedures. The use of analgesics in postoperative period may have affected the intensity and outcome of postoperative complications such as dysphagia and sore throat in the period after 12 hours.

CONCLUSION

From the results of our study we conclude that, LMA SupremeTM during general anaesthesia for access and maintenance of airway is safe and effective as endotracheal intubation with an added advantage of reduction in haemodynamic response during insertion and removal. Use of LMA SupremeTM reduces incidences of coughing and laryngospasm during emergence and also reduces the incidence of neck pain and dysphonia in postoperative period after 12hours.

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