

## SAFETY AND EFFICACY OF THE SUPREME LARYNGEAL MASK AIRWAY DURING LAPAROSCOPIC CHOLECYSTECTOMY

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### ABSTRACT

**Background:** Supraglottic airway devices are currently the most commonly used instruments in airway management. Some of the newer supraglottic airway devices have been modified to improve sealing and have separate respiratory and gastrointestinal tracts. One of the most popular types of airway devices is the Proseal Laryngeal Mask Airway device.

**Objectives:** To evaluate of the ease of the insertion of the LMA Supreme device and the gastric tube.

To evaluate of the adverse effects of the insertion of LMA Supreme device and side effects in postoperative period.

**Material and Methods:** One hundred seventy patients undergoing laparoscopy cholecystectomy were prospectively studied. Ease of insertion of the device and the drain tube were evaluated. Blood pressure, pulse rate and oxygen saturation were monitored. Adverse effects were noted.

**Results:** Insertion of the LMA Supreme was successful in all patients (in first attempt, n=155; in second attempt, n=14; and in third attempt, n=1). Mean insertion time was 15.3±4.2 seconds. Gastric tube insertion was successful in all patients (easy, n=164; difficult, n=6). Initial mechanical ventilation was adequate in almost all cases by  $P_{peak}$ ,  $P_{mean}$ ,  $V_{t}$ ,  $V_{te}$ ,  $SpO_2$  and  $EtCO_2$ . Mean cuff pressure was 48.12±4.86 cm H<sub>2</sub>O. Mean peak airway pressure before pneumoperitoneum was 17.17±2.01 cm H<sub>2</sub>O, and 21.29±2.64 cm H<sub>2</sub>O, after pneumoperitoneum. No significant differences in the blood pressure, heart rate and oxygen saturation between before and after LMA Supreme insertion were found. Sixteen patients (9.41%) complained about a mild sore throat postoperatively. Coughing and dysphonia occurred in eleven patients (6.47%) and eighteen patients (10.59%). Blood was noted after removal of the LMA Supreme in five cases (2.91%). No other complications were reported.

**Conclusion:** LMA Supreme is easy for insertion, and it is effective ventilatory device, for laparoscopic cholecystectomy. It provides a functional airway seal with minimum adverse events.

**Keywords:** Laryngeal mask airway, supraglottic airway devices, supreme, ventilation, laparoscopic cholecystectomy.

### I. INTRODUCTION

Supraglottic airway devices are currently the most commonly used instruments in airway management. Some of the newer supraglottic airway devices have been modified to improve sealing and have separate respiratory and gastrointestinal tracts. One of the most popular types of airway devices is the Proseal Laryngeal Mask Airway (LMA) device.

The LMA Supreme device was introduced in 2007 which was a disposable airway device with its own gastric drainage channel, fixed curve tube, and maneuverable handle. All these factors are designed to reduce gastric insufflation, regurgitation, and subsequent pulmonary aspiration.

Since 2002, several clinical studies have recommended its use for laparoscopic surgery.

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We present a prospective evaluation of the use of the LMA Supreme for laparoscopic cholecystectomy in 170 patients.

**Objectives:** To evaluate of the ease of the insertion of the LMA Supreme device and the gastric tube.

To evaluate of the adverse effects of the insertion of LMA Supreme device and side effects in postoperative period.

## II. MATERIAL AND METHODS

### 2.1. Patient selection

After the institutional ethics committee approval regarding the study, we studied on 170 patients (average aged  $47.3 \pm 11.6$  years) who were at ASA (American Society of Anesthesiologists) I-III undergoing laparoscopic cholecystectomy at Department of Anaesthesiology and Critical Care B of Hue Central Hospital from February 2011 to August 2013. Patients were excluded if they were at ASA class IV or V, had features or history of a difficult airway, or had a history of gastroesophageal reflux.

### 2.2. Study Procedures

The LMA Supreme sizing was guided by manufacturers' recommendations, based on weight. A water-soluble lubricant was applied to the surface of the LMA Supreme.

Patients were premedicated with midazolam 0.04 mg/kg intravenously not routinely. Patients were anaesthetised in the supine position, with the patient's head on a standard pillow. Patients were pre-oxygenated for three minutes.

Anaesthesia was induced with fentanyl 2–3 mcg/kg, propofol 2–3 mg/kg, administered over 30 seconds and rocuronium 0.6 mg/kg. The patient underwent manual ventilation with 100% oxygen until adequate conditions for LMA Supreme insertion were achieved, including loss of eyelash reflex, jaw relaxation, immobility and apnoea.

Cuff pressure was monitored with a handheld manometer (Storz) to achieve 60 cm H<sub>2</sub>O. The number of insertion attempts was recorded. Three attempts were allowed before insertion was

considered to be a failure. Time taken for insertion was defined as the time taken from removal of the face mask from the patient, to the presence of a capnography tracing. We passed a well-lubricated gastric tube via the drain tube, and ease of insertion was recorded, namely being easy to insert, difficult to insert, and impossible to insert, as well as the number of attempts required. We secured the LMA Supreme to the patient's face with adhesive tape over the fixation tab.

A circle anaesthesia breathing system was connected (inspired tidal volume 8 ml/kg, respiratory rate of 12 breaths/minute, I:E ratio of 1:2, and fresh gas flow 1.5 l/minute). Effective ventilation was defined as a square-wave capnograph trace with end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>) values from 30 cm H<sub>2</sub>O–45 cm H<sub>2</sub>O, and normal thoracoabdominal movements.

General anaesthesia was maintained with sevoflurane (2%–3% end-tidal) in the air and oxygen mixture. Once stable ventilation and anaesthesia had been obtained, the oropharyngeal leak pressure was determined by the audible sound of gas escaping from the mouth when the expiratory valve of the circle system was closed. When mechanical ventilation was not effective (maximum expired tidal volume <6 ml/kg or EtCO<sub>2</sub> > 45 mmHg if correctly positioned), efforts to improve it were made by gentle up-and-down, or lateral, movements of the mask. If ventilation was still impossible, one further insertion attempt was allowed. If ventilation was impossible or ineffective after the second attempt, endotracheal intubation was performed.

Cardiorespiratory data were collected every three minutes during the anaesthetic procedure. Ventilatory variables were monitored continuously and adjusted accordingly by P<sub>peak</sub>, P<sub>mean</sub>, V<sub>ti</sub>, V<sub>te</sub>, SpO<sub>2</sub> and EtCO<sub>2</sub> to maintain SpO<sub>2</sub> > 95% and EtCO<sub>2</sub> < 45 mmHg. Peritoneal insufflation time and total anaesthetic time were also recorded.

During emergence from anaesthesia, not routinely using neostigmine 0.04 mg/kg and atropine 20 µg/kg intravenously. Removed the LMA Supreme when the patient was awake, and able to open mouth on command. Complications were recorded,

namely coughing, regurgitation and aspiration, laryngeal stridor, laryngospasm, bronchospasm, hypoxia ( $SpO_2 < 90\%$ ), and the presence of blood, following removal of LMA Supreme. Assessed the gastroesophageal reflux by the pH scale at the surface of the mask with litmus paper.

Postoperative pain was measured using a verbal questionnaire, which evaluated the presence of a sore throat, and dysphagia and dysphonia using a 0-10 visual analogue scale (VAS). All the patients received paracetamol 1g and ketorolac 30 mg intravenously for postoperative analgesic.

#### Statistical analysis

Data were entered and analysed using a spreadsheet programme (Microsoft Office Excel), with the SPSS 16.0 statistical package.

### III. RESULTS

#### 3.1. Demographic data

A total of 170 patients were included in the analysis. The mean age was  $47.3 \pm 11.6$  years, mean body weight was  $51.9 \pm 8.3$  kg. Ninety-one patients were categorised as ASA classification status ASA I, 60 patients as ASA II, and 19 patients as ASA III (most co-existing diseases were cardiometabolic diseases of the elder patients). Mean surgical procedure time was  $54.6 \pm 19.4$  minutes, and mean time of pneumoperitoneum was  $43.6 \pm 11.7$  minutes (see Table 1).

Table 1: Demographic data

Age (years)	$47.3 \pm 11.6$
ASA (I,II and III)	91/60/19
Sex (male and female)	74/96
Weight (kg)	$51.9 \pm 8.3$
Duration of surgical procedure (minutes)	$54.6 \pm 19.4$
Duration of pneumoperitoneum (minutes)	$43.6 \pm 11.7$

#### 3.2. Safety, efficacy and utility data using LMA Supreme

Insertion of the LMA Supreme was possible in

all our patients (100%), 155 on the first attempt (91.17%), 14 on the second attempt (8.26%), and one on the third attempt (0.57%). Insertion of the gastric tube was successful in all the cases, and it was recorded as difficult in six patients only (3.53%). In 170 patients, initial ventilation quality was classified as effective (97.64%), and during the surgical procedure, adequate ventilation was achieved in those patients.

Table 2: Safety, efficacy and utility data using LMA Supreme

Insertion success rate (%)	100
Attempt success rate: first, second, third (%)	155/14/1
Ventilation effective (%)	97.64
Ease of gastric tube insertion (easy or difficult)	164/6
Time taken for insertions (second)	$15.3 \pm 4.2$
Peak airway pressure before pneumoperitoneum ( $cmH_2O$ )	$17.17 \pm 2.01$
Peak airway pressure after pneumoperitoneum ( $cmH_2O$ )	$21.29 \pm 2.64$

Mean time for LMA Supreme insertion was  $15.3 \pm 4.2$  seconds. Mean peak airway pressure before pneumoperitoneum was  $17.17 \pm 2.01 cm H_2O$ . Mean peak airway pressure after pneumoperitoneum in the supine position was  $21.29 \pm 2.64 cm H_2O$  (see Table 2).

#### 3.3. Complications and side effects of LMA Supreme use

No episodes of laryngeal stridor, laryngospasm, bronchospasm, hypoxia, regurgitation or aspiration were seen. Coughing occurred in 11 patients (6.47%), and blood was noted after removal of the airway device in five cases (2.94%).

Table 3: Complications and side effects of LMA Supreme use

Coughing		11	6.47
Sore throat	Mild	12	7.06
	Slight	4	2.35
Dysphonia		18	10.59
Dysphagia		0	0
Blood after LMA Supreme removal		5	2.94
Regurgitation		0	0
Laryngospasm		0	0
Bronchospasm		0	0

Twelve patients (7.06%) complained about a mild sore throat at zero hours postoperatively (pain less than 3 on a scale of 0-10), which was associated with blood or trauma on removal of the device. Four patients (2.35%) referred to a slight sore throat two hours postoperatively (less than 3 on the scale). No patients reported dysphagia or dysphonia (see Table 3).

#### IV. DISCUSSION

The widespread use of supraglottic airway devices has revolutionised some clinical scenarios in modern anaesthetic practice, and on many occasions, is a good alternative to the endotracheal tube. LMA Supreme is a new airway device for which innovative applications are constantly being developed. Numerous studies have been published about these applications. Our study tested the effectiveness and safety of LMA Supreme for anaesthesia during cholecystectomy laparoscopy in 170 patients.

Regarding ease of insertion, we obtained the same insertion results with the first attempt (almost 91.17%) and second attempt (8.26%). In one patient, a third attempt was necessary. Mean insertion time was  $15.3 \pm 4.2$  seconds. The placement of a gastric tube via the drain tube was also successful in 164 cases (96.47%). Two of the gastric tube insertions that were graded as difficult were probably caused

by a folded LMA Supreme. The other four cases were probably due to insufficient lubrication of the gastric tubes. In Beleña JM et al study, mean insertion time was  $13 \pm 5$  seconds and the placement of a gastric tube via the drain tube was also successful in 96.5% of patients.

In almost 97.64% of patients, ventilation was classified as adequate which was assessed by  $V_{te}$ ,  $EtCO_2$  and the audible sound of gas escaping from the mouth. In our study, three patients (0.36%) required endotracheal intubation due to excessive oropharyngeal leak and ventilation failure during surgery.

The aim of our study was to evaluated the safety and efficiency of ventilation and the technique for LMA Supreme insertion. We did not aim to study the changes of hemodynamic and oxygen saturation. But overall, compared to the result of this study and our other study of LMA Supreme for laparoscopic surgery in October 2011 and results of the other studies of other author, there was no significant differences. In other words, can be observed that the use of LMA Supreme in laparoscopic surgery causes less changes in hemodynamic and oxygen saturation.

The incidence of complications and side-effects in our study was low, with a sample size that was large enough. This result is nearly similar with the result of Maltby JR et al study in 2002 and Natalini G et al study of LMA Proseal in 2003 and Timmermann A et al study of LMA Supreme in 2009 with the sample size ranged from 70 to 140 patients. There were no serious complications such as pulmonary aspiration. The result of pH measurements at the surface of LMA Supreme with litmus paper was higher than 7 which meant not having occurrence of gastroesophageal reflux. However, no reflux during laparoscopic cholecystectomy in this study was due to surgical position. Patients were operated in the supine position with a steep head-up so that occurrence of gastroesophageal reflux could hardly happen. Twelve patients (7.06%) complained about a mild sore throat at zero hours postoperatively and four patients (2.35%) referred to a slight sore

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throat at two hours postoperatively. Coughing occurred in eleven patients (6.47%). However, these respiratory complications can be onset in the long-term. We monitored and evaluated in a relatively short postoperative period (range: 2-3 days) so longer researchs were needed. Blood was noticed on surface after removing the LMA Supreme in five cases (2.91%) was due to respiratory lesions. There were no other serious complications such as laryngospasm, bronchospasm and severe hypoxia in this study. Therefore, we assessed that the LMA Supreme is a device with high safety and high efficacy levels.

## V. CONCLUSION

This study shows that the LMA Supreme is an effective ventilation device for cholecystectomy laparoscopic surgery in a standard group of patients. The LMA Supreme can be inserted easily, and supports airway pressures greater than those reached during surgery. It is easy to insert a gastric tube a the drain tube. The LMA Supreme provides low morbidity in the postoperative period, and is a safe, efficacious, and easy-to-use disposable supraglottic airway device in laparoscopic cholecystectomy.

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