

The Laryngeal Mask Airway Supreme™: safety and efficacy during gynaecological laparoscopic surgery

Beleña JM,^a MD, Staff Anaesthesiologist, Núñez M,^b MD, Staff Anaesthesiologist, Gracia JL,^a MD Staff Anaesthesiologist, Pérez JL,^a MD, Staff Anaesthesiologist, Yuste J,^a MD, PhD, Chief Anaesthesiologist

^aDepartment of Anaesthesiology and Critical Care, Hospital del Sureste, Arganda del Rey, Madrid, Spain

^bDepartment of Anaesthesiology and Critical Care, Hospital Ramón y Cajal, Madrid, Spain

Correspondence to: José M. Beleña, e-mail: josemariabelena@yahoo.es

Keywords: Laryngeal Mask Airway Supreme™, ventilation, gynaecological, laparoscopy, oropharyngeal leak pressure

Abstract

Background: Laryngeal Mask Airway Supreme™ (LMA Supreme™) is a new single-use polyvinyl chloride supraglottic device that offers gastric access. To date, studies that have tested the LMA Supreme™ for use in laparoscopic surgery have been reported. We present the largest evaluative study that describes the use of this mask for anaesthesia in gynaecological laparoscopic surgery.

Method: Hospital ethics board approval was obtained, and 140 fasted patients undergoing elective gynaecological laparoscopy were prospectively studied. We evaluated the ease of insertion of the device and the drain tube, the oropharyngeal leak pressure (OLP), incidence of postoperative sore throat, and other adverse events.

Results: Insertion of the LMA Supreme™ was successful in all patients (first attempt, $n = 123$; second attempt, $n = 16$; and third attempt, $n = 1$). Gastric tube insertion was successful in all patients (easy, $n = 135$; difficult, $n = 5$). Initial mechanical ventilation was adequate in almost all cases. Mean OLP at the level of 60 cmH₂O cuff pressure was 28.2 ± 5.1 cmH₂O. Mean peak airway pressure before pneumoperitoneum was 17 ± 3.5 cmH₂O, and 22.1 ± 4 cmH₂O, after pneumoperitoneum.

Fourteen patients (10%) complained of a mild sore throat postoperatively. Coughing occurred in 10 patients (7.1%), and blood was noted after removal of the LMA Supreme™ in five cases (3.5%). No other complications were reported.

Conclusion: We conclude that LMA Supreme™ is an easy to insert, and effective ventilatory device, for gynaecological laparoscopic surgery. It provides a functional airway seal with minimum adverse events.

© Peer reviewed. (Submitted: 2011-11-29. Accepted: 2012-01-24.) © SASA

South Afr J Anaesth Analg 2012;18(3):143-147

Introduction

The Laryngeal Mask Airway Supreme™ (LMA Supreme™), (The Laryngeal Mask Company, Le Rocher, Victoria, Mahé, Seychelles), is a new airway device that combines the functionality of the LMA ProSeal™ and LMA Fastrach™ airways.

The LMA Supreme™ design offers a cuff that allows a higher seal pressure than the LMA Classic™ and a drain tube that allows venting of the stomach contents, and blind insertion of standard gastric tubes.¹ All these factors are designed to reduce gastric insufflation, regurgitation, and subsequent pulmonary aspiration.² These properties of the laryngeal mask airways (LMA ProSeal™ and LMA Supreme™) are theoretic advantages, and suggestive of greater protection with regard to aspiration pneumonitis. Consequently, they have been used for airway management in patients with

increased risk of aspiration. The most popular device among this group has been the LMA ProSeal™. The recently introduced LMA Supreme™ has some similar characteristics to the LMA ProSeal™.

Since 2002, several clinical studies have recommended its use for laparoscopic surgery.³⁻⁶ We present a prospective evaluation of the use of the LMA Supreme™ for gynaecological laparoscopy in 140 patients. This study evaluates the ease of insertion of the device and the gastric tube, oropharyngeal leak pressure (OLP), postoperative sore throat, and adverse events.

Method

With institutional ethics committee approval and written informed consent, we studied 146 fasted females [American Society of Anesthesiologists (ASA) I-III] undergoing elective

gynaecological laparoscopy, day-case surgery included. Patients were excluded if they were < 18 years, were ASA class IV or V, had features or history of a difficult airway, or had a history of gastroesophageal reflux.

The LMA Supreme™ sizing was guided by manufacturers' recommendations, based on weight.¹ A water-soluble lubricant was applied to the surface of the LMA Supreme™. Routine monitoring was applied, before induction of anaesthesia. All patients were premedicated with midazolam 0.04 mg/kg¹ intravenously. 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 remifentanyl 0.3 µg/kg/minute, and propofol 2-3 mg/kg, administered over 30 seconds. No muscle relaxant was used at this time. 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. The LMA Supreme™ was inserted with the patient's head in the "semi-sniffing" position, using a single-handed technique, such as that suggested by the manufacturer.¹ Cuff pressure was monitored with a handheld manometer (Ambu, Ballerup, Denmark) to achieve 60 cmH₂O. The number of insertion attempts was recorded. Three attempts were allowed before insertion was considered to be a failure. 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 3 l/minute). Effective ventilation was defined as a square-wave capnograph trace with end-tidal CO₂ (EtCO₂) values from 30 cmH₂O-45 cmH₂O, and normal thoracoabdominal movements. Time taken for insertion was defined as the time taken from removal of the face mask from the patient by the anaesthesiologist, to the presence of a capnography tracing. Drain tube air leaks were detected by placing lubricant into the drain tube, and detecting upcoming bubbles during ventilation. When mechanical ventilation was not effective (maximum expired tidal volume < 6 ml/kg or EtCO₂ > 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, it was defined as ventilation failure. Endotracheal intubation was performed in the case of insertion or ventilation failure.

We passed a well-lubricated #14 Salem® sump gastric tube (Vecmedical Spain, Barcelona, Spain) via the drain tube, and ease of insertion was recorded, namely easy to insert, difficult to insert, and impossible to insert, as well as the number of attempts. Finally, we secured the LMA Supreme™ to the patient's face with adhesive tape over the fixation tab. Four anaesthesiologists, who were experienced in the

use of LMA Classic™, LMA ProSeal™, and LMA Supreme™, participated in the study.

General anaesthesia was maintained with sevoflurane (2% end-tidal) in the air and oxygen mixture and remifentanyl 0.15-0.5 µg/kg/minute. Cisatracurium was given to maintain the neuromuscular blockade at one twitch of a train-of-four (TOF-Watch®, Organon, Dublin, Ireland). Once stable ventilation and anaesthesia had been obtained, the oropharyngeal leak pressure (OLP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/minute, and the airway pressure (maximum allowed was 40 cmH₂O for safety concerns), at which equilibrium was reached was noted (audible sound of gas escaping from the mouth).⁷

We recorded the peak airway pressure from the anaesthesia system Fabius® GS (Dräger Medical, Lübeck, Germany). Peak airway pressures were recorded before and after carboperitoneum in the supine position, and in the Trendelenburg position. Peritoneal insufflation pressure was set at 13 mmHg,⁸ and head-down tilt was limited to 30 degrees.

Cardiorespiratory data were collected every three minutes during the anaesthetic procedure by the monitoring computer programme (Picis Care Suit Anaesthesia Manager®, Picis, USA). Ventilatory variables were monitored continuously and adjusted accordingly to maintain SpO₂ > 95% and EtCO₂ < 45 mmHg. Peritoneal insufflation time and total anaesthetic time were also recorded.

During emergence from anaesthesia, neuromuscular blockade was reverted when train-of-four showed ≥ 2 twitches using neostigmine 0.04 mg/kg, and atropine 20 µg/kg intravenously. The anaesthesiologist removed the LMA Supreme™ when the patient was awake, and able to open her mouth on command. Complications were recorded, namely coughing, regurgitation and aspiration, laryngeal stridor, laryngospasm, bronchospasm, hypoxia (SpO₂ < 90%), and the presence of blood, following removal of LMA Supreme™. An experienced anaesthesiologist was in charge to detect complications in the operating theatre. Postoperative pain was measured using a verbal questionnaire, which evaluated the presence of a sore throat, and dysphagia and dysphonia, before leaving the operating room (0 hours), and two hours postoperatively in the recovery room (2 hours), using a 0-10 visual analogue scale (VAS). We considered "0" to be the absence of a sore throat, dysphagia or dysphonia, and "10" to be an unbearable sore throat, and total dysphagia or dysphonia. This questionnaire was obtained by the recovery anaesthesiologist. All the patients received a standard postoperative analgesic regime, based on paracetamol 1 g and dexketoprofen 50 mg intravenously.

Data were entered and analysed using a spreadsheet programme (Microsoft Office Excel® 2003, Microsoft Corporation, Redmon, Washington, USA), with the SPSS® 13.0 statistical package 2004 (SPSS, Chicago, Illinois, USA). Values are mean \pm standard deviation (SD), or number of patients, unless otherwise stated.

Results

A total of 146 adult females consented to the study. Three patients whose scheduled procedure was changed from laparoscopic to open surgery, based on surgical reasons, were excluded. Three patients were intubated due to an excessive oropharyngeal leak and ventilation failure, after the second attempt for ventilation with LMA Supreme™. A total of 140 patients were included in the analysis. The mean age was 32 ± 14 years, mean height 164.2 ± 8.7 cm, mean body weight 60.4 ± 14 kg, and mean BMI 25 ± 4 kg/m². Five patients had a mean BMI in excess of 35 kg/m². Seventy-five patients were categorised as ASA classification status ASA I, 51 patients as ASA II, and 14 patients as ASA III. Mean surgical procedure time was 51 ± 20 minutes, and mean time of pneumoperitoneum was 34 ± 15 minutes (see Table I).

Table I: Demographic data

Age (years)	32 ± 14
ASA ^a (I, II and III)	75/51/14
Sex (male and female)	0/140
Height (cm)	164.2 ± 8.7
Weight (kg)	60.4 ± 14
Body mass index (kg/m ²)	25 ± 4
Duration of surgical procedure (minutes)	51 ± 20
Duration of pneumoperitoneum (minutes)	34 ± 15

a = American Society of Anesthesiologists
Mean \pm standard deviation (SD)

Insertion of the LMA Supreme™ was possible in all our patients (100%), 123 on the first attempt (87.8%), 16 on the second attempt (11.4%), and one on the third attempt (0.7%). Insertion of the gastric tube was successful in all the cases, and it was recorded as difficult in five patients only (3.5%). In 140 patients, initial ventilation quality was classified as effective (97.9%), and during the surgical procedure, adequate ventilation was achieved in those patients.

Mean time for LMA Supreme™ insertion was 13 ± 5 seconds. Mean OLP at the level of 60 cmH₂O cuff pressure was 28.2 ± 5.1 cmH₂O. In 13 patients, OLP was over 35 cmH₂O. Mean peak airway pressure before pneumoperitoneum was 17 ± 3.5 cmH₂O. Mean peak airway pressure after pneumoperitoneum in the supine position was 22.1

± 4 cmH₂O, and after the Trendelenburg position was 22.3 ± 4 cmH₂O (see Table II).

The type of surgery performed was 56 ovarian cystectomies (40%), 40 tubal ligations (28.5%), 34 salpingectomies (24.2%), and five endometrial ablations/resections (3.5%).

Table II: Safety, efficacy and utility data using Laryngeal Mask Airway Supreme™

Insertion success rate (%)	100
Attempt success rate: first, second, third (%)	123/16/1
Ventilation effective (%)	97.9
Ease of gastric tube insertion (easy or difficult)	135/5
Time taken for insertions	13 ± 5
Oropharyngeal leak pressure (cmH ₂ O)	28.2 ± 5.1
Peak airway pressure before pneumoperitoneum (cmH ₂ O)	17 ± 3.5
Peak airway pressure after pneumoperitoneum (cmH ₂ O)	22.1 ± 4

Mean \pm standard deviation (SD)

No episodes of laryngeal stridor, laryngospasm, bronchospasm, hypoxia, regurgitation or aspiration were seen. Coughing occurred in 10 patients (7.1%), and blood was noted after removal of the airway device in five cases (3.5%). Fourteen patients (10%) complained of 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. Nine patients (6.4%) referred to a slight sore throat at two hours postoperatively (less than 3 on the scale). No patients reported dysphagia or dysphonia.

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 are increasingly being published about these applications. A few articles have been published studying the use of the LMA Supreme™ for gynaecological laparoscopy.⁹⁻¹¹ The largest studied cohort included 70 patients. Our study tested the effectiveness and safety of LMA Supreme™ for anaesthesia during gynaecological laparoscopy in 140 patients.

We did not select ASA I and II patients only. Ten per cent were ASA III. The mean BMI of the whole study group was 25 kg/m², but obese patients were also included; five with a BMI in excess of 35 kg/m². In these five cases, the LMA Supreme™ proved to be safe, with no leaks measured with the different methods of assessing the airway sealing pressure, namely audible noise, oral capnography, manometric stability and auscultation.^{7,12} Adequate ventilation was achieved.^{5,6}

Regarding ease of insertion, we obtained the same insertion results with the first attempt (almost 88%) and second attempt (11.4%), as that achieved in previous studies where the device was deflated completely.^{12,13} Mean insertion time was also similar (13 seconds). In one patient, a third attempt was necessary. In almost 98% of patients, ventilation was classified as adequate, and only three patients required endotracheal intubation due to excessive oropharyngeal leak and ventilation failure. The placement of a gastric tube via the drain tube was also successful in 135 cases (96.5%), which is similar to success rates reported with LMA Supreme™.⁹ and also with other types of masks, e.g. LMA ProSeal™.^{4,5,14} Two of the gastric tube insertions that were graded as difficult were probably caused by an incorrect choice of tube size (#16 Salem gastric tubes). The other three cases were probably due to insufficient lubrication of the gastric tube.

OLP values are commonly performed with the laryngeal mask airway to indicate the degree of airway protection, the feasibility for using positive pressure ventilation, and the likelihood of successful supraglottic airway placement.⁷ In our study, we found a mean OLP of 28.2 cmH₂O with OLP over 35 cmH₂O in 13 patients, comparing favourably with other well-conducted clinical evaluations of the LMA Supreme™.^{9-12,14-17} These results reinforce the suggestion made by Timmermann et al¹² that no second posterior cuff is necessary to provide the same OLP as similar devices such as the LMA ProSeal™. Although Van Zundert et al¹⁸ has shown better OLP values, they had a fewer number of patients in the cohort.

The mean peak pressure at the different surgical phases was always lower than the OLPs, which supports the use of LMA Supreme™ for laparoscopic procedures in our population group.

The incidence of complications and side-effects in our study was low, with a sample size that was large enough. These results are similar to other studies that evaluated airway devices such as LMA ProSeal™ and LMA Supreme™ with sample sizes between 60-100 patients.^{8,12,14,19} Severe complications such as aspiration were not seen (the incidence of aspiration was less than 1:140 patients). Fourteen patients (10%) complained of a mild sore throat when emerging from anaesthesia, and another nine, of referred pain, two hours later in the recovery room. On extraction of the laryngeal mask airway, some signs of trauma to the airway, such as blood on the surface of the device, were recorded in five cases. Coughing occurred in 10 patients, with no clinical importance. Dysphagia, dysphonia and other severe airway complications, such as laryngeal stridor, laryngospasm, bronchospasm, hypoxia,

regurgitation, or aspiration were also not seen. Therefore, we suggest that the LMA Supreme™ is a safe, non-harming device.

Our study has a number of limitations. Firstly, this was a descriptive study. Randomisation and other statistical aspects, such as blinding, were not possible. We only found a few studies where the LMA Supreme™ was compared with endotracheal tubes (ETT)^{10,11} and other laryngeal mask airway devices⁹ for anaesthesia in gynaecological laparoscopy. More studies comparing the LMA Supreme™ with ETT and other well-tested laryngeal mask airway devices, such as LMA ProSeal™, should be carried out. Secondly, we studied a female population with normal airways, undergoing elective gynaecological laparoscopy. The data collected cannot directly be extrapolated to the use of LMA Supreme™ in males and other clinical scenarios. Although the use of LMA Supreme™ in the obese patients included in our study was satisfactory, their number was far too small to extract any valuable conclusions. Despite the promising results, larger studies have to be conducted regarding this group of patients.

Hence, all the conclusions that can be derived from our study have to be limited to procedures with the patient in the Trendelenburg position, and with similar surgical times, pneumoperitoneum times and intra-abdominal insufflation pressures.

At the end, postoperative airway morbidity was assessed only two hours postoperatively, when the effects of analgesic drugs such as opioids were still present, which means that sore throats could have developed later. Whether the stability of cuff pressure in the LMA Supreme™ might result in a lower incidence of sore throats, or other complications, will require a larger study with adequate power.

In conclusion, this study shows that the LMA Supreme™ is an effective ventilation device for gynaecological 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 via the drain tube. The LMA Supreme™ provides a low morbidity in the postoperative period, and is a safe, efficacious, and easy-to-use disposable supraglottic airway device in gynaecological laparoscopy.

References

1. The Laryngeal Mask Airway Supreme™. Instruction manual. Maidenhead: Intavent Orthofix; 2007.
2. Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: a review of the literature. *Can J Anaesth.* 2005;52(7):739-760.
3. Lu PP, Brimacombe J, Yang C, Shyr M. ProSeal versus the Classic laryngeal mask airway for positive pressure ventilation during

- laparoscopic cholecystectomy. *Br J Anaesth.* 2002;88(6):824-827.
4. Maltby JR, Beriault MT, Watson NC, et al. The LMA-ProSeal™ is an effective alternative to tracheal intubation for laparoscopic cholecystectomy. *Can J Anesth.* 2002;49(8):857-862.
 5. Maltby JR, Beriault MT, Watson NC, et al. LMA-Classic™ and LMA-ProSeal™ are effective alternatives to endotracheal intubation for gynecologic laparoscopy. *Can J Anesth.* 2003;50(1):71-77.
 6. Natalini G, Lanza G, Rosano A, et al. Standard Laryngeal Mask Airway™ and LMA-ProSeal™ during laparoscopic surgery. *J Clin Anesth.* 2003;15(6):428-32.
 7. Keller C, Brimacombe JR, Keller K, Morris R. Comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. *Br J Anaesth.* 1999;82(2):286-287.
 8. Hosten T, Gurkan Y, Ozdamar D, et al. A new supraglottic airway device: LMA Supreme™, comparison with LMA-ProSeal™. *Acta Anaesthesiol Scand.* 2009;53(7):852-857.
 9. Lee AK, Tey JB, Lim Y, Sia AT. Comparison of the single-use LMA Supreme with the reusable ProSeal LMA for anaesthesia in gynaecological laparoscopic surgery. *Anaesth Intensive Care.* 2009;37(5):815-819.
 10. Abdi W, Amathieu R, Adhoum A, et al. Sparing the larynx during gynecological laparoscopy: a randomized trial comparing the LMA Supreme and the ETT. *Acta Anaesthesiol Scand.* 2010;54(2):141-146.
 11. Yao T, Yang XL, Zhang F, et al. The feasibility of Supreme laryngeal mask airway in gynecological surgery. *Zhonghua Yi Xue Za Zhi* 2010;90(29):2048-2051 (abstract).
 12. Timmermann A, Cremer S, Eich C, et al. Prospective clinical and fiberoptic evaluation of the Supreme Laryngeal Mask Airway™. *Anesthesiology.* 2009;110(2):262-265.
 13. Verghese C, Ramaswamy B. LMA-Supreme a new single-use LMA with gastric access: a report on its clinical efficacy. *Br J Anaesth.* 2008;101(3):405-410.
 14. Eschertzhuber S, Brimacombe J, Hohlieder M, Keller C. The Laryngeal Mask Airway Supreme™: a single use laryngeal mask airway with an oesophageal vent. A randomized, cross-over study with the Laryngeal Mask Airway ProSeal™ in paralyzed, anaesthetised patients. *Anaesthesia.* 2009;64(1):79-83.
 15. Brimacombe J, Keller C, Brimacombe L. A comparison of the laryngeal mask airway LMA-ProSeal™ and the laryngeal tube airway in paralyzed anesthetized adult patient undergoing pressure-controlled ventilation. *Anesth Analg.* 2002;95(3):770-776.
 16. Brimacombe J, Keller C, Boehler M, Puehringer F. Positive pressure ventilation with the ProSeal versus Classic laryngeal mask airway: a randomized, crossover study of healthy female patients. *Anesth Analg.* 2001;9(5)3:1351-1353.
 17. Keller C, Puehringer F, Brimacombe J. The influence of cuff volume on oropharyngeal leak pressure and fibreoptic position with the laryngeal mask airway. *Br J Anaesth.* 1998;81(2):186-187.
 18. Van Zundert A, Brimacombe J. The LMA Supreme: a pilot study. *Anaesthesia.* 2008;63(2):209-210.
 19. Cook TM, Gatward JJ, Handel J, et al. Evaluation of the LMA Supreme™ in 100 non-paralysed patients. *Anaesthesia.* 2009;64(5):555-562.