REPORTS OF ORIGINAL INVESTIGATIONS



The LMA SupremeTM in 700 parturients undergoing Cesarean delivery: an observational study

Utilisation du LMA SupremeTM chez 700 parturientes accouchant par césarienne: une étude observationnelle

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Abstract

Background The LMA SupremeTM (SLMA) is a singleuse supraglottic device that provides a good seal for positive pressure ventilation. It has a double aperture design that facilitates the introduction of an orogastric tube to aspirate gastric contents. This observational study evaluated the role of the SLMA in parturients undergoing Cesarean delivery under general anesthesia.

Methods Non-obese parturients with at least four hours of fasting and antacid prophylaxis scheduled for uncomplicated Cesarean delivery were recruited from June 2009 through May 2010 at the Quanzhou Women's and Children's Hospital, China. We recorded the number of SLMA

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insertion attempts, the time to effective ventilation, the incidence of aspiration, and other anesthetic and obstetric outcomes. Postoperatively, we noted the presence of blood on the SLMA, postoperative sore throat, and patient satisfaction. Analysis included comparison of results between parturients having elective and urgent Cesarean delivery. Results We recruited 700 parturients (576 elective, 124 urgent). Mean (standard deviation) body mass index was 25.6 (2.5) $kg \cdot m^{-2}$. All SLMA insertions were successful, with 686 (98%) inserted on first attempt and a time to effective airway of 19.5 (3.9) sec. We maintained ventila-

tion and oxygenation in all parturients with a good seal

and there was no evidence of aspiration. Eighteen parturients (2.6%) had blood on the SLMA upon removal, 24 (3.4%) had sore throat, and patient satisfaction was 85

(7)%. These results were similar in elective and urgent

Conclusions In a carefully selected group of parturients, the SLMA is a useful alternative to tracheal intubation for Cesarean delivery, providing effective ventilation and a low incidence of side effects or complications.

Résumé

cases.

Contexte Le LMA SupremeTM (SLMA) est un dispositif supraglottique à usage unique qui procure une bonne étanchéité en cas de ventilation à pression positive. Son concept à double ouverture facilite l'introduction d'un tube orogastrique pour l'aspiration du contenu gastrique. Cette étude observationnelle a évalué le rôle du SLMA chez des parturientes subissant une césarienne sous anesthésie générale.

Méthodes Des parturientes non obèses, à jeun depuis au moins quatre heures avec prophylaxie antiacide, dont l'accouchement par césarienne non compliqué avait été programmé, ont été recrutées entre juin 2009 et mai 2010 à



l'hôpital pour femmes et enfants de Quanzhou, en Chine. Nous avons enregistré le nombre de tentatives d'insertion du SLMA, le délai d'instauration d'une ventilation efficace, l'incidence d'inhalation ainsi que d'autres critères d'évaluation anesthésiques et obstétricaux. En postopératoire, nous avons noté la présence de sang sur le SLMA, le mal de gorge postopératoire et la satisfaction de la patiente. L'analyse a inclus une comparaison des résultats entre les parturientes ayant eu une césarienne programmée et celles ayant eu une césarienne en urgence.

Résultats Nous avons recruté 700 parturientes (576 césariennes programmées, 124 urgentes). L'indice de masse corporel moyen (écart-type) était 25,6 (2,5) kg·m $^{-2}$. Toutes les insertions de SLMA ont réussi: 686 (98%) ont été insérés à la première tentative et le délai d'instauration d'une ventilation efficace a été de 19,5 (3,9) s. Nous avons maintenu la ventilation et l'oxygénation de toutes les parturientes avec une bonne étanchéité et il n'y a eu aucun signe probant d'inhalation. Dix-huit parturientes (2,6 %) avaient du sang sur le SLMA au moment de son retrait, 24 (3,4 %) avaient mal à la gorge et le score de satisfaction des patientes a été de 85 (7) %. Les résultats ont été comparables entre les cas programmés et les cas urgents. Conclusions Dans un groupe soigneusement sélectionné de parturientes, le SLMA constitue une alternative utile à l'intubation trachéale pour l'accouchement par césarienne; il est associé à une ventilation efficace et à une faible incidence d'effets indésirables ou de complications.

The LMA SupremeTM (SLMA) (Intravent, Orthofix, Maidenhead, UK) is a single-use supraglottic device that provides a good seal for positive pressure ventilation. It has a rigid double-lumen tube with a double aperture design that facilitates the introduction of an orogastric tube to aspirate gastric contents, and it can be inserted without use of introducer devices. In clinical trials, the SLMA has been found comparable with the reusable LMA ProSealTM (PLMA),¹ with the SLMA having a higher rate of success on first attempt insertion.²⁻⁵

Previous studies have shown the use of the PLMA and SLMA in non-paralyzed patients, ⁶ in anesthetized patients with a simulated difficult airway, ⁷ and in patients undergoing laparoscopy procedures. ^{8,9} More recent studies and case reports have shown that it is effective in providing ventilation and oxygenation in challenging cases, such as the morbidly obese patients, ¹⁰ patients in the prone position, ^{11,12} and those who have suffered from multiple trauma. ¹³

The use of the PLMA as an airway device in emergency Cesarean deliveries has been reported in case series and case reports, ¹⁴⁻¹⁸ and it has been used without adverse effects for postpartum tubal ligation. ¹⁹ Our prospective

observational study aims to evaluate the role of the SLMA in providing ventilation and oxygenation in carefully selected parturients undergoing lower segment Cesarean delivery under general anesthesia after at least four hours of fasting.

Methods

The study protocol was approved by the Institutional Review Board at the Women's and Children's Hospital of Quanzhou, and the study is registered with the local hospital's ethics trial registry (number: 20101008). All parturients provided written informed consent prior to study participation.

Participation

From June 2009 through May 2010, we recruited American Society of Anesthesiologists' physical status I and II parturients who were scheduled for elective Cesarean delivery under general anesthesia at the Women's and Children's Hospital of Quanzhou, Fujian Province, China. The majority of Cesarean deliveries in Fujian Province, China are performed under general anesthesia, usually because of patient preference. We excluded parturients with regional anesthesia, those in labour, or those fasting less than four hours. The SLMA is frequently used as routine care in parturients receiving general anesthesia at our institution. The airway was evaluated using the modified Mallampati classification, and only patients with Mallampati classification grades 1-3 were recruited. Parturients with a body mass index (BMI) $> 35 \text{ m.kg}^{-2}$, gastroesophageal reflux, or evidence of a potentially difficult airway (neck pathology or upper respiratory tract pathology) were excluded from the study. The parturients were fasted for at least six hours for elective surgery and from four to six hours for urgent Cesarean delivery (e.g., failed induction, intrauterine growth retardation, or oligohydramnios). Once the parturient satisfied the criteria for recruitment, consent for participation in the study was obtained in the antenatal ward, delivery suite, or induction room before the parturient arrived in the operating theatre.

Study protocol

The size of SLMA selected for each parturient was based on the manufacturer's recommendation. However, at the discretion of the attending anesthesiologist, a more appropriate size could be selected based on parturient height, BMI, and mouth opening.

The two investigators (Yao and Li), each with more than five years of anesthetic experience, inserted the airway



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device for all parturients. Both investigators were proficient with the SLMA, each having performed more than 100 SLMA placements in anesthetized parturients prior to the start of the trial.

Premedication consisted of sodium citrate 30 mL and ranitidine 150 mg, both given by mouth. Electrocardiogram, pulse oximetry, capnography, and non-invasive blood pressure measurements were applied to the parturient. After preoxygenation for three minutes, rapid sequence induction was carried out with cricoid pressure applied by an anesthetic nurse. Anesthesia was induced with propofol 2-3 $\text{mg}\cdot\text{kg}^{-1}$ iv and rocuronium 0.5 $\text{mg}\cdot\text{kg}^{-1}$ iv. Fentanyl 2 μg·kg⁻¹ was administered after the delivery of the fetus. No manual ventilation was used, and after clinical assessment that muscle paralysis had been achieved (such as timing of dose, adequate mouth opening, and neck movement), the SLMA was inserted using the technique described by the manufacturer, i.e., using a single-handed rotational technique until resistance was met. The cuff was then inflated with air to a pressure of 60 cm H₂O, as measured by an intracuff pressure monitor, and the volume of air needed to achieve this pressure was recorded. Once the SLMA was in place, the cricoid pressure was released, the cuff was inflated, and the ability to ventilate was confirmed.

Successful placement was confirmed by auscultation and the presence of end-tidal carbon dioxide on the capnogram. We recorded the number of attempts needed to achieve successful placement, with an attempt being defined as insertion and complete withdrawal of the device from the patient's airway. We also measured the time to effective airway placement, defined as the interval from when the device was picked up until appearance of the first end-tidal carbon dioxide waveform. After successful placement, a pre-mounted #14 orogastric tube was advanced via the gastric drainage aperture of the SLMA. Suction was performed at the beginning of the surgery and at the end of the surgery before emergence. The number of orogastric tube insertion attempts and failure to pass the orogastric tube were recorded. The oropharyngeal leak pressure was recorded by closing the adjustable pressurelimiting valve and insufflating the closed breathing system with 3 L·min⁻¹ of fresh gas flow. The peak circuit airway pressure achieved was recorded.

The investigator was allowed to use additional maneuvres (chin lift, jaw thrust, head extension) if necessary to achieve airway patency. If successful placement could not be achieved (i) after two attempts, (ii) within 60 sec, or (iii) before desaturation occurred (oxygen saturation or ${\rm SpO}_2 < 92\%$), the patient's airway was secured using direct laryngoscopy and tracheal intubation.

The surgical procedure was allowed to proceed if the following criteria were met:

- A square-wave capnograph tracing was present;
- The pilot cuff was inflated to 60 cm H₂O and checked with a manometer;
- The bite block of the SLMA was sitting between the incisors:
- The gastric tube was inserted into the drain tube, and the position was checked using insufflation of 5 mL of air and a stethoscope over the epigastric region, followed by performing active/passive suction and then by passive drainage of the gastric tube;
- The leak pressure was checked, and the observed peak circuit airway pressure achieved was ≥ 20 cm H_2O .²⁰

Anesthesia was maintained with 1.5-2.0% sevoflurane and 50% nitrous oxide in oxygen. All parturients were placed in the left tilted supine position. During maintenance of anesthesia, complications were recorded, including loss of airway, desaturation, inadequate ventilation, and bleeding onto the SLMA. The investigator could use additional maneuvres (chin lift, jaw thrust, head extension) or reposition the airway device if inadequate ventilation or desaturation (SpO₂ < 92%) occurred during anesthesia. Intravenous muscle relaxant, opioids, antibiotics, and antiemetics were administered according to our institution's protocol. The tidal volume was set from 6 mL·kg $^{-1}$ to 10 mL·kg $^{-1}$, and the respiratory rate ranged from 10-16 breaths·min $^{-1}$ to maintain an end-tidal carbon dioxide concentration of 30-40 mmHg. If there were signs of aspiration—as evidenced by perioperative hypoxemia, wheezing or crepitations upon auscultation of lungs, or postoperative dyspnoea—the parturient was followed up with chest x-ray, and long-term complications were documented upon the follow-up visit.

The obstetricians were given instructions to avoid excessive fundal pressure during extraction of the fetus. Upon completion of the surgery, the muscle paralysis was reversed, and the orogastric tube was suctioned and removed. After regular spontaneous respiration had returned in the lateral position and the parturient was conscious, the SLMA was removed and inspected for visible blood. Parturients were monitored in the postanesthetic care unit, and the presence of sore throat was assessed by an independent assessor prior to discharge.

The primary outcome was the incidence of aspiration, defined as gastric contents identified on the inner bowl of the SLMA with pH < 4.

Secondary outcomes were:

Anesthetic outcomes

- Incidence of regurgitation (gastric contents identified in the mouth with pH < 4),²¹
- Number of insertion attempts,



- Time to effective ventilation,
- Seal pressure/oropharyngeal leak pressure,
- Ventilatory parameters (tidal volume, respiratory rate, peak airway pressures) to maintain effective oxygenation and ventilation, defined as the ability to maintain SpO₂ ≥ 92% and an end-tidal carbon dioxide concentration of < 50 mmHg, using inspired oxygen concentration ≤ 0.5 with respiratory rate 10-18 breaths·min⁻¹ and tidal volume 6-10 mL·kg⁻¹,
- Amount (mL) and pH of gastric aspirate.

Obstetric outcomes

- Neonatal weight (g),
- Neonatal APGAR,
- Umbilical venous cord pH.

Maternal outcomes

- Parturient satisfaction with the whole anesthetic experience at 24 hr post-surgery, rated as a percentage (0-100%),
- Presence of sore throat,
- Presence of blood on the SLMA.

In addition, we compared the results of parturients who fasted for at least six hours for elective Cesarean delivery with the results of parturients who fasted four to six hours for urgent Cesarean delivery. Data were analyzed using SPSS® 14 software (Chicago, IL, USA). Parametric data were analyzed using the Student's *t* test, and non-parametric data were analyzed using the Mann-Whitney U test. Categorical data were analyzed using the Chi square test or Fisher's exact test.

Results

During the one-year period of the study at the hospital, 1,527 parturients underwent Cesarean delivery. Regional anesthesia was administered in 257 parturients, and 508 were in labour or had been fasting for less than four hours. Sixty parturients had exclusion criteria, including obesity and evidence of potential difficult airway, and two parturients did not give consent for this study. Thus, 700 parturients were recruited, and there was no withdrawal or dropout. Of these, 576 underwent elective Cesarean delivery (> six hours of pre-surgery fasting), and 124 had an urgent Cesarean delivery (four to six hours of pre-surgery fasting). Patient demographics are presented in

Table 1. All 700 parturients recruited for the study were included in our analysis.

A size-4 SLMA was inserted for airway management in all patients. There was no clinical evidence of aspiration or regurgitation in any of the parturients; insertion of the SLMA was successful in all cases, and we were able to maintain ventilation and oxygenation in all parturients. A second insertion attempt was required in 14 (2%) patients, each time because of fold-over of the laryngeal cuff during the first attempt. No more than two attempts were required for effective airway placement in all parturients. Time to effective airway was 19.5 (3.9) sec. Gastric tube placement was successful in 695 (99.3%) parturients on the first attempt and 5 (0.7%) parturients on the second attempt. Gastric volume aspirated was 25 mL (range, 3-90 mL), and the aspirated gastric fluid pH was 2.2 (0.4). The oropharyngeal leak pressure was 28 cm H₂O (range, 20-38 cm H₂O) and intracuff volume was 29.7 (2.5) mL. Tidal volume was 8.3 (0.6) mL·kg⁻¹ and the median peak airway pressure was 16 cm H₂O (range, 10-24 cm H₂O). The median difference between oropharyngeal leak pressure to peak airway pressure was 12 cm H₂O (range, 3-22 cm H₂O). No oropharyngeal leak pressure was lower than the peak airway pressure in this study. There was no leak detected clinically. We found no significant differences in airway insertion and ventilatory factors between parturients admitted for elective procedures and those admitted for urgent procedures (Table 2).

The duration of Cesarean delivery was 31 (6) min. No episodes of hypoxemia ($SpO_2 < 92\%$), laryngospasm, or bronchospasm were observed intraoperatively, and none of the parturients had clinical evidence of aspiration.

Neonatal weight was 3.12 (0.36) kg with a median APGAR score of 9 at one minute post-delivery and 10 at five minutes post-delivery. Cord venous pH was 7.31 (0.06). Blood was observed on the SLMA when it was removed in 18 patients (2.6%). Twenty-four parturients (3.4%) complained of sore throat. Parturient satisfaction was 85 (7)% after 24 hr postpartum. We found no significant differences between parturients admitted for elective procedures and parturients admitted for urgent procedures with regard to neonatal outcomes, complications, or side effects (Table 3).

Discussion

In this prospective observational study in a large sample of parturients, we found that the SLMA provided an acceptable means of ventilating and oxygenating parturients' Cesarean delivery.



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Table 1 I	Demographic	data
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Characteristic All Elective SLMA Urgent SLMA P value > 6 hr of fasting 4-6 hr of fasting Patients n = 700n = 576n = 124Age (yr) 28.1 (4.6) 28.0 (4.5) 28.0 (5.0) 0.460 Height (cm) 159.3 (4.0) 0.149 159.2 (4.1) 160.0 (3.6) Weight (kg) 65.0 (6.8) 64.9 (6.8) 65.0 (6.8) 0.912 BMI $(kg \cdot m^{-2})$ 25.6 (2.5) 25.6 (2.5) 25.5 (2.6) 0.556 Duration of surgery (min) 30.6 (6.1) 30.6 (6.1) 30.3 (6.1) 0.616 ASA 1 (1-2) 1(1-2)1 (1-2) 0.693 Mallampati score 1 (1-3) 1 (1-3) 1 (1-3) 0.703 Duration of Pregnancy (weeks) 38.8 (1.3) 38.8 (1.3) 39.9 (1.2) 0.736

Values are mean (standard deviation) or median (minimum-maximum)

SLMA = LMA SupremeTM;

BMI = body mass index,

ASA = American Society of Anesthesiologists' physical status classification

Table 2 Airway insertion and ventilatory profile

Characteristic	Elective procedures > 6 hr of fasting $n = 576$	Urgent procedures 4-6 hr of fasting $n = 124$	P value
No. of successful insertions after 1 st attempt (%)	563 (97.7)	123 (99.2)	0.295
Time to successful airway placement(s) (sec)	19.6 (3.9)	19.4 (3.7)	0.668
No. of attempts for success gastric tube insertion	1 (1-2)	1 (1-2)	0.893
Amount of gastric fluid aspirated (mL)	25 (5-90)	25 (3-80)	0.614
pH of aspirated gastric fluid	2.16 (0.46)	2.13 (0.38)	0.488
Cuff volume (mL)	29 (3)	29 (2)	0.200
Oropharyngeal leak pressure (cm H ₂ O)	28 (20-38)	28 (20-36)	0.306
Peak airway pressure (cm H ₂ O)	16 (10-22)	15 (10-24)	0.695
Respiratory rate (breaths·min ⁻¹)	12 (10-14)	11 (10-14)	0.194
Tidal Volume (mL⋅kg ⁻¹)	8.3 (0.6)	8.3 (0.6)	0.851

Values are in number of parturients (%), mean (standard deviation), or median (range) SLMA = LMA SupremeTM

Table 3 Neonatal outcomes, complications, and side effects associated with the airway device

Characteristic	Elective procedure > 6 hr of fasting $n = 576$	Urgent procedure 4-6 hr of fasting $n = 124$	P value
Neonatal weight (kg)	3.1 (0.4)	3.1 (0.3)	0.605
APGAR at 1 min	9 (6-10)	10 (5-10)	0.652
APGAR at 5 min	10 (7-10)	10 (7-10)	0.739
Umbilical venous cord pH	7.30 (0.06)	7.31 (0.57)	0.387
Blood on airway device n (%)	17 (3)	1 (0.8)	0.172
Sore throat n (%)	21 (3.6)	3 (2.4)	0.497
Patient satisfaction (0-100 scale)	85.8 (6.7)	84.9 (6.6)	0.165

Values are in number of parturients (%), mean (standard deviation), or median (minimum-maximum). SLMA = LMA SupremeTM

SLMA and risk of aspiration

Previous studies showed that both the PLMA and the SLMA have the ability to separate the gastric contents from the respiratory tract²² and prevent gastric insufflation during positive pressure ventilation.²³ Subsequent studies have

shown that the PLMA provided a good seal and could withstand an esophageal pressure of up to 82 cm H₂O before the esophageal seal was lost. This was shown in both cadaveric studies and *in vivo* studies.^{22,24,25}

While the PLMA and SLMA are seldom used electively for patients at risk of aspiration, the above studies suggest



that the adequate seal provided will allow drainage of gastric fluid even at high intragastric pressure without increasing the risk of aspiration. This can be achieved when the airway devices are positioned correctly. An *in vivo* study using methylene blue dye injected into the hypopharynx via the gastric drainage tube showed that a properly positioned PLMA can successfully prevent fluid in the hypopharynx from entering the airway.²⁶ This finding has led to justifying the use of the PLMA and SLMA in the management of the difficult airway in obstetrics.²⁷

Despite the low incidence of aspiration (1:667), even in the high-risk population, 28 there is still a need for prospective studies powered adequately to validate the safety of supraglottic devices in protecting against aspiration during anesthesia. Han et al. 29 found no cases of aspiration in 1,060 patients who underwent elective LSCS with a LMA ClassicTM, and Halaseh et al.³⁰ found no cases of aspiration in 3,000 patients who underwent elective LSCS with a PLMA. Our data will add to the current available literature on the use of supraglottic airway devices and the risk of aspiration in parturients. The SLMA showed an adequate seal in all of our parturients with no incidence of obstruction, loss of airway, or desaturation. Furthermore, the SLMA is a single-use disposable device that reduces the theoretical risk of transfer of infectious material or body fluids compared with improperly cleaned reusable devices. However, we emphasize that correct positioning of the SLMA is vital to achieve a good seal. If in doubt, fibreoptic bronchoscopic vision should be available to ascertain the correct placement of the device.

Risk of difficult intubation

The gold standard for securing a parturient's airway for Cesarean delivery has been tracheal intubation. However, this gold standard is not without its pitfalls. The incidence of difficult intubation is eight times greater in obstetric patients than in general surgical patients, with the risk of failed intubation ranging from 0.05-0.30%. 31-33 Difficult intubation has resulted in complications, including regurgitation, aspiration, airway truama, dental trauma, esophageal intubation, maternal and fetal hypoxemia, and even death. Difficult intubation with ensuing hypoxia—not aspiration per se—is the leading anesthetic cause of maternal death. 34-37 The use of PLMA and SLMA may reduce the complications of multiple attempts while providing a good method of oxygenation and ventilation.

Limitations

Although this study is an extensive review of the use of the SLMA in parturients undergoing Cesarean delivery, it does

have some limitations. The study size is small for capturing a rare event, such as aspiration, and without a single case in the study, the risk of aspiration cannot be estimated when using the device in this population. Furthermore, the parturients in our study were relatively slim with normal airways, and they had a relatively low risk of aspiration, hence, future larger trials will need to be conducted. We excluded parturients with a high BMI because of the greater risk of regurgitation and inadequate ventilation. The mean BMI in our patient group was only 25.6 kg·m⁻². Many women can have considerable weight gain during pregnancy, and the safe use of a supraglottic device in obese parturients requires further evaluation. Cesarean delivery in our study had an average duration of 31 min; however, complicated Cesarean deliveries, especially those involving hysterectomy, may take considerably longer. Prolonged surgery is not a contraindication for the use of a SLMA provided adequate measures are taken to maintain the intracuff pressure and correct positioning of the SLMA. This study involved very experienced anesthesiologists, each with more than two years of experience in using the SLMA. We do not advocate that this technique be used by operators unfamiliar with the SLMA. Although antacid prophylaxis was administered prior to induction of anesthesia, the measured volume of gastric contents was relatively low, but pH was low. This reiterates the importance of fasting and careful selection of parturients when supraglottic airway devices are used during Cesarean delivery. Also, excessive fundal pressure should be avoided during delivery of the fetus to prevent excessive intragastric pressure.³⁰

In conclusion, our findings suggest that the SLMA might be a useful alternative to tracheal intubation for Cesarean delivery in a carefully selected population of relatively slim parturients undergoing elective or semi-urgent Cesarean deliveries with at least four hours of fasting. We are not advocating that the use of tracheal intubation be abandoned, but merely highlight an alternative method of airway management in the obstetric population. The use of the SLMA may decrease the risk of complications associated with difficult intubation in obstetric patients. With careful patient selection, experienced users may find this technique useful, particularly in early conversion to SLMA in failed intubation scenarios, therefore potentially decreasing anesthesia-related maternal morbidity.

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