The laryngeal mask airway is effective (and probably safe) in selected healthy parturients for elective Cesarean section: a prospective study of 1067 cases

[Le masque laryngé est efficace et, probablement, sans risque pour une césarienne non urgente chez des parturientes en bonne santé : une étude prospective de 1 067 cas]

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Purpose: To report on the use of the laryngeal mask airway (LMA) for elective Cesarean section in 1067 consecutive ASA I–II patients preferring general anesthesia.

Methods: Patients were excluded if they had pharyngeal reflux, a pre-pregnancy body mass index >30, or had a known/predicted difficult airway. Patients were fasted for six hours and given ranitidine/sodium citrate. A rapid sequence induction was performed with thiopentone and suxamethonium. The LMA was inserted by experienced users. Anesthesia was maintained with N_2O and 50% O_2 and a volatile agent. Cricoid pressure was maintained until delivery, but was relaxed if insertion/ventilation was difficult. Patients were intubated if an effective airway was not obtained within 90 sec, or SpO_2 <94%, or end-tidal CO_2 >45 mmHg. Postdelivery, vecuronium and fentanyl were administered.

Results: An effective airway was obtained in 1060 (99%) patients, 1051 (98%) at the first attempt and nine (1%) at the second or third attempt. Air leakage or partial airway obstruction occurred in 22 (21%) patients, and seven (0.7%) patients required intubation. There were no episodes of hypoxia (SpO_2 <90%), aspiration, regurgitation, laryngospasm, bronchospasm or gastric insufflation. Surgical conditions were satisfactory and all APGAR scores were ≥7 after five minutes.

Conclusion: We conclude that the LMA is effective and probably safe for elective Cesarean section in healthy, selected patients when managed by experienced LMA users.

Objectif : *Présenter l'usage du masque laryngé (ML) pour la césarienne de 1 067 patientes successives d'état physique ASA I-II qui ont demandé une anesthésie générale.*

Méthode : *Des patientes ont été exclues de l'étude si elles souffraient de reflux pharyngien, présentaient un indice de masse corporelle prégrossesse > 30 ou si l'intubation avait déjà été difficile ou s'annonçait comme tel. Un jeûne de six heures a été exigé et on a administré de la ranitidine et du citrate de sodium. Une induction à séquence rapide a été réalisée avec du thiopental et du suxaméthonium. Le ML a été inséré par des utilisateurs expérimentés. Le maintien de l'anesthésie s'est fait avec du N_2O et de l'O_2 à 50 % et un anesthésique volatil. La pression du cricoïde, maintenue jusqu'à l'accouchement, a été relâchée si l'insertion du masque ou la ventilation était difficile. Les patientes ont été intubées si on ne pouvait libérer efficacement les voies aériennes en moins de 90 s, ou si la SpO_2 était < 94 %, ou le CO_2 télé-expiratoire > 45 mmHg. Après l'accouchement, du vécuronium et du fentanyl ont été administrés.*

Résultats : *La libération des voies aériennes a été efficace chez 1 060 (99 %) patientes, au premier essai chez 1 051 (98 %) et au second ou au troisième essai chez neuf patientes (1 %). Une fuite d'air ou une obstruction partielle s'est produite chez 22 (21 %) patientes, et sept (0,7 %) patientes ont eu besoin d'intubation. Il n'y a pas eu d'hypoxie (SpO_2 < 90 %), d'aspiration, de régurgitation, de laryngospasme, de bronchospasme ou d'insufflation gastrique. Les conditions chirurgicales ont été satisfaisantes et tous les indices d'Apgar ont été ≥ 7 après cinq minutes.*

Conclusion : *Le ML est efficace et, probablement, sans risque pour la césarienne chez des femmes sélectionnées et en bonne santé, lorsqu'il est manipulé par des utilisateurs expérimentés.*

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THE laryngeal mask airway (LMA) has been used successfully for elective surgery where the patient would traditionally be considered at increased risk of aspiration either because of the type of surgery,[1,2] or because of co-existing upper gastrointestinal disease.[3] The current standard of practice for airway management of patients undergoing Cesarean section is to perform a rapid sequence induction followed by laryngoscope-guided tracheal intubation to protect the airway and facilitate ventilation.[4] The use of the LMA for Cesarean section has been limited to failed[5] or awake intubation[6] because of the perceived risk of aspiration and/or the need for positive pressure ventilation in the presence of high intraabdominal pressure. However, the risk of aspiration without tracheal intubation may have been overestimated in the obstetric population.[7] Furthermore, the incidence of aspiration with the LMA for elective surgery is similar to that with tracheal intubation,[8] reflux is rare with the LMA even in at risk patients,[3] and the LMA has provided adequate ventilation in situations where intraabdominal pressure is raised such as pneumoperitoneum,[1] obesity[9] and failed intubation in obstetric patients.[5] The LMA also offers potential advantages over the tracheal tube for elective patients in terms of hemodynamic responses, pulmonary physiology, emergence and postoperative airway morbidity.[10] In the following prospective study, we describe the use of the LMA for elective Cesarean section in 1067 healthy, selected patients.

Methods

With Ethics Committee approval and written informed consent, we prospectively studied ASA I–II consecutive patients presenting for elective Cesarean section who preferred general anesthesia. Patients were excluded if they had symptoms of pharyngeal reflux, a pre-pregnancy body mass index >30, or had a known/predicted difficult airway. The study was conducted at our Medical Center between January 1999 and July 2000 where the number of deliveries ranges from 150–200 per month with a Cesarean section rate of 40–50%. There were seven anesthesiologists participating in the trial each with more than seven years experience with the LMA.

A standard anesthesia protocol was followed and routine monitoring applied. Patients were fasted (solids and fluids) for six hours and given ranitidine 50 mg intravenously one hour before surgery and sodium citrate 30 mL orally immediately before surgery. In the operating room, patients were placed in the supine position with 15–25 left lateral tilt. The head was on a firm pillow. Patients were preoxygenated with four vital capacity breaths of oxygen 100% and underwent a rapid sequence induction with thiopentone 3–4 $mg \cdot kg^{-1}$, suxamethonium 1.5 $mg \cdot kg^{-1}$ and single-handed cricoid pressure by an assistant. Patients were ventilated via a face mask with oxygen 100% until the fasciculations had ceased. The LMA (size 3 <45 kg; size 4 $\geq$ 45 kg) was then inserted according to the manufacturer's recommended guidelines with the neck flexed and head extended.[11] The insertion technique included full deflation of the cuff, careful placement of the cuff flat against the hard palate and pushing the device into and along the posterior palato-pharyngeal curve using the index finger. The cuff was inflated with air in 2–3 mL increments until an effective airway was obtained or until the maximum recommended volume was reached (size 3, 20 mL; size 4, 30 mL). An effective airway was defined as chest wall movement and a square wave capnograph trace. If an effective airway could not be obtained, cricoid pressure was relaxed and the position of the LMA adjusted, or the LMA was removed and re-inserted. Cricoid pressure was reapplied if an effective airway was eventually obtained and only relaxed if ventilation was impeded. The best level of cricoid pressure that was compatible with effective ventilation was maintained until delivery. Anesthesia was maintained with 50% N_2O in O_2 and either enflurane 1.0–1.5%, or isoflurane 0.5–1.5%. Patients were ventilated at 8–12 $mL \cdot kg^{-1}$ via a circle system. Anesthesiologists were free to adjust the inspired oxygen concentration or minute volume to maintain $SpO_2 \geq 94\%$ and the end tidal $CO_2 \leq 45$ mmHg. If an effective airway could not be obtained within 90 sec, or the SpO_2 <94%, or the end-tidal CO_2 >45 mmHg at any time during the procedure, the patient underwent conventional laryngoscope-guided tracheal intubation. Patients were face-mask ventilated with cricoid pressure applied between insertion attempts. Delivery was either manual or with forceps. If fundal pressure was applied during delivery, positive pressure ventilation was briefly halted to reduce the risk of gastric insufflation.

Following delivery, oxytocin 20 units was given to contract the uterus, vecuronium 0.05 $mg \cdot kg^{-1}$ was given to improve surgical conditions and fentanyl was given in 100 μg increments for analgesia. Neuromuscular blockade was reversed at the time of skin closure with glycopyrrolate 0.008 $mg \cdot kg^{-1}$ and pyridostigmine 0.3 $mg \cdot kg^{-1}$. Emergence was in the operating room in the supine position. The LMA was removed when the patient was able to open her mouth to command. The presence/absence of any clear or bile stained fluid or blood was noted upon removal of

TABLE APGAR scores at one and five minutes postdelivery for patients managed with the laryngeal mask airway. Data are numbers (%)

Score	*1 min*	*5 min*
2	3 (0.3)	0
3	0 (0)	0
4	10 (1)	0
5	8 (8)	0
6	4 (4)	0
7	6 (6)	1 (0.1)
8	443 (42)	2 (0.2)
9	179 (17)	15 (1.4)
10	410 (39)	1,042 (98)

the LMA. The postanesthesia care unit nurse collected information about the presence/absence of sore throat before discharge to the ward.

The anesthesiologist conducting the case recorded the number of insertion attempts, the volume of air to obtain an effective airway, any episodes of hypoxia (SpO_2 <90%) and any other major adverse events (regurgitation, aspiration, laryngospasm, bronchospasm, gastric insufflation). Regurgitation was diagnosed if clear or bile stained fluid was seen during the procedure or at LMA removal. Aspiration was diagnosed if bile-stained fluid was seen in the lungs with a fibreoptic endoscope or if postoperative radiological evidence was present. Laryngospasm was diagnosed by the characteristic sound associated with partial airway obstruction and relieved by suxamethonium. Bronchospasm was diagnosed by auscultation of the lungs. Gastric insufflation was diagnosed by auscultation of the epigastrium. Fibreoptic and radiological investigations were performed only if regurgitation occurred or aspiration was otherwise suspected (hypoxia, bronchospasm, laryngospasm). Epigastric auscultation was performed only if there was an air leak than was not oropharyngeal or if gastric distension was seen. A failed insertion attempt was defined as removal of the device from the mouth. The pediatrician or midwife recorded the APGAR scores at one and five minutes. Patients were followed up until the time of home discharge.

Results

The mean (SD, range) age, height and body weight (pre-pregnancy/and at term), was 29 (4, 18–44) yr, 159 (5, 130–173) cm and 54 (8, 34–86) kg / 67 (9, 45–110) kg respectively. Only ten patients were excluded because of pharyngeal reflux. The mean (SD, range) for duration of surgery was 41 (11, 30–91). The commonest indications for elective Cesarean section were: previous Cesarean section (n=521) and cephalopelvic disproportion (n=410). Other indications were breech presentation (n=62), premature rupture of membranes (n=33), failed induction (n=10), potential fetal problems (n=9), age over 45 yr (n=8), twins (n=5), transverse lie (n=1), pre-eclampsia (n=1), double vagina (n=1) and hysterostomy (n=1). The LMA provided an effective airway in 1060 (99%) patients, 1051 (98%) at the first attempt and 8 (1%) at the second or third attempt. Air leakage or partial airway obstruction occurred in 22 (21%) patients and seven (0.7%) patients required tracheal intubation. There were no episodes of hypoxia and no aspiration, regurgitation, laryngospasm, bronchospasm or gastric insufflation was detected. The mean (SD) volume of air required to form an effective airway was 15 (3) mL. All APGAR scores were 7 or greater after five minutes (Table). There was no clear or bile stained fluid following removal, but in three (0.3%) patients there was blood on the posterior surface of the cuff. Five (0.5%) patients managed with the LMA complained of a sore throat. All obstetricians were satisfied with the pre- and postdelivery surgical conditions. There was no evidence of aspiration in any patient before home discharge. No patient was admitted to the intensive care unit.

Discussion

We found that LMA insertion was successful at the first attempt in 98% of patients with cricoid pressure applied. The success rate for LMA insertion with cricoid pressure varies between studies from 15 to 100% with most studies averaging 63%.[12] We attribute our high insertion success rate to adherence to the recommended technique, a high level of skill with the LMA, the use of suxamethonium to provide optimal conditions and the policy of easing up on cricoid pressure and reapplying it if insertion was unsuccessful. Unfortunately, we did not collect data on the frequency with which cricoid pressure was relaxed. We released cricoid pressure following delivery because we considered that the reduction in intraabdominal pressure would reduce the risk of reflux. We were also concerned that prolonged application of cricoid pressure might traumatize the esophageal mucosa and cause sore throat. The safety and efficacy of cricoid pressure in clinical practice has been recently reviewed and its role in anesthesia remains opinion rather than evidence-based.[1 3]

We found that the LMA provided an effective airway in 99.3% of patients. Similarly, high success rates have been reported by others.[2,14] There are no studies of positive pressure ventilation using the LMA in obstetric patients, but the LMA has been shown to be effective in patients with a body mass index >30[9] and

during pneumoperitoneum for laparoscopic cholecystectomy.[1] Interestingly, there is some evidence that the efficacy of seal of the LMA is greater in large patients and this may have contributed towards the high ventilatory success rate.[15]

Obstetric patients are considered to be at high risk of aspiration because of the reduction in barrier pressure and upper esophageal sphincter pressure, particularly if they have symptoms of heartburn.[4] However, this risk may have been overestimated. The incidence of aspiration in obstetric patients has been reported by a number of groups. Ezri *et al.*[7] found the incidence was 0.053% (1/1870) for peripartum anesthesia without tracheal intubation, Kranz and Edwards[16] 0.228% (7/3076) and Olsson *et al.*[17] 0.15% (4/2643) for Cesarean section in intubated patients. These studies included both elective and emergency cases and the risk in elective cases alone is likely to be lower. The incidence of aspiration for intubated patients undergoing elective outpatient surgery is approximately 0.02%.[18] We detected no adverse events in 1069 patients. Assuming a binomial distribution for the incidence of adverse events, the upper limit for the probability of an adverse event occurring when no adverse events have been observed in 1069 patients is 0.004.[19] Therefore we can state with 95% confidence that the technique appears to be safe in at least 99.6% of healthy, selected patients. A much larger study would be needed to compare the incidence of regurgitation and/or aspiration between the LMA and tracheal tube in elective obstetric patients, but we feel that such a study is justified. Interestingly, we found no clinical evidence of regurgitation, which is five to ten times more common than aspiration with the LMA.[8] We attribute our lack of regurgitation/aspiration to careful patient selection, adherence to fasting guidelines and antacid prophylaxis, muscle relaxation for LMA insertion, the application of cricoid pressure, the use of highly experienced anesthesiologists, use of the recommended insertion/fixation techniques, the rapid deployment of a failed LMA drill and avoidance of difficult laryngoscope-guided tracheal intubation. There is evidence that most episodes of gastroesophageal reflux during anesthesia occur from and during bucking.[20,21] In addition, there is evidence from cadavers that the correctly placed LMA tip can prevent liquid flow between the esophagus and pharynx.[22] Expansion of the cuff secondary to diffusion of nitrous oxide does not cause displacement of the cuff from the hypopharynx.[23] Of note, Stone *et al.*[24] in a study of in- hospital cardiac arrest found that when the patient was ventilated with the face mask alone, or the face mask followed by tracheal intubation, the incidence of regurgitation was 12.4%, but when the patient was ventilated by the LMA alone, or the LMA followed by tracheal intubation, the incidence of regurgitation was 3.5%.[24]

We found the incidence of bleeding and sore throat to be 0.3% and 0.5% respectively. The incidence of bleeding varies between 1[25] and 44%[26] and the incidence of sore throat varies between 0 to 70% with an average of 10%.[27] We attribute our low incidence of bleeding and sore throat to careful insertion and using the minimal cuff volume required to form an effective seal. Some studies have shown that suxamethonium increases the risk of sore throat,[28] but this was not apparent in our study. We used suxamethonium to provide rapid optimal conditions to LMA insertion without giving large doses of induction agent and to provide optimal conditions for intubation should LMA insertion have failed.

The LMA is recommended for airway rescue in failed obstetric intubation.[29] Gature *et al.*[5] reported the successful use of the LMA in 21/24 patients for failed intubation in obstetrics. In some of these patients the LMA was used as an airway intubator. Our data suggests that there may be no need to attempt intubation through the LMA if it is used for airway rescue in similarly prepared and selected obstetric cases. Interestingly, the incidence of failed LMA insertion in obstetric patients was similar to that for tracheal intubation.[30]

We performed face mask ventilation following induction of anesthesia prior to LMA insertion. Some experts consider that this puts the patient at risk of gastric insufflation and hence regurgitation and aspiration.[4] However, there is no prospective evidence to support this opinion and cricoid pressure is known to prevent gastric insufflation during face mask ventilation.[13] We allowed patients to awake in the supine position because we considered that the process of moving the patient into the lateral position puts the patient at greater risk of regurgitation and aspiration than leaving them in the supine position.

Our study has a number of limitations. First, although cricoid pressure was applied by trained assistants, the level of force was unknown. Second, we did not routinely measure tracheal pH or obtain postoperative chest *x-rays* and so we cannot exclude silent regurgitation/aspiration. Third, data was collected by the anesthesiologist conducting the case rather than an independent observer, a source of possible bias. Fourth, we only collected sore throat data in the immediate postoperative period and the incidence may have been underestimated.

Based on this prospective study of 1067 cases, we conclude that the LMA is effective and probably safe for elective Cesarean section in healthy, selected patients when managed by experienced LMA users.

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