The LMA-ProSeal™ is an effective alternative to tracheal intubation for laparoscopic cholecystectomy

[Le LMA-ProSeal™ remplace efficacement l'intubation endotrachéale pendant la cholécystectomie laparoscopique]

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Purpose: To compare LMA-ProSeal™ (LMA-PS) with endotracheal tube (ETT) with respect to pulmonary ventilation and gastric distension during laparoscopic cholecystectomy.

Methods: We randomized 109 ASA I–III adults to LMA-PS or ETT after stratifying them as non-obese or obese (body mass index > 30 $kg \cdot m^{-2}$). After preoxygenation, anesthesia was induced with propofol, fentanyl and rocuronium. An LMA-PS (women #4, men #5) or ETT (women 7 mm, men 8 mm) was inserted and the cuff inflated. A #14 gastric tube was passed into the stomach in every patient and connected to continuous suction. Anesthesia was maintained with nitrous oxide, oxygen and isoflurane. Ventilation was set at 10 $mL \cdot kg^{-1}$ and 10 $breaths \cdot min^{-1}$. The surgeon, blinded to the airway device, scored stomach size on an ordinal scale of 0–10 at insertion of the laparoscope and upon decompression of the pneumoperitoneum.

Results: There were no statistically significant differences in SpO_2 or $P_{ET}CO_2$ between the two groups before or during peritoneal insufflation in either non-obese or obese patients. Median (range) airway pressure at which oropharyngeal leak occurred during a leak test with LMA-PS was 34 (18–45) cm water. Change in gastric distension during surgery was similar in both groups. Four of 16 obese LMA-PS patients crossed over to ETT because of respiratory obstruction or airway leak.

Conclusions: A correctly seated LMA-PS or ETT provided equally effective pulmonary ventilation without clinically significant gastric distension in all non-obese patients. Further studies are required to determine the acceptability of the LMA-PS for laparoscopic cholecystectomy in obese patients.

Objectif : *Comparer le LMA-ProSeal™ (LMA-PS) et le tube endotrachéal (TET) quant à la ventilation pulmonaire et à la distension gastrique pendant la cholécystectomie laparoscopique.*

Méthode : *Le tirage au sort de 109 adultes d'état physique ASA I–III, répartis en deux groupes, LMA-PS ou ETT, a été stratifié sur les facteurs non obèses ou obèses (indice de masse corporelle > 30 $kg \cdot m^{-2}$). Après la préoxygénation, l'anesthésie a été induite avec du propofol, du fentanyl et du rocuronium. Un LMA-PS (no 4 : femmes et no 5 : hommes) ou un TET (7 mm : femmes et 8 mm : hommes) a été inséré, et le ballonnet gonflé. Un tube gastrique no 14 a été poussé dans l'estomac et relié à une aspiration continue. L'anesthésie a été maintenue avec du protoxyde d'azote, de l'oxygène et de l'isoflurane. La ventilation a été instaurée à 10 $mL \cdot kg^{-1}$ et 10 $respirations \cdot min^{-1}$. Le chirurgien a coté, sans connaître le dispositif d'intubation utilisé, la taille de l'estomac selon une échelle ordinale de 0–10 au moment de l'insertion du laparoscope et lors de la décompression du pneumopéritoine.*

Résultats : *Les SpO_2 et $P_{ET}CO_2$ n'ont pas présenté de différence intergroupe statistiquement significative avant ou pendant l'insufflation péritonéale chez les patients obèses ou non. La pression médiane des voies aériennes (limites) à laquelle une fuite oropharyngienne est survenue pendant une épreuve d'étanchéité avec le LMA-PS a été de 34 (18–45) cm d'eau. La variation de distension gastrique peropératoire a été comparable entre les groupes. Quatre des 16 patients obèses porteurs du LMA-PS ont été intégrés au groupe TET à cause d'obstruction respiratoire ou d'une fuite du masque laryngé.*

Conclusion : *Un LMA-PS ou un TET bien installé permet une ventilation également efficace sans distension gastrique significative chez tous les patients non obèses. D'autres études devront déterminer l'acceptabilité du LMA-PS pour la cholécystectomie laparoscopique chez les obèses.*

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BRAIN designed the original laryngeal mask airway, now designated the LMA-Classic™ (LMA-C; The Laryngeal Mask Company, Henley-on-Thames, UK) as an alternative to the endotracheal tube (ETT) or face mask for use with either spontaneous or positive pressure ventilation (PPV).[1] He reported the successful use of an LMA prototype with PPV for 16 cases of gynecologic laparoscopy in 1983,[1] thus challenging the belief that tracheal intubation was always essential for PPV. Other investigators have used PPV with the LMA-C with minimal morbidity.[2–7] Widespread acceptance of the LMA-C for gynecologic laparoscopic procedures[8] in the United Kingdom suggests that the risks of an unprotected airway, hypoventilation and gastric distension are no more frequent than with tracheal intubation. However, use of the LMA-C is not recommended in obese patients and those with reduced pulmonary compliance because leak of gases to atmosphere may occur with airway pressure > 20 cm water.

The LMA-ProSeal™[9] (LMA-PS; Laryngeal Mask Company, Henley-on-Thames, UK) became commercially available in Canada in 2000. Its cuff extends over the posterior surface of the mask as well as around its periphery. This pushes the mask anteriorly to provide a better seal around the glottic aperture and permits peak airway pressure > 30 cm water without leak. A drain tube, parallel to the ventilation tube, passes through the bowl of the mask and tip of the cuff to lie at the upper esophageal sphincter. This permits drainage of passively regurgitated gastric fluid away from the airway, or blind passage of a gastric drain tube. The LMA-PS may therefore be more suitable than the LMA-C in patients with decreased total lung compliance who require PPV, and for surgical procedures in which intraoperative gastric drainage or decompression is desirable.

In a previous study in non-obese patients undergoing laparoscopic cholecystectomy with PPV,[7] we confirmed that there were no clinically significant differences in pulmonary ventilation measurements or gastric distension between the LMA-C and ETT. In this study, we compared pulmonary ventilation measurements, gastric distension and emergence outcomes between the LMA-PS and ETT in non-obese and obese patients for laparoscopic cholecystectomy. We chose this procedure because increased intra-abdominal pressure from pneumoperitoneum requires the higher airway pressures for adequate pulmonary ventilation for which the LMA-PS was designed. In addition, the surgeon may assess the stomach visually without resort to clinical surrogate markers, and determine whether gastric distension interferes with the surgical field.

Methods

The University of Calgary Conjoint Health Research Ethics Board approved the study protocol and all patients gave written informed consent. One hundred and nine patients, aged ≥ 18 yr, ASA physical status I–III, scheduled for elective laparoscopic cholecystectomy under general anesthesia were randomized to either LMA-PS or ETT using a computer-generated table of random numbers after being stratified as non-obese or obese [body mass index (BMI) > 30 $kg \cdot m^{-2}$] to assure approximately equal distribution between LMA-PS and ETT. Patients with a history of gastroesophageal reflux or hiatus hernia were included, provided they were currently asymptomatic and had taken an H_2 receptor blocker or proton pump inhibitor on the morning of surgery. Patients fasted according to current Canadian Anesthesiologists' Society guidelines. Sedative premedication was given if requested by the patient.

The four investigators had extensive experience over several years with the LMA-C and six months experience with the LMA-PS. Non-invasive blood pressure, electrocardiogram, and pulse oximeter monitors were placed on each patient. Preoxygenation was maintained for three minutes to avoid bag and mask ventilation between induction of anesthesia and inflation of the cuff of the airway device. Anesthesia was induced with 20 mg lidocaine, 2–2.5 $mg \cdot kg^{-1}$ propofol, 1–2 $\mu g \cdot kg^{-1}$ fentanyl, and up to 0.75 $mg \cdot kg^{-1}$ rocuronium intravenously.

In the LMA-PS group, we used size 4 for women and size 5 for men. The cuff was inflated to 45 mmHg pressure, equivalent to the manufacturer's recommended 60 cm water. After connecting the LMA-PS to the anesthetic circuit and observing chest movement and $P_{ET}CO_2$ waveform during manual ventilation, we used three additional tests to confirm correct placement. First, we performed a pressure leak test. We set a continuous fresh gas flow (FGF) of 3 $L \cdot min^{-1}$ with the circuit connected to the reservoir bag and the adjustable pressure limiting valve closed. We recorded the airway pressure plateau at which an audible leak occurred. We then set tidal volume at 10 $mL \cdot kg^{-1}$ and frequency 10·min^{-1}. Next, we filled the proximal 3 cm of the drain tube with a water-soluble lubricant jelly. If a gas bubble rose through the jelly, this indicated a gas leak into the drain tube and we corrected the LMA-PS position. Finally, we passed a #14 Salem sump gastric tube into the stomach via the drain tube to confirm that the tip of the cuff lay correctly at the upper esophageal sphincter, to assess the ease of passing the gastric tube and to determine whether gastric suction ensured a 'flat' stomach.

In the ETT group, we used size 7 mm for women, 8 mm for men and inflated the cuff until no leak was

TABLE I Demographic data

	LMA-PS *n = 50*	*ETT* *n = 55*
Sex (F/M)	33/17	43/12
Age (yr)	44 ± 13	44 ± 15
Weight (kg)	78 ± 16 (45–122)	81 ± 18 (53–133)
Body mass index ($kg \cdot m^{-2}$)	28 ± 6 (18–47)	29 ± 6 (19–45)
Anesthetic time (min)*	95 ± 36 (43–225)	104 ± 52 (46–326)
Peritoneal insufflation time (min)	57 ± 35 (18–129)	59 ± 31 (14–179)

*Includes procedures converted to open cholecystectomy. Values are mean ± SD (range). LMA-PS = laryngeal mask airway ProSeal™; ETT = endotracheal tube.

TABLE II Non-obese patients. Ventilation variables before and during peritoneal insufflation

	Before peritoneal insufflation		*During peritoneal insufflation*	
	LMA-PS *n = 50*	*ETT* *n = 55*	*LMA-PS* *n = 50*	*ETT* *n = 55*
SpO_2	99 ± 1	99 ± 1	98 ± 2	98 ± 2
$P_{ET}CO_2$ (mmHg)	31 ± 3	31 ± 4	36 ± 4	37 ±4
FIO_2	43 ± 7	44 ± 7	40 ± 5	39 ± 6
Vmin (L)	6.8 ± 1.5	6.9 ± 1.7	6.6 ± 1.5	6.9 ± 1.8
Airway pressure (cm H_20)	18 ± 5	19 ± 5	25 ± 5	25 ± 5

Values are mean ± SD. LMA-PS = laryngeal mask airway ProSeal™; ETT = endotracheal tube.

audible, and passed the gastric tube through a Williams Airway Intubator™ (Anesthesia Associates, San Marcos, CA, USA).

The gastric tube was connected to suction for the duration of the surgical procedure in both groups. The patient's head and neck were covered to conceal the airway device before the surgeon entered the operating room.

We maintained anesthesia with isoflurane and nitrous oxide in 30–50% oxygen with incremental doses of fentanyl. Rocuronium was given to maintain the neuromuscular blockade at one twitch of a train-of-four. High initial FGF (6 $L \cdot min^{-1}$) was reduced to maintenance flows according to each anesthesiologist's normal practice. The surgeon inserted a trochar into the peritoneal cavity under direct vision. Peritoneal insufflation pressure was preset and maintained at 15 mmHg. Head-up and lateral tilt were provided at the surgeon's request. Measurements of SpO_2, FIO_2, $P_{ET}CO_2$, FGF, minute ventilation and peak airway pressure were recorded before peritoneal insufflation and approximately five minutes before peritoneal deflation. Each surgeon inspected the stomach laparoscopically at a) initial entry of the laparoscope and b) immediately before removal of the laparoscope at the end of the surgical procedure. They scored the size of the stomach on an ordinal scale 0–10, where 0 = empty stomach and 10 = distension that interfered with surgical exposure. Peritoneal insufflation time and total anesthetic time were recorded. The occurrence of cough, vomiting, laryngeal stridor or spasm and the need for airway intervention during emergence from anesthesia were recorded. Each patient was contacted on the first postoperative day to identify anesthesia related morbidity.

For sample size, we addressed the following comparisons. This protocol had a 90% chance of detecting a difference with 31 patients in each group if differences between groups in SpO_2 exceeded 2% and $P_{ET}CO_2$ exceeded 5 mmHg. This protocol had a 90% chance of detecting a difference with 31 patients in each group if no clinically significant change in stomach size ($\uparrow \leq 2$ score) occurred in 50% of those in the LMA-PS group and in 90% of patients in the ETT group. Accordingly, the number of patients recruited was sufficient to detect clinically meaningful differences.

The LMA-PS patients and ETT patients were compared using an independent group's t test (for measured variables) and Fisher's exact test (for discrete variables). Fisher's exact test was used to assess changes in gastric distension after the scores were converted into three clinically relevant ranges: slight decrease ($\downarrow$ 1–2), no change or slight increase ($\uparrow$ 0–2), marked increase ($\uparrow$ 3–6). No adjustments were made for multiple comparisons. When *P* values were less than 5%, comparisons are noted in the tables.

Results

Complete data were obtained from 105 of the 109 original randomized patients because four of 16 obese patients in the LMA-PS group were crossed over to the ETT group and their data were excluded from analysis. The remaining 105 comprised 76 non-obese and 29 obese patients. The groups were comparable for age, weight, BMI, peritoneal insufflation time and total anesthetic time (Table I).

The median (range) airway pressure during the pressure leak test with *continuous* PPV immediately after inflation of the LMA-PS cuff was 34 (18–45) cm water. However, even when the leak test plateau pressure was low, adequate peak airway pressures without gas leak were achieved with *intermittent* PPV during the surgical procedure. Peak airway pressure during peritoneal insufflation in obese patients for LMA-PS and ETT were 30 ± 5 and 30 ± 4 cm water. Differences in ventilation measurements of SpO_2,

TABLE III Gastric distention change (exit score - entry score) during peritoneal insufflation

	LMA-PS *n = 50**	*ETT* *n = 55**
Entry score: median (range)	2 (0–7)	3 (0–7)
Change in score from entry		
↓ 1–2	6	3
↑ 0–2	41	46
↑ 3–6	1	4

*Stomach completely obscured by fat in two patients in each group. LMA-PS = laryngeal mask airway ProSeal™; ETT = endotracheal tube.

TABLE IV Respiratory events at extubation

Event	*LMA-PS* *n = 50*	*ETT* *n = 55*
None	48*	6*
Cough	2*	48*
Laryngeal stridor or spasm	2	5
Positive pressure ventilation	0	1
Tracheal intubation	0	0

*$P < 0.05$ LMA-PS *vs* ETT. LMA-PS = laryngeal mask airway ProSeal™; ETT = endotracheal tube.

FIO_2, $P_{ET}CO_2$, minute volume and airway pressure between LMA-PS and ETT groups were not statistically significant, either before or during peritoneal insufflation (Table II). There was no correlation between BMI and SpO_2, FIO_2 or $P_{ET}CO_2$. During maintenance of anesthesia, three of the four anesthesiologists reduced FGF to the minimum required to refill the reservoir bag and used 250–600 $mL \cdot min^{-1}$ in all their cases. The fourth anesthesiologist used 1–2 $L \cdot min^{-1}$ in all his cases.

Median score and range of stomach size on entry of the laparoscope, and change in stomach size during surgery, were similar in both groups (Table III). The stomach appeared distended in some patients, despite continuous suction, but this did not interfere with surgery in any patient in either group.

Coughing during emergence from anesthesia occurred in two of 50 patients in the LMA-PS group and in 48 of 55 patients in the ETT group. Laryngeal stridor following extubation was mild, except in one patient in the ETT group who briefly required manual PPV (Table IV).

Discussion

Our results demonstrate that the LMA-PS was as effective as an ETT to maintain pulmonary ventilation within acceptable clinical limits, except in four obese patients who required crossover from LMA-PS to ETT. Stomach size at insertion of the laparoscope and change in stomach size during surgery were similar in both groups. These results are similar to those in our previous study[7] in which we compared LMA-C *vs* ETT in non-obese patients and did not pass a gastric tube. The only statistically significant differences in this study were related to smoother emergence from anesthesia in the LMA-PS group.

Data from the four obese patients crossed over from LMA-PS to ETT were excluded from analysis. The first cross-over occurred when three attempted insertions of the LMA-PS resulted in respiratory obstruction and oxygen desaturation, and laryngoscopy revealed a large floppy epiglottis pressed against the posterior pharyngeal wall. In the second case, two insertion attempts were required, the gastric tube passed easily and gastric fluid was identified. However, peak airway pressure was 53 cm water, rhonchi were audible over both lungs and clear colourless secretions were aspirated from the airway. Following crossover to ETT, airway pressure was initially unchanged but settled to 45 cm water with administration of nebulized salbutamol. The other two crossovers occurred 60 min and 90 min into the surgical procedure, one because of sudden gas leak and one from a sudden increase in airway pressure, and immediate attempts to correct the problems were unsuccessful. None of these patients suffered postoperative pulmonary complications. These failures may represent the presence of a learning curve on our part, rather than a problem with the device. Immediate fibreoptic examination of the upper airway, which was not part of our protocol, might have revealed the cause of the LMA-PS failure.

Passage of a #14 Salem sump gastric tube was easily performed in all patients through the drain tube of the LMA-PS or through the Williams airway intubator in the ETT group. There has been one report of distension of the stomach with positive pressure ventilation through the LMA-PS during laparoscopic cholecystectomy.[10] The device appeared to be correctly positioned when the anesthesiologist confirmed that there was adequate chest expansion, no audible gastric insufflation, and no air leakage up the drain tube. No attempt was made to pass a gastric tube. Peak airway pressure of 17 cm water rose to 28 cm water during peritoneal insufflation. On insertion of the laparoscope, the surgeon observed that the stomach was inflating with each breath. Attempts to pass a gastric tube were unsuccessful and passage of a fibreoptic bronchoscope showed that the tip of the LMA-PS had folded back on itself.

This case highlights the clinical value of passing a gastric tube insertion through the drain tube as an additional test of correct seating of the LMA-PS.

Independent laparoscopic assessment of stomach size by our General Surgery colleagues, who were blinded to the airway device being used, enabled us to avoid the use of surrogate auditory markers to detect gas leakage into the stomach.[11,12] Increase in stomach size in this study never interfered with surgical exposure. This was also the finding in our previous study of the LMA-C and ETT, when none of the 53 patients in the LMA-C group required gastric decompression. Blind passage of the #14 gastric tube through the LMA-PS drain tube into the esophagus and stomach was smooth in all patients. Our use of continuous gastric suction during low flow anesthesia (< 600 $mL \cdot min^{-1}$) excludes the possibility of major gas leak into the digestive tract and eliminates the possibility that gastric distension was due to nitrous oxide diffusion. However, continuous suction did not guarantee a flat stomach and the observed changes in stomach size may represent changes in visible surface area rather than distension.

An increase in intra-abdominal pressure has long been known to cause a reflex increase in the tone of the lower esophageal sphincter (LES).[13] The belief that the increase in intra-abdominal pressure during laparoscopic surgery increases the risk of gastroesophageal reflux is erroneous.[14] Peritoneal insufflation that produces an intra-abdominal pressure of 15 mmHg during the laparoscopy also increases LES tone. This increases the normal barrier pressure of 30 cm water and provides further protection from passive reflux of gastric contents. In those patients in whom an intraoperative cholangiogram was performed (n = 33), 50–200 mL brownish liquid was suctioned through the gastric tube before the end of surgery. One patient vomited immediately after removal of the LMA-PS, but did not aspirate. The reported incidence of clinically significant pulmonary aspiration in healthy patients undergoing elective surgery with the LMA-C is 1 in 5,000 to 1 in 12,000.[3,15] This is a similar order of magnitude to the incidence with ETT or facemask in ASA I or II patients undergoing elective surgery.[16] The drain tube of the LMA-PS may not reduce this incidence, but it does provide easy access for deflation of the stomach and reduction of gastric fluid volume.

Different airway devices and methods of airway management each have their advantages and disadvantages. Many anesthesiologists consider tracheal intubation to be the gold standard for airway management for all but short general anesthetics with spontaneous respiration. However, the gold loses its glister when limitations such as failed tracheal intubation, the 'can't intubate, can't ventilate' situation, patient refusal of advised awake fibreoptic-assisted intubation, airway problems following extubation and dental damage, are considered. The advent of the LMA-PS may circumvent some of these problems, even in obese patients and others who require high airway pressures for adequate pulmonary ventilation.

Despite some uneasiness regarding the safety of the LMA-C with PPV and neuromuscular blockade,[17] small randomized studies[6,7,18] and large non-randomized studies[3,19] afford reassurance of its safety to the practicing anesthesiologist or airway clinician. The LMA-PS addresses some of the limitations of the LMA-C by permitting higher peak airway pressure and providing ready access for gastric drainage.

We conclude that adequate pulmonary ventilation without gastric distension can be achieved equally well with the LMA-PS or ETT in non-obese patients. Obese patients who did not require crossover had similar outcomes to non-obese. Laparoscopic surgery provides the most severe test for efficacy of supraglottic airway device during PPV, and a larger number of obese patients will be required to determine if the LMA-PS has an acceptable performance profile. Separation of alimentary and respiratory tracts represents a significant advance for airway management in selected patients. The LMA-PS may prove to be a more acceptable alternative to tracheal intubation for those anesthesiologists who are reluctant to use PPV with the LMA-C. Use of this alternative in airway management needs to be taught and experienced as recommended by the Canadian Airway Focus Group.[20]

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