LMA-Classic™ and LMA-ProSeal™ are effective alternatives to endotracheal intubation for gynecologic laparoscopy

[Le ML Classique™ et le ML ProSeal™ peuvent remplacer efficacement l'intubation endotrachéale pour la laparoscopie gynécologique]

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Purpose: To compare the laryngeal mask airways (LMA), LMA-Classic™ (LMA-C) and LMA-ProSeal™ (PLMA) with the endotracheal tube (ETT) with respect to pulmonary ventilation and gastric distension during gynecologic laparoscopy.

Methods: We stratified 209 women, aged ≥ 18 yr, ASA physical status I–III, by body mass index as non-obese (≤ 30 $kg \cdot m^{-2}$) or obese (> 30 $kg \cdot m^{-2}$) and randomized them to LMA-C/PLMA or ETT groups for airway management. Anesthesia was induced with propofol, fentanyl and succinylcholine or rocuronium. In the LMA-C/PLMA group we used a size 4 LMA-C in non-obese patients and size 4 or 5 PLMA in obese patients. In the ETT group we used a cuffed 7.0 mm ETT in all patients. Anesthesia was maintained with isoflurane in nitrous oxide and 30–50% oxygen, fentanyl and neuromuscular blockade with mechanical ventilation (tidal volume 10 $mL \cdot kg^{-1}$). The staff surgeon, blinded to the type of airway, scored stomach size on an ordinal scale 0–10 at initial insertion of the laparoscope and immediately before the conclusion of the surgical procedure.

Results: There were no crossovers and no statistically significant differences between LMA-C/PLMA and ETT groups for SpO_2, $P_{ET}CO_2$ or airway pressure before or during peritoneal insufflation in short (≤ 15 min) or long (> 15 min) periods of peritoneal inflation. Differences between groups with respect to stomach size changes during surgery were not statistically significant.

Conclusion: A correctly placed LMA-C or PLMA is as effective as an ETT for positive pressure ventilation without clinically important gastric distension in non-obese and obese patients.

Objectif : *Comparer les masques laryngés (ML), ML Classique™ (MLC) et le ML ProSeal™ (MLP), au tube endotrachéal (TET) quant à la ventilation pulmonaire et à la distension gastrique pendant la laparoscopie gynécologique.*

Méthode : *Nous avons réparti 209 femmes, ≥ 18 ans, d'état physique ASA I–III, selon l'indice de masse corporelle, comme non obèses (≤ 30 $kg \cdot m^{-2}$) ou obèses (> 30 $kg \cdot m^{-2}$) et leur avons assigné au hasard le MLC/MLP ou le TET pour maintenir la perméabilité des voies aériennes. L'anesthésie a été induite avec du propofol, du fentanyl et de la succinylcholine ou du rocuronium. Dans le groupe MLC/MLP, un MLC de taille 4 a été utilisé chez les patientes non obèses et un MLP de taille 4 ou 5 chez les patientes obèses. Dans le groupe TET, un TET de 7,0 mm à ballonnet a été inséré chez toutes les patientes. L'anesthésie a été entretenue avec de l'isoflurane dans du protoxyde d'azote et de l'oxygène à 30–50 %, du fentanyl et un blocage neuromusculaire associé à une ventilation mécanique (volume courant de 10 $mL \cdot kg^{-1}$). Le chirurgien en service, qui ne connaissait pas le type d'appareil utilisé pour les voies aériennes, a évalué la taille de l'estomac sur une échelle ordinale de 0–10 lors de l'insertion initiale du laparoscope et immédiatement avant la fin de l'intervention chirurgicale.*

Résultats : *Il n'y a pas eu d'abandon de technique respiratoire et aucune différence significative au plan statistique entre les groupes MLC/MLP et TET, concernant la SpO_2, la $P_{ET}CO_2$ ou la pression des voies aériennes, avant ou pendant l'insufflation péritonéale, qu'il s'agisse d'insufflation courte (≤ 15 min) ou longue (> 15 min). Les différences intergroupes quant aux changements de la taille de l'estomac pendant l'opération n'ont pas été statistiquement significatives.*

Conclusion : *Un MLC ou un MLP bien mis en place sont aussi efficaces qu'un TET pour la ventilation à pression positive sans distension gastrique significativement importante chez des patientes obèses ou non.*

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THE original laryngeal mask airway LMA-Classic™ (LMA-C; The Laryngeal Mask Company, Henley-on-Thames, UK) was designed for use with either spontaneous or positive pressure ventilation (PPV).[1] It challenged the gold standard of tracheal intubation with a cuffed endotracheal tube (ETT) for maintaining a clear airway and providing PPV. Brain described 16 cases of gynecologic laparoscopy with PPV in his first clinical series of 23 uses of a prototype LMA.[1] It has been used with PPV for abdominal surgery, including gynecologic laparoscopy, with minimal morbidity in lean patients who did not have gastroesophageal reflux (GER).[2–5] These studies suggest that the clinical performance of a properly sized and seated LMA-C is comparable to that of an ETT.

The LMA-ProSeal™ (PLMA; The Laryngeal Mask Company, Henley-on-Thames, UK)[6] was designed to permit higher airway pressure than the LMA-C (approximately 20 cm water) without leak of anesthetic gases. Its cuff extends over the posterior surface of the bowl to push the mask anteriorly to sustain airway pressure > 30 mmHg. A second tube, parallel to the ventilation tube, passes through the bowl of the mask to the tip of the cuff where it opens at the upper esophageal sphincter. This drain tube separates the respiratory tract from the esophagus. It directs passively regurgitated gastric fluid away from the airway, and provides a conduit for blind passage of a gastric tube for aspiration of gas or liquid contents from the stomach. The PLMA is therefore more appropriate than the LMA-C for obese patients and those with pulmonary disease who require higher airway pressures for adequate ventilation, and for surgical procedures in which intraoperative gastric drainage is desirable and in patients with GER.

In this study, we compared ventilation measurements, change in stomach size and emergence outcomes for the LMA-C (non-obese patients) or PLMA (obese patients) with the ETT during gynecologic laparoscopy.

Methods

The University of Calgary Conjoint Health Research Ethics Board approved the study protocol and all patients gave written, informed consent. Two hundred and thirteen consecutive patients, aged ≥ 18 yr, ASA physical status I–III, scheduled for elective gynecologic laparoscopy under general anesthesia were stratified by body mass index (BMI) as non-obese (BMI ≤ 30 $kg \cdot m^{-2}$) or obese (BMI > 30 $kg \cdot m^{-2}$) and randomized to the appropriate LMA device (LMA-C for non-obese, PLMA for obese) or ETT using computer-generated tables of random numbers. The stratification ensured approximately equal distribution of non-obese and obese patients in each group. Patients with a history of GER or hiatus hernia were included, provided they were currently asymptomatic and had taken an H_2 receptor blocker or proton pump inhibitor on the day of surgery. Patients fasted according to current Canadian Anesthesiologists' Society Guidelines (minimum two hours after clear liquid, six hours after a light meal).[7] No sedative premedication was given unless requested by the patient.

The four investigators had extensive experience over several years with the LMA-C and six months experience with the PLMA. Short cases (≤ 15 min peritoneal insufflation) were diagnostic or sterilization procedures and long cases (> 15 min peritoneal insufflation) were operative procedures. Criteria for crossover were: a) failure to place the randomly assigned airway device within three attempts; b) respiratory obstruction; c) persistent oropharyngeal leak with inadequate ventilation ($P_{ET}CO_2$ ≥ 39 mmHg before peritoneal insufflation, ≥ 45 mmHg during peritoneal insufflation); d) gastric distension interfering with surgical field.

After placement of the electrocardiogram, pulse oximeter, and non-invasive blood pressure monitor, preoxygenation was maintained until F_EO_2 was > 80%. Anesthesia was induced with 20 mg lidocaine, 2–2.5 $mg \cdot kg^{-1}$ propofol, 1–2 $\mu g \cdot kg^{-1}$ fentanyl, and 1.5 $mg \cdot kg^{-1}$ succinylcholine or ≤ 0.75 $mg \cdot kg^{-1}$ rocuronium intravenously. Bag and mask ventilation was avoided between induction of anesthesia and insertion of the airway device.

Non-obese patients randomized to the LMA-C/PLMA group received a size 4 LMA-C, and obese patients a size 4 or 5 PLMA. The cuff was inflated with room air to the manufacturer's recommended cuff pressure of 60 cm water before the anesthetic circuit was connected and the patient's lungs ventilated. After observing bilateral chest movement, square $P_{ET}CO_2$ waveform during manual ventilation, and silent epigastrium by stethoscope auscultation, we performed an airway pressure leak test. We set a continuous fresh gas flow (FGF) of 3 $L \cdot min^{-1}$ with the adjustable pressure-limiting valve closed and the circuit connected to the reservoir bag. The leak pressure was recorded when airway pressure reached a plateau, which was simultaneously marked by a clearly audible oropharyngeal leak around the LMA cuff. We then reverted to intermittent PPV with V_T 10 $mL \cdot kg^{-1}$ and f 10·min^{-1}. With the PLMA, we filled the proximal 3 cm of the drain tube with a water-soluble lubricant jelly; if a gas bubble rose through the jelly during

inspiration, indicating a gas leak into the esophagus, we corrected the position of the PLMA and repeated the test until no bubble appeared.

In the ETT group, we inserted a 7.0-mm internal diameter tube in all patients and inflated the cuff until no leak was audible during manual ventilation. Each patient's head and neck were covered with a towel to conceal the ETT or LMA before the surgeon entered the operating room. A gastric tube was not passed prophylactically in either group, but was permitted in individual patients if gastric distension interfered with the surgeon's operative field.

We maintained anesthesia at 1.0–1.3 MAC with isoflurane and nitrous oxide in 30–50% oxygen with incremental doses of fentanyl. Neuromuscular blockade was maintained at ≤ 1 twitch of a train-of-four for long cases. High initial FGF (6 $L \cdot min^{-1}$) was reduced to maintenance flows according to each investigator's normal clinical practice. Trendelenburg tilt ≤ 15° was provided at the gynecologist's request. We recorded SpO_2, FIO_2, $P_{ET}CO_2$, FGF, minute ventilation and peak airway pressure before insertion of the Veress needle for peritoneal insufflation to 15 mmHg, and immediately before peritoneal deflation at the end of the procedure. Each surgeon scored the size of the stomach on an ordinal scale of 0–10 (0 = empty stomach and 10 = distension of stomach that interfered with surgery) at initial insertion of the laparoscope and immediately before its removal at the end of the surgical procedure. Neuromuscular blockade was reversed and the airway device was removed in the operating room when the patient responded to verbal commands. Cough, laryngeal stridor or spasm and the need for airway intervention during emergence from anesthesia were recorded. Patients were still blinded to their randomization when the research nurse contacted them on the first postoperative day to identify anesthesia-related morbidity.

Data for respiratory variables and change in stomach size were analyzed according to short (≤ 15 min) or long (> 15 min) duration of peritoneal insufflation. Our primary respiratory variable was $P_{ET}CO_2$. In our matched groups with predetermined ventilator settings, a statistically significant difference in $P_{ET}CO_2$ would reflect a difference in clinical performance of the airway devices. We based our sample size on $P_{ET}CO_2$ results obtained during a previous laparoscopic cholecystectomy study.[8] If $P_{ET}CO_2$ during peritoneal insufflation was 41 ± 5 mmHg in the LMA group and 36 ± 5 mmHg in the ETT group, then a two-sided test with $\alpha = 0.05$ would have power (1-ß) greater than 99% of detecting that difference with 40 patients in each group. It also had a 90% chance of detecting a difference if a clinically significant increase (↑ ≥ 3 score) in stomach size occurred in 50% of patients in the LMA group and in 10% of patients in the ETT group.

TABLE I Demographic data, duration of anesthesia and peritoneal insufflation of all patients

	LMA-C/PLMA *n = 104*	ETT *n = 105*
Age (yr)	35 ± 8	37 ± 9
Weight (kg)	70 ± 16 (49-130)	69 ± 15 (41-110)
BMI ($kg \cdot m^{-2}$)	26 ± 6 (18-49)	25 ± 6 (16-41)
Non-obese:obese	87:17	85:20
Anesthetic time (min)*	42 (8-214)	36 (10-174)
Peritoneal insufflation time (min)*	16 (1-135)	15 (2-142)

Values are mean ± SD (range) or *median (range). LMA-C = laryngeal mask airway Classic™; PLMA = ProSeal™ laryngeal mask airway; ETT = endotracheal tube; BMI = body mass index. Differences between LMA-C/PLMA and ETT groups are not statistically significant.

The groups were compared using an independent group's t test (for measured variables) and the Fisher exact test (for discrete variables). The Fisher exact test was used to assess changes in gastric distension after the scores were converted into three clinically relevant ranges: slight decrease (↓ 1–2), no change or slight increase (↑ 0–2), marked increase (↑ 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 209 of the 213 randomized patients. Data were excluded from three randomized patients whose scheduled procedure was changed from laparoscopic to open surgery after examination under anesthesia, and from a fourth for a protocol violation. Thirty-seven patients were obese. The differences in non-obese:obese ratios in short cases (LMA 41:8 *vs* ETT 43:12), and in long cases (LMA 46:9 *vs* ETT 42:8) were not statistically significant. The groups were comparable for age, weight, BMI, total anesthetic time and peritoneal insufflation time (Table I). The median (range) airway pressure during the leak test with *continuous* airway pressure immediately after inflation of the LMA cuff was 20 (10–38) cm water for the LMA-C in non-obese patients, and 30 (14–50) cm water for the PLMA in obese patients. Even when gas leaked at a low airway pressure (< 20 cm water) during the leak test, adequate airway pressure without gas leak was achieved with *intermittent* PPV during the laparoscopic procedure. There were no crossovers from LMA-C/PLMA

TABLE IIA Ventilation variables in short procedures (peritoneal insufflation ≤ 15 min)

	Before peritoneal insufflation		*During peritoneal insufflation*	
	LMA-C/PLMA	*ETT*	*LMA-C/PLMA*	*ETT*
	n = 49	*n = 55*	*n = 49*	*n = 55*
SpO_2	100 ± 1	99 ± 1	99 ± 1	99 ± 1
$P_{ET}CO_2$ (mmHg)	33 ± 3	33 ± 4	34 ± 4	35 ± 5
F_IO_2	50 ± 10	50 ± 9	48 ± 11	46 ± 6
Vmin (L)	6.1 ± 1.1	6.5 ± 1.3	5.8 ± 1.3	6.0 ± 1.7
Airway pressure (cm H_2O)				
Non-obese	13 ± 3	15 ± 4	19 ± 4	21 ± 6
Obese	20 ± 1	23 ± 9	29 ± 5	28 ± 5

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

TABLE IIB Ventilation variables in long procedures (peritoneal insufflation > 15 min)

	Before peritoneal insufflation		*During peritoneal insufflation*	
	LMA-C/PLMA	*ETT*	*LMA-C/PLMA*	*ETT*
	n = 55	*n = 50*	*n = 55*	*n = 50*
SpO_2	100 ± 1	100 ± 1	100 ± 1	99 ± 2
$P_{ET}CO_2$ (mmHg)	32 ± 2	33 ± 3	37 ± 5	36 ± 4
F_IO_2	48 ± 7*	52 ± 8*	43 ± 6	44 ± 6
Vmin (L)	6.5 ± 1.2	6.2 ± 1.1	6.2 ± 1.6	6.1 ± 1.3
Airway pressure (cm H_2O)				
Non-obese	15 ± 4	15 ± 3	22 ± 4	22 ± 5
Obese	24 ± 6	22 ± 4	33 ± 6	32 ± 3

Values are mean ± SD. LMA-C = laryngeal mask airway Classic™; PLMA = ProSeal™ laryngeal mask airway; ETT = endotracheal tube. *P < 0.01 PLMA-C/PLMA *vs* ETT.

to ETT, and none from ETT to LMA-C/PLMA.

Differences between LMA-C/PLMA and ETT groups for SpO_2, F_IO_2 and $P_{ET}CO_2$ were not statistically significant before or during peritoneal insufflation in either the short or long cases (Tables IIa and IIb). There was no correlation between BMI and SpO_2, F_IO_2 or $P_{ET}CO_2$. During maintenance of anesthesia, three of the four anesthesiologists reduced FGF to the minimum required to refill the ventilator reservoir bag (300–600 mL·min^{-1}). The fourth anesthesiologist used 1–2 L·min^{-1}, as was his usual practice.

Median (range) of stomach size on entry of the laparoscope, and change in stomach size during surgery, were not statistically significantly different between LMA-C/PLMA and ETT groups in either short or long cases (Table III). In more than 90% of cases, the surgeon estimated that the change in stomach size was not clinically significant (↑score ≤ 2). Greater increase (↑score ≥ 3) in stomach size in long cases was observed in 7/51 patients in the LMA-C/PLMA group and in 2/49 in the ETT group. This difference was not statistically significant and in no case did the size of the stomach interfere with surgery. The drain tube of the PLMA filled with gastric fluid in one patient, immediately before deflation of the pneumoperitoneum. There was no visual contamination of the anterior surface of the PLMA bowl or the pharyngeal wall, and respiration was not affected immediately or postoperatively.

There was a ten-fold difference in frequency of coughing at removal of the ETT 87% *vs* LMA-C/PLMA 8%, which was statistically significant (P < 0.0001; Table IV). Sore throat 24 hr postoperatively was more common with ETT than LMA-C/PLMA (28% *vs* 17%; P < 0.05). No patient reported numbness of the tongue or other morbidity attributable to the airway devices.

Discussion

The results in this study confirm that PPV assessed by $P_{ET}CO_2$ is equally satisfactory through the LMA-C/PLMA or ETT during gynecologic laparoscopy. There were no statistically significant differences in pulmonary ventilation measurements between the LMA-C/PLMA and ETT during either short or long procedures. There were no crossovers from LMA-

TABLE IIIA Gastric distension change (exit score-entry score) during short procedures (≤ 15 min peritoneal insufflation)

Change in score from baseline	*LMA-C/PLMA n = 48/49**	*ETT n = 53/55**
↓1–2	3	6
↑0–2	44	47
↑3–6	1	0

LMA-C = laryngeal mask airway Classic™; PLMA = ProSeal™ laryngeal mask airway; ETT = endotracheal tube. *Stomach concealed by fat in one PLMA case and two ETT cases.

TABLE IIIB Gastric distension change (exit score-entry score) during long procedures (> 15 min peritoneal insufflation)

Change in score from baseline	*LMA-C/PLMA n = 51/55**	*ETT n = 49/50**
↓1–2	4	6
↑0–2	40	41
↑3–6	7	2

LMA-C = laryngeal mask airway Classic™; PLMA = ProSeal™ laryngeal mask airway; ETT = endotracheal tube. *Stomach concealed by fat in four PLMA cases and one ETT case.

TABLE IV Emergence outcomes of all patients

Events related to extubation	*LMA-C/PLMA n = 104*	*ETT n = 105*
Cough	8*	91*
Laryngeal stridor	2	6
Positive pressure ventilation	0	2
Tracheal intubation	0	0

LMA-C = laryngeal mask airway Classic™; PLMA = ProSeal™ laryngeal mask airway; ETT = endotracheal tube. *$P < 0.0001$ LMA-C/PLMA *vs* ETT.

C/PLMA to ETT or vice versa. The surgeons' blinded assessment of change in stomach size failed to show statistically significant difference between LMA-C/PLMA and ETT in either short or long cases. No surgeon requested passage of a gastric tube to deflate the stomach in any patient. Cough and laryngeal stridor during emergence, and sore throat postoperatively, were more common in the ETT patients. There was no suspicion of pulmonary aspiration of gastric contents in any patient.

Measurement of $P_{ET}CO_2$ may not be as accurate as blood gas analysis for assessing adequacy of pulmonary ventilation, particularly in obese patients and those in the Trendelenburg position. However, any error would apply equally to patients with LMA-C/PLMA or ETT. We were comparing the clinical efficacy of LMA-C/PLMA and ETT rather than seeking absolute scientific values. We do not believe that, for this type of clinical study, the potential morbidity of invasive monitoring is justified when capnography is the standard measurement used in clinical practice.

The LMA-C is considered safe and effective in moderate obesity, but is not recommended in the morbidly obese.[9] Weight or BMI criteria may vary for each category and non-obesity and grades of obesity are a continuum. We chose 30 $kg \cdot m^2$ as the BMI above which we would use the PLMA instead of the LMA-C in the LMA-C/PLMA group.

Brimacombe and Brain[10] initially included a "rule of 15" in guidelines for use of the LMA-C during laparoscopic surgery. These "rules" were Trendelenburg tilt < 15°, peritoneal insufflation < 15 cm water and duration of the procedure < 15 min. In our study, the head down tilt was ≤ 15° and peritoneal insufflation pressure was preset at 15 mmHg. We did not limit the duration of peritoneal insufflation to 15 min because inadequate ventilation or gastric distension should be evident within 15 min of starting the laparoscopic procedure. If it does not occur within 15 min, it should not occur later, provided that anesthetic depth and muscular relaxation are adequate and the LMA-C/PLMA is not dislodged. Furthermore, we had previously shown that the LMA-C and ETT with PPV were equally effective during laparoscopic cholecystectomy in non-obese patients, when mean peritoneal insufflation time was 47 min.[7]

The PLMA permitted higher airway pressures without leak in all obese patients, satisfactory pulmonary ventilation without clinically significant gastric distension, and use of basal or near-basal FGF. Our inclusion of obese patients with a history of GER may be controversial. We ensured that they all took appropriate medication on the day of surgery to minimize gastric fluid volume and acidity. In addition, the PLMA drainage tube prevents passively regurgitated liquid from contaminating the airway,[11–14] as happened in one patient in this study.

Gastric distension may occur when high airway pressure is employed to overcome a partially obstructed airway, or from inadvertent esophageal intubation.[15–17] The surgeon may then perforate the distended stomach with the Veress needle or trochar. There were reports of at least 13 such gastric perforations before the danger of a distended stomach and the necessity of deflating it with a gastric tube (rather than manual compression) were fully recognized. The potential for gastric distension exists with all airway devices. If the LMA is malpositioned it may cause partial or complete respiratory obstruction and air will be forced into the stomach. If it is too small, the tip may enter the upper esophagus and

allow gas to enter the stomach. Cases of marked gastric distension have been reported during PPV with the LMA-C[18–20] and, when this occurs, both the cause and its effect must be treated.

Gastric inflation may also occur with the PLMA, despite its gastric drainage tube.[21] If the tip of the PLMA turns back on itself during insertion, this may not be recognized unless the anesthesiologist also tries to pass a #14 or #16 gastric tube through the drainage tube and finds this impossible. We did not use this additional test because we had not encountered this problem when we prepared our protocol. In a previous study of PLMA *vs* ETT during laparoscopic cholecystectomy,[22] a #14 gastric tube passed easily through the drainage tube into the stomach in all patients in whom initial tests indicated correct placement. In the present study, laparoscopic assessment of stomach size by our gynecologist 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.[23,24] In no patient did change in stomach size interfere with the surgical field.

The PLMA broadens the application of supraglottic devices to include clinical situations for which the LMA-C is not recommended. Keller *et al.* confirmed its ventilatory efficacy in 60 morbidly obese patients.[25] Oropharyngeal leak pressure was 32 ± 4 cm water and PPV without leaks was possible in 57/60 patients. There was no gastric leak, no air leak into the drain tube and no $P_{ET}CO_2$ > 45 mmHg in any patient. They then replaced the PLMA with an ETT for surgery in 58/60 patients. In the remaining two patients, intubation was impossible. The PLMA was reinserted and the surgery was completed uneventfully.

Our study was too small to determine the safety of the LMA-C/PLMA with respect to pulmonary aspiration. Nevertheless, the best available evidence indicates that the incidence in similar elective surgical patient populations is approximately 1 in 5–12,000.[4,26] The PLMA drain tube allows passively regurgitated gastric contents to be vented without soiling of the patient's airway.[12–14] This suggests that the PLMA may be safer than the LMA-C in patients with untreated GER. However, Brimacombe and Keller demonstrated in fresh cadavers that a correctly placed LMA-C prevented passage of saline from the esophagus into the pharynx until the fluid pressure reached 39 cm water.[27] Resting intragastric pressure in healthy subjects is 12.1 (± SE 0.82) cm water,[28] and does not rise until intragastric volume reaches 1000–1500 mL.[29] The LMA-C may therefore prevent passively regurgitated fluid from reaching the pharynx, whereas the PLMA allows its safe, visible drainage. Whether the PLMA drain tube is equally effective when gastric contents are vomited with a pressure > 60 cm[30] is not yet known. A clinical trial to demonstrate a 50% reduction in the frequency of clinically significant aspiration for the PLMA *vs* LMA-C would require approximately 1.3 million patients in each group.[13]

We conclude that the LMA-C and ETT in non-obese patients provide adequate pulmonary ventilation as assessed by $P_{ET}CO_2$ without gastric distension during gynecologic laparoscopic examination or surgery. Since laparoscopic surgery provides the most severe test for efficacy of supraglottic airway devices, the LMA-C should be effective during PPV in other types of surgery in non-obese patients. The PLMA and ETT appeared to be equally effective in obese patients, but larger numbers of obese patients are required to confirm this. The higher airway pressure afforded by the PLMA, and its separation of alimentary and respiratory tracts, represent significant advances for airway management.

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