Gastric distension and ventilation during laparoscopic cholecystectomy: LMA-Classic vs. tracheal intubation

J. Roger Maltby MB BCHIR FRCA FRCPC,
Michael T. Beriault MD FRCPC,
Neil. C. Watson MB FRCPC,
Gordon H. Fick BSc MSc PhD*

Purpose: The standard laryngeal mask airway LMA-Classic was designed as an alternative to the endotracheal tube (ETT) or the face mask for use with either spontaneous or positive pressure ventilation. Positive pressure ventilation may exploit leaks around the LMA cuff, leading to gastric distension and/or inadequate ventilation. We compared gastric distension and ventilation parameters with LMA *vs* ETT during laparoscopic cholecystectomy.

Methods: One hundred and one, ASA I-II adults scheduled for elective laparoscopic cholecystectomy were randomly assigned to LMA-Classic or ETT. Patients with BMI >30 $kg \cdot m^{-2}$, hiatus hernia or gastroesophageal reflux were excluded. Following induction of anesthesia, an in-and-out orogastric tube was passed to decompress the stomach before insertion of the LMA (women size #4, men size #5) or ETT (women 7 mm, men 8 mm). Anesthesia was maintained with isoflurane in nitrous oxide and oxygen (FIO_2 0.3-0.5), rocuronium and fentanyl. The surgeon, blinded to the type of airway, scored gastric distention 0-10 at insertion of the laparoscope and immediately before removal at the end of the surgical procedure.

Results: Incidence and degree of change in gastric distension were similar in both groups. Ventilation parameters during insufflation (mean ± SD) for LMA and ETT were: S_PO_2 98 ± 1 *vs* 98 ± 1, $P_{ET}CO_2$ 38 ± 4 *vs* 36 ± 4 mm Hg and airway pressure 21 ± 4 *vs* 23 ± 3 cm water.

Conclusion: Positive pressure ventilation with a correctly placed LMA-Classic of appropriate size permits adequate pulmonary ventilation. Gastric distension occurs with equal frequency with either airway device.

Objectif : Le masque laryngé classique (ML) a été conçu comme une solution de remplacement au tube endotrachéal (TET) ou au masque lors de ventilation à pression positive ou de ventilation spontanée. La ventilation à pression positive accentue les fuites autour du ballonnet du ML. Nous avons comparé la distension gastrique et les paramètres de la ventilation avec le ML *vs* le TET pendant la cholécystectomie laparoscopique.

Méthode : Cent un patients d'état physique ASA I-II, dont la cholécystectomie laparoscopique avait été planifiée, ont été répartis au hasard en deux groupes : ML et TET. Les patients dont l'IMC était >30 $kg \cdot m^{-2}$, ou qui présentaient une hernie hiatale ou du reflux gastro-œsophagien ont été exclus de l'étude. Après l'induction de l'anesthésie, un cathéter orogastrique (placé et enlevé) a été introduit pour décompresser l'estomac avant l'insertion du ML (modèle 4 pour les femmes, 5 pour les hommes) ou un TET (7 mm pour les femmes, 8 mm pour les hommes). L'anesthésie a été maintenue avec de l'isoflurane dans un mélange de protoxyde d'azote et d'oxygène (FIO_2 0,3-0,5), du rocuronium et du fentanyl. Le chirurgien, qui ne connaît pas le type de canule utilisée, a coté la distension gastrique de 0 à 10 à l'insertion du laparoscope et immédiatement avant son retrait à la fin de l'intervention chirurgicale.

Résultats : L'incidence et le degré de changement de distension gastrique ont été similaires dans les deux groupes. Les paramètres de ventilation notés pendant l'insufflation (moyenne ± écart type) pour le ML et le TET ont été de : S_PO_2 98 ± 1 *vs* 98 ± 1, $P_{ET}CO_2$ 38 ± 4 *vs* 36 ± 4 mm Hg et la pression des voies aériennes de 21 ± 4 *vs* 23 ± 3 cm d'eau.

Conclusion : La ventilation à pression positive avec un ML bien placé et de grandeur appropriée permet une ventilation pulmonaire adéquate. La distension gastrique survient selon la même fréquence avec le ML ou le TET.

From the Departments of Anesthesia and Community Health Sciences,* University of Calgary, Alberta, Canada.
Address correspondence to: Dr. J. Roger Maltby, Department of Anesthesia, Foothills Medical Centre, 1403 - 29th Street NW, Calgary, Alberta, T2N 2T9 Canada. Phone: 403-670-1667; Fax: 403-670-1667; E-mail: maltby@ucalgary.ca
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THE term clinical equipoise[1] means that there is controversy and genuine uncertainty in the clinical community about the comparative merits of different forms of clinical management. The laryngeal mask airway (LMA) has challenged the assumption that tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation. Brain designed the LMA as "an alternative to either endotracheal tube or the face-mask for use with either spontaneous or positive pressure ventilation."[2] His first clinical series included 16 cases of gynecological laparoscopy with positive pressure ventilation. Nevertheless, for some anesthesiologists the combination of positive pressure ventilation with an LMA evokes fears of gastric distension, pulmonary aspiration of gastric contents, and inadequate ventilation. Despite this, the LMA has gained widespread popularity for gynecological laparoscopic procedures in the United Kingdom[3–6] where Malins and Cooper had no cases of pulmonary aspiration in 3,000 patients by 1994,[2] while Brimacombe and Verghese had none in 1469 cases.[4] However, neither these studies nor those in which the LMA was used during laparoscopic cholecystectomy[4,7] measured gastric distension or oropharyngeal leak. Investigators who used surrogate markers to detect air entry into the stomach[8–11] exceeded the manufacturer's recommended range for tidal volumes and airway pressures.[1,2] One group acknowledged that the qualitative, not quantitative, method to detect gastroesophageal insufflation was the weak point of their study.[9]

This study compared the quantitative clinical performances of LMA-Classic and ETT regarding gastric distension and positive pressure ventilation during laparoscopic cholecystectomy.

Methods

The University of Calgary Conjoint Health Research Ethics Board approved the study protocol. One hundred and five patients, age ≥ 18 yr, ASA physical status I or II, scheduled for elective laparoscopic cholecystectomy under general anesthesia were assigned to either LMA or ETT for airway management, using a computer-generated table of random numbers. Patients with a history of hiatus hernia, gastroesophageal reflux, body mass index (BMI) > 30 $kg \cdot m^{-2}$ or diabetes mellitus were excluded. Age, sex, weight, height, BMI, and Mallampati score were recorded. Each anesthesiologist investigator had at least seven years experience with use of the LMA.

Patients fasted after midnight except for clear liquids until three hours before their scheduled time of surgery. No premedication was given. After placement of routine monitoring devices and pre-oxygenation, anesthesia was induced with 20 mg lidocaine, 2-2.5 $mg \cdot kg^{-1}$ propofol, 1-2 $\mu g \cdot kg^{-1}$ fentanyl and 0.75 $mg \cdot kg^{-1}$ rocuronium *iv*. A multi-orifice #18 Salem sump tube (Sherwood Medical, St. Louis MO 63103) was passed through a Williams airway intubator (Anesthesia Associates, San Marcos CA) into the stomach, gas and fluid were aspirated, and the gastric tube and airway intubator were removed. Positive pressure was not used until after insertion of the LMA or ETT.

For women randomized to the LMA group, a size #4 LMA inflated with 30 mL air was used and for men a size #5 LMA inflated with 40 mL. The clinically correct position of the LMA was confirmed by the absence of leak on auscultation of the epigastrium and neck, and adequate chest expansion at airway pressure 20 cm water during manual ventilation.[1,3] For patients randomized to ETT, a 7.0 mm (women) or 8.0 mm (men) ID tube was inserted, its cuff was inflated to provide an airtight seal and its correct position confirmed by auscultation and capnography. The LMA or ETT was concealed from the surgeon's view.

Anesthesia was maintained at MAC 1.0-1.3 (Datex-Ohmeda AS3, Helsinki, Finland or Marquette Medical Systems Inc., Milwaukee WI) with isoflurane in nitrous oxide and oxygen with FIO_2 0.3-0.5 administered through a circle system with CO_2 absorption. Sampled gases were returned to the inspiratory limb of the circle. Supplementary fentanyl was given as required. Neuromuscular blockade was maintained at one train-of-four twitch during the laparoscopic portion of the surgery. Residual blockade was reversed with 1.2 mg atropine and 3.0 mg neostigmine.

Ventilation parameters were set initially at a tidal volume 10 $mL \cdot kg^{-1}$ at a rate of $10 \cdot min^{-1}$ and adjusted as required to maintain an $P_{ET}CO_2$ 30-45 mm Hg. High initial fresh gas flows ($6\ L \cdot min^{-1}$) were reduced for maintenance according to each anesthesiologist's normal practice. Peritoneal insufflation pressure was preset and maintained at 15 mm Hg. Airway pressure, SpO_2, FIO_2, $P_{ET}CO_2$, fresh gas flow and minute volume were recorded before and during peritoneal deflation. The surgeon scored gastric distension on a visual analogue scale 0-10, where 0 = empty stomach and 10 = distension that interfered with surgical exposure at a) entry of the laparoscope following peritoneal insufflation and b) immediately before removal of the laparoscope at the end of the surgical procedure. Insufflation time and total anesthetic time were recorded. The occurrence of cough, vomiting, laryngospasm, and need for airway intervention during

emergence from anesthesia were recorded for all except the first four patients, as were ventilation parameters in recovery room. On the first postoperative day each patient was contacted to identify any unforeseen complications.

For sample size, we addressed the following comparisons. If no gastric inflation occurred in 90% of patients in the ETT group and in 50% of those in the LMA group, this protocol had a 90% power of detecting that difference with 31 patients in each group. If the incidence of clinically relevant increase (score 3-5) gastric distention was 0.1% in the ETT group and 20% in the LMA group, this protocol had an 80% chance of detecting that difference with 45 patients in each group.

The LMA patients and ETT patients were compared using an independent group's t test (for measured variables) and Fisher's exact test (for discrete variables). When *P* values were less than 5%, comparisons are noted in the Tables with a star (*). In particular, after grouping the scores for change in gastric distension into clinically relevant ranges, Fisher's exact test was used to assess the changes in gastric distension. No adjustments were made for multiple comparisons.

Results

One hundred and five patients were recruited to the study. Two patients were excluded from analysis because of protocol violations and two patients had their operation postponed. Data were analyzed from 101 patients, one of whom had adhesions that prevented assignment of gastric distension score. Five procedures were converted to an open cholecystectomy.

Demographic data, peritoneal insufflation time and total anesthetic time were similar for both groups (Table I). There were no failures in placement of either airway device and no crossovers between groups. The LMA was correctly placed on the first attempt in 50 of 53 patients. Tracheal intubation was successful on the first attempt in 47 of 48 patients. Baseline scores for size of the stomach at insertion of the laparoscope varied from 0 through 7. Changes in gastric distension scores were determined by by subtracting the surgeon's baseline score from exit score (Table II). Gastric size stayed the same or increased slightly (score 0-2) in approximately 80% of patients in both groups. Clinically relevant gastric distension (score 3-5) occurred with equal frequency in both groups, and required deflation in one patient in the ETT group. Apparent decrease in gastric size was observed in 8% of LMA patients and 2% of ETT patients. The protocol had a low power to detect minor differences in gastric insufflation between groups.

TABLE I Demographic data

	LMA *n = 53*	*ETT* *n = 48*
Sex (F:M)	42 : 11	41 : 7
Age (yr)	43 ± 16	45 ± 14
Weight (kg)	72 ± 14	71 ± 11
BMI ($kg \cdot m^{-2}$)	26 ± 3	26 ± 3
Anesthetic time (min)	89 ± 39 (52 – 300*)	82 ± 30 (39 – 215*)
Insufflation time (min)	47 ± 19 (12 – 110)	47 ± 22 (15 – 115)

*Includes procedures converted to open cholecystectomy
Values are mean ± SD (range)

TABLE II Gastric distension change (exit score – entry score) during peritoneal insufflation.

*Change in score from baseline**	*LMA* *n = 53*	*ETT* *n = 48*
↓ 1 – 2	4	1
↑ 0 – 2	43	40
↑ 3 – 5	6	7

P = 0.516 using Fisher's exact test
* range of baseline scores varied from 0 through 7

TABLE III Ventilation parameters

Parameter	*Baseline* *LMA* *n = 53*	*ETT* *n = 48*	*Insufflation* *LMA* *n = 53*	*ETT* *n = 48*
SpO_2	99 ± 1	99 ± 1	98 ± 1	98 ± 1
$P_{ET}CO_2$ (mm Hg)	32 ± 3	30 ± 4*	38 ± 4	36 ± 5*
FIO_2	39 ± 7	40 ± 7	37 ± 6	37 ± 4
FGF ($L \cdot min^{-1}$)	1.9 ± 1.6	1.6 ± 1.3	1.1 ± 1.0	1.0 ± 0.9
Vmin (L)	6.5 ± 1.3	6.4 ± 1.3	6.4 ± 1.3	6.2 ± 1.1
Airway pressure (cm water)	16 ± 4	17 ± 3	21 ± 4	23 ± 3*

* $P < 0.05$ ETT *vs* LMA
Values are mean ± SD

TABLE IV Emergence outcomes

Events related to extubation	*LMA* *n = 49*	*ETT* *n = 48*
none	40	2
cough	8	38
laryngospasm	1	5
positive pressure ventilation	0	3
tracheal intubation	0	0

$P < 0.001$ using Fisher's exact test

There were no statistically significant differences between groups for S_pO_2, FIO_2, fresh gas flow or minute volume, either at baseline or during peritoneal insufflation (Table III). The increase in mean $P_{ET}CO_2$

from baseline to peritoneal insufflation was the same in both groups. The difference for $P_{ET}CO_2$ between groups at baseline may account for the same difference during peritoneal insufflation. The higher mean airway pressure in the ETT group during insufflation was due to greater rise from baseline than in the LMA group. These differences were not clinically significant. Maintenance median fresh gas flows of 350 and 650 mL·min^{-1} for both LMA and ETT were used by two investigators who commonly use low flow anesthesia. However, two of the 35 (6%) LMA patients in that low flow subgroup required fresh gas flow >1 L·min^{-1} to compensate for leak around the LMA cuff *vs* none in the ETT group.

Airway problems, particularly coughing, were more common during emergence in the ETT group (Table IV). There were no differences in recovery room SpO_2 values, oxygen supplementation or ventilation scores. Follow-up on the first postoperative day revealed no difference in the incidence of sore throat or hoarseness, and no unforeseen complications.

Discussion

Our results demonstrate that change in the degree of gastric distension with positive pressure during peritoneal insufflation was similar with both airway devices, and that ventilation parameters were acceptable in both groups. Fresh gas flow 350 mL·min^{-1} was possible in 30% of 35 LMA patients in whom low flows were attempted, and 650 mL·min^{-1} in another 40%. Such low flows are only achievable if circuit leak with the LMA is minimal.

Previous investigators used qualitative surrogate markers to detect leak of airway gases into the stomach during a range of high inspiratory pressures (> 20 cm water) through the LMA.[8–11] Investigators who used an epigastric microphone that detects as little as 2 mL gas entering the stomach[8] reported an 27% incidence of gastric insufflation with tidal volumes 18-44 mL·kg^{-1}. Such large tidal volumes required inspiratory pressures up to 33 cm water that far exceeds the manufacturer's recommendation of 20 cm water.[12,14] Our study differed in several important respects from those of previous investigators.[8–11] They used LMA size #3 and size #4 respectively for women and men, whereas we used the larger sizes #4 and #5. Our use of tidal volumes of 10 mL·kg^{-1} produced airway pressure in the LMA group of 16 ± 4 cm water before peritoneal insufflation, rising to 21 ± 4 cm water during peritoneal insufflation. Despite modestly exceeding the LMA manufacturer's recommendation, changes in gastric distension were similar in the LMA and ETT groups.

Circuit leak of anesthetic gases to the atmosphere during positive pressure ventilation may lead to hypoventilation and theatre pollution. Although Devitt *et al.*[11] and Ho-Tai *et al.*,[10] did not report fresh gas flow, their leak fraction, defined as a fraction of inspired volume, was >20% of tidal volume. This represents a waste of up to 2,000 mL·min^{-1} (180-200 mL from each of 10 breaths) and would not permit the low fresh gas flow achieved with larger LMAs. Our use of positive pressure ventilation during positive pressure ventilation without loss of tidal volume confirms Brimacombe's finding that larger size LMAs permit airway pressures >20 cm water with minimal leak.[15]

Some authors state that the increase in abdominal pressure during laparoscopy may result in an increase in gastroesophageal reflux.[16] However, an increase in abdominal pressure causes a reflex increase in tone of the lower esophageal sphincter (LES).[17] Increased intra-abdominal pressure from peritoneal insufflation during laparoscopy also increases LES tone.[18] This increases the normal barrier pressure of 30 cm water and provides further protection from passive reflux. Our randomized controlled study was too small to determine the danger of an 'unprotected' airway and the risk of aspiration pneumonitis. However, the overall incidence of pulmonary aspiration with the LMA in healthy patients undergoing elective surgery is between 1 in 5,000[19] and 1 in 11,910.[4] This incidence is similar to the 1 in 9,000 in comparable patients managed with ETT or facemask.[20]

We conclude that the risks of gastric distension and inadequate ventilation during positive ventilation with the LMA have been overestimated. Our results should not be interpreted to mean that gastric distension does not occur in laparoscopic surgery, but rather that it occurs with equal frequency and to the same degree with both the LMA and ETT. Benumof called for valid comparison of airway devices in clinical situations.[21] The Canadian Airway Focus Group alluded to the paucity of well-designed randomized, controlled trials of airway devices and strategies.[22] Our randomized, controlled trial demonstrated that, in healthy patients in the supine position, a correctly placed LMA of appropriate size may be a safe and effective alternative to an ETT for positive pressure ventilation.

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References

1 *Freedman B.* Equipoise and the ethics of clinical research. N Eng J Med 1987; 317: 141–5.
2 *Brain* AIJ. The laryngeal mask – a new concept in airway management. Br J Anaesth 1983; 55: 801–5.
3 *Malins AF, Cooper GM.* Laparoscopy and the laryngeal mask airway (Letter). Br J Anaesth 1994; 73: 121.
4 *Verghese C, Brimacombe JR.* Survey of laryngeal mask airway usage in 11,910 patients: safety and efficacy for conventional and nonconventional usage. Anesth Analg 1996; 82: 129–33.
5 *Bapat PP, Verghese C.* Laryngeal mask airway and the incidence of regurgitation during gynecological laparoscopies. Anesth Analg 1997; 85: 139–43.
6 *Swann DG, Spens H, Edwards SA, Chestnut RJ.* Anaesthesia for gynaecological laparoscopy – a comparison between the laryngeal mask airway and tracheal intubation. Anaesthesia 1993; 48: 431–4.
7 *Buniatian AA, Dolbneva EL.* Laryngeal mask under total myoplegia and artificial pulmonary ventilation during laparoscopic cholecystectomies. (Russian) Vestn Ross Akad Med Nauk 1997; 9: 33–8.
8 *Weiler N, Latorre F, Eberle B, Goedecke R, Heinrichs W.* Respiratory mechanics, gastric insufflation pressure, and air leakage of the laryngeal mask airway. Anesth Analg 1997; 84: 1025–8.
9 *Latorre F, Eberle B, Weiler N, et al.* Laryngeal mask airway position and the risk of gastric insufflation. Anesth Analg 1998; 86: 867–71.
10 *Ho-Tai LM, Devitt JH, Noel AG, O'Donnell, MP.* Gas leak and gastric insufflation during controlled ventilation: face mask *versus* laryngeal mask airway. Can J Anaesth 1998, 45: 206–11.
11 *Devitt JH, Wenstone R, Noel AG, O'Donnell MP.* The laryngeal mask airway and positive-pressure ventilation. Anesthesiology 1994; 80: 550–5.
12 *Brain AIJ.* The Laryngeal Mask Airway (LMA) Instruction Manual. Intavent Research Limited 1995: 39.
13 *Joshi S, Sciacca RR, Solanki DR, Young WL, Mathru MM.* A prospective evaluation of clinical tests for placement of laryngeal mask airways. Anesthesiology 1998; 89: 1141–6.
14 *Brimacombe JR, Brain AIJ, Berry AM, Verghese C, Ferson D.* Gastric insufflation and the laryngeal mask (Letter). Anesth Analg 1998; 86: 914–20.
15 *Brimacombe JR.* Positive pressure ventilation with the size 5 laryngeal mask. J Clin Anesth 1997; 9: 113–7.
16 *Doyle MT, Twomey CF, Owens TM, McShane AJ.* Gastroesophageal reflux and tracheal contamination during laparoscopic cholecystectomy and diagnostic gynecological laparoscopy. Anesth Analg 1998; 86: 624–8.
17 *Lind JF, Warrian WG, Wankling WJ.* Responses of the gastroesophageal junctional zone to increases in abdominal pressure. Can J Surg 1966; 9: 32–8.
18 *Jones MJ, Mitchell RW, Hindocha N* Effect of increased intra-abdominal pressure during laparoscopy on the lower esophageal sphincter. Anesth Analg 1989; 68: 63–5.
19 *Brimacombe JR, Berry A.* The incidence of aspiration associated with the laryngeal mask airway: a meta-analysis of published literature. J Clin Anesth 1995; 7: 297–305.
20 *Warner MA, Warner ME, Weber JG* Clinical significance of pulmonary aspiration during the perioperative period. Anesthesiology 1993; 78: 56–62.
21 *Benumof J.* Laryngeal mask airway. Indications and contraindications (Editorial). Anesthesiology 1992; 77: 843–6.
22 *Crosby ET, Cooper RM, Douglas MJ, et al.* The unanticipated difficult airway with recommendations for management. Can J Anaesth 1998; 45: 757–76.