

# **Comparison of early postoperative recovery between laryngeal mask airway and endotracheal tube in laparoscopic cholecystectomy**

# A randomized trial

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#### Abstract

**Background:** Laryngeal mask airway (LMA) insertion provokes fewer stress responses than endotracheal intubation. This study aimed to evaluate the LMA Protector for assessing improvements in intraoperative hemodynamic stability and to reduce postoperative discomfort compared with endotracheal intubation in laparoscopic cholecystectomy.

**Methods:** Fifty-six patients who underwent laparoscopic cholecystectomy while under sevoflurane-based general anesthesia were randomly allocated to airway management using LMA (LMA group) or endotracheal tube (ETT group). Heart rate, blood pressure, and peak airway pressure were recorded before and after carboperitoneum. Postoperative pain and analgesic requirements were assessed, in addition to nausea, hoarseness, dysphonia, and sore throat during the first 1 hour postoperatively and until postoperative day 1.

**Results:** All patients underwent successful LMA or ETT placement within 2 attempts. There was no difference in highest mean (SD) peak airway pressure during carboperitoneum between the LMA and ETT groups (17.7 [2.8] mm Hg vs 19.1 [3.8] mm Hg, P = .159, respectively). The incidence of high systolic blood pressure and bradycardia was higher in the LMA group. The highest pain scores 1 hour postoperatively and on postoperative day 1 were lower in the LMA group than in the ETT group (3.9 [2.0] vs 5.4 [2.3], P = .017 and 5.6 [1.9] vs 6.7 [1.7], P = .042, respectively); requirements for analgesics were similar in the 2 groups. The incidence of nausea was lower in the LMA group than in the ETT group until postoperative day 1 (4/28 [14%] vs 12/28 [43%], P = .031, respectively).

**Conclusion:** The LMA Protector was an effective ventilator device associated with fewer intraoperative hemodynamic stress responses and improved the quality of early recovery after laparoscopic cholecystectomy.

Abbreviations: BIS = bispectral index, ETT = endotracheal tube, LMA = laryngeal mask airway, SPI = surgical pleth index.

Keywords: endotracheal tube, laparoscopic cholecystectomy, laryngeal mask airway, nausea, pain, recovery

## 1. Introduction

Laparoscopic cholecystectomy is the most minimal invasive surgical technique for benign biliary disease. Improvements in surgical and anesthetic techniques, as well as modifications in postoperative care, have led to the surgery being performed on an outpatient or inpatient basis, with short a duration of admission. Pain, nausea/vomiting, and pulmonary complications, among

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others, are important issues resulting in prolonged admissions or readmissions.  $^{\left[ 1,2\right] }$ 

The use of the laryngeal mask airway (LMA) has led to improved hemodynamic and respiratory stability, less restricted mucociliary clearance, and a reduced need for anesthetics.<sup>[3,4]</sup> Supraglottic airway devices result in a lower incidence of laryngospasm and coughing during recovery, as well as a lower incidence of postoperative hoarseness, sore throat, and nausea in particular, compared with the use of an endotracheal tube (ETT).<sup>[5,6]</sup>

Recently, a second-generation supraglottic airway device has enabled the application of higher respiratory pressure, and possible drainage of regurgitated material or the introduction of a gastric tube via integrated gastric access. The presence of a gastric drainage channel helps to reduce the aspiration of gastric contents, including air, to properly expose the surgical field.<sup>[7,8]</sup> Reported adverse events, such as aspiration, associated with the use of the LMA in laparoscopic surgery are low.<sup>[9]</sup> Thus, ventilation using LMA could be considered an effective alternative to endotracheal intubation, despite the use of laparoscopic procedures.<sup>[10,11]</sup> Nevertheless, clear advantages of using LMA during laparoscopic cholecystectomy remain unknown. Thus, we evaluated the effects of using a secondgeneration supraglottic airway, the LMA Protector Airway (Teleflex Medical, Westmeath, Ireland) in early recovery after

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laparoscopic cholecystectomy. We hypothesized that the use of LMA causes improvements in intraoperative hemodynamic stability and reduces postoperative discomfort.

#### 2. Methods

#### 2.1. Study design

This prospective randomized study was approved by the Institutional Review Board of Samsung Medical Center (Seoul, South Korea; SMC 2018-07-054), and clinical trial registered on Korean clinical trial identifier (KCT0003173). This study was performed between September and December 2018 at the Samsung Medical Center. Patients from 20 to 80 years of age with an American Society of Anesthesiologists physical status I to III, who underwent *elective* laparoscopic cholecystectomy *due to biliary colic*, were enrolled in the study after providing written informed consent. Exclusion criteria included arrhythmia, creatinine level >2.0 mg/dL, difficult airway, and refusal to participate. Patients were also excluded if the LMA or ETT was not properly positioned within 2 attempts.

Randomization was performed using computer-generated random numbers with a fixed block size of 4 and a 1:1 ratio; the allocation was sealed in an opaque envelope. A corresponding author opened the sealed envelope immediately before anesthesia and provided the LMA or ETT according to the group assignment. An attending anesthesiologist, who was not involved in the study, recorded the intraoperative data. The coauthor blinded to the group allocation collected data regarding postoperative results and analysis.

#### 2.2. Anesthesia and pain management

After arrival to the operating room, patients were monitored using electrocardiogram, noninvasive arterial pressure measurement, pulse oximetry, bispectral index (BIS), and surgical pleth index (SPI; GE Healthcare, Freiburg, Germany). Anesthetic induction was then performed using propofol 1.5 to 2 mg/kg<sup>-</sup>, fentanyl 25 µg and rocuronium 0.8 mg/kg with sevoflurane. Patients were provided with LMA (LMA group) or ETT (ETT group). A maximum of 2 attempts were permitted to obtain an effective airway. A failed attempt was defined as removal of the device from the mouth. The Protector LMA enabled continuous cuff pressure monitoring and until the cuff pressure indicator was within the green zone (30-44 mm Hg) with air inflation. The ETT cuff pressure of 20 to 30 cmH<sub>2</sub>O was inflated with *air using* a cuff manometer. Mechanical ventilation was initiated at a tidal volume of 8 mL/kg per ideal body weight with a mixture of O2 and air with fraction of inspired oxygen (FiO<sub>2</sub>) 0.5 and adjusted to maintain end-tidal CO<sub>2</sub> pressure of 35 to 45 mm Hg. BIS was maintained at 40 to 60 and SPI score was only observed. In cases in which systolic blood pressure increased to >160 mm Hg or 30% of baseline, nicardipine 300 mg was administered. If systolic blood pressure dropped to <80 mm Hg, ephedrine 5 mg was administered. If heart rate increased to >120 beats/min, esmolol 20 mg was administered, and if heart rate decreased to <45 beats/ min, glycopyrrolate 0.2 mg was administered. A prophylactic antiemetic, palonosetron 0.075 mg, was administered after induction. Fentanyl 50 µg and ketorolac 30 mg were administrated on initiation of peritoneum closure. Heart rate, systolic blood pressure, peak airway pressure, and SPI were recorded at 5 time points: before anesthesia; after insertion of the airway

device; starting and stopping carboperitoneum; and at the conclusion of surgery. The intensity of gastric distension during surgery was queried from the *surgeon*.

Glycopyrrolate 0.4 mg and pyridostigmine 15 mg were injected to reverse muscle relaxant. Patients were transferred to the recovery room after the airway devices were removed. After evaluation of orientation regarding person and place, pain was assessed using a numerical rating scale (NRS). Patients who complained of pain, with NRS  $\geq$  4, were treated with hydromorphone 0.01 mg/kg intravenously. Pain level was reassessed and treated every 10 minutes. Nausea, vomiting, aspiration, coughing, hoarseness, dysphonia, and sore throat were assessed during the first 1 hour postoperatively in the recovery room and until postoperative day 1. An interview surveying satisfaction with surgery and anesthetic management was performed at the time of discharge from the recovery room. Pain was assessed  $\geq 4$ times every day during the hospital stay; patients complaining of pain with NRS  $\geq$  4 were treated with intravenous pethidine 50 mg in the ward. And if patients did not have fever or dietary problems after surgery, they discharged the next day after surgery.

#### 2.3. Statistical analysis

A previous study reported differences in morphine consumption in the LMA group and ETT group was mean (SD) 17 (7.2) versus 12.1 (5.4) mg for laparoscopic gynecological surgery.<sup>[5]</sup> The initial sample size calculation yielded 28 patients in each group with an  $\alpha$  error of 5% (based on a 2-tailed test) and power of 80%.

All data were tested for normal distribution using the Kolmogorov–Smirnov test. Data are expressed as mean (SD) or median (interquartile range), as appropriate. Demographic data, perioperative data, and clinical outcomes between the 2 groups were examined using the  $\chi^2$  test or Fisher exact test for categorical variables, and the independent *t* test or Mann–Whitney *U* test for continuous variables. Repeated measures ANOVA was used for the analysis of intergroup differences over time. Multiple comparisons of outcomes at specific intervals were corrected using the Bonferroni method. Ordinal data were tested using the Cochran–Armitage test. All analyses were performed using SPSS version 24 (IBM Corporation Armonk, NY); a 2-sided  $\alpha$  of 0.05 was used for all statistical tests.

#### 3. Results

Fifty-six patients were randomly allocated to airway management using LMA (LMA group, n=23) or ETT (ETT group, n=23) (Fig. 1). There were no cases in which placement of either airway device failed within 2 attempts. Before and after carboperitoneum, oxygenation and ventilation were optimal in all patients in both groups. All enrolled patients were included in analysis. There were no significant differences in patient characteristics or surgical data (Table 1).

The *mean pain score* during the first 1 hour postoperatively and *the highest pain score* until postoperative day 1 were lower in the LMA group than in the ETT group (3.6 [2.0] vs 5.3 [2.2], P = .02 and 5.6 [1.9] vs 6.7 [1.7], P = .042, respectively). However, requirements for analgesics were not significantly different between the 2 groups (Fig. 2). In addition, differences in pain score disappeared 6 hours postoperatively.

More patients in the ETT group experienced coughing during anesthetic emergence than in the LMA group (21/25 [84%] vs



# Table 1

Patient, surgical, and anesthetic characteristics for both groups.					
	LMA group (n=28)	ETT group (n=28)	Р		
Age, y	50 (14)	53 (9)	.296		
Gender, male/female	19/9	16/12			
Height, cm	159.3 (7.5)	163.3 (8.0)	.081		
Weight, kg	67.1 (9.0)	64.4 (11.0)	.066		
BMI, kg/m <sup>2</sup>	23.2 (3.1)	24.1 (3.4)	.316		
ASA grade, I/II	19/9	18/10			
Insertion attempt					
First	22	24			
Second	6	4			
Single port surgery	5 (18%)	3 (11%)			
Peak airway pressure after intubation, mmH <sub>2</sub> O	12.2 (2.2)	12.7 (2.3)	.256		
Peak airway pressure in carboperitoneum, mmH <sub>2</sub> O	17.7 (2.8)	18.7 (3.5)	.412		
Change of peak airway pressure, mmH <sub>2</sub> O	5.5 (1.9)	6.0 (2.1)	.354		
Intraoperative crystalloid, mL	246 (72)	282 (104)	.217		
Duration of surgery, min	46 (13)	42 (27)	.510		
Duration of anesthesia, min	78 (13)	73 (27)	.400		

Values are mean (SD) or number (%).

3/25 [12%], P < .001, respectively). Postoperative outcomes are summarized in Table 2. Dysphonia and hoarseness were less common with LMA than with ETT 1 hour postoperatively; however, these symptoms spontaneously recovered in all patients the next day.

Comparing the ETT and LMA groups, peak airway pressure was lower in the ETT group after insertion of the devices and after induction of carboperitoneum, but was not significantly different (17.7 [2.8] mmH<sub>2</sub>O vs 18.7 [3.5] mmH<sub>2</sub>O; P=.412). Hemodynamic and SPI changes recorded in the 2 groups are presented in Figure 3. Although similar hemodynamic values at baseline were exhibited by the 2 groups, larger hemodynamic fluctuation was exhibited by patients in the ETT group compared with those in the LMA group after airway device insertion and at the conclusion of surgery. Repeated measures ANOVA revealed a significant group × time interaction in ETT patients compared with the LMA group, and higher values of systolic blood pressure (P=.007). However, patients in the ETT group, and especially on time of starting carboperitoneum in ETT group, exhibited a significantly higher incidence of bradycardias (<45 beats/min) than those in the LMA group (3/25 [12%] vs 6/25 [24%], P=.021). The frequency of using nicardipine and ephedrine during surgery was lower in the LMA group (0/23 [0%] vs 1/23 [3%], P=.317 and 3/23 [13%] vs 10/23 [43%], P=.028; LMA





group vs ETT group, respectively). SPI scores were not significantly different between the 2 groups.

Satisfaction scores measured at discharge from the recovery room revealed significant differences between the LMA and ETT groups (4 [3.5] vs 3 [2.4], P=.002, respectively) (Table 3). The surgeons did not report significant gastric distention, and were not aware of the differences in airway devices used.

### 4. Discussion

We found that the LMA Protector was as effective as an ETT in maintaining pulmonary ventilation without disturbances in peak airway pressure. Consistent with our hypothesis that the LMA Protector would yield advantages of early recovery, we found reduced postoperative nausea and pain during the first 1 hour postoperatively. Transient dysphonia and hoarseness were significantly lower in the LMA group; however, all advantages disappeared by postoperative day 1 at discharge.

However, we could not confirm the difference in the amount of morphine consumption because of lower pain score than our assumption. We thought that the administration of fentanyl and ketorolac before arousal caused these results. Activation of the

Table 2				
Postoperative outcome data.				
	LMA group	ETT group	Р	
PACU time, min	52 [52–55]	52 [50-53]	.127	
Hospital stay from surgery day, d	2 [2-2]	2 [2-2]	.144	
Postoperative 1 h				
Nausea	3 (11%)	11 (39%)	.014	
Vomiting	0	0		
Sore throat	3 (11%)	9 (32%)	.051	
Hoarseness and dysphonia	1 (4%)	9 (36%)	.005	
Postoperative day 1				
Nausea	4 (14%)	12 (43%)	.031	
Vomiting	0	0		
Sore throat	1 (4%)	1 (4%)		
Hoarseness and dysphonia	0	0		
The pain score on discharge	2 [1-3]	2 [0-3]	.504	

Values are median [IQR], or number (%).

sympathetic nervous system, and increases in the release of catabolic and immunosuppressive pituitary hormones, can be attributable to the surgical stress response.<sup>[12,13]</sup> Therefore, attenuating intraoperative stress is a key factor in improving early recovery. Tracheal intubation is the gold standard method for maintaining the airway during anesthesia; however, it initially provokes a stress response during anesthesia and surgery. Previous studies have reported that the insertion and removal of the LMA was less invasive and induces fewer stress responses.<sup>[3,12]</sup> From our findings, we believe that stimulation from the ETT may cause hemodynamic variation at the time of starting and at discontinuation of pneumoperitoneum.

Previous studies have reported controversial results regarding the use of LMA in reducing the frequency of postoperative nausea, vomiting, and analgesic requirements.<sup>[5,6,14]</sup> We observed immediate reductions in postoperative pain, nausea, and dysphonia using LMA. Removal of the airway device after surgery can lead to the possibility of adverse events, such as straining, coughing, clenching, breath holding, and gross purposeful movement linked to increasing abdominal pressure. Thus, the quality of immediate postoperative recovery was improved in the LMA group.

The primary issues in using LMA during laparoscopic surgery have been gastric distension, pulmonary aspiration of gastric contents, and inadequate ventilation. An increase in intraabdominal pressure has been known to cause a reflex increase in the tone of the lower esophageal sphincter.<sup>[15]</sup> In our study, peak airway pressure before and after establishing pneumoperitoneum ranged from 3 to 8 cmH<sub>2</sub>O. In addition, clinical relevant gastric distension was not observed by the surgeons, and there were no cases of vomiting or pulmonary aspiration. These results were obtained because the Protector LMA was designed with a largevolume conduit with gastric access and a fixed curved structure to facilitate insertion. However, for these functions, it has a relatively bulky shape compared with other supraglottic airway devices. During this study, the corresponding author performed insertion of all Protector LMA devices and ETT. Although the Protector LMA is prone to high first-time insertion failure rates and trauma, insertion was not difficult with increasing experience and manipulation using the tip of a finger to make a curved end; when removing the LMA, there were no traumatic events such as



Figure 3. Intraoperative systolic blood pressure (A), heart rate (B), and surgical pleth index changes (C): 1, before anesthesia; 2, after insertion of the airway device; 3 and 4, starting and stopping carboperitoneum; 5, at the conclusion of surgery. \*<.05 after Bonferroni corrections for *t* test comparing variables between 2 groups.

bleeding. The incidence of sore throat was similar to other LMA devices.<sup>[6,16]</sup> Although they are bulky, the silicone cuffs may reduce the risk for sore throat and achieve higher seal pressures. Moreover, continuous cuff pressure monitoring also could reduce the incidence of sore throat and dysphonia.<sup>[17,18]</sup>

However, the advantages LMA insertion were not maintained over the 6-hour postoperative period. There have been many recommendations to improve the quality of recovery after laparoscopic cholecystectomy.<sup>[19–21]</sup> Dexamethasone is recommended in laparoscopic surgery for reducing pain and nausea/ vomiting. The effects of preoperative dexamethasone were evident 48 hours after surgery. Thus, using LMA with dexamethasone may lead to prolonged effects that extend into recovery in the ward and result in significant clinical outcomes.

There were several limitations to our study. First, the satisfaction questionnaire was administered at the time of discharge from the recovery room. Therefore, we could not confirm improved immediate postoperative recovery affected on the recovery. Most patients were discharged in the morning, the day after surgery, and it was difficult to investigate status at the time of discharge. Second, we did not measure the rate of carbon dioxide insufflation and the aspiration of pneumoperitoneum after surgery. However, the same insufflation device was used in all patients, with 12 mm Hg and the same surgical procedure. Third, we enrolled patients who were noncardiovascular comprised and otherwise healthy. Therefore, the effects of

Table 3

Satisfaction with anesthesia and surgery reported by participants 1 hour after surgery.

Satisfaction	LMA group (n=28)	ETT group (n=28)	Р
Highly unsatisfactory	0	1	
Unsatisfactory	1	7	
Neutral	9	13	.002
Satisfactory	16	6	
Highly satisfactory	2	1	

Values are number.

hemodynamic stress response and ventilation was not adjusted for all patients.

We conclude that the frequency of immediate postoperative pain, nausea, and hoarseness was lower in patients in whom the Protector LMA device was inserted compared with ETT in laparoscopic cholecystectomy. However, the effects were *attenuated* 6 hours postoperatively. Thus, using an LMA in a multimodal approach may contribute to establishing early postoperative recovery from laparoscopic cholecystectomy.

#### Author contributions

Data curation: Se Hee Kang, MiHye Park. Investigation: Se Hee Kang, MiHye Park. Supervision: MiHye Park. Writing – original draft: Se Hee Kang, MiHye Park. Writing – review and editing: MiHye Park. MiHye Park orcid: 0000-0002-3760-1067.

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