Comparison of intra-gastric pressure between endotracheal tube and supraglottic airway devices in laparoscopic hepatectomy: A randomised, controlled, non-inferiority study

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Abstract

Background Supraglottic airway (SGA) devices do not definitively protect the airway from regurgitation of gastric contents. Increased gastric pressure and long operation time are associated with development of complications such as aspiration pneumonia. The aim of this study was to compare intra-gastric pressure between second-generation SGA and endotracheal tube (ETT) devices during long-duration laparoscopic hepatectomy.

Methods A total of 66 patients was randomly assigned to two groups; 33 patients each in the ETT and SGA groups. Intra-gastric pressure was continuously measured via a gastric drainage tube with a three-way stopcock connected to the pressure monitoring device. Normal saline was added to the end of the gastric drainage tube at each operation time point.

Results Intra-gastric pressure during pneumoperitoneum was no different between the two groups ($p = 0.146$) or over time ($p = 0.094$). The mean (SD) pH of the SGA tip measured after operation was 6.7 (0.4), and a pH less than 4 was not observed. Relative risk of postoperative complications was significantly higher in the ETT group relative to the SGA group (sore throat, 5.5; cough, 13.0).

Conclusions Use of SGA devices does not further increase intra-gastric pressure, even during prolonged upper abdominal laparoscopic surgery. Also, the frequency of postoperative sore throat and cough was significantly lower when the second-generation SGA device was used.

Clinical trial registration of Korea (<https://cris.nih.go.kr/cris/index.jsp>): KCT0003512 Principle investigator: G S K; date of registration February 15, 2019, <https://cris.nih.go.kr/cris>).

Background

Supraglottic airway (SGA) devices can be used as an alternative for endotracheal tube (ETT) during general anaesthesia.[1] SGAs are quick and easy to use and have a lower incidence of postoperative complications such as sore throat, dysphagia, and hoarseness.[2, 3] However, SGAs do not offer definitive airway protection from regurgitation of gastric contents.[3]

Increased gastric pressure is associated with development of complications such as aspiration pneumonia.[4] In particular, intragastric pressure increases in laparoscopic surgery which can increase the likelihood of gastroesophageal reflux with SGA.[5, 6] In previous studies, intra-gastric pressure and visually scaled gastric distension score were not different between SGA and ETT during laparoscopic surgery.[7] However, these studies were limited to pediatric or short operation time and used first-generation SGA (classic laryngeal mask airway). Long operation times increase the incidence of regurgitation of gastric contents.[8] On the other hand, second-generation SGAs with gastric drainage ports improve safety of aspiration.[9] However, no studies have addressed the safety of second-generation SGAs in major abdominal surgery with long operation time under laparoscopy.

Therefore, we conducted the present study to compare the intra-gastric pressures between second-generation SGA and ETT during long-duration laparoscopic hepatectomy. The primary outcome was difference in intra-gastric pressure between the second-generation SGA and ETT. The secondary outcome was difference in postoperative complications.

Methods

Ethics and study design

This prospective study was performed at Samsung Medical Center in Seoul, Korea, after approval from Samsung Medical Center Institutional Review Board (IRB No. 2018-10-111). This trial was registered at Clinical Trials of Korea (KCT 0003512). This study was retrospectively registered (February 15, 2019) after enrolment of the first participant (February 04, 2019). Patients with an American Society of Anaesthesiologists physical status of I-III and who were scheduled for elective laparoscopic hepatectomy were enrolled between February 2019 and March 2019. Patients were excluded if they had lung disease, upper respiratory infection symptoms, esophageal varix, or previous stomach surgery. Written informed consent was obtained from all participants. This manuscript adhered to the CONSORT guidelines (Fig. 1).

Blinding And Randomisation

All patients were randomly assigned to one of two groups using a randomisation list administered by a nurse who did not participate in the study. A sealed envelope with group assignment was given to the investigator just before the operation. One experienced investigator performed the airway management, and the intraoperative data were recorded by those who did not participate in airway management.

Anaesthesia Protocol

All patients underwent midnight NPO. Standard monitoring such as electrocardiography, pulse oximetry, noninvasive blood pressure, and bispectral index monitoring were performed on arrival at the operating room. Anaesthesia was induced using 5 mg kg^{-1} of thiopental sodium and 8 vol% of sevoflurane. After loss of consciousness (LOC) was confirmed, 0.8 mg/kg rocuronium was administered. Mask ventilation was performed such that the airway pressure did not exceed 20 cm H₂O. Endotracheal intubation or SGA insertion was performed after confirming maximum neuromuscular blockade with twice Train-of-Four (TOF) count 0. And, the surgical procedure was performed in a deep neuromuscular block (no responses to TOF and two or fewer responses to post-tetanic count). Endotracheal tube (Shiley™, Hi-Contour Oral Tracheal Tube Cuffed, Covidien, Germany) intubation (Group ETT) or second-generation SGA (LMA® Protector™, Teleflex Medical Ltd., Athlone, Ireland) insertion (Group SGA) was performed. Mask ventilation was performed such that the airway pressure did not exceed 20 cm H₂O. The SGA size was selected according to manufacturer recommendations. Air was insufflated into the SGA cuff until the pilot balloon

black line was located within the green zone.[10] After successful ventilation was confirmed on capnography, mechanical ventilation was started. Cuff pressure of the SGA was adjusted using a digital cuff pressure monitor (Shiley™ Pressure Control, Covidien, Germany) to maintain less than or equal to 60 cm H₂O. SGA devices were replaced by ETTs in the following situations for patient safety if a) the SGA was not inserted in more than 3 attempts, b) persistent oropharyngeal leak with inadequate ventilation (end-tidal CO₂ $\geq$ 45 mmHg during pneumoperitoneum), and/or c) the stomach was inflated enough to cause visual disturbance under laparoscopic view. If the SGA was replaced by ETT, the patient was dropped from the study. The ETT size was selected according to sex (7.0 mm for women, 8.0 mm for men). The ETT cuff pressure was monitored using a digital cuff pressure monitor to ensure that it did not exceed 25 cm H₂O.[11, 12]

Tidal volume was 8 mL kg⁻¹ (ideal body weight), and respiratory rate was adjusted as required to maintain end-tidal CO₂ at 35 to 40 mmHg. Tidal volume was reduced if airway pressure exceeded 25 cm H₂O. After ETT intubation or SGA insertion, a non-compressible 14 French gastric drainage catheter (ST probe, Lucky Medical Co., LTD, Seoul, Korea) was inserted and fixed up to 60 cm through the mouth or the SGA gastric drainage port. After anaesthesia induction, patient posture was adjusted to the lithotomy and left tilting position by surgeon request. The surgeon inserted a trocar into the peritoneal cavity, and the CO₂ insufflator was maintained to 12 mmHg during pneumoperitoneum. The surgeon confirmed that the gastric drainage catheter tip was located on the stomach. After operation, the gastric drainage catheter was sufficiently suctioned and carefully removed.

Intra-gastric Pressure Monitoring And Data Acquisition

After gastric drainage catheter insertion, sufficient intragastric suction was performed. The gastric drainage catheter with a three-way stopcock was connected to the pressure monitoring device and filled with normal saline. Intra-gastric pressure was continuously measured by a pressure monitoring device (Edward Life Science, TruWave™ 3 cc / 60 in; Fig. 2.). The gastric drainage catheter with a three-way stopcock was connected to the pressure monitoring device and filled with normal saline. The pressure transducer was calibrated and placed at the intersection of the anterior axillary line and a transverse line at the level of the xyphoid.[13] In SGA, the airway sealing pressure was controlled by a pressure value that reached equilibrium at a fresh gas flow of 3 L min⁻¹ with the adjustable pressure limiting valve closed. [14] If the sealing pressure increased above 30 cm H₂O, we stopped the measurement. Intra-gastric pressure was collected at several time points (baseline, T1-T6 during pneumoperitoneum every 30 min, and at the end of surgery) during the anaesthesia period by the monitoring computer program (Picis Care Suit Anaesthesia Manager; Picis Ltd., Wakefield, MA, USA). The pH was measured after removing the SGA by sampling secretions on the tip of the SGA using a spatula and placing the drop at the tip of a pH meter (2K712, ISFETCOM Co., Ltd., Japan). Total anaesthesia time, total operation time, and total pneumoperitoneum time were recorded. Postoperative complications such as sore throat, cough,

hoarseness, and laryngospasm were assessed from the time immediately after removal of the airway device to discharge from the post anaesthesia care unit.

Statistics

In an initial pilot study, sample size calculations were performed using a non-inferiority test with Student's *t*-test to identify differences between intra-gastric baseline and peak pressures in ETT and SGA. Changes of intra-gastric pressure during surgery were 14.8 mmHg in ETT and 14 mmHg in SGA (standard deviation 2.8, non-inferiority margin 3.0). The sample size was calculated with a power of 0.9 and an alpha error of 0.05. Assuming a 10% dropout rate, we planned to recruit a total of 66 patients (33 subjects for each group).

The change of difference between intra-gastric baseline and peak pressures in ETT and SGA was calculated with a 95% confidence interval (CI). If the lower limit of the 95% CI was less than 3 mmHg, non-inferiority of SGA compared with ETT was demonstrated. Continuous variables are presented as the mean $\pm$ standard deviation (SD) or median (interquartile range, IQR) as appropriate. Continuous variables were compared using Student's *t*-test or Wilcoxon's signed-rank test, and the Shapiro–Wilk test was used to explore normality. Categorical variables were analyzed using Pearson's chi-square test or Fisher's exact test as appropriate. The difference between baseline and each time point of intra-gastric pressure between the two groups was analyzed using generalized estimating equations (GEE). Bonferroni's correction for post-hoc analysis was applied. Statistical analyses were performed using SPSS version 22 (SPSS Inc., Chicago, IL, USA). A *p*-value less than 0.05 was considered statistically significant.

Results

In this prospective randomised study, a total of 66 patients was enrolled, of which 33 were included in each the ETT and SGA groups. One patient in the SGA was excluded due to open conversion during operation, and one patient in the ETT was excluded due to pressure monitoring device error. Therefore, a total of 64 patients was analyzed.

There were no significant differences in patient characteristics and surgery/anaesthesia data (Table 1). The difference between intra-gastric baseline and peak pressure was 10.63 mmHg in the ETT and 11.81 mmHg in the SGA (mean difference, -1.188 mmHg; 95% CI, -2.845 to 0.470 mmHg; *p* = 0.157). The lower limit of the 95% CI was less than 3 mmHg, demonstrating non-inferiority of SGA compared with ETT. However, superiority was not significant. The intra-gastric pressure at each time point is shown in Fig. 3. The intra-gastric pressure during pneumoperitoneum was no different between the two groups (*p* = 0.146) or over time (*p* = 0.094). The mean (SD) intra-gastric pressure at baseline and at the end of surgery were 7.3 (2.8) mmHg and 8.3 (3.6) mmHg in ETT (mean difference, 0.9 mmHg; 95% CI, 0 to 1.9 mmHg; *p* = 0.047), respectively, and 8.1 (2.6) mmHg and 8.4 (2.9) mmHg in SGA (mean difference, 0.4 mmHg; 95% CI, -0.8 to 1.6 mmHg; *p* = 0.544). The mean (SD) pH of the SGA tip measured after operation was 6.7 (0.4),

and a pH less than 4 was not observed. The median (IQR) of SGA leakage pressure was 25 (21 to 30) mmHg immediately after anaesthesia induction and 24 (20 to 29) mmHg after pneumoperitoneum.

Table 1
Patient characteristics and surgery/anesthesia data

	SGA (n = 32)	ETT (n = 32)
Sex (Female/Male)	9/23	10/22
Age, months	55.1 (11.3)	59.0 (9.7)
Weight, kg	66.1 (11.9)	65.0 (12.0)
Height, cm	164.0 (6.0)	164.8 (8.3)
BMI	24.4 (3.2)	23.8 (3.1)
ASA PS (I/II/III)	14/16/2	12/18/2
HCC size	2.5 [1.9,6.7]	2.7 [1.7,4.0]
Anesthetic time (min)	204 (64)	208 (55)
Operation time (min)	159 (62)	153 (56)
Insufflation time (min)	129 (51)	124 (54)
Data are presented as the mean (SD), median [IQR], or number.		
ASA PS, American Society of Anesthesiologists physical status; BMI, body mass index; HCC, hepatocellular carcinoma		

Postoperative complications such as sore throat and cough were significantly higher in ETT than in SGA (RR [relative risk] = 5.5, $p < 0.001$; RR = 13.0, $p < 0.001$, respectively; Table 2). However, hoarseness was not significantly different between the two groups ($p = 0.113$), and laryngospasm did not occur in either group. There were no cases where SGA was replaced by ETT for patient safety.

Table 2
Postoperative airway complications

	SGA (n = 32)	ETT (n = 32)	RR [95% CI]	<i>p-value</i>
Sore throat	4 (13)	22 (69)	5.5 [2.1, 14.2]	< 0.001
Cough	1 (3)	13 (41)	13.0 [1.8, 93.6]	< 0.001
Hoarseness	0 (0)	4 (13)	9.0 [0.5, 160.6]	0.113
Laryngospasm	0 (0)	0 (0)	-	-
Data are presented as number (%).				
RR, relative risk; CI, confidence interval				

Discussion

We compared changes in intra-gastric pressure according to airway device to investigate the changes of intra-gastric pressure in laparoscopic hepatectomy with long operation time. Our results showed that use of SGA or ETT in laparoscopic hepatectomy did not reveal significant differences in intra-gastric pressure. In addition, postoperative airway complications such as sore throat and cough were significantly less frequent in SGA.

Pulmonary aspiration is associated with predisposing factors such as delayed gastric emptying, no fasting, ileus, pregnancy, and emergency surgery. However, a decrease in lower esophageal tone due to the effects of anaesthesia and surgery itself, and reflux of acid with increased intra-gastric pressure can cause aspiration pneumonitis. Anaesthesiologists are reluctant to use SGA in prolonged laparoscopic upper abdominal surgery as prolonged use of SGA increases the risk of pulmonary aspiration.[8, 15–17] SGA does not guarantee a complete seal around the larynx, which increases the risk of aspiration pneumonia due to the increase in intra-gastric pressure.[18, 19] Thus, we conducted a study of laparoscopic upper abdominal surgery with long operation time. In our study, mean CO₂ insufflation time of laparoscopic surgery was 126 min; however, intra-gastric pressure increased about 11–13 mmHg in both groups compared with baseline, and intra-gastric pressure did not significantly increase in the SGA over time compared to in the ETT. During pneumoperitoneum, intra-gastric pressure increases, and the risk of aspiration is increased.[19] However, when the lower esophageal sphincter pressure is higher than the intra-gastric pressure, the risk of aspiration is reduced.[20] Micheal et al.[21] demonstrated that lower esophageal sphincter pressure increased by 11.6 mmHg as abdominal pressure increased by 7.7 mmHg during pneumoperitoneum. This mechanism can reduce the risk of gastroesophageal reflux by increasing esophageal sphincter tone with an adaptive response when intra-abdominal pressure increases. In our study, when we increased the abdominal pressure by 12 mmHg during pneumoperitoneum, intra-gastric pressure increased by 11–13 mmHg in both the SGA and ETT groups. Intra-gastric peak pressure were distributed 17–19 mmHg in both groups. The maximum value of intra-gastric peak pressure was 29 mmHg in the ETT group and 25 mmHg in the SGA group. The pH of the SGA tip measured after

surgery was never lower than pH 4, indicating a lack of gastric content aspiration.[22] Although our results suggest no difference in the use of SGA or ETT in long-duration laparoscopic upper abdominal surgery, safety from gastric content aspiration is not assured with SGA.

The incidence of aspiration pneumonitis when using SGA is 0.02%.[23] First-generation SGAs lack design features to reduce the risk of aspiration, while second-generation SGAs offer improved safety against aspiration and regurgitation through separate access to the respiratory tracts and esophageal drainage.[24] The second-generation SGA (Protector™) used in our study has special features to increase the safety associated with gastric reflux prevention through a sufficient sealing pressure and suction of gastric contents through a suction port.[25] Thus, second-generation SGAs provide a means of gastric decompression and reduce the gastric distension and the risk of pulmonary aspiration.[26] Use of an ST probe as the gastric pressure measurement device in our study further increased the safety of SGA.

Generally, ETT is related with a greater risk of postoperative sore throat, cough, and/or hoarseness relative to SGA.[27, 28] One of the most common complications was sore throat after general anaesthesia, with an incidence rate of 62% in a previous study.[27] Although the incidence of postoperative sore throat in SGA is lower than that of ETT, it remains significant at up to 49%.[29] In our study, postoperative sore throat was observed in 69% of the ETT group and in 13% of the SGA group. This disparity is probably attributable to differences in quantifying postoperative sore throat and/or different study methodologies and equipment. Airway complications such as postoperative cough and hoarseness were also lower in SGA than in ETT in this study.

There are several limitations to our study. First, barrier pressure is thought to prevent gastroesophageal reflux and is measured by subtracting intra-gastric pressure based on lower esophageal sphincter pressure.[20] We did not measure lower esophageal sphincter pressure, only intra-gastric pressure. Therefore, further studies are recommended to confirm barrier pressure. Second, the relationship of intra-gastric pressure with pneumoperitoneum duration could not be clearly confirmed. The proportion of patients with duration of pneumoperitoneum greater than 120 minutes was 47% in the ETT group and 53% in the SGA group. There was a limit to obtaining statistically significant results according to time course. Third, we could not be certain that the position of the pressure monitoring transducer was exactly in the stomach. We use an anatomical landmark to locate the transducer of the pressure monitoring device relatively close to the stomach. Fourth, pH of the pharynx was measured only in the SGA group to determine postoperative regurgitation of gastric content. Fifth, we did not measure the grade of gastric distension. visually assessed gastric distension score is too subjective to evaluate the degree of gastric insufflation consistently. Whereas, our study has the advantage of confirming the degree of gastric insufflation using an objective values of intra-gastric pressure. Sixth, our study population was mainly ASA class 1–2 and BMI was relatively low, 23–24. Depending on the presence of underlying disease or in obesity patients, different results may be obtained. Therefore, it is difficult to apply the study results to all populations.

Conclusions

The use of SGA does not further increase intra-gastric pressure, even during prolonged upper abdominal laparoscopic surgery. Also, the frequency of postoperative sore throat and cough was significantly less with SGA. Nevertheless, risk of pulmonary aspiration cannot be eliminated, but continued use of a gastric drainage catheter can be reduce the risk.

List Of Abbreviations

SGA, Supraglottic airway; ETT, endotracheal tube; SD, standard deviation; CI, confidence interval

Declarations

Ethics approval and consent to participate : The date of IRB approval : December 4, 2018

The number of IRB approval: Samsung Medical Center Institutional Review Board SMC 2018-10-111, Chairperson Prof. Suk-Koo Lee, Seoul, Korea.

Written informed consent was obtained from all participants.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions

JHA, JSJ and GSK designed the study, wrote the first manuscript, interpreted the data, analysed the data and revised the manuscript. EAC, SHK designed the study, interpreted the data, revised the manuscript, and gave critical comments. JY, JMK and GSC gave critical comments, interpreted the data, and revised the manuscript. All authors read and approved the final manuscript.

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Figures

Figure 1

CONSORT flow diagram.

Figure 2

Schematic diagram of intra-gastric pressure measurement. (A) LMA® Protector™, (B) Gastric drainage catheter, (C) Normal saline with pressure bag, (D) Pressure monitoring sensor (*This image is author's own work, freely available to use.)

Figure 3

Intra-gastric pressure at each time point. T1-T6, during pneumoperitoneum every 30 min.

Supplementary Files

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